Reducing barriers to assistive technology: Utilising co-design to develop personalised assistive technology solutions

Jonathan David Howard

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Summary

Assistive technology can play a key role in increasing the independence, health and wellbeing of individuals and reduce the burden of chronic conditions on healthcare services and society. However, to date the full potential of assistive technology has yet to be realised. This research aims to identify the barriers to assistive technology use and then evaluate the impact of utilising end-user involvement in the design process to improve the use of assistive technology.

Individuals face a broad range of barriers to accessing and using assistive technology common across different health conditions. This includes societal barriers, awareness and information and psychological barriers. This research will predominantly focus on overcoming two other key barriers related to the design and function, and service provision of assistive technology.

A user-centred design methodology, referred to as co-design, was evaluated within a healthcare setting to provide customised assistive devices for individuals with chronic health conditions. Three separate empirical studies were undertaken to understand if the approach is feasible to be used within healthcare services; measuring the impact on the individual and the implications for healthcare services.

Results show how a co-design approach can be used to produce customised assistive devices to help individuals with a diverse range of chronic health conditions overcome different challenges in daily living. Individuals were highly satisfied with the devices provided with improvements in function and independence for the individuals. Additional wider benefits were found relating to improvements in physical and mental health and wellbeing.

The cost-efficiency gains associated with modifying and re-using designs were shown, providing promise about the implications for scaling-up the co-design process. This research provides evidence for benefits of end-user involvement in the design and provision process of assistive technology. The research was limited by small-sample size and only being conducted within a single healthcare service.

Declarations & Statements

DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed [redacted]

Date: 12/12/2022

STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated. Where correction services have been used, the extent and nature of the correction is clearly marked in a footnote(s).

Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

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Date: 12/12/2022

STATEMENT 2

I hereby give consent for my thesis, if accepted, to be available for photocopying and for inter-library loans **after expiry of a bar on access approved by the Swansea University.**

Signed [redacted]

Date: 12/12/2022

The following people and institutions contributed to the publication of work undertaken as part of this thesis:

Authorship Declaration	
Candidate	**Jonathan Howard** **School of Psychology**
Author 1	Professor Jeremy Tree Swansea University
Author 2	Dr Zoe Fisher Swansea University and Swansea Bay University Health Board
Author 3	Dr Lorna Tasker Swansea Bay University Health Board
Author 4	Professor Andrew Kemp Swansea University
Author 5	Dr Stephen Lindsay Glasgow University (formally Swansea University)
Author 6	Dr Mark Bowtell Swansea Bay University Health Board

Author Details and their Roles:

Paper 1 "*Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review*".

Located in Chapter 2

Candidate contributed design of study, database searching and data collection, analysis of papers, writing of paper (75%)

Author 1 contributed design of study, analysis of papers, reviewing and writing of paper (5%)

Author 2 contributed design of study, analysis of papers, reviewing and writing of paper (5%)

Author 3 contributed design of study, reviewing and writing of paper (5%)

Author 4 contributed design of study, analysis of papers, reviewing and writing of paper (5%)

Author 5 contributed analysis of papers, reviewing and writing of paper (5%)

Paper 2 "*Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service: a service evaluation*".

Located in Chapter 4

Candidate contributed design of study, conducting study and data collection, analysis of data, writing of paper (79%)

Author 1 contributed design of study, supervision of conducting study, analysis of data, reviewing and writing of paper (7%)

Author 2 contributed design of study, supervision of conducting study, analysis of data, reviewing and writing of paper (7%)

Author 3 contributed design of study, supervision of conducting study, analysis of data, reviewing and writing of paper (7%)

Paper 3 "*Can a previously co-designed device be used by others? A service evaluation of the use of the Sativex Spray holder for individuals with multiple sclerosis*" (Currently under peer review)

Located in Chapter 6

Candidate contributed design of study, conducting study and data collection, analysis of data, writing of paper (80%)

Author 1 contributed design of study, analysis of data, reviewing and writing of paper (5%)

Author 2 contributed design of study, analysis of data, reviewing and writing of paper (5%)

Author 3 contributed design of study, analysis of data, reviewing and writing of paper (5%)

Author 6 contributed design of study, analysis of data, reviewing and writing of paper (5%)

We the undersigned agree with the above stated "proportion of work undertaken" for each of the above published peer-reviewed manuscripts contributing to this thesis:

Signed Candidate [redacted]

Author 1 [redacted]

Author 2 [redacted]

Author 3 [redacted]

Author 4 [redacted]

Author 5 [redacted]

Author 6 [redacted]

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Publications, Conferences, and Awards

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Abbreviations

ANOVA	Analysis of Variance
APS	Artificial Pancreas System
AT	Assistive Technology
CAD	Computer Aided Design
CASP	Critical Appraisal Skills Programme
COREQ	Consolidated Criteria for Reporting Qualitative Studies
CSRI	Client Service Receipt Inventory
CGM	Continuous Glucose Monitoring
DIY	Do-It-Yourself
FDM	Fused Deposition Modelling
GP	General Practitioner
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IPPA	Individualised Prioritised Problem Assessment
ISO	International Organisation for Standardisation
PLA	Polylactic Acid
PIADS	Psychosocial Impact of Assistive Device Scale
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUEST	Quebec User Evaluation of Satisfaction with assistive Technology
RCT	Randomised Control Trial
SQUIRE	Standards for Quality Improvement Reporting Excellence
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale
WHO	World Health Organisation

1 Introduction

1.1 Background

Finding more effective methods to manage chronic health conditions will be key to improving the sustainability of healthcare services. Between 1990 and 2017 the global challenge of disability increased as the number of years people are living with a disability increased from 562 million to 853 million (Kyu et al., 2018). The prevalence of disability is predicted to continue to rise due to an ageing population and an increase in chronic health conditions due to life style factors such as diabetes, cardiovascular disease and mental illness (Foreman et al., 2018; World Health Organisation and World Bank, 2011). Global health expenditure is thus predicted to double from US$10 trillion in 2015 to $20 trillion by 2040 (Dieleman et al., 2018). This presents an urgent need to develop solutions that reduce the burden of chronic conditions on healthcare systems and improve the health and wellbeing of those living with chronic conditions.

One tool to support individuals is assistive technology. Assistive technology is an umbrella term for a wide range of equipment including physical devices, electronic equipment, instruments and software. Assistive devices are a sub-category of assistive technology and include for example: wheelchairs, prosthetics, communication aids and aids for daily living. The World Health Organisation (WHO) recognises the key role of assistive technology in maintaining and improving an individual's function, independence and wellbeing (World Health Organisation, 2018). Globally, it is predicted that as much as 1 in 3 people need some form of assistive device (World Health Organisation and the United Nations Children's Fund (UNICEF), 2022). Whilst the demand for assistive technology is expected to rise with the increasing prevalence of disability, current global estimates are that only 1 in 10 people who need assistive technology currently have access to it (World Health Organisation, 2018). Additionally, people who do have access end up abandoning devices with cited abandonment rates in the literature ranging between 20-70% (Martin et al., 2011; Phillips & Zhao, 1993; Scherer, 2005; Scherer, 2014; Sugawara et al., 2018). It is the twin targets of improving the use and reducing the abandonment of assistive technology that forms the focal point of this thesis.

A second motivation for this research is a need to address the way chronic conditions are managed by healthcare services. The traditional acute medical model, that western healthcare services are predominantly based on, assumes health conditions can be 'fixed' and thus an individual is able to return to a 'pre-injury' state (Keller & Carroll, 1994). However, for chronic conditions, this model is clearly inappropriate. It is widely accepted that chronic conditions cannot be 'fixed' and instead interventions should focus on promoting health and wellbeing for these individuals to live 'well' with their chronic condition (Kemp et al., 2022). One model of wellbeing that looks to facilitate pathways to this is the GENIAL wellbeing model (Kemp, Arias, & Fisher, 2017; Kemp & Fisher, 2022; Mead, Fisher, & Kemp, 2021). This biopsychosocial model describes wellbeing as a multi-faceted entity for the individual, community and the environment related to emotional balance, healthy bodies, personal relationships, connectiveness to communities and the natural environment. These domains are impacted by social, environment (for example climate change) and political constructs. As such wellbeing for individuals living with chronic conditions cannot simply be seen as the absence of impairment as per the traditional acute medical model. Current and future healthcare services need to consider this in their clinical practice.

Healthcare services are seeking to put greater emphasis on encouraging individuals with chronic conditions to self-manage their own health, rather than relying on formal healthcare services (Ekman et al., 2011). Self-management refers "*to an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition"* (pp.177) (Barlow et al., 2002). Self-management strategies are increasingly recognised as essential for supporting patients to be active collaborators in their own care, rather than being passive recipients of care (Dineen-Griffin et al., 2019; Jordan et al., 2008). Assistive technology can enable individuals to better self-manage their own health through increased independence and function (World Health Organisation, 2018).

In terms of the delivery of healthcare services, greater patient involvement in care decisions is increasingly important for the management of chronic conditions (Department of Health, 2012; Welsh Government, 2018). Co-production supports this and is a person-centred approach where patients are placed in equal partnership with healthcare professionals for managing their own health and wellbeing and making decisions about their care (Realpe & Wallace, 2010). Co-production identifies the user as the expert in their own condition with lived experience and unique knowledge of how they manage their own health. A review concluded that co-production of healthcare paves the way for improved health outcomes,

enhanced patient satisfaction, better service innovation and cost savings for healthcare services (Palumbo, 2016).

The underlying principle of co-production has many similarities with co-design, a design methodology that similarly looks to include the end user in the design of products. This seeks to empower individuals by: encouraging them to input their lived experiences into the design process; involving them in key decision making processes; and enabling them to provide feedback during the design process (Hakobyan, Lumsden, & O'Sullivan, 2014; Vines et al., 2013). This thesis will explore how a co-design methodology, which will include the principles of co-production, can be utilised within healthcare services to enhance the use of assistive technology for individuals with chronic health conditions.

1.2 Rationale and objectives

This thesis aims to improve the access to and use of assistive technology for individuals living with chronic health conditions through involving individuals in the design and development of customised assistive devices.

The research takes a multi-disciplinary approach combining methodologies and knowledge from engineering, psychology, and healthcare science, with a primary focus on developing interventions from a healthcare service perspective looking at the role of healthcare professionals in addressing the barriers to assistive technology use. Specifically, it looks at the way end-user collaboration in the design and provision process, co-design, could be used to improve the use of assistive devices by creating devices more tailored to an individual's needs. It will investigate the impact such devices have on the user's health and wellbeing and seek to understand if it is feasible to adopt such an approach into existing healthcare services. This will be achieved by analysing the resources and costs associated with co-designing and exploring whether further benefits were achieved.

To add further new evidence within this field, the thesis has five main objectives:

1) Identify the current barriers to accessing and using assistive technology for individuals living with chronic health conditions (Chapter 2)
2) Identify the current evidence gaps related to increasing end-user involvement in the design and provision of customised assistive devices through reviewing the current scientific literature. (Chapter 3)
3) Investigate if co-design can be implemented within a current healthcare service to provide customised assistive devices for individuals with a range of chronic health conditions (Chapter 4 & 5).
4) Evaluate the impact for the individuals and the implications for healthcare services of providing customised devices using the co-design methodology through mixed methods analysis of questionnaire and semi-structured interviews (Chapter 4 & 5)
5) Investigate if a previously co-designed device can be re-used to meet the need of other individuals through provision of the Sativex spray holder. (Chapter 6)

It is acknowledged that there is a large global un-met need for assistive technology, and this impacts the context of this research. Whilst researching the first objective, identifying the barriers to assistive technology (Chapter 2), studies from multiple different countries around the world were included to provide a global perspective. However, in the subsequent

research chapters (Chapters 4-6) the methodology chosen and thus findings should be interpreted within the local context where the research was based, a National Health Service(NHS) service based in Southwest Wales, UK. Whilst findings may be applicable to other settings, the work does not aim to directly address the wider global issues around access to assistive technology.

1.3 Structure of thesis

The thesis is split into six further chapters, outlined below.

Chapter 2 provides further background information about the burden of chronic conditions, models of health and wellbeing and the role of assistive technology in this. Then, through a meta-synthesis review of the current literature, it seeks to establish what are the current barriers to accessing and using assistive technology for those with chronic health conditions. It uses a trans-diagnostic approach, inclusive across a range of different health conditions, in achieving this goal to understand if barriers are common across different health conditions. This chapter will summarise the barriers identified and discuss opportunities to reduce these barriers. This chapter is published in the Journal of Disability and Rehabilitation: Assistive Technology under the title: "*Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review*" (Howard et al., 2022a).

Chapter 3 reviews the current scientific literature around the customisation of assistive technology. It focuses on three different approaches. The first is Do-it-Yourself (DIY) practices and the impact this may have for users creating their own customised assistive devices. Next it summarises the current literature around co-designing assistive devices, where the end user is involved throughout the design process to create customised solutions. Finally, this chapter looks at the provision of customised assistive devices within healthcare settings. It seeks to understand why advances in digital design and manufacturing techniques, for example 3D printing, which are commonly used in the DIY and co-design approaches are not currently being utilised to their full potential within healthcare services.

Chapter 4 looks to evaluate the use of co-design to produce customised assistive devices within a current NHS healthcare service through three case study examples. It seeks to understand the type of customised devices required, the impact providing such devices has on the user as well as the resources and costs involved with providing such devices. A concurrent mixed-methods approach is used for the evaluation of the devices and the co-design process. This chapter is published in the Journal of Disability and Rehabilitation: Assistive Technology under the title: "*Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service: a service evaluation*" (Howard et al., 2022b).

Chapter 5 looks to further evaluate the feasibility of co-designing customised assistive devices within an NHS healthcare service. It builds on the methodology established in

Chapter 4 with a larger sample size. It similarly employs a concurrent mixed-method evaluation to investigate the impact of the co-design intervention and the devices provided using questionnaires and semi-structured interviews. Additionally, it investigates any impact on healthcare services being accessed by individuals and evaluates the resources involved in the co-design process.

Chapter 6 looks to expand on the work of Chapter 4 by studying whether the devices previously developed through the co-design approach could be used by other individuals – that is the degree to which previously designed bespoke solutions may be generalizable to the needs of others. One of the devices developed in Chapter 4 is prescribed to other individuals who have similar assistive device needs. This chapter seeks to understand mechanisms that may make the co-design process more cost-effective by reducing the time required to initially design a custom assistive device. At the time of submission, this chapter is currently under peer-review for publication in the Journal of Disability and Rehabilitation: Assistive Technology under the title: "*Can a previously co-designed device be used by others? A service evaluation of the use of the Sativex spray holder for individuals with multiple sclerosis*".

Finally, Chapter 7 outlines the main findings from across the Chapters, discussing the outcomes in the context of reducing barriers to assistive technology, improving health and wellbeing outcomes for those individuals living with chronic conditions and its contribution to the scientific literature. Finally, this chapter presents a service model blueprint for co-designing customised assistive devices, identifies key recommendations for future research to expand upon the findings of this thesis and summarises the main contributions of this research to the scientific literature.

2 Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review

This chapter identifies the barriers individuals with chronic health conditions face in accessing and using assistive technology. It will initially provide further background about the burden of chronic conditions, models of health and wellbeing and the role of assistive technology in this. Then, through a meta-synthesis review of the current literature, it establishes what are the current barriers to accessing and using assistive technology for those with chronic health conditions. It uses a trans-diagnostic approach in achieving this goal to understand if barriers are common across different health conditions. This chapter will summarise the barriers identified and discuss opportunities to reduce these barriers.

This chapter is the accepted manuscript of an article published in the Journal of Disability and Rehabilitation: Assistive Technology under the title:

"Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review"

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2.1 Introduction

Finding more effective methods to manage chronic health conditions will be key to improving the sustainability of healthcare services. Between 1990 and 2017 the global challenge of disability increased as the number of years people are living with a disability increased from 562 million to 853 million (Kyu et al., 2018). Current estimates are that one billion people (15% of the global population) are now classified as disabled with non-communicable health conditions accounting for 80% of the global burden of disability (Kyu et al., 2018; World Health Organisation and World Bank, 2011). The prevalence of disability is predicted to continue to rise due to an increasingly ageing population arising from increases in average global life expectancy of 4.4 years by 2040, and an increase in chronic health conditions due to life style factors such as diabetes, cardiovascular disease and mental illness (Foreman et al., 2018; World Health Organisation and World Bank, 2011). The increase in disease prevalence is predicted to double global health expenditure from US$10 trillion in 2015 to $20 trillion by 2040 (Dieleman et al., 2018). This presents an urgent need to develop solutions that address the burden chronic conditions are posing on healthcare systems as well as an opportunity to provide more effective services to this population.

Historically, the greatest burden on healthcare systems were acute medical conditions and accordingly the 'acute medical model' became the dominant model of healthcare. However, in the past decade there has been an epidemiological shift whereby chronic conditions have now replaced acute medical conditions as the leading burden of morbidity, mortality, and health care expenditure, but models of healthcare have not adapted to reflect this shift (Department of Health, 2012). As such, the acute medical model has formed the basis of how healthcare systems operate for people with chronic conditions. Inherent in the acute medical model is the assumption that: injuries and diseases can be fixed; a person can return to a pre-injury state and an individual is a passive recipient of care (Keller & Carroll, 1994). It assumes that health and wellbeing can be achieved through the absence of impairment.

For chronic conditions the acute medical model is inadequate as the condition cannot be fixed and return to a pre-injury state is not achievable (Mead et al., 2019). Moreover, a plethora of research shows that health and wellbeing is not simply the absence of impairment and thus the goals of the acute medical model do not translate well to chronic conditions (Anderson, 1995). Instead, chronic conditions must be managed by implementing lifestyle changes to: enhance functional status, minimise distressing symptoms, prolong life through secondary interventions and enhance quality of life through care of the whole

person (Grumbach, 2003). The management of chronic conditions requires the individual to be an active collaborator in their own care, enabling them to effectively self-manage their own health (Ekman et al., 2011). Self-management refers "*to an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition"* (pp.177) (Barlow et al., 2002). Self-management strategies are increasingly recognised as essential for the management of chronic conditions by supporting patients to be actively involved in their own care (Dineen-Griffin et al., 2019; Jordan et al., 2008).

Services should therefore be designed to promote independence, health and wellbeing rather than simply aiming to ameliorate impairment or illness. For example, the recently proposed 'GENIAL' biopsychosocial model helps understand the components needed to facilitate health and wellbeing for people living with chronic conditions. Building upon previous models, it defines wellbeing as: "*positive psychological experience, which can be impacted on by positive health behaviours, and is promoted through a sense of connectedness to ourselves as individuals, as well as to the communities and environment within which we live*." (Kemp et al., 2017; Mead et al., 2019). This framework highlights a potential role for a self-sustaining cycle of positive health and wellbeing underpinned by positive psychological experiences, health behaviours, communities, and environments, despite the limitations imposed by a chronic condition. In terms of service provision, the GENIAL framework suggests that in order to promote pathways to health and wellbeing for people with chronic conditions, as opposed to simply ameliorating illness, services must facilitate opportunities for positive psychological experiences, positive health behaviours, positive social relationships, and community integration.

Similarly, to the GENIAL model, the International Classification of Functioning Disability and Health (ICF) framework is also based on a biopsychosocial model. It defines disability as the interaction between the individual's health condition and their personal and environmental contextual factors (World Health Organisation, 2001). The environmental factors are classified by: products and technology, the natural and built environment, support and relationships, attitudes and services, systems and policies whilst personal factors are recognised as an individual's motivation and self-esteem. Both GENIAL and the ICF emphasise the influence of the social and physical context within which individuals live on participation, psychological experience, and capacity to engage in health behaviours. In the context of wellbeing, if an individual is not able to overcome the limitations brought about by their disability, this will likely lead to negative spirals of ill-health, distress and social

isolation, further contributing to a deterioration in mental and physical health (Kemp et al., 2017). Both frameworks therefore provide useful theoretical groundwork to help understand the multitude of factors that impact on an individual's health and wellbeing, enabling more effective treatments to be prescribed to help manage chronic conditions (Alford et al., 2015). Products and technology are one aspect of the ICF's environmental factors. The use of assistive technology to help people with chronic conditions will be the focus of this work.

Assistive technology has great potential to address the burden of chronic conditions on individuals, families, communities, and societies. Assistive technology refers to *"any product either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing"* (pp. 2229)(Khasnabis, Mirza, & Maclachlan, 2015). The benefits of using assistive technology include enhancing function and independence, improved safety, promoting social inclusion and increasing participation in education, employment, and society. (Abrilahij & Boll, 2019; McNicholl et al., 2019). Assistive technology can also support the management, education, and monitoring of individuals with chronic conditions, reducing the need for formal and informal care and enhancing individual health and wellbeing (Mechling, 2007; O'Neill & Gillespie, 2014; van Ommeren et al., 2018; Whitehead & Seaton, 2016). Providing the right assistive technology thus has the potential to reduce the burden of chronic conditions on the individual themselves, caregivers and the wider society (Lansley, 2004; Madara Marasinghe, 2016; Mitzner et al., 2010; van Ommeren et al., 2018; World Health Organisation, 2018). With an eye on enhancing health and wellbeing in people living with chronic conditions and developing more sustainable healthcare systems, the current review will clarify the existing barriers to fully realising the potential of assistive technology using a systematic review and meta-synthesis.

A major challenge to realising the full potential of assistive technology is the poor correspondence between device utility and end user needs, often leading to assistive technology not being adopted over the long-term. It is unclear from the literature what the uptake of assistive technology is but cited abandonment rates for people using assistive technology range between 20-70% (Martin et al., 2011; Phillips & Zhao, 1993; Scherer, 2005; Scherer, 2014; Sugawara et al., 2018). The abandonment of assistive technology can be due to both positive (e.g., improved health condition), and negative factors (e.g., poor usability of the design). Key issues relating to the non-use of assistive technology include a lack of user involvement in the design and decision making process (Alqahtani et al., 2019; Martin et al., 2011; Orejuela-Zapata, Rodriguez, & Ramirez, 2019; Robinson et al., 2013), a lack of

information about products and services (Abdi et al., 2019; Boot et al., 2018; Newton et al., 2016) and the usability of assistive technology for the user (Abrilahij & Boll, 2019; Dawe, 2006; Mitzner et al., 2010; van Ommeren et al., 2018). The use of assistive technology varies amongst different groups. Individuals with severe mobility and sensory limitations are more likely to use assistive technology, whilst those with mental health or cognitive conditions are less likely to use assistive technology (Kaye, Yeager, & Reed, 2008). It is unclear whether the different usage of assistive technology between different populations reflects the different needs of these groups or is a bias in service provision in favour of people with physical disabilities. The non-use and abandonment of assistive technology may not only hinder an individual's functional ability and their social inclusion, but also reflects a waste of public resources supplying the equipment (Sugawara et al., 2018). This review will systematically explore the reasons for the abandonment of assistive technology to ensure new devices and healthcare interventions are implemented that reflect the needs of the end user to reduce the abandonment rate of assistive technology.

Previous systematic reviews identifying barriers to assistive technology use have tended to focus on specific health populations and groups: older adults, people with intellectual disabilities, spinal cord injuries, Alzheimer's, cognitive impairments, stroke (Abdi et al., 2019; Abrilahij & Boll, 2019; Boot et al., 2018; Klimova, Valis, & Kuca, 2018; Orejuela-Zapata et al., 2019; Thordardottir et al., 2019); specific types of assistive technology: mobility or devices for upper-limb rehabilitation (Alqahtani et al., 2019; van Ommeren et al., 2018), and specific environments such as assistive technology use in higher education (McNicholl et al., 2019). However, an initial review of the literature suggests that many of the barriers to using assistive technology are common across multiple chronic conditions and devices.

The aim of the current meta-synthesis is therefore to identify all of the potential barriers that service users with chronic conditions face when trying to access and use assistive technology by summarising the current state of the research on the barriers to the access and use of assistive technology.

An inclusive, transdiagnostic search strategy was used. Based on current literature many of the barriers to assistive technology adoption were predicted to be common across different health morbidities. This approach differs from the majority of previous work that focus on particular health population groups. The GENIAL framework emphasises that people with different chronic conditions share common barriers to wellbeing: undesirable health behaviours, negative psychological experiences, social isolation and exclusion (Kemp et al.,

2017; Mead et al., 2019). An individual's health condition is therefore one component that interacts with personal, community and environment contributions that impact on health and wellbeing. As such, there may be considerable similarities in the experience of the individual across different health populations. The advantages of this approach is that if barriers are common across multiple health conditions, transdiagnostic interventions can be implemented more efficiently and effectively by focusing on commonalities across diagnoses (Gutner et al., 2016).

A systematic review by Larsson and Lidstrom (2019) encompassed multiple health conditions into their systematic review, focusing on the satisfaction of the user with the service delivery process for assistive technology (Ranada & Lidstrom, 2019). The review, however, did not focus on aspects related to the design and usability of the assistive technology provided, which had been identified as a barrier in other reviews (Abrilahij & Boll, 2019; Alqahtani et al., 2019; van Ommeren et al., 2018). By only focusing on the service delivery process, Larsson and Lidstrom may have omitted key reasons for the abandonment of assistive technology both prior to and after provision. The current review will expand on this to include barriers to both acquiring and using assistive technology. To ensure all aspects are considered, the present review will focus on the views of key assistive technology stakeholders including: end-users, family members, carers and healthcare professionals, across different chronic conditions. To date no work has been published aiming to identify the barriers relating to all aspects of the use and provision of assistive technology across different chronic conditions. Identifying the barriers to the use of assistive technology will serve to better understand how to help realise the enormous potential that assistive technology has in improving the health and wellbeing of people with chronic conditions as well as reducing the burden on health and social services. It is hoped that this will inform better service design which addresses the identified barriers to assistive technology use.

2.2 Materials and methods

A meta-synthesis was conducted following the guidelines published by Lachal et al. (2017) and applying the structured methodological approach for systematic reviews described by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009).

2.2.1 Search terms and Information sources

The search strategy was developed based on two groups of search terms relating to "assistive technology" and "barriers/use". A full list of terms used is presented in Table 2-1. Consensus for all the search terms was reached with all the authors prior to undertaking the database searches. Boolean logic was used to combine the search terms within each group using the operator OR and between the two groups using the operator AND.

The full search terms were inputted into 5 electronic databases to identify relevant studies: PubMed, SCOPUS, PsycINFO, CINAHL and Medline. The databases were searched from the earliest available records to 4th November 2019. Studies were identified which included the terms in the title and abstract only and when full text articles in English were available.

Table 2-1: Full search terms used for PubMed database. Plurals were allowed by using wildcard (*)

Search Group	Terms
Assistive Technology	"Assistive Technology" OR "Assistive Technologies" OR "Assistive Device*" OR "Assistive Technology Device*" OR "Assistive Aid*" OR "Assistive Equipment" OR "Self-help device*" OR "Assistive product*" OR "Self-help equipment" OR "Self-help technology" OR "Self-care device*" OR "Self-care equipment" OR "Self-care technology"
Barriers/use	Barrier* OR Use OR Usage OR Failure* OR misuse OR Abandon OR Abandonment OR obstacle* OR attitude* OR perception* OR acceptance

2.2.2 Study Selection

After removing duplicates, studies were selected using a multi-stage process shown in Figure 2-1.

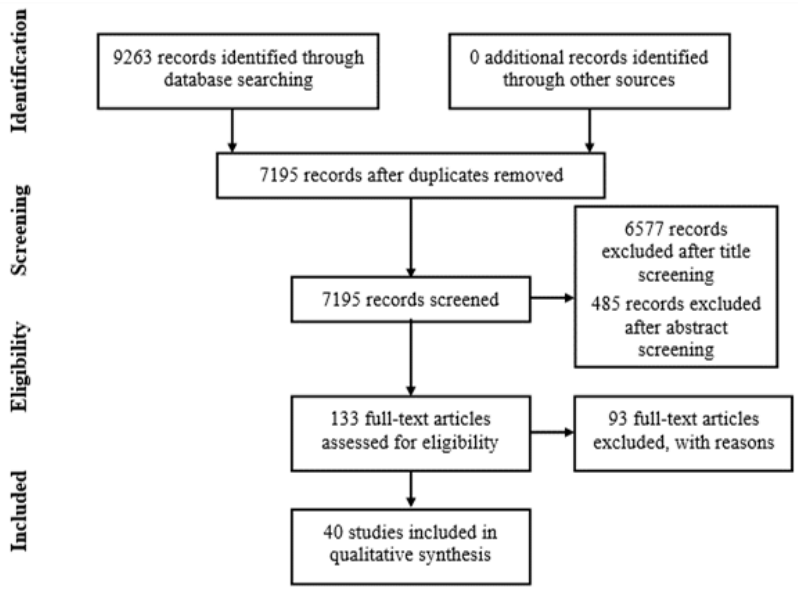

Figure 2-1: PRISMA flow diagram showing the number of articles identified and screened for eligibility during the meta-synthesis (Moher et al., 2009).

Using the predefined inclusion/exclusion criteria, studies were first screened by title and then by abstract to identify articles for full text reading. Articles that passed the abstract screening were then read and compared against the inclusion/exclusion criteria in Table 2-2. The screening criteria were developed to capture qualitative studies concerning adults with chronic conditions and the barriers they experience to assistive technology use. This included qualitative studies involving carers, family members and healthcare professionals. These stakeholders play a key role in the provision and usage of assistive technology and therefore their opinions are important when identifying barriers to assistive technology access and use. All authors agreed the inclusion/exclusion criteria prior to undertaking the search.

Table 2-2: Inclusion and exclusion criteria used for identifying relevant articles.

Inclusion Criteria	Exclusion criteria
Published peer reviewed journal articles	
Chronic Conditions	
Adult population (>18)	Children or teenagers
Empirical data	Non-empirical (review papers)
Qualitative studies	Quantitative, questionnaire or case studies (1-3 participants)
Included verbatim statements from subjects	Product testing of a singular product or system
Explores reasons for use/non-use of current AT provision	Outcome measures and physiological measures related to AT

2.2.3 Data extraction and analysis

Forty studies met all the inclusion criteria. For each study, the following data were extracted and summarised in Table 2-3: Author/s, publication year, country of origin, aim, sample population, type of AT.

2.2.3.1 Thematic analysis

Results from the studies were combined using the three-phase process of thematic synthesis described by Thomas and Harden (2008) (Lachal et al., 2017; Thomas & Harden, 2008). This thematic synthesis has been used in other systematic reviews (Abdi et al., 2019; van Ommeren et al., 2018). Initially the first author became familiar with the studies by reading and re-reading each article. Next line-by-line coding of the findings from the studies was used to inductively generate descriptive themes. Similar themes were then grouped together, and definitions created for each theme. Next, all the articles were re-read and a deductive thematic approach was used to ensure all the themes in each article had been identified. Finally, overarching analytical themes were generated and finalised through reaching consensus with a wider research group of academics and healthcare professionals with backgrounds in psychology, engineering, and computer science.

2.2.3.2 Evaluation of studies

The level of evidence in each study was evaluated using the Critical Appraisal Skills Program (CASP) checklist for qualitative research (Critical Appriasal Skills Programme, 2018). The assessment was weighted using a three-point scale for each of the 10 criteria, (0 = not met, 1 = partially met and 2 = totally met) to give a total score for each article out of 20. This method of applying a weighted scale is recommended by the Cochrane Collaboration (Lachal et al., 2017).

Table 2-3: Summary information of articles included in the meta-synthesis

Author (year)	Country	Aim	Sample characteristics	Types of assistive technology	Identified barriers	CASP Score
Adolfsson et al. (2016)	Sweden	Explore how adults with cognitive disabilities perceive the influence of environmental factors on the use of electronic planning devices	Adults with cognitive disabilities (n = 12)	Electronic planning devices	Awareness & information Design and function Service provision Societal barriers Support network	17
Andregard and Magnusson (2017)	Sierra Leone	Describe the experience of using and attitudes towards orthotic and prosthetics devices in Sierra Leone from the perspective of people with poliomyelitis and amputations	Polio or amputations (n = 12)	Mobility aids	Design and function Service provision Societal barriers	14
Asghar, Cang, and Yu (2018)	Pakistan	Investigate the advantages, limitations, functions and impacts of assistive technology for people with dementia and explore future requirements for assistive technology	Dementia (n = 20)	Mixed	Awareness & information Design and function Service provision Support network	17
Baldwin, Powell, and Lorenc (2011)	UK	Expand on the current understanding of factors that influence the use of compensatory aids and strategies for people with acquired brain injuries	Acquired Brain Injury (n = 8)	Memory aids	Design and function Psychological Service provision Societal barriers Support network	14

Boger et al. (2014)	Canada	Investigate what assistive technology is in use, what factors affect use and gaps in current assistive technology use to support the daily occupations of community-dwelling older adults with dementia and family caregivers	Dementia (n = 13; 3 family caregivers and 10 occupational therapists)	Mixed	Awareness & information Design and function Psychological Service provision Support network	14
Boot, MacLachlan, and Dinsmore (2019)	Ireland	Understand the barriers and facilitators to effectively access and use essential assistive technology for people with intellectual disabilities	Intellectual disability (n = 30; 15 with intellectual disability and 15 assistive technology providers)	Mixed	Awareness & information Design and function Service provision Societal barriers Support network	15
Cook et al. (2016)	UK	Explore the factors that impact patients' decisions to initially adopt and continually engage with telehealth and telecare applications	Mixed (n = 40; 28 users and 12 non-users)	Telehealth and telecare	Awareness & information Design and function Psychological Service provision Societal barriers	17
Creemers et al. (2014)	Netherlands	Explore the experience of patients with amyotrophic lateral sclerosis during the application and provision process of assistive technology	Amyotrophic Lateral Sclerosis (n = 179)	Mixed	Awareness & information Design and function Service provision	9
Darcy, Maxwell, and Green (2016)	Australia	Explore the perceptions of a mobile technology platform as experienced by people with a disability, their significant others and service providers	Mixed (n = 15; 10 intellectual, 4 physical and 1 cognitive disability)	Information and communications technology	Awareness & information Design and function Service provision Support network	14

Demain et al. (2013)	UK	Identify the barriers and facilitators to the use of upper-limb rehabilitation and assistive technology to support stroke self-management	Stroke (n = 21)	Upper limb rehabilitation aids	Awareness & information Design and function Psychological Service provision	17
Dorjbal et al. (2019)	Mongolia	Identify environmental barriers and their impacts on daily lives as perceived by individuals living with Spinal Cord Injury in Mongolia	Spinal Cord Injury (n = 16)	Mixed	Awareness & information Design and function Service provision Societal barriers Support network	14
Durham et al. (2016)	Lao People's Democratic Republic	Investigate client satisfaction with their prosthetic and orthotic devices and services in Lao People's Democratic Republic	Mixed (n = 34)	Prosthetics and orthotics	Awareness & information Design and function Service provision Societal barriers	13
Elnady, Mortenson, and Menon (2018)	Canada	Describe user's perceptions of assistive technology for the upper extremities, investigate if there is a need to develop new devices and identify factors that would limit the utilisation of any new devices	Stroke (n = 16; 8 with stroke and 8 healthcare professionals)	Upper limb rehabilitation	Awareness & information Design and function Psychological Service provision	19
Fager and Burnfield (2014)	USA	Describe individual perceptions of technology used for environment controls and therapeutic exercise during in-patient rehabilitation	Mixed (n = 10; 5 with Spinal Cord Injury, 2 with stroke, 1 with Traumatic Brain Injury, 1 Scleroderma and 1 pulmonary insufficiency)	Environmental controls & augmentative and alternative communication aids	Awareness & information Design and function Service provision	12

Fomiatti et al. (2014)	Australia	Explore the lived experience of individuals who used a scooter to compensate for limited mobility and explore the benefits, barriers and enablers to inclusion and social participation	Mobility limitation (n = 14)	Mobility scooter	Awareness & information Design and function Service provision Societal barriers	15
Gelinas-Bronsard et al. (2019)	Canada	Identify the needs of older adults and family caregivers relating to assistive technology procurement and how to offer remote support through an internet-based intervention	Mixed (n = 30; 5 assistive technology users, 5 carers, 5 healthcare professionals, 5 decision makers, 5 community partners, 5 researchers)	Mixed	Awareness & information Design and function Service provision Support network	19
Gerber (2003)	USA	Identify the benefits of and barriers to computer use for people who are visually impaired	Visual impairment (n = 41)	Computer access	Awareness & information Design and function Service provision Societal barriers	7
Gibson et al. (2015)	UK	Explore how people with dementia and their families use assistive technology in their everyday lives	Dementia (n = 39; 13 with dementia, 18 family carers and 8 formal carers)	Mixed	Awareness & information Design and function Psychological Service provision Support network	13
Gitlin, Luborsky, and Schemm (1998)	USA	Examine the personal meanings associated with the first-time encounters with device use following the acute onset of disease	Stroke (n = 103)	Mixed	Awareness & information Design and function Psychological Service provision Societal barriers	13

Hedberg-Kristensson, Ivanoff, and Iwarsson (2007)	Sweden	Investigate older persons' experiences of using mobility devices	Mobility impairments (n = 22)	Mobility device	Awareness & information Design and function Psychological Service provision Societal barriers	16
Holthe et al. (2018)	Norway	Examine the role of and the experiences that family carers of people with young onset dementia have concerning the use of assistive technology to support everyday life	Dementia (young onset) (n = 13, carers)	Mixed	Awareness & information Design and function Service provision Support network	17
Holz et al. (2018)	Canada	Explore individual perceptions of using rollators to identify factors that may inform ways in which clinicians can promote optimal usage of rollators	Chronic obstructive pulmonary disease (n = 12)	Rollators	Awareness & information Design and function Psychological Service provision Societal barriers	12
Jamieson et al. (2019)	UK	Investigate the barriers and solutions to the performance of meaningful activities for people receiving rehabilitation for brain injuries	Acquired Brain Injury (n = 24, 9 with Acquired Brain Injury, 12 formal carers and 3 family carers)	Mixed	Awareness & information Design and function Psychological Service provision	11
Lenker et al. (2013)	USA	Explore device outcomes that are most valued by assistive technology users and	Mixed	Mixed	Awareness & information Design and function	14

		identify elements in the device acquisition process that affect outcomes	(n = 24; Spinal Cord Injury, cerebral palsy, hearing impairments, blindness, physical disability, vision loss and other developmental disabilities)		Service provision	
Mann and Tomita (1998)	USA	Examine how satisfied people are with assistive devices they own, what problems they have with them and what suggestions for new devices they have	Mixed (frail elders) (n = 508)	Mixed	Awareness & information Design and function Service provision Societal barriers	8
McGrath and Astell (2017)	Canada	Explore the decision-making processes of older adults with age related vision loss relating to acquisition and use of assistive technology	Age-related vision loss (n = 10)	Mixed	Awareness & information Design and function Psychological Service provision Societal barriers	12
Mortenson et al. (2018)	Canada	Explore caregivers' experiences with assistive technology to facilitate care recipients' independence and understand the experience of caregivers in identifying and selecting assistive technology	Mobility limitation (n = 27, carers)	Mixed	Service provision Support network	14
Myburg et al. (2017)	Australia	Investigate the prescription and utilisation of environmental control systems from the consumer perspective.	Spinal Cord Injury (n = 15)	Environmental control systems (ECS)	Awareness & information Design and function Service provision Support network	16

Newton et al. (2016)	UK	Explore the views and experiences of general practitioners, people with dementia and family carers on their knowledge and experience of accessing information about and use of assistive technology in practice	Dementia (n = 56; 13 with dementia, 17 General Practitioners and 26 carers)	Mixed	Awareness & information Service provision Societal barriers Support network	15
Okonji and Ogwezzy (2019)	Nigeria	Explore barriers to adoption and access to assistive technology among visually impaired people in Nigeria	Blind and visually impaired (n = 20)	Visual aids	Awareness & information Design and function Psychological Service provision Societal barriers Support network	14
Orellano-Colon et al. (2016)	Puerto Rico	Identify barriers to successful use of assistive technology from the perspective of community-dwelling older Hispanics with functional limitations living in Puerto Rico	Mixed (n = 60 musculoskeletal, hypertension, diabetes, visual, respiratory, cardiac, overweight)	Mixed	Awareness & information Design and function Psychological Service provision Societal barriers	16
Oyesanya et al. (2019)	USA	Investigate the views of technology from the perspective of individuals with traumatic brain injuries to address their health, wellness, and safety concerns	Traumatic Brain Injury (n = 27; 15 with Traumatic Brain Injury, 12 carers)	Mixed	Design and function Psychological	18
Pereira et al. (2019)	Brazil	Identify the main facilitators and barriers in the use of alternative and augmentative communication systems by adults diagnosed with aphasia	Aphasia (n = 3, healthcare professionals)	Alternative and augmentative communication	Design and function Support network	13

Ravneberg (2012)	Norway	Explore the usability of and reasons for the abandonment of assistive technology	Hearing loss (n = 12; 5 with hearing loss, 7 service providers)	Hearing aids and signalling devices	Awareness & information Design and function Psychological Service provision Societal barriers	6
Riikonen, Paavilainen, and Salo (2013)	Finland	Explore factors that facilitate the use of technology in the daily life of home-living people with dementia	Dementia (n = 25)	Mixed	Awareness & information Design and function Psychological Service provision Support network	15
Seymour, Geiger, and Scheffler (2019)	Uganda	Determine what community-based rehabilitation workers in Uganda perceive as the challenges to wheelchair provision and use, factors contributing to these challenges and what facilitators they need to overcome the challenges	Mobility (n = 21, community-based rehabilitation workers)	Wheelchairs	Awareness & information Design and function Psychological Service provision Societal barriers Support network	15
Smith et al. (2002)	Australia	Explore factors affecting the acceptability and use of assistive technology by older people	Mixed (n = 40; stroke, fractures, arthritis, and motor neurone disease) (25 focus group and 15 interviews)	Mixed	Awareness & information Design and function Service provision Societal barriers Support network	15
Taherian and Davies (2018)	New Zealand	Understand the experiences and perspectives of assistive technology from different stakeholders involved in assistive technology provision in New Zealand	Cerebral Palsy (n = 13; 5 with Cerebral Palsy, 3 carers and 5	Mixed	Awareness & information Design and function Psychological Service provision	15

			healthcare professionals)		Societal barriers Support network	
Van Den Heuvel, Jowitt, and McIntyre (2012)	UK	Explore the barriers to the uptake of and the unmet needs of assistive technology for people with dementia	Dementia (n = 12, carers)	Mixed	Awareness & information Support network	11
Weerasinghe et al. (2015)	Sri Lanka	Describe the barriers in using assistive technology among community-dwelling residents with unilateral lower limb disabilities in central Sri Lanka	Amputees (lower limb) (n = 12)	Prosthetics	Awareness & information Design and function Psychological Service provision Societal barriers	15

2.3 Results

2.3.1 Article characteristics and level of evidence

9263 articles were identified through database searching of which 7195 remained once duplicates were removed, Figure 2-1. 6577 studies were excluded during title screening and a further 485 excluded after abstract reading. One hundred and thirty-three articles were read in full of which 93 were excluded. A total of 40 articles were included in the analysis and are summarised in Table 2-3.

The majority of the studies were undertaken in European (n=14) or North American (n=12) countries with the remainder conducted in Australasia (n=5), Asia (n=4), Africa (n=3) and South America (n=2). A wide range of health conditions were covered in the articles: dementia (n=7), mobility impairments (n=7), hearing and visual impairments (n=4), stroke (n=3), acquired/traumatic brain injuries (n=3), spinal cord injury (n=2), cerebral palsy (n=1), cognitive disabilities (n=1), intellectual disability (n=1), chronic obstructive pulmonary disease (n=1), amyotrophic lateral sclerosis (n=1), aphasia (n=1) and studies recruiting a mix of health conditions (n=8). A mix of different assistive technologies are reported on including mobility aids, environmental controls, alternative and augmentative communication, telehealth and telecare and memory/planning aids.

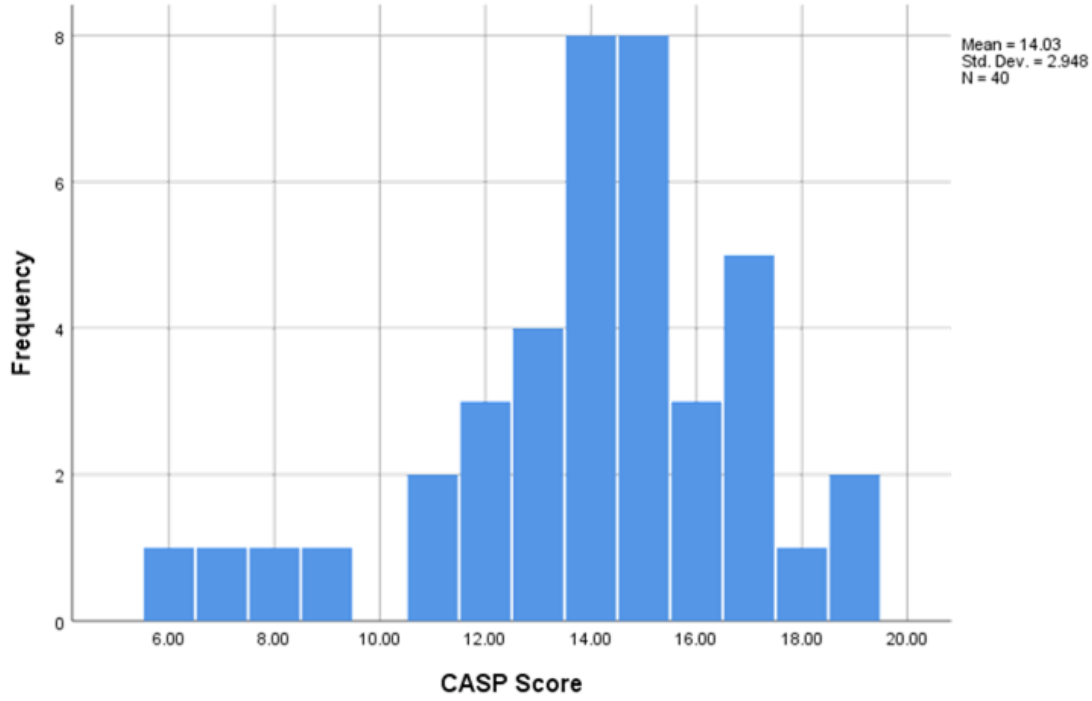

Figure 2-2: Histogram plot of the CASP scores for all forty articles reviewed

The CASP score evaluating the quality of the articles was checked in order to identify any themes that only appeared in lower quality work. The scores ranged from 6 to 19 out of a possible 20, Figure 2-2. Out of the 40 articles, 27 had a score of 14 or greater and 4 had a score less than 10. The majority of the articles had a clear statement about their aims, findings and had taken ethical issues into consideration for the research, Table 2-4. The research design (question 3) was only partially appropriate in 21 of the 40 studies, often failing to justify the type of collection method used. Twenty-four of the studies only partially met the recruitment strategy (question 4) with studies not fully stating the recruitment process or inclusion/exclusion criteria used. Data collection (question 5) was only fully met by 14 of the studies; 24 of the studies partially met the criteria with the development of the interview guide or data collection strategy not fully explained. The majority of the articles, n = 30, failed to consider the relationship between the researcher and the participants of the studies (question 6). No themes were found to be limited to weaker articles only so the CASP scores were not considered further.

Table 2-4: Number of studies that met, partially met and did not meet each question of the Critical Appraisal Skills Program (Critical Appriasal Skills Programme, 2018)

Criteria	# Of studies totally met (score = 2)	# Of studies partially met (score = 1)	# Of studies not met (score = 0)
1. Was there a clear statement of the aims of the research?	29	11	0
2. Is a qualitative methodology appropriate?	38	2	0
3. Was the research design appropriate to address the aims of the research?	19	21	0
4. Was the recruitment strategy appropriate to the aims of the research?	13	24	3
5. Was the data collected in a way that addressed the research issue?	14	24	2
6. Has the relationship between researcher and participants been adequately considered?	1	9	30
7. Have ethical issues been taken into consideration?	28	8	4
8. Was the data analysis sufficiently rigorous?	16	18	6
9. Is there a clear statement of findings?	28	12	0
10. How valuable is the research?	24	12	4

2.3.2 Analysis findings

Six analytical themes describing the barriers to assistive technology were derived from the grouping of the fifty-one descriptive themes identified in the articles, Figure 2-3. The six analytical themes related to: the design and function of assistive technology, awareness and information, the service provision of assistive technology, personal psychological barriers, support network and societal barriers. Each analytical theme and subsequent descriptive themes are described in more detail.

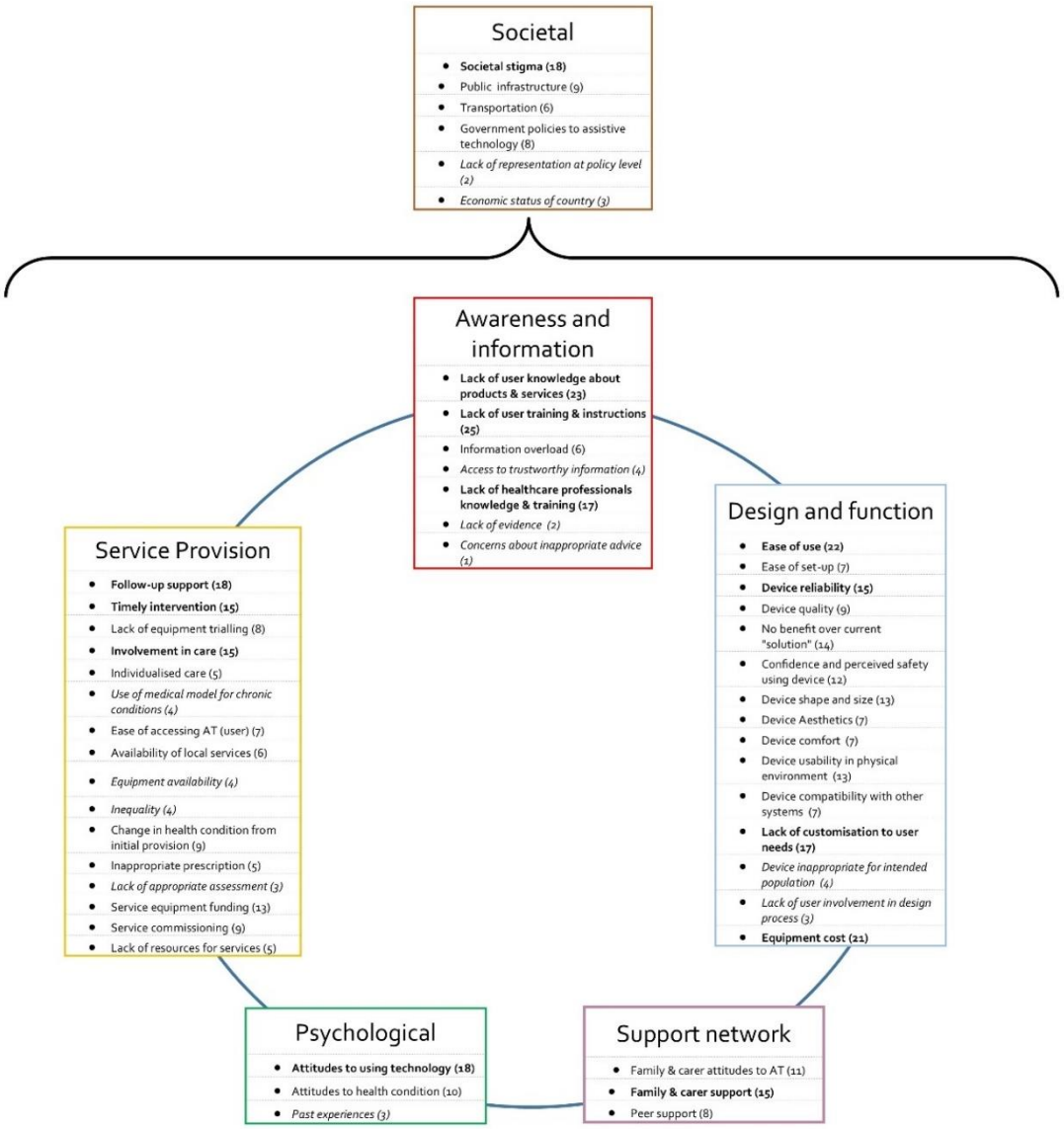

Figure 2-3: Summary of analytical and descriptive themes. Bold: descriptive themes identified 15 times or more. Italics: descriptive themes identified less than 5 times.

2.3.2.1 Theme 1: Design and function

This theme groups the descriptive themes identified relating to the design and function of assistive technology.

Ease of use: Users remarked that the ease of use of devices was a barrier to the on-going use of assistive technology. Users wanted devices that were simple to use and operate (Adolfsson et al., 2016; Asghar et al., 2018; Baldwin et al., 2011; Boger et al., 2014; Cook et al., 2016; Darcy et al., 2016; Demain et al., 2013; Elnady et al., 2018; Fager & Burnfield, 2014;

Fomiatti et al., 2014; Gitlin et al., 1998; Holthe et al., 2018; Mann & Tomita, 1998; McGrath & Astell, 2017; Myburg et al., 2017; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Pereira et al., 2019; Riikonen et al., 2013; Seymour et al., 2019; Taherian & Davies, 2018).

Ease of set-up: The ease of set-up of their assistive technology, for example how difficult or how much of a 'hassle' a device was to set-up, would influence the users decision to use assistive technology (Cook et al., 2016; Demain et al., 2013; Elnady et al., 2018; Fager & Burnfield, 2014; Mann & Tomita, 1998; Myburg et al., 2017; Taherian & Davies, 2018).

Device reliability: Device reliability refers to if the device was able to perform consistently its intended function. Poor reliability, such as devices giving false notifications or being inconsistent in performing a function, led to low confidence in the performance of the device and abandonment of the assistive technology (Adolfsson et al., 2016; Andregard & Magnusson, 2017; Asghar et al., 2018; Cook et al., 2016; Fager & Burnfield, 2014; Gerber, 2003; Gibson et al., 2015; Holthe et al., 2018; Jamieson et al., 2019; Mann & Tomita, 1998; Myburg et al., 2017; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Pereira et al., 2019; Taherian & Davies, 2018).

Quality of the device: The quality of the device was also a barrier that was identified by users. This related to devices breaking easily due to being too fragile or not durable enough for the intended use of the assistive technology (Dorjbal et al., 2019; Fager & Burnfield, 2014; Gerber, 2003; Gitlin et al., 1998; Holthe et al., 2018; Lenker et al., 2013; Mann & Tomita, 1998; Orellano-Colon et al., 2016; Weerasinghe et al., 2015).

Perceived benefit over current "solutions": The perceived benefit over current "solutions" relates to the assistive technology having to be more useful than any previous or current solutions that users were accustomed to using for it to be accepted by the user (Baldwin et al., 2011; Boger et al., 2014; Cook et al., 2016; Darcy et al., 2016; Gibson et al., 2015; Holthe et al., 2018; Mann & Tomita, 1998; McGrath & Astell, 2017; Myburg et al., 2017; Orellano-Colon et al., 2016; Ravneberg, 2012; Riikonen et al., 2013; Smith et al., 2002; Taherian & Davies, 2018).

Confidence and safety using devices: Participants also had concerns regarding their confidence and safety when using the device. This related to users being un-sure how to use the device, having concerns regarding feeling safe or how the assistive technology impacted on their privacy (Asghar et al., 2018; Boger et al., 2014; Cook et al., 2016; Demain et al., 2013; Gelinas-Bronsard et al., 2019; Gibson et al., 2015; Gitlin et al., 1998; Mann & Tomita, 1998;

Myburg et al., 2017; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Weerasinghe et al., 2015).

Shape, size and weight: Aspects relating to the physical shape, size and weight of a device were also identified by users as a barrier to using their assistive technology. Examples identified included the assistive technology being too big for the user to carry or too heavy to use (Adolfsson et al., 2016; Andregard & Magnusson, 2017; Asghar et al., 2018; Boot et al., 2019; Cook et al., 2016; Durham et al., 2016; Elnady et al., 2018; Gitlin et al., 1998; Holz et al., 2018; Mann & Tomita, 1998; Orellano-Colon et al., 2016; Pereira et al., 2019; Ravneberg, 2012).

Aesthetic appearance: The aesthetics of a device were also discussed by some users as a barrier to using their assistive technology. Users were concerned that devices looked too medical and not enough like mainstream technology; this resulted in user's feeling stigmatised and embarrassed to use the devices (Darcy et al., 2016; Mann & Tomita, 1998; Mortenson et al., 2018; Myburg et al., 2017; Orellano-Colon et al., 2016; Ravneberg, 2012; Taherian & Davies, 2018).

Comfort: How comfortable a device was to use, and wear was identified as another barrier. Issues with device discomfort included pain which limited the use of the device (Durham et al., 2016; Elnady et al., 2018; Fomiatti et al., 2014; Gitlin et al., 1998; Hedberg-Kristensson et al., 2007; Mann & Tomita, 1998; Weerasinghe et al., 2015).

Usability in physical environment: Participants described how the design of the device made it unsuitable for use in certain environments. This included due to the outside climate, for example sunlight causing glaring on screens or high temperatures causing overheating, and due to the constraints in a user's home, for example narrow spaces and carpets. Additionally, the devices being unsuitable for the local environment they resided in for example on dirt roads, where there are no paved roads or foot paths available, or being unsuitable for the local language and cultural needs (Adolfsson et al., 2016; Boger et al., 2014; Boot et al., 2019; Dorjbal et al., 2019; Fomiatti et al., 2014; Holthe et al., 2018; Holz et al., 2018; Lenker et al., 2013; Mann & Tomita, 1998; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Seymour et al., 2019; Taherian & Davies, 2018).

Compatibility with other systems: The compatibility of the assistive technology with other systems and devices restricted user's usage of the assistive technology. For example, being able to access their phone or control the television through their wheelchair controls or

communication devices (Adolfsson et al., 2016; Elnady et al., 2018; Fager & Burnfield, 2014; Gitlin et al., 1998; Lenker et al., 2013; Mann & Tomita, 1998; Pereira et al., 2019).

Lack of customisation to user needs: Another barrier with the design of assistive technology related to the lack of customisation to the end user needs. Both users and prescribers described how a universal design or one size fits all approach to assistive technology design was not appropriate to cover the individual needs and circumstances of each user (Adolfsson et al., 2016; Asghar et al., 2018; Boot et al., 2019; Cook et al., 2016; Darcy et al., 2016; Durham et al., 2016; Elnady et al., 2018; Fager & Burnfield, 2014; Fomiatti et al., 2014; Lenker et al., 2013; Mann & Tomita, 1998; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Pereira et al., 2019; Ravneberg, 2012; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Device inappropriate for intended population: Another sub-theme that restricts usage of assistive technology was if the device was inappropriate for the intended population. Users felt that devices were too difficult or too childish for older adults to use as they were not designed with older users in mind. Additionally, if the device function did not adequately compensate for the limitation, then it was not appropriate for the population being used for (Adolfsson et al., 2016; Asghar et al., 2018; Gibson et al., 2015; Pereira et al., 2019).

Lack of user involvement in design process: A lack of user involvement in the design process for assistive technologies was another barrier. End users, carers and therapists believed they could provide useful feedback and suggestions during the development and testing of new assistive technology to improve the design of devices (Demain et al., 2013; Lenker et al., 2013; Ravneberg, 2012).

Equipment cost: The final sub-theme relating to the design and function of assistive technology was the initial equipment cost and on-going maintenance cost for participants and services. Assistive technologies deemed as medical devices were perceived as being too expensive to purchase, especially compared to conventional products and technology (Andregard & Magnusson, 2017; Boger et al., 2014; Creemers et al., 2014; Demain et al., 2013; Dorjbal et al., 2019; Durham et al., 2016; Elnady et al., 2018; Gelinas-Bronsard et al., 2019; Gerber, 2003; Gibson et al., 2015; Jamieson et al., 2019; Lenker et al., 2013; Mann & Tomita, 1998; McGrath & Astell, 2017; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Pereira et al., 2019; Ravneberg, 2012; Smith et al., 2002; Weerasinghe et al., 2015).

2.3.2.2 Theme 2: Awareness and information

This theme groups the descriptive themes related to the awareness of and information about assistive technology.

Lack of user training and instructions: A lack of training and instructions provided to the end user, family, and carers regarding the safe and appropriate use of the assistive technology was a barrier to people using their assistive technology. This included a lack of written information and a lack of time spent familiarising the user with the device (Asghar et al., 2018; Boger et al., 2014; Boot et al., 2019; Cook et al., 2016; Darcy et al., 2016; Elnady et al., 2018; Fager & Burnfield, 2014; Fomiatti et al., 2014; Gelinas-Bronsard et al., 2019; Gerber, 2003; Gibson et al., 2015; Gitlin et al., 1998; Hedberg-Kristensson et al., 2007; Holz et al., 2018; Mann & Tomita, 1998; McGrath & Astell, 2017; Myburg et al., 2017; Newton et al., 2016; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Riikonen et al., 2013; Seymour et al., 2019; Smith et al., 2002; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Lack of knowledge about produces and services: A barrier to accessing the assistive technology for users, family members and carers was a lack of knowledge about the products and services available to them. Users were unsure about who was responsible for providing the equipment, how to access the services and what equipment was available (Adolfsson et al., 2016; Boger et al., 2014; Boot et al., 2019; Cook et al., 2016; Creemers et al., 2014; Demain et al., 2013; Durham et al., 2016; Elnady et al., 2018; Fager & Burnfield, 2014; Fomiatti et al., 2014; Gelinas-Bronsard et al., 2019; Gerber, 2003; Gibson et al., 2015; Holthe et al., 2018; Holz et al., 2018; Mann & Tomita, 1998; McGrath & Astell, 2017; Newton et al., 2016; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Ravneberg, 2012; Seymour et al., 2019; Van Den Heuvel et al., 2012; Weerasinghe et al., 2015).

Information overload: Information overload describes users and carers who were given too much information about products and services available. The overload of information meant people struggled to manage and understand all of the information provided and as a result individual's felt overwhelmed so they retained very little information (Cook et al., 2016; Gelinas-Bronsard et al., 2019; Holthe et al., 2018; Myburg et al., 2017; Riikonen et al., 2013; Taherian & Davies, 2018).

Access to trustworthy information: Accessing trustworthy information about products and service available was a barrier to acquiring assistive technology as individuals wanted un-biased opinions from trusted sources about whether the assistive technology was going to be useful for them. Individuals had concerns relating to the quality and relevance of

information from the internet, national press, and sales representatives (Demain et al., 2013; Lenker et al., 2013; Newton et al., 2016; Van Den Heuvel et al., 2012).

Lack of healthcare professionals knowledge and training: Another barrier was the lack of knowledge and training of healthcare professionals about assistive technology that was available. End users felt that healthcare professionals lacked sufficient training on the operation of the devices, up to date knowledge about both products available and how to access them (Adolfsson et al., 2016; Boger et al., 2014; Creemers et al., 2014; Demain et al., 2013; Dorjbal et al., 2019; Fager & Burnfield, 2014; Gelinas-Bronsard et al., 2019; Gerber, 2003; Gibson et al., 2015; Holthe et al., 2018; Jamieson et al., 2019; Lenker et al., 2013; Myburg et al., 2017; Newton et al., 2016; Orellano-Colon et al., 2016; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Lack of evidence: An additional barrier to the provision of assistive technology was the lack of evidence available to healthcare professionals and commissioners regarding the effectiveness of assistive technology. Information regarding relevant and accessible research and clinical testing of assistive technology was limited (Demain et al., 2013; Elnady et al., 2018).

Concerns about inappropriate advice: The final theme relating to information and awareness was healthcare professional's concerns about giving inappropriate advice about assistive technology that could influence the decision to purchase a product privately. Therapists were concerned about endorsing products that had limited evidence (Demain et al., 2013).

2.3.2.3 Theme 3: Service provision

This theme groups all the descriptive themes related to the provision of assistive technology to the end user by the service and equipment provider. Sixteen descriptive themes were categorised under this theme.

Follow-up support: A common barrier to the use of assistive technology was the lack of follow-up support by service providers to the end users. Users described how they received no specific follow-up after the device was issued to check on the equipment to support its ongoing use. This included a lack of maintenance and repair support for when devices broke (Adolfsson et al., 2016; Andregard & Magnusson, 2017; Boot et al., 2019; Cook et al., 2016; Darcy et al., 2016; Demain et al., 2013; Durham et al., 2016; Gelinas-Bronsard et al., 2019;

Gibson et al., 2015; Holthe et al., 2018; Mann & Tomita, 1998; Myburg et al., 2017; Newton et al., 2016; Riikonen et al., 2013; Seymour et al., 2019; Smith et al., 2002; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Timely intervention: The timing of the intervention when assistive technology was provided to the user was an important factor in its uptake. Examples included equipment being provided too late after the user's condition had deteriorated past the point it was useful. Long wait times for appointments and/or delivery of the equipment were regularly mentioned in relation to this theme (Adolfsson et al., 2016; Boger et al., 2014; Boot et al., 2019; Creemers et al., 2014; Fager & Burnfield, 2014; Gelinas-Bronsard et al., 2019; Gibson et al., 2015; Hedberg-Kristensson et al., 2007; Holthe et al., 2018; McGrath & Astell, 2017; Mortenson et al., 2018; Myburg et al., 2017; Orellano-Colon et al., 2016; Riikonen et al., 2013; Taherian & Davies, 2018).

Lack of equipment trialling: A lack of equipment trialling to test if the equipment will work in a user's real-life context prior to equipment provision was another barrier. Many user's wanted but did not get a period of time to try out equipment in different environments before choosing if the equipment was appropriate for them (Darcy et al., 2016; Demain et al., 2013; Elnady et al., 2018; Fomiatti et al., 2014; Gelinas-Bronsard et al., 2019; Hedberg-Kristensson et al., 2007; Smith et al., 2002; Taherian & Davies, 2018).

Involvement in care: A lack of involvement in care decisions and assistive technology choice was another barrier to the use of assistive technology. Users wanted individual choice in the equipment being provided to them and a lack of involvement resulted in frustration and disagreement with the prescriber (Adolfsson et al., 2016; Asghar et al., 2018; Baldwin et al., 2011; Boot et al., 2019; Cook et al., 2016; Darcy et al., 2016; Gibson et al., 2015; Hedberg-Kristensson et al., 2007; Holz et al., 2018; Lenker et al., 2013; Mann & Tomita, 1998; Mortenson et al., 2018; Myburg et al., 2017; Riikonen et al., 2013; Smith et al., 2002).

Individualised care: Failure to account for individualised care needs showed users wanted to be treated on an individual basis and not feel like they were being categorised (due to their health condition). Use of generic evidence to assess benefits of equipment, the use of scoring system for assessments and being insensitive to personal attitudes, habits and environment all made the process seem impersonal to the user (Darcy et al., 2016; Demain et al., 2013; Gibson et al., 2015; Riikonen et al., 2013; Seymour et al., 2019).

Use of medical model for chronic conditions: The use of the medical model for treating chronic conditions by healthcare services limited the availability and provision of assistive technology. A focus on short term rehabilitation goals, for example, discharge from hospital, resulted in a lack of consideration to providing assistive technology that could provide long-term benefit (Demain et al., 2013; Gelinas-Bronsard et al., 2019; Gibson et al., 2015; Newton et al., 2016).

Ease of accessing AT for user: The ease of accessing assistive technology due to the paperwork and number of steps required was a barrier to acquiring the assistive technology. Participants expressed it took a lot of time and energy to go through the application processes (Adolfsson et al., 2016; Creemers et al., 2014; Durham et al., 2016; Gerber, 2003; Lenker et al., 2013; Mortenson et al., 2018; Orellano-Colon et al., 2016).

Availability of local services: The availability of local services was a barrier to accessing the services and assistive technology required. Long travel times to and from services meant participants would give up accessing services (Durham et al., 2016; Elnady et al., 2018; Gelinas-Bronsard et al., 2019; Okonji & Ogwezzy, 2019; Seymour et al., 2019; Weerasinghe et al., 2015).

Equipment availability: Another barrier was the availability of equipment services could provide to the end user. Services had difficulties sourcing and obtaining appropriate products within the country (Boot et al., 2019; Dorjbal et al., 2019; Jamieson et al., 2019; Seymour et al., 2019).

Inequality: Some users were unable to access assistive technology from services due to inequality in who equipment was provided to, with their disability considered not severe enough. Strict eligibility criteria limited the availability of potentially useful equipment to certain groups (Boot et al., 2019; Elnady et al., 2018; Seymour et al., 2019; Weerasinghe et al., 2015).

Changes in health condition from the initial provision: Changes in health condition from the initial provision of the assistive technology meant that the assistive technology was no longer appropriate for the user to use. Changes could be due to an improvement or deterioration in cognitive or physical abilities (Boger et al., 2014; Cook et al., 2016; Fager & Burnfield, 2014; Gitlin et al., 1998; McGrath & Astell, 2017; Myburg et al., 2017; Riikonen et al., 2013; Smith et al., 2002).

Inappropriate prescription: An inappropriate prescription was a barrier when the device provided to the user was unsuitable to meet their needs. Examples included incorrect sizing, the user never needing the device, or the user was cognitively not being able to operate the device (Mann & Tomita, 1998; Ravneberg, 2012; Seymour et al., 2019; Smith et al., 2002; Weerasinghe et al., 2015).

Lack of appropriate assessment: An appropriate assessment was required to ensure all the requirements for the individual were captured prior to device provision. Assessments needed to be undertaken in an appropriate environment, potentially multiple locations, that was suitable for the individual to prevent future issues with the use of the assistive technology (Boot et al., 2019; Myburg et al., 2017; Taherian & Davies, 2018).

Service equipment funding: Limitations in equipment funding for services to purchase and provide assistive technology was another barrier. Funding restraints on services limited the quantity and range of equipment available through public services and meant equipment provision often had to be prioritised to users with the greatest need (Boger et al., 2014; Boot et al., 2019; Demain et al., 2013; Dorjbal et al., 2019; Elnady et al., 2018; Gelinas-Bronsard et al., 2019; McGrath & Astell, 2017; Mortenson et al., 2018; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Seymour et al., 2019; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Service commissioning: The commissioning of services restricts the provision of certain types of assistive technology, introducing in-equality in the provision of services. Funding decisions for assistive technology based on generic evidence, irregularities between geographical locations in a country and low priority status of some health conditions results in bias and inequality in service provision (Adolfsson et al., 2016; Boot et al., 2019; Demain et al., 2013; Gelinas-Bronsard et al., 2019; Gibson et al., 2015; Newton et al., 2016; Orellano-Colon et al., 2016; Ravneberg, 2012; Taherian & Davies, 2018).

Lack of resources for services: A lack of resources for healthcare and equipment services was another barrier to assistive technology. Time pressures and resource limitations restricted the ability of services to effectively provide, train and follow-up with clients (Demain et al., 2013; Gelinas-Bronsard et al., 2019; Newton et al., 2016; Seymour et al., 2019; Taherian & Davies, 2018).

2.3.2.4 Theme 4: Psychological

The psychological theme group's the descriptive themes relating to the user's personal opinions and perceptions that act as a barrier to accessing and using assistive technology.

Attitudes to using technology: A negative attitude towards using technology and assistive technology by the end user was a barrier to using assistive technology. When the end user was against the idea of using technology due to it being perceived as annoying, awkward or not appropriate for them, the personal attitude of the individual influenced the use of the assistive technology (Baldwin et al., 2011; Boger et al., 2014; Cook et al., 2016; Demain et al., 2013; Elnady et al., 2018; Gibson et al., 2015; Gitlin et al., 1998; Hedberg-Kristensson et al., 2007; Holz et al., 2018; McGrath & Astell, 2017; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Oyesanya et al., 2019; Ravneberg, 2012; Riikonen et al., 2013; Seymour et al., 2019; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Attitudes to health condition: The end user's attitudes towards their health condition relates to the end user's need to accept their current health condition and the need for help before they are willing to use assistive technology. The acceptance of needing help could be distressing and depressing for the users; this barrier needed to be overcome before assistive technology was accepted (Baldwin et al., 2011; Cook et al., 2016; Elnady et al., 2018; Gibson et al., 2015; Gitlin et al., 1998; Hedberg-Kristensson et al., 2007; Holz et al., 2018; McGrath & Astell, 2017; Riikonen et al., 2013; Weerasinghe et al., 2015).

Past experiences: Past negative experiences with assistive technology influenced the acceptance of the current assistive technology by the user. Examples included if a device did not work in the past, caused pain or the user had past disappointments with a service (Jamieson et al., 2019; Seymour et al., 2019; Weerasinghe et al., 2015).

2.3.2.5 Theme 5: Support network

The theme support network describes the influence that the close support network to the individual, for example family, carers, and friends, can have on acquiring and using assistive technology.

Family and carer attitudes to assistive technology: The negative attitudes of family and carers towards assistive technology could influence the use or non-use of assistive technology by the user. A perception by family and carers that equipment is not wanted or required influences the attitude of the user and impacts on the use of the equipment.

(Adolfsson et al., 2016; Baldwin et al., 2011; Boger et al., 2014; Boot et al., 2019; Darcy et al., 2016; Dorjbal et al., 2019; Gibson et al., 2015; Riikonen et al., 2013; Seymour et al., 2019; Taherian & Davies, 2018; Van Den Heuvel et al., 2012).

Family and carer support: Another theme relating to the support network was the consequence of a lack of engagement and inclusion of family and carers to support the user during the prescription, issuing and training of the assistive technology. If the family and carers did not "buy into the idea" of the assistive technology, then users lacked the required support to use and become familiar with the assistive technology for more independent use (Adolfsson et al., 2016; Boger et al., 2014; Boot et al., 2019; Darcy et al., 2016; Gelinas-Bronsard et al., 2019; Gibson et al., 2015; Holthe et al., 2018; Mortenson et al., 2018; Myburg et al., 2017; Newton et al., 2016; Pereira et al., 2019; Riikonen et al., 2013; Seymour et al., 2019; Smith et al., 2002; Taherian & Davies, 2018).

Peer support: Users also wanted to learn about how to use assistive technology from those with similar conditions who knew what it was like to use the assistive technology through a peer support environment instead of being given information by therapists and equipment suppliers. Currently users felt there was a lack of opportunities to access peer support (Adolfsson et al., 2016; Asghar et al., 2018; Baldwin et al., 2011; Boot et al., 2019; Gelinas-Bronsard et al., 2019; Newton et al., 2016; Okonji & Ogwezzy, 2019; Seymour et al., 2019).

2.3.2.6 Theme 6: Societal barriers

This theme group's descriptive themes relating to wider societal issues that are a barrier to the access and use of assistive technology.

Societal stigma: Users often felt stigmatised by society when using assistive technology. The negative attitudes of others towards them made individuals feel vulnerable, self-conscious and embarrassed using their assistive technology in public places (Adolfsson et al., 2016; Andregard & Magnusson, 2017; Baldwin et al., 2011; Boot et al., 2019; Cook et al., 2016; Dorjbal et al., 2019; Fomiatti et al., 2014; Gerber, 2003; Gitlin et al., 1998; Hedberg-Kristensson et al., 2007; Holz et al., 2018; Mann & Tomita, 1998; McGrath & Astell, 2017; Orellano-Colon et al., 2016; Ravneberg, 2012; Smith et al., 2002; Taherian & Davies, 2018; Weerasinghe et al., 2015).

Public infrastructure: The design and construction of public infrastructure**,** for example buildings, roads and paths reduced the accessibility of the physical environment to assistive

technology users, becoming a barrier to its use. Lack of access ramps, narrow corridors and aisles, high counters and a lack of appropriate parking spaces all limited assistive technology use (Andregard & Magnusson, 2017; Dorjbal et al., 2019; Fomiatti et al., 2014; Hedberg-Kristensson et al., 2007; Holz et al., 2018; Mann & Tomita, 1998; Okonji & Ogwezzy, 2019; Orellano-Colon et al., 2016; Weerasinghe et al., 2015).

Transportation: Limited and poorly designed public transportation was also a barrier to the use of assistive technology in the community (Andregard & Magnusson, 2017; Dorjbal et al., 2019; Fomiatti et al., 2014; Holz et al., 2018; Seymour et al., 2019; Weerasinghe et al., 2015).

Government policies to assistive technology: The government policies towards assistive technology priorities, commissioning and provision of equipment produced barriers accessing assistive technology. For example, policy driven agendas towards increasing diagnosis rates of dementia, national assistive technology lists and a lack of recognition for assistive technology in a government's agenda impacted on the provision and use of assistive technology (Adolfsson et al., 2016; Boot et al., 2019; Dorjbal et al., 2019; McGrath & Astell, 2017; Newton et al., 2016; Okonji & Ogwezzy, 2019; Seymour et al., 2019; Weerasinghe et al., 2015).

Lack of representation at policy level: Assistive technology users were concerned that they had a lack of representation at policy level, which impacted on the national agenda and government policies towards assistive technology (Boot et al., 2019; Durham et al., 2016; Okonji & Ogwezzy, 2019).

Economic status of country: A final sub-theme relating to societal barriers was the economic status of the country**.** Issues such as widespread poverty limited the availability of funding for assistive technology and people lacked funds to purchase assistive technology themselves (Okonji & Ogwezzy, 2019; Seymour et al., 2019).

2.4 Discussion

Assistive technology could reduce the burden that chronic conditions puts on healthcare services and increase the independence, participation and social engagement of individuals with chronic conditions (Lansley, 2004; Madara Marasinghe, 2016; Mitzner et al., 2010; van Ommeren et al., 2018; World Health Organisation, 2018). However, this potential is unrealised with assistive technology abandonment rates between 20-70% (Martin et al., 2011; Phillips & Zhao, 1993; Scherer, 2005; Scherer, 2014; Sugawara et al., 2018). This meta-synthesis identified six overarching barriers to obtaining and using assistive technology: design and function of assistive technology, awareness and information, the service provision of assistive technology, personal psychological barriers, support network and societal barriers, Figure 2-3. The barriers are common across health morbidities, Table 2-3, and multiple themes are present in each article. Therefore, the barriers should be considered in combination as a summary of the researchers understanding of the issues that inhibit assistive technology deployment. To improve the usage of assistive technology, a single strategy targeting one of these aspects - for example improving the design and function of assistive technology - would fail if related interlinked barriers were not also addressed. The themes interlinking and relationship to the wider biopsychosocial models of disability and wellbeing form the basis of this discussion.

2.4.1 Design of assistive technology

Berkun (2004) describes the three elements of 'good' design (Berkun, 2004):

- Performance: how well it does the job it is fit for
- Engineering: how safe, well-engineered and reliable it is
- The aesthetics of experience: how the whole interaction with the product/service feels and is experienced

Barriers relating to all three of these aspects such as ease of use, reliability, and comfort were identified in the analysis and are consequences of 'bad' design. The idea of 'good' or 'bad' design is subjective and what a designer perceives as 'good' due to meeting design specifications, may not meet the needs of users. This problem is discussed throughout design literature and stems from a range of misunderstandings but in healthcare a significant reason for this difference is a gap in perspective between designers and people living with the impairments they are designing support for (Orpwood, 1990). Increased user involvement in

the design of assistive technology would improve this (Alqahtani et al., 2019; Martin et al., 2011; Orejuela-Zapata et al., 2019; Robinson et al., 2013).

This analysis showed assistive technology lacked the customisability needed to meet an individuals' needs. The success of technology rests on integration into the users' local, habitual routines (Gibson et al., 2019; Orpwood et al., 2004). However, their experiences and assisted living needs are diverse and unique (Greenhalgh et al., 2015) due to the individual, community and the wider-environmental contexts they reside within (Mead et al., 2019; World Health Organisation, 2001). Therefore, assistive technology does not lend itself to standardised solutions or 'one size fits all' approaches. Pols and Willems (2011) argue that integrating technology depends on individuals tinkering with it to make it meet their needs (Pols & Willems, 2011). Lopez (2015) suggests that technology uptake is dependent on mundane yet complex socially situated and embodied activities that determine the individual's relationship with technology (López Gómez, 2015). Therefore, a core feature of assistive technology is that is must be 'adaptable' or 'modifiable' to fit into everyone's circumstances.

Greenhalgh et al. (2013) use the phrase 'Bricolage' to describe how individuals, family members and informal carers (the bricoleurs), adapt everyday technology to meet the user's needs (Greenhalgh et al., 2013). Bricolage combines new and second hand materials to produce one-off devices that solve one-off problems (Büscher et al., 2001; Hartswood et al., 2000). This adaption of everyday technology to meet an individual's needs and circumstances is found in studies relating to telehealth, telecare, and dementia care (Gibson et al., 2019; Greenhalgh et al., 2013). Gibson et al. (2019) found bricolage is commonly used informally by carers and, to a lesser extent, people with dementia to overcome everyday issues in place of formally provided assistive technology (Gibson et al., 2019).

The success of bricolage hinges on: using everyday items that are already part of an individual's routine; understanding user's needs through the close relationship between user and bricoleur; adapting devices when needs change due to changes in the user's health or circumstance; and saving money with low-cost everyday technologies overcoming the barrier of equipment cost. However, bricolage is dependent on the creative engagement and problem solving by the bricoleur, so it is not accessible to all people. Given the evidence from this analysis shows many of the barriers to assistive technology are common across different health conditions, it would be interesting to investigate how bricolage techniques are used across other health populations alongside formal assistive technology provision.

2.4.2 Social context

Based on this review, an individuals' societal context presents barriers to assistive technology use. This is in line with the ICF and GENIAL frameworks that emphasise the impact of communities and wider environmental context on disability and wellbeing (Kemp et al., 2017; Mead et al., 2019; World Health Organisation, 2001). Government policies on assistive technology link to the social context of ICF and GENIAL and ultimately influence barriers including accessible infrastructure and transportation, commissioning and funding of assistive technology services and equipment cost.

Overcoming infrastructure and transportation barriers requires work to address them in the urban environment's planning and building and assistive technology's design. National and local governments must ensure environments are open to assistive technology use to promote accessibility and companies must ensure device designs are usable in these environments.

The commissioning and funding of services needs to reflect a change in approach to chronic condition management. Government policies are more focused on diagnosis (Newton et al., 2016) and short-term rehabilitation treatment goals, based on the traditional acute medical model, rather than focusing on services to promote long-term self-management for individuals with chronic conditions. The use of bricolage, alongside more formal assistive technology provision, could overlap with self-management principles by the user or their family. However, more funding would be needed to support and implement any long-term strategies for managing chronic conditions. This approach is challenging as it must be balanced against short term emergency medicine and care needs.

The barriers related to societal issues must also be placed in the wider economic context of the country. For example, several articles discussing less economically developed countries such as Nigeria and Uganda, highlight that assistive technology is a low priority due to more wide-spread social and economic issues such as poverty, famine and lack of infrastructure within the country (Okonji & Ogwezzy, 2019; Seymour et al., 2019).

Societal stigma as identified in previous work (Orejuela-Zapata et al., 2019; Parette & Scherer, 2004) arises due to a lack of awareness, lack of education and misperception (Arboleda-Flórez, 2002). Assistive technology stigma is also partly due to the aesthetics of the assistive technology (Parette & Scherer, 2004): *"Why does it all have to be beige-brown*

and look like it's out of the infectious disease ward? You know, we already stick out enough, we don't need anything else added." (pp.652) *(Taherian & Davies, 2018).* The behaviour and attitudes of the wider public influence the attitudes of the individual and their family (Cioffi, 2000). This has implications for social participation, mental health, and physical health (Parette & Scherer, 2004). This stigma causes some people to avoid using their assistive technology when out in public and raises the question of how to make assistive technology look less "medical" and more "mainstream". Changing the wider public's views about assistive technology, and more widely views regarding disability, is needed to promote the use of assistive technology for the individual.

The adaption and use of more mainstream technology, improvements to the aesthetic design of assistive technology and information strategies to improve the wider public's awareness of assistive technology could all help to address societal stigma. Again involving end users in the design process could add considerable value in reducing the 'stigma' barrier.

2.4.3 Individual context

The device itself is important, but so is understanding the psychological processes that may facilitate its usage. Psychological barriers identified in this review related to both the individuals' acceptance of needing help and negative views associated with the use of assistive technology. The ICF and GENIAL frameworks characterise the factors influencing the experience of disability by an individual including age, gender, social background, education and professional background, character and behaviour patterns (Kemp et al., 2017; Mead et al., 2019; World Health Organisation, 2001). In the context of assistive technology, these individual factors could influence the perception and acceptance of devices. Theories of behaviour change might help to overcome the psychological barriers to assistive technology to reduce the abandonment rate. A systematic review identified five factors as key to maintaining behaviour change. These include motivation to want to change, self-regulation through goal-setting, developing new favourable habits, resource - both psychological and physical - to overcome the barriers to change, and the influences of both the social and environmental context (Kwasnicka et al., 2016). Research from the field of positive psychology further emphasises a key role for positive affective processes in sustaining new behaviours (Van Cappellen et al., 2018). Enabling positive experiences with assistive technology can cultivate in positive nonconscious motives for using such devices, increasing the chance of future engagement in using them. By changing the perception of assistive

technology to being an enabler, rather than associated with a loss of function, this can help encourage positive experiences of using assistive technology. Overcoming the barriers to assistive technology therefore also needs to consider positive psychological support for the individual alongside providing the right assistive technology.

Failure to improve over current solutions, Figure 2-3, showed individual context must be considered when deploying assistive technology. Assistive technology should be sought out by the user, or their support network as opposed to being pushed onto them assuming it is an improvement over their current coping mechanism. Deployment should be based on a user's wishes and, where possible, enhance rather than replace their current management strategies. This requires collaboration between clinicians, users and support networks to understand what matters to the client (Greenhalgh et al., 2015). This would also necessitate involving the client in their care decision-making process, moving away from the acute medical model's 'passive recipients' of care approach.

Social influences on behaviour change are also linked to societal stigma. The attitude of one's support network to using assistive technology may be a barrier as is the typically unmet desire for peer support from others who have used the equipment when learning about it. According to the GENIAL model, community can drive change (Mead et al., 2019). Greenhalgh et al. (2015) established that personal interactions with social networks can make or break telehealth and telecare (Greenhalgh et al., 2015). This research builds on this by showing the importance of the social network for assistive technology solutions. This leads to ask how community can be better integrated into assistive technology. Creating a community for providing assistive technology would encourage peer support and knowledge sharing as well as having secondary benefits like social engagement and inclusion that influence positive behaviour change and wellbeing.

2.4.4 Healthcare context

The service provision of assistive technology needs to include more support to users following provision, more timely interventions, and more involvement of users in their care to make it suitable for their needs, Figure 2-3. Personal context is not static, rather context and use are dynamic and co-constitutive (Dourish, 2004). Follow-up support can identify if changes in health, personal or environmental factors mean a device is no longer appropriate. Wherton et al. (2015) argue that the installation of assistive technology must cease to be a one-off technical event and instead be an ongoing process where personal and social

supports are built through continued relationships and social networks (Wherton et al., 2015). This analysis shows this is applicable beyond their context of telehealth and telecare provision and should be explored in relation to all assistive technology provision. This requires a change in focus from user's being viewed as passive consumers to instead integrating them into their care, building strong inter-personal relationships and enabling technology to be readily adapted to a change in context.

Restrictions on service provision are partly due to lack of equipment funding, service commissioning and resources. As previously identified, this is partly driven by government policies and funding for assistive technology. With more funding, services would be able to overcome many of the barriers as they could, for example, provide more follow up support, more timely interventions and let the user trial assistive technology. However, not all barriers in service provision are related to funding, for example, the need for individualised care. Substantial increases in funding and resources are unlikely in the short term so services need to focus on developing more effective methods to provide and support individuals. Transdiagnostic services could achieve this by reducing duplication in staff and resources, providing more cost-effective strategies as barriers to assistive technology are similar across chronic conditions.

Co-production could address users' feeling they had a lack of individualised and involvement in their care. Co-production is a person-centred approach where service-users are placed into an equal partnership with healthcare professionals for managing their health and wellbeing (Realpe & Wallace, 2010). The approach differs from traditional models of healthcare where clinicians are seen as the "expert" and users are passive recipients of care (Keller & Carroll, 1994). Co-production instead identifies the user as the expert in their own condition and lived experience with unique knowledge of how they manage their own health. This changes the role of the clinician from a prescriber, using pre-defined criteria to give a "menu" of assistive technology choices, to adviser. The clinician instead uses their experience and knowledge to work with the client to implement strategies, techniques, and, where appropriate, technology. This closely links back to the idea of bricolage previously discussed (Greenhalgh et al., 2013). In this respect the client can learn from the clinician, but equally importantly the client teaches the clinician what works for them based on their lived experience, improving the clinician's knowledge which can in turn be shared with other clients. Integrating co-production approaches would require a culture shift of how services are designed to manage chronic conditions; this presents many challenges. Exploring the practicalities of such an approach should be the subject of future research.

2.4.5 Information and awareness

Users and therapists lacked reliable information and awareness about assistive technology (Boot et al., 2018; Ranada & Lidstrom, 2019; van Ommeren et al., 2018). Increased information and education could improve awareness and inform users and healthcare professionals about the products and services available, enabling users to make a choice to engage. It can also ensure users are competent in operating devices and helps inform and improve awareness in wider society of assistive technology which discourages stigma. Users lacked information about how to access and use assistive technology, and lacked information about the benefits of using assistive technology; this is important in the context of behaviour change for motivating adoption (Kwasnicka et al., 2016). Healthcare services have a role in the provision of information that is unbiased and trustworthy however, there is a fine balance between insufficient information and overloading with too much information. Information also needs to be available to users, family, carers, and healthcare professionals that is accessible and trustworthy.

Healthcare professionals need to maintain up to date knowledge and training if they are to appropriately respond to user's needs. This is linked to service provision and currently a lack of resources may influence healthcare professional's capacity to keep up to date with the range of assistive technology available. Online databases could help collate information about assistive technology and include everyday technologies and strategies people use. This could enable user's and therapists to share information, strategies and reviews about what works for them. For example, 'Dementia Circle' (www.dementiacircle.org) evaluates and shares products and digital solutions to help people living with dementia. To ensure such a resource is accessible and useful for other assistive technology, it must be developed with input from the stakeholders: users, family, carers, and healthcare professionals.

2.4.6 The role of evidence in assistive technology

Although a lack of evidence was only directly identified in two articles, it can have a causal impact on multiple other barriers including government policy, service commission and equipment funding. The lack of evidence should be examined in the context of the current dominant model: evidence-based medicine (also referred to as evidence-based healthcare) (Pope, 2003). Evidence based medicine aimed to ensure that clinical practice became more

scientific and empirically grounded. Evidence from large, randomised control trials (RCTS) and observational studies are used to produce clinical guidelines to determine the commissioning and funding of treatments. The approach relies on the assumption that "best evidence" would be objectively verifiable and readily updated with new research (Wieringa et al., 2017). However, it is now facing a crisis as evidence quality has been misappropriated by vested interests, the volume of evidence and clinical guidelines are unmanageable, statistically significant benefits may be marginal i.e. not clinically meaningful, inflexible guidelines produce care that is management driven and not patient centred, and guidelines map poorly to complex multi-morbidities (Greenhalgh, 2012; Greenhalgh, Howick, & Maskrey, 2014; Ioannidis, 2005).

The use of evidence-based medicine shares barriers with assistive technology. First, a limited number of randomised control trials have been successfully reported on with assistive technology, especially compared to other healthcare interventions like drug trials. Second, traditional evidence-based medicine is based on controlled laboratory testing dealing with objective, carefully-controlled measures (Greenhalgh et al., 2014). However, as evidenced in this review and GENIAL and ICF frameworks show, the use of assistive technology is personal, complex, and has a host of confounding factors associated with the individual, community and environment (Kemp et al., 2017; Mead et al., 2019; World Health Organisation, 2001). This complexity may explain why RCTs are rare. It also indicates that generic evidence produced about an assistive technology is not as generalisable as drug trial results are. For example, Demain et al. (2013) state "*(stroke patients) were less interested in generic findings, arguing that every person with stroke is different and that evidence of benefit should be sought on a case-by-case basis*" (pp. 9) (Demain et al., 2013).

The need for evidence-based medicine and high quality RCTs is not disputed, instead it is questioned the applicability of this type of evidence for assistive technology provision. Real evidence based medicine addresses some of the concerns with evidence based medicine (Greenhalgh et al., 2014) as it emphasises ensuring healthcare is individualised to the patient, that care is based on clinical judgement and not wholly prescriptive rules and the importance of a strong patient, clinician relationships. It calls for patient's experiences to be included through qualitative techniques that are complementary to the application of research evidence (Mol, 2008). For example, experiential knowing, through having lived with a condition, is demonstrated as important evidence for self-management practices (Greenhalgh et al., 2013; Hinder & Greenhalgh, 2012; Ruston, Smith, & Fernando, 2012). Similarly for assistive technology it is important that policy makers and service

commissioners recognise that provision is centred on an individual's unique needs and social context. Such subjectivity cannot be reproduced in randomised control trials and therefore the evidence required for assistive technology funding should reflect a more individualised, patient focused approach. How to practically achieve this approach is challenging and complex, requiring a culture shift at all levels of healthcare provision: clinicians, management, and commissioners.

2.4.7 **Comparison with other literature**

The ARCHIE framework defines the quality principles for designing, installing and supporting telehealth and telecare products and services (Greenhalgh et al., 2015). ARCHIE was developed from interviews, ethnographic, and workshop activities focused on telehealth and telecare. It states that services should: anchor in a shared understanding of what matters to the users, take realistic approaches to illness progression, continuously co-create solutions with users and carers, encourage inter-personal relationships to support use, integrate methods of sharing knowledge between individuals and services, and be rigorously evaluated using appropriate research methods. The reasoning behind the development of this framework follows many of the barriers identified in this review: lack of customisation and user involvement, poor information sharing and knowledge, and lack of ongoing social interaction and support. Therefore, based on the results of this analysis, a similar framework could be suitable for the provision of all assistive technology.

Instead of traditional assistive technology provision, the role of healthcare services could instead be implementing approaches that support the client's discovery of techniques and strategies that help them manage themselves. This approach would focus on both physical and mental health and operate as a multi-disciplinary, trans-diagnostic service supporting self-management, health, and wellbeing. The use of technology, for example bricolage solutions or assistive technology, can form part of this, but should not be considered the overall goal. This is not routinely done and achieving this requires a re-think of how services operate (Greenhalgh et al., 2015). Aspects of the Maker movement, community based spaces where individuals can design and fabricate their own technology (Dougherty, 2012), could provide an approach that more formally encourages the development of bricolage solutions in healthcare services. A maker space is also a community space and could encourage collaboration, social engagement and support between the user, family, peers, and healthcare professionals. This can enable the sharing of knowledge, skills, and adaptions

of devices already being used by people to overcome everyday issues. This approach is very different to current assistive technology provision based on 'menus' of products that can be supplied and strict eligibility criteria and encourages collaboration, creative thinking and problem solving. Exploring how aspects of the Maker approach could be incorporated into formal healthcare services to encourage strategies of, for example, self-management using bricolage would be an intriguing avenue for future research. This should be explored with reference to making more effective and cost-efficient models of healthcare provision.

2.4.8 Limitations

One limitation of a meta-synthesis is the information analysed is dependent on the results and quality of the articles included. The articles reviewed were characterised by varied research questions and methodologies deployed in different environments and contexts. The meta-synthesis process may thus mask certain shortcomings of articles, especially those with low methodological quality. This concern is, in part, ameliorated by the use of the CASP tool, facilitating the assessment of article quality and aiding comparison between studies undertaken in different contexts. Although there is no standardised method for assessing the quality of research currently, the CASP tool has been widely used in previous work.

Another limitation with meta-syntheses is that the context of each individual article can be lost during the synthesis and the context of one study may not carry over to other studies. However, this research examines and report on country, population, and type of assistive technology for each article, enabling the reader to establish the context for themselves.

A final limitation of meta-syntheses is that thematic analysis of data are subjective, based on the author's own background and understanding of the topic. This concern was ameliorated through regular discussion with the wider research team at different stages of the research process, including discussion of theme synthesis and convergent interpretation of the results. This served to reduce the bias relating to individual subjective interpretation of the data.

2.4.9 Implications for future research and practical applications

This meta-synthesis aimed to identify the common barriers to assistive technology in the context of establishing more effective healthcare services to improve health and wellbeing

in individuals with chronic conditions. The findings demonstrate the issue is multifaceted, relating to a wide range of aspects from the design of assistive technology devices to attitudes of the individual, provision of healthcare services and wider societal barriers. The evidence suggests individuals want more customised solutions and greater involvement in their care to better support their bespoke needs. While the initial focus was on assistive technology, it is argued that assistive technology must be implemented alongside current solutions and techniques already used by the individual and should encourage the adaption of everyday technologies that are readily available and customisable to meet individual needs. Exploring how individuals adapt strategies and everyday household technologies to meet their needs warrants further research. This research has identified how aspects of the Maker movement could be used to overcome the barriers to assistive technology and more widely be used to encourage positive health behaviours for health and wellbeing. The extent to which this is practically feasible for creating more effective models of healthcare for chronic conditions and its impact on health and wellbeing also warrants future research efforts.

Another important consideration is the access to and dissemination of information to both user's and healthcare professionals. Strategies to ensure trustworthy, accessible, and relatable information are important to ensure people are aware of the service and technical solutions available to them, either household technologies or more formal assistive technology. Future research should look at the use of online tools to better disseminate information about solutions people use. This should be done in collaboration with key stakeholders. Future research should also look at the issues presented by social stigma and how to change the perceptions of disability and assistive technology by the wider public.

The approaches put forward here require a cultural shift from traditional assistive technology provision and is no doubt a complex and challenging solution. However, the approaches are based on the results of this systematic analysis combined with established models of health and wellbeing, a focus on individualised care, self-management, and pre-existing frameworks for assistive technology provision. It requires buy in from all levels of society: government, industry, commissioners, management, clinicians and the users themselves. Several key challenges to achieving this are summarised below:

- How to change the service delivery of assistive technology from the "expert" clinician medical model of care to a more patient centred model for the provision of more patient specific solutions, where individuals are involved in their care and

decisions are based on the individuals lived experience, their personal and social context.

- How to encourage both healthcare professionals and end-user to think more creatively in solving problems; enabling the exploration of both everyday technology and assistive technology that is better suited to the user needs, rather than relying on restrictive, prescription-based lists for the provision of assistive technology.
- How to better evaluate the way assistive technology is provided and the impact it has on an individual. A change in outcomes is required from purely measurable objective outcomes to outcome measures that reflect changes in health and wellbeing for the individual.

3 Customisation of assistive technology: a review of the literature

3.1 Introduction

One barrier identified with the design and function of assistive technology was the lack of customisation to the user's needs. This meant characteristics of a device, for example the shape, size, aesthetics, comfort, usability, and ease of set up, were not suitable for an individual's needs – barriers also identified previously. With the end goal of helping to realise the potential of assistive technology, one proposed solution is to increase the involvement of the end-user in the design and decision-making processes (Alqahtani et al., 2019; Martin et al., 2011; Orejuela-Zapata et al., 2019; Robinson et al., 2013). Similarly, within the analytical theme of 'service provision' a lack of patient involvement in their own care and a lack of individualised care were also identified as barriers to assistive technology use. There are multiple different approaches that could be used to increase user-involvement and produce more customised assistive technology. This chapter will explore three of them: do-it-yourself (DIY) practices and Maker-movement; a co-design approach where the end-user works closely with designers throughout the design process; and look at how to utilise current healthcare professionals who prescribe assistive technology.

This chapter will first explore each of these approaches in terms, first by reviewing the literature around DIY practices and Maker-movement and its implications for producing custom assistive technology for the user. Next, reviewing the use of co-design and its application for producing customised assistive technology solutions with the end user. Finally, the use of advances in low-cost, small-scale digital design and manufacturing technologies within healthcare settings will be reviewed and how traditional assistive technology providers currently use this technology. This chapter will then summarise and discuss these findings in the context of how these methodologies have the potential to reduce the barriers to accessing and using assistive technology, identifying further research opportunities required to evaluate these practices.

3.2 Do-It-Yourself practices and Maker movement

Do-it-yourself (DIY) is described by Kuznetsov & Paulos (2010) as "*the creation, modification or repair of objects, without the aid of paid professionals*", (pp.295) (Kuznetsov & Paulos, 2010). It captures a vast array of creative activities where people use, repurpose and modify material to produce something (Buechley et al., 2009). As a cultural movement, the 54ractices has grown over the past few decades due to the emergence of new web-based sharing mechanisms enabling individuals to share ideas and projects to a wider global audience (Kuznetsov & Paulos, 2010). A second driver for this growth is due to technological advances, for example user-friendly rapid prototyping tools such as 3D printing, which has enabled personal scale manufacturing to become accessible at a lower cost (Gershenfeld, 2007). This has led to the emergence of both in-person and online groups which bring people together to share techniques and develop social communities. These spaces encourage a sense of community where individual's share skills, thoughts and ideas through conversations with likeminded individuals to create and solve issues (Dougherty, 2012).

The maker culture is a technology-based sub-culture of the DIY culture whereby individuals come together in a community to learn through making, taking things apart, re-assembling and trying different techniques. Physical community maker spaces, also called hackerspaces and Fab Labs, enable resources to be pooled together to provide access to equipment for making that individuals would not be able to afford on their own and provide a physical space where expertise can be shared (Lindtner, Hertz, & Dourish, 2014). These physical spaces allow individuals to learn from one another, collaborate and share projects, to create communities (Tanenbaum et al., 2013).

In the previous chapter, it was discussed how aspects of the Maker movement could be utilised to produce low-cost, highly adaptable assistive technology where the end-user themselves are involved in the making process. It could also help encourage collaboration and social engagement for individuals living with chronic conditions. Within tele-health, tele-care and dementia there were already examples of this being done at an individual level at home, described by the term 'bricolage' (Gibson et al., 2019; Greenhalgh et al., 2013). These DIY practices could in theory lead to true 'self-management' strategies for individuals with chronic conditions, where the individual is self-sufficient in making and maintaining their own solutions. This is an aim for healthcare services to help individuals manage their own health need and could significantly reduce the input required of healthcare services (Dineen-Griffin et al., 2019; Ekman et al., 2011; Jordan et al., 2008).

Therefore, with the aim of encouraging individuals to self-manage their own health, this sub-chapter aims to summarise the current scientific literature around DIY practices and the maker-movement in relation to assistive technology. This will help inform the current level of evidence around these practices. Prior to exploring the implications of DIY and maker culture on the design and provision of assistive technology, the first sub-section will more widely explore some of the motivations and values behind DIY communities.

3.2.1 Motivations for DIY practices

Kuznetsov & Paulos (2010) studied the motivations of six different DIY communities through online surveys and follow-up questionnaires (Kuznetsov & Paulos, 2010). The communities were a mixture of online websites and in-person community groups. The motivations of individuals to become involved in the communities included: looking for inspiration and new project ideas, learning new concepts, receiving feedback on current work, educating others, learning new techniques and feeling connected with others. A key part of the community was sharing work with others, with over 90% of responses indicating they shared at least some of their project with others.

Wang & Kaye (2011) identified common themes across different group activities associated with maker practices and communities (Wang & Kaye, 2011). Similar to Kuznetsov & Paulos (2010), themes included individuals wanting to openly share information as the 'norm', individuals participating in a community to form social groups, and the idea of learning through both practical work and engagement with other like-minded individuals. Wang & Kaye (2011) also discussed how being involved in DIY practices was a form of resistance and challenging authority, with making as resistance mainstream consumerism culture.

Tanenbaum et al. (2013) presented a point of view on how DIY and maker practices were democratizing technology (Tanenbaum et al., 2013). DIY practices helped individuals create personal, contextually relevant objects, where the process of making and creating something was a source of pride and satisfaction for the end user. This experience was similar to the "*I designed It myself*" effect described by Franke et al. (2010), where the feeling of accomplishment arising from the process of self-designing an object impacts on the subjective value of wanting to use it (Franke, Schreier, & Kaiser, 2010). Whilst Franke et al. (2010) observed this effect in the customisation of commercial products; there were similarities with an individual's motivations for being involved in DIY practices.

Tanenbaum et al. (2013) further commented on how the emerge of DIY and maker cultures had implications for innovations in software development and product prototyping (Tanenbaum et al., 2013). Research and development activities were no longer restricted to well-funded professionals, but instead were available to more of a mass market. Lindtner et al. (2014) similarly identified how maker spaces could not only be seen as community social hubs, but were also sources of innovation in the development of products and software (Lindtner et al., 2014). The authors emphasized how maker spaces brought together like-minded individuals encouraging collaboration and access to the necessary technological resources to promote innovation that could challenge traditional research and development practices.

However, Tanenbaum et al. (2013) noted the context of these communities, with "*the current generation of Makers and hackers are often possessed of sufficient free time and access to resources to engage in relatively risk-free making*" and as such these communities may not be accessible to everyone (pp. 2605)(Tanenbaum et al., 2013). Lindtner et al. (2016) similarly discussed that individuals may be encouraged or discouraged to be involved in DIY communities due not only to technical factors, but socio-political factors as well (Lindtner, Bardzell, & Bardzell, 2016). For example, individuals being able to access Maker spaces, the equipment and engagement with others in the communities. As Lindtner et al. (2016) put it "*If individuals cannot see themselves in an existing collective, they will not join in*" (pp. 1399); this may have implications for the access to DIY and making communities for individuals with assistive technology needs.

The above studies discussed several motivations for why individuals involve themselves in DIY practices and communities. Some of the key themes included: the open sharing of ideas and information, a culture of learning and engaging with other like-minded individuals through sense of community, a place to express creativity and individuality and a sense of achievement gained through the practice of making (Kuznetsov & Paulos, 2010; Wang & Kaye, 2011). The DIY culture has created new avenues for research and development, with more affordable, personal manufacturing equipment and online platforms that encourage knowledge sharing (Lindtner et al., 2014; Tanenbaum et al., 2013). These motivations have potential implications to reducing the barriers to accessing and using of assistive technology previously identified (Howard et al., 2022a). For instance, could DIY be used to improve the design and function of devices through greater customisation of devices? Could it be done at lower costs compared to off-the-shelf products? Could the culture of learning and engaging with other like-minded individuals help improve access to information about

assistive technology and improve peer support? Could involvement in DIY communities help individuals with chronic-health conditions learn new skills and be engaged in community groups? Could DIY impact on the stigmatisation and attitudes to assistive technology, with the sense of achievement in making or the "*I designed it myself effect*" reducing stigmatisation? The next sections will seek to explore some of these questions by reviewing how DIY practices relate to creating and supporting the use of assistive technology through summarising current literature.

3.2.2 DIY and assistive technology

This section summarises some of the early examples in the literature of where individuals have been involved with creating DIY assistive technology (DIY-AT), whether for themselves, for family members or for other people.

Hurst & Tobias (2011) explored different scenarios of how DIY-AT was currently being used (Hurst & Tobias, 2011). In one case study a community group had created custom helmets for helping individuals paint when no off-the-shelf solutions were available. This involved the adaption of face shields using simple, low-cost materials. In a second case study, an individual had set-up an online platform for sharing assistive technology designs they had built using hand-held workshop tools. The designs looked to modify low-cost, house-hold items, making solutions cheap and accessible for people to make themselves. Hurt & Tobias (2011) established that individuals using assistive technology, or working closely with users, were already involved in DIY-AT practices. To enable this to become more widespread, the authors highlighted some of the technical challenges – for example how novices can engage with creating DIY-AT and how to promote others to share successful DIY solutions. The authors concluded that both personal-scale manufacturing and online communities could help make DIY-AT more accessible.

Greenhalgh et al. (2013) used the phrase 'Bricolage' to describe how individuals, family members and informal carers (the bricoleurs), adapted new and second hand materials to produce one-off devices to meet the user's needs (Büscher et al., 2001; Greenhalgh et al., 2013; Hartswood et al., 2000). This DIY practice has been documented in studies exploring telehealth and telecare services and dementia care. (Gibson et al., 2019; Greenhalgh et al., 2013). Gibson et al. (2019) found bricolage was commonly used informally by carers and, to a lesser extent, people with dementia to overcome everyday issues in place of formally provided assistive technology (Gibson et al., 2019). The success of this approach hinged on:

using everyday items that were already part of an individual's routine; understanding the user's needs through the close relationship between user and bricoleur; being easily able to adapt devices when needed due to changes in the user's health or social circumstance; and saving money with low-cost everyday technologies. However, it was not known how much this bricolage approach was dependent on the creative problem-solving skills of the bricoleur and their relationship with the end user. This level of skill could vary from household to household.

Hook et al. (2014) explored the challenges related to DIY-AT for children with disabilities through eleven semi-structured interviews with different stakeholders involved in the use, provision and adaption of assistive technology (Hook et al., 2014). The study found evidence of DIY-AT practices both by parents at home and in a school setting, although the occupational therapists interviewed believed this to be a rare occurrence. The majority of solutions parents created involved the purchasing and adaptation of everyday items and current assistive technology products. The authors found individuals tended to shy away from making assistive technology from scratch due to: a lack of confidence in their own practical making skills; a scarcity of time to design and make solutions; and being reluctant to start making an item without knowing if it would work for their child. The interviewees also raised concerns around the robustness, longevity and safety of devices made through DIY practices, with devices being created without the necessary skills, knowledge, and experience.

Similar to Hurst & Tobias (2011), Hook et al. (2014) suggested how solutions such as rapid prototyping, participation in wider maker communities and knowledge sharing could improve uptake of DIY-AT for children with disabilities (Hook et al., 2014; Hurst & Tobias, 2011). However, the authors established interviewees currently lacked any awareness of DIY communities and concluded the existence alone of DIY communities was not sufficient for individuals to engage with them. The suggestions from Hook et al. (2014) did not address the concerns raised about the robustness and safety of DIY-AT solutions and how to share solutions. They additionally do not suggest how parents, who reported a lack of free time due to looking after a child with a disability, would have the time to make solutions for themselves or engage with wider DIY communities. This relates to the suggestion by Tanenbaum et al. (2013) that most makers currently have *"sufficient free time and resources to engage in making solutions risk free"* (pp.2605) (Tanenbaum et al., 2013); whereas perhaps this is not the case for individuals needing assistive technology themselves or supporting others.

This section has explored several examples where DIY practices have been used to create assistive technology for individuals with the creation of solutions mainly through adaption of everyday household objects. In the case reported about DIY-AT for children, parents felt they lacked the skill and expertise to look at creating anything more complex and concerns were raised about the robustness and safety of devices. The use of online sharing platforms and personal scale-manufacturing, key recent drivers of the DIY movement, were highlighted as means to increase access and awareness to DIY-AT by Hurst & Tobias (2011) and Hook et al. (2014). The next section will explore examples of how technological advances and online-sharing platforms have been used in relation to DIY and commercial assistive technology.

3.2.3 DIY-AT: Accessibility and sharing

Hurst & Kane (2013) explored how online communities and new technology could make DIY practices more accessible for assistive technology (Hurst & Kane, 2013). Websites such as Thingiverse.com and Instrucables.com were open-source platforms that enabled users to share their designs free of charge with others, encouraging discussion, feedback and collaboration. The authors found a small community of users on such sites who shared assistive technology solutions; further work exploring Thingiverse.com was conducted by Buehler et al. (2015) and is described later (Buehler et al., 2015).

Hurst & Kane (2013) additionally described two tools intended to help make DIY more accessible. The first automatically produced 3D printable graphs to enable visualisation of mathematical graphs for those with limited vision. The second tool was an interactive tabletop surface to create digital snapshots of existing objects and design sketches, with the aim to make 3D modelling simpler for non-experts of computer aided design (CAD) software. The digital snapshots could be digitally manipulated using hand gestures. Unfortunately, the authors did not report any testing or evaluation of this tool. Whilst the work presented a few theoretical examples of tools to make DIY more accessible, no validation of either the online open-source websites or the two tools were presented and therefore conclusions cannot be drawn if they improved the accessibility of DIY practices.

Buehler et al. (2015) explored designs uploaded to Thingiverse.com, identifying 363 unique designs that could be classified as assistive technology (Buehler et al., 2015). The authors found the majority of the designs were either mimics of or adaptions to commercially available assistive technology. Although several designs were highly specialised with no

commercial alternative available. Seventy individuals, who had uploaded some of the designs, completed a questionnaire to gather demographic information, their motivations, perceptions, and skills. The majority of the designers had no disability, with 48% working in a STEM occupation (Science, Technology, Engineering and Mathematics) and 13% working in a healthcare occupation. The most frequent motivation for making a device was to help someone the designer knew, whilst in 13 instances the designer made it for themselves. Other motivations included as a personal challenge, required as part of a class or research project.

This study indicates DIY-AT was being shared on online platforms, however it raises questions about who is uploading the designs, who is accessing them and how they are being used. Buehler et al. (2015) suggested changes were needed to help create more opportunities for individuals with disabilities to self-design through: simplifying design tools, creating alternative design interfaces, and providing accessible tutorial information (Buehler et al., 2015). Additionally, the authors' suggested improvements were required to help individuals identify relevant designs on such websites through improvements in categorising and searching for designs. Finally, the authors noted there were limited end-user testimonials rating the designs and providing evidence if a design was able to overcome a challenge. The authors proposed including end-user feedback to help create more of a community around DIY-AT, encouraging others to share their DIY solutions. The next study moves away from DIY-AT, reporting on the development of an online community to encourage knowledge sharing for assistive technology users.

Layton et al. (2021) aimed to develop an online peer-support network through the development of a website "*AT-chat.com.au*", to simplify the process of finding assistive technology (Layton et al., 2021). The website was developed to encourage peer-to-peer support, that is the support that people with lived experiences give to one another, to choose appropriate assistive technology beyond the traditional healthcare professional engagement. The key objectives of *"AT-chat"* were to:

- Provide information to the end user to help make decisions and choices in relation to assistive technology
- Provide high quality, accessible, peer led information
- Actively contribute to leading, shaping, and influencing the AT community of users
- Contribute to a culture of shared understanding, collaboration, and leadership.

An initial evaluation indicated the website enabled people to be more informed, increased their capacity and understanding and therefore individuals were better able to exert their choice about their assistive technology needs. Whilst not explicitly related to DIY-AT, the work does value the concept of community, sharing of information and peer-to-peer support; key motivators for individuals being involved in DIY communities (Kuznetsov & Paulos, 2010). Such an online platform could include DIY-AT solutions, alleviating some of the difficulties in searching and validating devices shared on other open-source platforms.

This section has reviewed examples of how online-platforms are currently being used to share DIY-AT solutions and tools to make DIY more accessible. Despite the need identified in previous studies, there was a very limited number of examples of DIY accessibility tools in the literature. Of the two examples found, no validation was reported and as such it is difficult to draw any conclusions about the current success of these. In the case of the online sharing platform DIY-AT was being uploaded, but it is unclear how widely these were being re-used. The work by Layton et al. (2021) showed how an online community can be set-up and used by assistive technology users. A similar concept could be explored for sharing of solutions and information around DIY-AT.

The next section discusses more specific examples of online DIY-AT communities. The first focuses on the 'hacking' of medical devices by the end-user to help with management of diabetes. The second explores the idea of "DIY-AT for others", specifically looking at the use of rapid-prototyping technology for the production of upper limb-prosthesis.

3.2.4 DIY-AT communities

This section explores two different DIY-AT communities, characterised by having online platforms for the sharing of blue-prints, designs, and knowledge. These two communities were chosen due to the current availability of scientific literature researching them. The two DIY communities are initially reviewed in turn, before a summary of the commonalities between them is discussed.

3.2.4.1 DIY 'hacking' for the management of diabetes

This section explores the current literature around DIY devices built by individuals to help them self-manage their diabetes.

The #wearenotwaiting movement was started by 'health hackers' back in 2013 who did not want to wait for the medical device industry to deliver the next generation of technology (Marshall et al., 2019). The process for medical device manufacturers to achieve regulatory approval means innovation is slow and associated with high costs, with the safety and efficacy of devices being of critical importance (Barnard et al., 2018). A second motivation was the dis-satisfaction with how current healthcare systems manage diabetes. Patients felt yearly check-up appointments were of limited value in monitoring their day-to-day challenges (Omer, 2016). Patients therefore looked to 'hack' their own continuous glucose monitoring (CGM) devices to gain access to real-time monitoring data which they could use under their own terms to help manage their diabetes. These data have been used to build digital apps to monitor CGM data on a smartwatch, remotely monitor children's blood sugar levels and provide automated medication delivery. For example, an open-source Artificial Pancreas System (APS or OpenAPS) was developed and shared online, providing individuals with instructions and blueprints to create their own system. The APS made use of a self-built mobile phone app to control an insulin pump and adjust insulin dosing in response to real time blood glucose data recorded from a CGM device (Marshall et al., 2019).

In an open letter to an editor, Lewis and Leibrand (2016) reported benefits from 18 individuals using a DIY-APS (Lewis & Leibrand, 2016). An improvement in quality of life was reported due to factors such as: an increased time in recommended blood glucose range, improvements in quality of sleep and more peace of mind. However, these results were self-reported with no scientific process followed in obtaining this feedback, limiting the reliability of the findings reported.

Marshall et al. (2019) published a commentary on the perspectives of 2 adults and one parent of a child using a DIY-APS (Marshall et al., 2019). Individuals' reported improvements in them being able to manage their diabetes, with improved glucose levels, reduced hypoglycaemic episodes (low blood sugar levels), better glucose control overnight and reduced burden on others. Individuals, therefore spent significantly less time managing their diabetes with improved results. The main barrier identified to using a DIY-APS was the help required to build and configure the app to manage their insulin pump. However, individuals described a 'strong DIY community' they could receive support from. Interestingly from a clinical perspective, the authors suggested it was important that healthcare professionals had no involvement in the set-up or building of a DIY-APS due to liability issues associated with device failure.

Kesavadev et al. (2020) reviewed the published literature relating to DIY-APS (Kesavadev et al., 2020). Nine articles were identified that reported glycaemic outcomes related to use of DIY-APS ranging across adults, adolescents, and children. The authors concluded that DIY-APS were able to attain stable glycaemic control comparable to other commercially developed technologies. This had indications for improvements in quality of life, reductions in healthcare treatment costs associated with better glycaemic control and lower risk of hypoglycaemia episodes. However, the authors noted that studies had small sample sizes and a lack of long-term reporting of results. They also noted the potential bias in those using a DIY-APS and reporting the results being technically adapt and motivated users, thus it was difficult to assess the use of these devices across the wider diabetes population.

Braune et al. (2021) conducted a web-based, multinational survey to investigate the motivations of individuals for using a DIY-APS and to collate self-reported clinical outcomes from end users 3 months before and after using a DIY-APS (Braune et al., 2021). 897 individuals from across 35 countries completed the survey. Participants were both adults with diabetes and guardians of children and adolescents with diabetes. The main motivations for using the DIY-APS systems were: better glycaemic control; a reduction in acute and long-term complications related to diabetes management; being able to "*auto-pilot"* their diabetes management and thus improved diabetes management and quality of life; a lack of availability of commercial alternatives; improved sleep for the individual with diabetes and for the caregivers; and involvement in the DIY-APS community. Further results from the self-reported clinical outcomes showed a significant decrease in average blood glucose levels following use of a DIY-APS. It should be noted these were self-reported and were not compared against any clinical records; from the methods described it was not apparent how individuals obtained these measurements and therefore it is difficult to access methodological consistency across the large sample.

Of particular note are the sample characteristics of the individuals using the DIY-APS reported by Braune et al. (2021). Of the 897 individuals, 85.4% of the respondents had a university degree or higher, with 19.2% having a professional background in biomedicine or healthcare and 26% in a technology field. This implies that users were generally of a higher socioeconomic status, representing a tech-savvy, highly educated sub-population of the whole diabetes population. This limits the scope of the finding as it is unclear if others outside of this sub-population would manage with building and maintaining a DIY-APS. Both Kesavadev et al. (2020) and Barnard et al. (2018) also noted this barrier (Barnard et al., 2018; Kesavadev et al., 2020). This has similarities about the maker movement described by

Tanenbaum et al. (2013) earlier, in that individuals who get involved in 'making' have sufficient free time and resources to engage relatively risk free (Tanenbaum et al., 2013). Whilst there were obvious risks if the devices were to fail, individuals likely had sufficient funds to purchase the components to make a DIY-APS without it being a significant financial investment.

Finally, Barnard et al. (2018) discussed the legal issues relating to using a DIY-APS for different groups (Barnard et al., 2018). The authors suggested healthcare professionals would become accountable if they were to recommend the use a DIY-APS, knowing that such a system was an unregulated medical device. The authors compared this to a healthcare professional prescribing an unauthorised drug - a violation of the law. For the end-users, they needed to understand the full legal implications of using an un-regulated product. For example, in the incidence of device failure no liability would lie with a medical device manufacturer. The individual themselves would therefore become liable in the result of any harm caused to them or others due to failure of a DIY-APS, with further implications for insurance claims. As such, the authors concluded DIY-APS users needed an understanding of the risks involved and the skills required to build and maintain a DIY-APS prior to exploring its use. In the case of caregivers or friends setting up a DIY-APS for someone they know, the caregivers need to understand they become liable for the set-up of the device, with it no longer being considered DIY. Similarly for DIY-APS developers, they should not be involved in the set-up of the device themselves, making it clear to the individual users that they use at their own risk. As such, developers would not be able to put anything on an 'app-store' for others to purchase or download, as they would then become the legal manufacturer of such an app.

This section has summarised how a group of individuals have taken it upon themselves to hack current medical devices to better manage their diabetes. It is an example of how DIY practices have led to the democratising of healthcare through use of accessible technology and online platforms to build a community that shares information, blue-prints, and offer support to users. It thus exemplifies aspects of the maker movement previously identified (Kuznetsov & Paulos, 2010; Wang & Kaye, 2011). Whilst there is evidence of the effectiveness of DIY-APS in helping individuals manage diabetes, results lacked rigorous scientific control and had limited long-term data. For example, there is no reporting of any adverse incidents from using the devices, as would be expected in trials of commercial medical device of this kind, and no reporting if any individuals were not able use a DIY-APS. Current evidence presented would suggest a positive bias in the results currently reported. Additionally, it is unclear the skill and expertise required to manage such a device and therefore how

applicable and accessible such a solution could be to the broader population. Finally, safety, legal and liability issues around using the device need to be considered and how this can clash with researchers, medical device manufacturers, regulators, and healthcare professionals in the development of medical devices and healthcare services. The next section will discuss another DIY-AT community where devices are made for other individuals, focusing on upper-limb prostheses.

3.2.4.2 "DIY-AT for others" and maker AT communities

Whilst Thingiverse.com is an online community not specifically targeted at assistive technology, other maker communities use online platforms to enable the end user direct access to the design and designers of custom assistive devices. Such online communities are described as "*DIY-AT for others*", where volunteers produce assistive devices on behalf of distant strangers (Parry-Hill et al., 2017). Example groups include e-NABLE, Makers Making Change, POSTA, Hack on Wheels, REMAP and MakeAbility. e-NABLE is one of the best examples of how the maker movement has made a widescale culture change to the provision of upper limb prosthesis (Holloway & Dawes, 2016). It provides devices "*to help those in underserved communities who have little to no access to medical care"* (Enabling the Future, 2022). These communities have grown due to two key drivers in DIY practices: low-cost digital fabrication and the sharing of designs online. This enables devices to be produced worldwide with access to the right fabrication tools. The next studies explore the implications of "*DIY-AT for others*" by focusing on the e-NABLE community.

Hofmann et al. (2016) explored the perspectives of makers and clinicians on the role of rapid prototyping and DIY practices in assistive technology provision following a summit with e-NABLE volunteers, healthcare clinicians and researchers (Hofmann et al., 2016a). The authors observed a large divide between current clinical practice and the work of volunteer e-NABLE designers. Whilst clinicians focused on a 'do no harm' approach to the provision of devices, the e-NABLE methodology was more representative of a trial-and-error based approach with little structure, follow-up, or feedback mechanisms in the provision process. Clinical practice provided a structure to follow-up with clients to check long-term suitability of a device; however, the e-NABLE community did not consistently follow-up with clients. There were also no formal mechanisms to enforce best practice in the manufacturing of devices within the global e-NABLE community. As such variation in the provision process had potential to

increase the risk to the end user, all of which went against the 'do no harm' philosophy of the clinicians.

Clinicians were also hesitant to get involved in such communities for fear of making them legally liable if the design were to fail and concerns about how open-source assistive devices may limit access to healthcare insurance and commercial assistive technology. Finally regulatory approval was another point of contention. There was a lack of regulatory oversight on the manufacturing and provision of devices by the e-NABLE community. However, the authors noted that "*the lack of oversight on groups like e-NABLE allows for rapid and unhindered growth in both positive and negative directions*" (pp.255). The innovative solutions produced by the e-NABLE community provides another example of how maker culture can be an alternative to traditional research in assistive device development. To resolve these tensions, the authors suggested greater collaboration between clinicians and e-NABLE volunteers to help share expertise and identify areas in the design of upper limb prosthesis where it was and was not appropriate for volunteers to manufacture solutions.

Parry-Hill et al. (2017) explored the motivations for being involved and barriers to participation in the e-NABLE community by interviewing three groups of stakeholders: volunteer designers, clinicians and self-fabricators of devices (Parry-Hill et al., 2017). The volunteer designers wanted to pursue the technical challenge of making a device, the satisfaction of achieving this and create a device that could positively impact on someone's life. Most volunteers had experience with CAD and 3D printers, enabling them to adapt a device to meet an individual's needs. The volunteers' concerns related to wanting professional healthcare input, as most had no training in prosthetics or medical devices.

Clinicians involved in the e-NABLE community wanted to add their clinical knowledge to encourage volunteers to look beyond the engineering of the device and think of the end user needs; as such they were motivated to ensure long-term success and safety for the users. Clinicians were concerned a negative experience with an e-NABLE device may impact the user wanting to use other assistive devices. They also had concerns about the lack of follow-up by e-NABLE volunteers, with true measures of device satisfaction made over time and not just when initially issuing a device. Self-fabricators were motivated by being able to maintain the device themselves without having to rely on others. They liked using the device due to its aesthetic value which helped reduce stigmatisation. The authors identified several areas of improvement in the e-NABLE network: development of a case management system to

help identify when clinical input is required; development of a platform to enable co-designing of solutions between the end-users, designers and clinicians; and development of platforms to encourage knowledge sharing between different stakeholders. The authors noted a lack of evidence on the number of devices being used, their long-term use and user satisfaction; this was another area where greater data reporting was required.

Both studies identified differences in approaches between the e-NABLE fabricators and clinicians, potentially alienating the two groups and reducing chances for collaboration (Hofmann et al., 2016a; Parry-Hill et al., 2017). Both studies focused on the fabricators and report no outcome measures from the end-users of the device. It is thus difficult to conclude the impact, if any, these devices have in helping access too and use of assistive technology. This may be an influencing factor on the clinicians' perspectives about these DIY devices compared to commercial products, whose approval by regulatory bodies provides better assurance about the quality, safety, and appropriateness of the device. Both studies have a small sample size and were conducted in the USA making it difficult to conclude how relevant these findings are across other volunteers and in other countries.

It should also be noted there is no current scientific literature exploring any of the other "*DIY-AT for other"* communities listed previously. For example, who and how many people are accessing them, are devices provided being used long-term and what are the benefits and barriers to accessing such communities. This lack of evidence limits individuals and clinicians from choosing to access devices through such communities and makes it difficult to conclude the impact these communities are having on improving access to and use of customised assistive technology.

3.2.4.3 Summary

This section summarises one final study comparing two open-source assistive devices based on the above-described DIY communities, before summarising some of the challenges to these DIY-communities found from this review of the literature.

Rivard et al. (2021) reported the quality and safety concerns of 31 healthcare innovator professionals on two open source projects: e-NABLE and Nightscout, a cloud based platform to help with diabetes management in children through hacking of the CGM (Rivard, Lehoux, & Alami, 2021). For Nightscout, concerns were raised about the ability of volunteers to develop and maintain the platform that was of good quality and safe to use. Particular

concerns related to instances of system failure, for example who would be liable, and issues about data privacy and security of this open-source approach. These concerns were similarly identified by Barnard et al. (2018) and Kesavadev et al. (2020) (Barnard et al., 2018; Kesavadev et al., 2020).

For e-NABLE, there were concerns about the varying quality of parts produced by 3D printing and due to the differing level of expertise of the volunteer makers (Rivard et al., 2021). There were additionally concerns about the consequences of a poor biomechanical fit between the devices and end-user, albeit the consequence of this was lower compared to the risk of failure of the Nightscout application. The health innovators were supportive of these open-source solutions as they addressed user needs and improved accessibility to solutions through being free to access for users. However, the authors suggested professional input was required to provide expertise and instigate formal processes for ensuring quality and safety standards were met. The authors also suggested guidance for clinicians to use when talking about the use of open-source solutions with patients to encourage them to make more informed choices.

Next a summary of three challenges common across both DIY communities are discussed to identify areas for future research: outcome measures, skills required and liability.

1) Outcome measures

These communities do well to feature in media good news stories, for example "*The garden shed full of helping hands*" (Kleinman, 2016) and in TED talks, "*Open Artificial Pancreas System*" (Lewis, 2017). Such stories may positively influence people's perceptions on the devices based on limited scientific evidence. Whilst self-reported measures were reported in the case of the DIY-APS, for the e-NABLE prosthetics no long-term end-user outcome measures or results about the mechanical safety of the devices are reported. Additionally, there was no reporting on how often devices did not work or were abandoned for either group. This has implications, alongside positive good news, for producing a positive bias in results about the effectiveness of such devices, creating false expectations for individuals. Improved stringent scientific reporting of outcome measures for these DIY solutions may help assure the medical community and regulatory bodies, whose cultures are based on a strong evidence base, about the use of such approaches in the future. This has implications for the use and growth of such DIY communities.

2) Skills required to produce devices

Both DIY communities required the use of technology to produce the devices. For diabetes management, e.g. OpenAPS, individuals were required to create mobile apps and 'hack' medical equipment, whilst fabricators in the e-NABLE network used both CAD and 3D printing. These tools differ from some of the DIY-AT solutions discussed previously, which focused more on adapting everyday objects using basic DIY tools (Greenhalgh et al., 2013; Hook et al., 2014). The use of more complex technology has implications both for the accessibility of such approaches - what skills and expertise are required to make and maintain such solutions? As well as the safety of these devices - how much is the quality of the final product dependant on the skill of the individual producing the part? In the OpenAPS community instructions and blueprints were available online and an online community exists that provides support, however long-term how sustainable is a volunteer community for maintaining medical devices? These issues may become more pertinent in the case of wider spread adoption of such devices.

3) Liability

Concerns about liability associated with using devices were raised by both clinicians and health innovator experts(Barnard et al., 2018; Hofmann et al., 2016a; Rivard et al., 2021). In the instance of self-fabricators, it was established individuals did so at their own risk and would therefore need to be aware of the potential implications in the result of device failure. In the instance of creating a device for someone else, Barnard et al. (2018) stated the person making the device becomes liable for the set-up of the device (Barnard et al., 2018). This was a reason why clinicians were hesitant to get involved with such projects (Hofmann et al., 2016a). In the case of the e-NABLE community this means the individual makers were potentially liable in the result of device failure. What is unclear currently in the literature is the extent to which end-users and makers are aware of these issues and implications. Some end-users may be willing and able to accept this level of risk, certainly this would be apparent for users of OpenAPS, but others may create such devices without being aware of such risks. It would therefore seem important to ensure sufficient information is available to enable individuals to make informed choices about whether to use DIY devices based on an understanding of the risks and benefits. Rivard et al. (2021) has already suggested categories

relating to the safety and quality of DIY devices that clinicians could use as a starting point (Rivard et al., 2021). These suggestions do provide an approach on how the two differing communities, the medical community and DIY communities, could work with each other in the future.

This section has discussed two different DIY-AT communities who have utilised technological advances and sharing of information online to create accessible assistive devices. Such communities have highlighted a culture clash between the traditional healthcare and DIY communities' approaches into the development and provision of devices. Through this, three areas have been identified in the current evidence base around these DIY-AT communities. Joint working between healthcare professionals, researchers, regulatory bodies, and these maker communities can help address these issues. This could help ensure devices are safe and effective based on rigorous scientific evidence, whilst still supporting use and development of these DIY approaches for those individuals interested. Next, the research considers the use of DIY by current healthcare professionals and how DIY solutions may be upscaled to solve public health problems.

3.2.5 DIY within healthcare

This section explores two examples of how DIY approaches have been used by healthcare professionals first by reporting on an in-hospital makerspace and secondly through healthcare professionals' involvement in a charity group producing a custom assistive device. Finally, this section summarises a study suggesting how individual DIY solutions could be upscaled as public-health interventions.

Marshall & McGrew (2017) account the opening of an in-hospital makerspace in Texas, USA, to provide a space for frontline healthcare providers to share ideas and create prototypes (Marshall & McGrew, 2017). The makerspace aimed to make use of interprofessional design and manufacturing experience to translate needs identified by healthcare staff into products to help both patients and providers. Within the first 18 months, it was reported over 250 healthcare professionals and students visited the space. Solutions created included improved coverings for wounds when showering, bracing structures for limbs, protection for intravenous lines from being disrupted and customised wrist bands for patients. The authors concluded the importance of the makerspace in helping to promote, realise and disseminate innovative ideas and the impact this could have in improving day-to-day delivery of care.

However, no scientific evidence was reported on the impact these solutions had in improving care outside the opinion of the authors. Nor does the article provide any detail about the costs, effectiveness, and sustainability of this in-hospital makerspace. From the limited evidence provided by this single article it is thus difficult to draw any conclusions about the long-term impact, if any, the in-hospital makerspace had in improving patient care.

Alharbi et al. (2020) studied the challenges healthcare therapists faced as builders of DIY-AT in the context of modifying a toy car into a mobility device for children (Alharbi et al., 2020). Eight clinicians were interviewed for the study. Results indicated the clinicians required additional engineering support as they lacked the confidence and skills to implement the modifications themselves. Clinicians also felt they lacked sufficient time to assess the child's needs and gather information, causing complications in configuring the device for the child. Whilst clinicians were involved in some aspects of the making process, the authors suggested further training was required to equip the clinician with the necessary engineering skills to work independently. This study was limited in looking only at paediatric mobility, itself a complex solution, and therefore it is unclear how the conclusions may translate to other assistive technology solutions.

Both previous studies explored how healthcare professionals were involved in the making of real-world solutions. Both studies lacked any empirical data to assess and evaluate the approaches used. However, they do provide examples of how healthcare professionals could in-theory be involved independently or as part of a design team in the development of solutions. In the context of healthcare, the next study suggests how the public could be innovators to public health challenges.

Von Hippel at al. (2018) explore the concept of the public as innovators in a public health intervention based on the theory that innovative products start with individuals designing and building devices to meet their own needs (von Hippel, 2018). National surveys indicated a widespread occurrence of individuals developing products to fulfil their own needs in all aspects of life; of these between 2-8% were related to medical and health issues. A survey of patients in Portugal revealed 53% of the sample innovated solutions to meet their own needs, of which 8% were considered novel solutions. The motivations individuals had for producing their own solutions included: the solution making it easier for them to manage their health condition, an improvement in device usage due to the 'I designed it myself effect', and a feeling of self-accomplishment through solving problems themselves. Whilst

most had a desire to share their innovative solution, only a fraction of individuals had done so.

In relation to public health, the authors suggested that public health experts needed to identify "*lead users*", individuals who innovated in a community to solve novel problems themselves, to discover real world solutions which could be disseminated across a wider health population. To help identify, support, and disseminate these DIY solutions the authors identified a role for maker spaces and web-based community sharing platforms. This proposal has similarities to the DIY Open-APS developed for diabetes management described previously, with lead users innovating the 'hack' in this instance and sharing the information online for others to follow (Marshall et al., 2019; Omer, 2016). This proposed model identifies the role public health experts have in working with the lead users to help with the dissemination. This may help with alleviating some of the concerns identified previously with the DIY Open-APS relating to outcome measures and liability. However, the proposed framework was only theoretical, with no testing presented in the study. Therefore, conclusions cannot be reached about the effectiveness of the proposed model and any real-world barriers such an approach may face.

This section has explored how clinicians and public health experts could cross-over with DIY practices in relation to both making devices and being involved in wider dissemination of solutions. Whilst all three of the studies lack any empirical data to scientifically evaluate the approaches, they provide concepts of how the healthcare sector could learn from and be involved in DIY practices that can be explored in future research. The next section will focus on how techniques common to DIY practices could be applied to produce custom assistive technology solutions for the end user.

3.2.6 Use of DIY design tools in producing custom AT

This section reports on two studies who propose methodologies that utilise DIY techniques to design and manufacture customised assistive technology.

Hofmann et al. (2016) sought to understand how 3D printing and other DIY practices could be used in an iterative-design process to create upper-limb prosthetics, customised to perform specific tasks (Hofmann et al., 2016b). The study followed a case-study approach for three individuals with recordings, interactions and notes taken over multiple unstructured interviews and design sessions. Findings indicated the designers found it necessary to design

iteratively to test how different aspects of the design impacted on aspects such as the comfort and functionality of the prosthetic. To achieve this, the authors used prototyping materials, for example Lego, foam, and zip ties, to modify the devices during the sessions. With the final design each participant was able to achieve the task they identified in a lab-setting. However, no follow-up data were reported to indicate long term use and success of the devices in a 'real world' setting. Additionally, two of the three participants in this study had professional design experience. This may have impacted on their compliance with and the insight they provided into the design process.

The work demonstrated how a trial-and-error approach to design and the use of low-cost materials could be used to produce task specific upper limb prosthetics with the end user (Hofmann et al., 2016b). Moving forward, the authors identified several challenges for the DIY community in more widely instigating such approaches: 1) how and when to provide clinical oversight in the design and manufacturing of such devices; 2) how best to educate individuals and volunteers to be able to manufacture such devices themselves; 3) how to provide long term follow-up support to the end user.

Garcia et al. (2021) sought to develop a framework to empower users through low-cost and DIY assistive technology (García et al., 2021). They identified three key parts of the framework: 1) identification of the user needs that can be met through low-cost AT; 2) creation of prototypes and testing with end users to see if their needs are met; 3) providing the device in the real world and obtaining feedback to modify the device as required. The framework was trialled in a preliminary study of 11 individuals with various health conditions. A total of 27 devices were created to help with mobility, self-care and functional upper-limb tasks using low-cost materials and 3D printed components. Results indicated the device designs were of good quality and matched well with the end user's needs. The proposed framework placed the user at the centre of the design process to create an emotional relationship between the person and the device. The authors hoped this would reduce stigmatisation with the devices and help educate, encourage, and empower the user in self-managing their own health.

Whilst the authors label this framework as "*low cost and do-it-yourself assistive technology*", it was not apparent in the preliminary work if the design and manufacturing was performed by the participants or by other individuals, such as the research team. For example, both low-cost materials and 3D printers were used to produce the final parts. From the sample solutions presented in the study, it would seem unlikely they were able to be created by

someone without some previous design experience. Thus, from the study it was not clear if solutions were generated by the end-user or if the design and manufacturing was done by other individuals. Instead, the proposed framework may be more appropriate to help standardise and gather outcome measures in the "*DIY-AT for-others*" approach described previously.

Both studies provide examples of how low-cost materials and 3D printing could be utilised within more structured DIY methodologies to help produce customised assistive technology within DIY communities. However, what is not clear from the studies is the extent to which the end-users created devices themselves or if the process was dependant on individuals with design experience and expertise. Additionally, no long-term usage data or outcome measures were reported. As such it is hard to establish the long-term feasibility of these frameworks in producing customised assistive devices from the results presented.

3.2.7 Summary

This section will summarise the key findings from the literature around DIY and DIY-AT and discuss this in the context of the barriers to assistive technology access and use previously identified. This section then poses some key future research questions related to DIY-AT.

This sub-section has explored DIY practices and the maker movement, the motivations for people being involved in this movement and how key drivers of the movement, affordable low-scale manufacturing technology and online community platforms, have been utilised for DIY-AT. Examples of DIY-AT have ranged from the adaption of everyday household objects using low cost materials, through to 3D printing custom devices and the development of complex open-source systems for management of diabetes (García et al., 2021; Hofmann et al., 2016a; Hofmann et al., 2016b; Hook et al., 2014; Hurst & Tobias, 2011; Lewis & Leibrand, 2016; Marshall et al., 2019; Omer, 2016). DIY practices can help reduce the barriers to assistive technology related to a lack of customisation and the cost of assistive devices by using low-cost materials compared to purchasing expensive commercial assistive technology (Howard et al., 2022a). Additionally, as the end-users, their family or carers are involved in making solutions, they can troubleshoot, fix and adapt the device themselves, as well as adapt devices in response to any changing needs. This point was highlighted in the bricolage approach described by Greenhalgh et al. (2013) (Greenhalgh et al., 2013). However, questions remain about the long-term quality, reliability and scalability of DIY devices. For

example, concerns about devices lacking regulatory oversight were especially pertinent to the open-source APS and the e-NABLE upper limb-prostheses (Hofmann et al., 2016a; Parry-Hill et al., 2017; Rivard et al., 2021).

Similarly, this sub-chapter has shown examples of how online platforms have been used to share designs, create networks of volunteers and communities of support. This was for both open-source software applications and in helping individuals choose commercial assistive technology (Buehler et al., 2015; Layton et al., 2021; Omer, 2016). This could help reduce the barriers to assistive technology relating to a lack of awareness and information and help to build peer support mechanisms, enabling users to learn from each other (Howard et al., 2022a). By individuals creating devices themselves, it may also help reduce some of the psychological barriers related to negative attitudes to assistive technology. For example, one motivation was the feeling of satisfaction and pride of having created an object, the "*I designed it my-self effect*" (Franke et al., 2010; Tanenbaum et al., 2013). Such motivation was reported as a reason for individuals being involved in making DIY-AT (Braune et al., 2021; Buehler et al., 2015; García et al., 2021; Parry-Hill et al., 2017).

Across the literature, however, there was a lack of evidence on the uptake, satisfaction, and impact of DIY-AT solutions. There was also a lack of evidence in relation to device safety and efficacy, which is of great significance to the online communities where device blue-prints are shared online for others to use (Rivard et al., 2021). This creates difficulties in assessing the effectiveness of the devices produced and the DIY philosophy, potentially limiting the impact of such an approach going forward. It is however worth noting a lack of evidence was identified as a barrier to assistive technology in general; this lack of evidence is thus not only limited to DIY-AT. Also, in some instances solutions were created everyday through necessity, without the individual necessarily identifying it as 'DIY', for example through the adaption of everyday household objects to meet a need (Greenhalgh et al., 2013; Hook et al., 2014). In any case, DIY practices and communities pose interesting questions for those involved in the healthcare sector (regulatory bodies, researchers, and healthcare professionals). For example, how DIY practices may fit into the self-management and care of those with chronic health conditions, what are the safety and legal implications of this and as such whether to advocate, work with or dismiss such communities and approaches.

Another important question around DIY-AT is how accessible is this approach to everyone? This includes access to the necessary manufacturing equipment and design software, access to online communities, and physical makerspaces. Tanenbaum et al. (2013) alluded that

'makers' had "*sufficient free time and access to resources to engage in relatively risk-free making"* (pp. 2605) *(Tanenbaum et al., 2013)*. However, in the case of parents with a child with disability this was shown not to be the case (Hook et al., 2014). It is unclear the extent this may apply to other individuals living with chronic conditions and is likely to vary from individual to individual.

Several studies also mentioned the need to make accessible toolkits and resources to improve access and help diversify designers, but currently no work has evaluated such tools (Buehler et al., 2015; Hook et al., 2014; Hurst & Kane, 2013; Hurst & Tobias, 2011). Similarly, another issue is the degree to which the processes depend on people having the knowledge and training to interact and engage with technology? Can this knowledge and expertise be easily taught to individuals? And how much does it depend on highly motivated individuals who are wanting to look and create solutions themselves? In the case of designs uploaded to Thingiverse.com, 48% worked in STEM fields and the majority of designers did not have a disability (Buehler et al., 2015). Similarly reported in the DIY-APS community, over 80% had a degree level qualification or higher, whilst in the e-NABLE community concerns were raised about how variations in the level of skill of makers could impact on the quality of devices produced (Braune et al., 2021; Rivard et al., 2021). Such factors may limit DIY approaches across wider populations and different health conditions.

Finally, how sustainable is it as an approach going forward in helping access and use of assistive technology? The answer to this may differ across different DIY-AT solutions. In the case where individuals themselves adapt and modify household with low-cost material, the chances are the approach is sustainable with the individual able to adapt and replace solutions easily and cheaply. However, for DIY communities reliant on open-source platforms, or instances where solutions are produced by volunteer enthusiasts, it is not clear how sustainable these approaches may be in the future. For example, what happens if those maintaining software and creating devices suddenly have to stop?

DIY practices do have promise in relation to improved use and access to assistive technology which merits further research. However, due to the issues discussed above, the DIY practices may exclude people who are unable to access the resources, lack the time, expertise, or confidence to use and create such solutions. Instead, individuals may be more confident to access assistive technology through more traditional routes, for example healthcare services. The next sub-chapter will review the use of a design methodology, co-design, to create

customised assistive technology which seeks to gain input from the end-user of the device throughout the design process.

3.3 Co-design of assistive technology

Co-design, or participatory design, is a design methodology that seeks to actively involve the end user of a product in the design process through collaboration with the designer (Sanders & Stappers, 2008). Co-designing can help empower the end-user by: encouraging them to input their knowledge and lived experiences into the design process; involving them in key decision making processes; and enabling them to provide feedback during the design process (Hakobyan et al., 2014; Vines et al., 2013). This enhances the voice of the end user by considering their ideas, desires and needs (Quintero, 2020). Capturing the user's intrinsic knowledge also helps create innovation in designs through establishing a mutual understanding of a user's unique challenges (De Couvreur et al., 2013; Hakobyan et al., 2014; Moody, 2015; Wu, Richards, & Baecker, 2004). This, in theory, means that co-design increases the likelihood that the final design will meet the user's needs and therefore could help improve the design and use of assistive technology (Gherardini et al., 2018; Santos & Silveira, 2020).

Co-designing assistive technology has previously been reported in the literature. For software development, co-design approaches have used in group workshop sessions to engage users in the design process (Mawson et al., 2014; McGee-Lennon, Smeaton, & Brewster, 2012; Moffatt et al., 2004; Nasr et al., 2016; Revenäs et al., 2015; Wu et al., 2004). This has included brainstorming ideas, providing feedback on different design aspects, and evaluating prototype designs. A review of studies developing assistive technologies for people with dementia highlighted the majority of work involved group workshops inputting into a single complex electronic or software based solution (Suijkerbuijk et al., 2019). Whilst this is one application of co-design, it does not necessarily overcome a lack of customisation of assistive technology to an individual's needs.

This sub-chapter will therefore look specifically at co-design methodologies used to produce custom assistive devices to meet individuals' needs. Compared to the DIY practices discussed in the previous sub-chapter, these methodologies are more structured, making use of design tools and techniques to facilitate producing solutions. The chapter starts by reviewing four key studies that utilise a co-design approach, discussing the similarities in the methodologies. Next the chapter will summarise other studies that incorporate some level of end-user involvement in the design and provision of customised assistive devices. Finally, the chapter will summarise the shortcomings in the current literature, identifying future research opportunities to assess the feasibility of co-designing customised assistive devices.

3.3.1 Co-designing custom assistive devices

This section will summarise four key studies that present frameworks that utilise a co-design approach to produce customised assistive devices.

De Couvreur et al. (2011) describe a framework, "*design for (every)one"*, where an iterative co-design process is used to incrementally bridge the gap between user wants and a device's design (De Couvreur & Goossens, 2011). Three different roles are identified in the process:

(1) The therapist, who helped determine the goals for assistive technology and evaluate the final solution.

(2) The user, who provided their own expert experience about their needs and whose involvement in the design process included creating, using, and adapting prototypes.

(3) The designer, who translated the user's values into prototypes and products. This involved using a hacking design concept where the designer manufactured with the resources at hand: for example, reusing devices or adapting basic materials available in a local context.

The framework established an individual could take multiple roles, for example an occupational therapist could take the role of therapist and designer. Feedback gathered from the user who trialled the designs was based around five key design attributes: performance, economy, convenience, identity, and pleasure. This feedback facilitated changes to the design. The authors presented three different devices produced based on this framework: a guitar slider for an individual with hemiplegia, a customised shuttlecock for an individual with hand-eye co-ordination difficulties and a unique ring to hold an ice-cream for an individual with a spinal cord injury. The authors claimed there was an increased level of commitment by the individuals to using the devices through their involvement in the design process. However, no data were reported to validate this claim. The authors also suggested how user involvement in the design process could reduce stigmatisation and change attitudes to assistive technology; these were barriers previously identified to assistive technology use (Howard et al., 2022a).

Santos and Silveira (2020) proposed a design methodology for assistive technology, called "*AT-d8sign"*, which focused on user-centred design and 3D technologies (Santos & Silveira,

2020). The methodology was split into three main phases: 1) design cross domain, 2) the conception spiral and 3) evaluation and refinement. Phases 2 and 3 formed an iterative design cycle; with feedback from the evaluation (phase 3), being used to implement design changes in phase 2. The process identified 5 key personnel in the process, each bringing unique knowledge and experience: end user; family/carers; healthcare professionals; engineer and relevant others. Designs created would be evaluated by the end user and family using interviews, observations, and assistive technology questionnaires, for example the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0). Additionally mechanical testing, for example fatigue, impact, and stress tests, would be conducted to ensure safety of the components. Whilst the proposed methodology was based on previous case study work, the authors did not present any results of the methodology being used to produce devices in this paper and thus it is difficult to assess the effectiveness of the described methodology.

Gherardini et al. (2018) presented findings from co-designing custom assistive devices using additive manufacturing (more commonly referred to as 3D printing) by an interdisciplinary design team (Gherardini et al., 2018). Nine people with rheumatoid arthritis and scleroderma were involved in the development of eight hand-held assistive devices. The work utilised parametric design, where the shape and size of devices could be re-configured to meet different users' needs by changing a few key design dimensions. Workshop sessions with the end-users helped map out their needs, define the variations needed in the designs and facilitated gathering feedback during validation testing. This feedback was used to implement further design changes. Outcome measures were collected for all eight devices using the Psychosocial Impact of Assistive Devices Scale (PIADS) and QUEST 2.0 questionnaires. These reported overall positive satisfaction with the devices both initially and at 6-month follow up. The authors report all devices were still being used daily by the participants at 6-months post issue and the co-design methodology was able to provide assistive devices that met their specific needs. The methodology used parametric design to make designs easily reconfigurable to different users. However, the study reports no results on if, or how, this feature was used - for example if multiple configurations of a single device were issued to different users.

Aflatoony et al. (2021) proposed a framework to co-design 3D printed custom assistive technology by using workshop sessions involving three parties: an end user, occupational therapists and industrial designers (Aflatoony, Lee, & Sanford, 2021). During four different workshop scenarios, the researchers observed the interaction between the three parties in

providing the end user with an assistive device to help with writing. The authors observed that the devices produced when the designers were encouraged to think creatively and co-design with the end user were more usable compared to when the designers were just technical facilitators to the ideas generated by the occupational therapists. The proposed framework consisted of four collaborative stages: co-experimentation, co-development, co-evaluation, and co-refinement. The authors suggested that short-prototyping cycles and hands-on prototypes were central to refining the design of a device. However, the proposed framework was based on a single person case-study only, with no long-term follow-up evaluation conducted to record ongoing device usage. The study made use of undergraduate/recent graduate design students and thus their experience, or lack of experience, may have influenced the design process. No further testing or evaluation of the proposed methodology was reported.

All four of the studies shared similarities in their methodologies: An iterative design process, the use of physical prototypes to communicate ideas between the end-user and design team, and utilising multiple personnel with unique expertise and experience into the process (Aflatoony et al., 2021; De Couvreur & Goossens, 2011; Gherardini et al., 2018; Santos & Silveira, 2020). Although, De Couvreur et al. (2011) do suggest how multiple roles could be fulfilled by a single individual (De Couvreur & Goossens, 2011). Three of the studies utilised 3D printing in their methodology, with Gherardini et al. (2018) further utilising parametric design software to easily vary the design of devices (Aflatoony et al., 2021; Gherardini et al., 2018; Santos & Silveira, 2020). As expected with co-design, the processes involved the end-user throughout to help define requirements, make decisions about the designs, and provide feedback. However, the framework presented by De Couvreur et al. (2011) is a more holistic approach instead of a clear methodology that could be replicated, whilst Santos and Silveira (2020) do not present any evidence of the methodology being applied to produce devices in the study. As such it is difficult to draw conclusions about the feasibility of co-designing customised assistive devices from these studies. The next section will discuss other examples in the literature where designers have utilised some level of user-input to create novel, customised assistive devices.

3.3.2 Novel custom assistive devices

This section presents other examples in the literature where novel custom assistive devices have been created which are customised to the needs of the end user. These case studies utilise both 3D printing and other manufacturing techniques to produce the devices.

Day and Riley (2018) utilised user feedback to produce a bespoke hand orthotic, enabling an individual with a partial hand amputation to play the French horn (Day & Riley, 2018). A custom device was produced over three design iterations using a mixture of 3D scanning, CAD and 3D printing. The authors additionally used finite element analysis, a computer simulation tool, to assess the risk of mechanical failure of the design. Overall, the authors reported the end-user was impressed with the final device, with improvements in comfort and function playing the French horn. However, no long-term follow-up data were reported. The authors additionally calculated the costs associated with creating the device compared to traditional hand-crafted manufacturing method, reporting a cost reduction of 56% in their approach. However, this calculation was based on the average costs of producing all three designs individually. As the process of iteratively designing the device was crucial to achieving the end result, the cost estimation should have been the total of the three designs and not the average, thus the costs reported would appear to be an underestimate of the true costs.

Lee et al. (2019) also produced a bespoke hand orthotic for an individual with limitations in gripping objects with their right hand (Lee et al., 2019). A custom made orthotic was produced with various attachments for a pen, stylus and cutlery. 3D scanning, CAD and 3D printing were all utilised in the production of the solution. Both functional tests by the end user and the QUEST w.0 questionnaire were completed as outcome measures, with the custom device showing improvements compared to an off-the-shelf alternative. The end-user was particularly satisfied with being able to use different accessories; this was not possible with the off-the-shelf alternative. The authors calculated the cost of 3D printing the device to be $32, compared to $490 for an off-the-shelf orthotic. However, this cost was only the material cost for manufacturing the device and did not include the time required to scan, design, and develop the device; these costs were not reported.

Ragoo et al. (2018) described the design of a novel assistive device for an individual who had lost function in the right side of his body following seizures (Ragoo et al., 2019). The individual wanted help gripping a pool cue to play pool. The authors reviewed current commercial products and gathered information from the end-user about his needs. A custom hand orthic was fabricated using a mixture of foam, Velcro straps, seatbelt webbing and support bars to

support the pool cue in the user's hand. The user reported the final design was able to fulfil his goal. Measurements of the time required to take a shot and the accuracy of a shot showed improvements over time from using the device. In sum, the authors concluded the device had improved the quality of life for the subject.

Whilst it was not clear from the methodologies of these studies the level of input the end-user had during the design processes, they do present examples of different, novel custom assistive devices required by individuals. The studies were limited to single case study examples and therefore it was difficult to effectively evaluate the wider application of the methodologies presented. There was also a lack of long-term follow-up data around device usage. Nevertheless, these case-studies do provide further examples of how design technologies can be utilised to create customised assistive devices beyond what is available from current commercial products. The next section will summarise a case-study building upon co-design to co-making, where the authors aimed to encourage the end-user to become a maker of their own device.

3.3.3 Co-design to co-making

Thorsen et al. (2019) built on the idea of co-design by training the end user to be a maker of their own personalised assistive technology utilising digital fabrication techniques (Thorsen, Bortot, & Caracciolo, 2019). The user, a quadruple amputee, wanted a device to help them independently feed themselves without formal carers. Over the first 6 months, the end-user worked with the design team to devise a bespoke solution using CAD and 3D printing. An iterative design process was used with seven interactions between the design team and end-user over this 6-month period. The authors made use of free, online CAD software enabling the designs to be shared easily between collaborators. During this period, 12 hours of training was provided to the end-user on the use of CAD software and 3D printing to enable them to make design changes themselves after the initial 6-month period had ended.

An evaluation conducted 6 months after the initial device was provided revealed the user had abandoned the device with it being less useful compared to their carers. They additionally had been unable to independently use the CAD software and 3D printer to evolve the design themselves due to technical issues. However, the authors discovered the participant had started to adapt everyday objects instead to solve their daily living needs. As such, their involvement in the process had facilitated them in becoming more engaged in personal innovative processes to solve their problems. This was evidenced by a decrease in

the difficulty of various activities of daily living, for example toileting and scratching, from the start to the end of intervention, with these activities being unrelated to the designed device.

This section has summarised a single case study which looked at initially co-designing the device with the user and then encouraging them to become a maker themselves by providing training in CAD and 3D printing. No other current literature has explored this, so it is unclear if the findings from this single case-study relate to other individuals. However, it is interesting to note the findings that by the user being involved in the process, they were more engaged in finding solutions to challenges they faced by adapting everyday household objects. This has similarities to the DIY practices described in the previous sub-chapter and indicates how involvement in co-design processes, with input from designers and therapists, may help patients become innovators. Consequently, it does also indicate that digital design and 3D printing tools may need to be more accessible for non-technically minded users. The next section summarises the findings from this sub-chapter and identifies current limitations in the literature around co-designing customised assistive technology solutions.

3.3.4 Summary

This sub-chapter has reviewed studies utilising user involvement in the design and provision process to produce a range of custom assistive devices. In these studies, the majority of the devices assisted with a range of functional upper-limb activities, with devices been able to be adapted specifically to the tasks identified by the end-user. This indicates one sub-set of assistive devices where more customised devices are currently required beyond what is currently available commercially or through healthcare services. It also shows where user-input, in terms of identifying activities and trialling out devices, would appear beneficial. Similarly, most of the studies utilised CAD and 3D printing to produce parts. It is only in recent years these tools have become more accessible and affordable, which may account for why it is only relatively recent that research has started exploring the co-design and provision of these types of custom assistive devices.

There was overall a lack of current literature around co-designing customised assistive devices and the implications for this long-term on the access to and provision of assistive technology. From the current literature reviewed, numerous shortcomings were identified to enable the feasibility of using co-design in a clinical setting to be evaluated:

1) *Long-term follow up with users.* Whilst Gherardini et al. (2018) and Thorsen et al. (2019) both reported evaluation at 6-months post device issue, none of the other studies reported results regarding long-term evaluation of devices. Long-term evaluation would help assess if the devices provided using a co-design methodology were able to improve compliance and reduce abandonment of assistive technology.
2) *Resources involved.* Previous studies provide limited accurate information about the resources involved in producing devices, including costs, equipment, and personnel. Current healthcare services already lack resources and funding for the provision of assistive technology (Howard et al., 2022a). If a co-design process cannot be shown to be cost effective, it is unlikely to be implemented within a health-care setting.
3) *Methodological limitations.* Various methodological limitations existed in the current studies including: no control groups for comparison; no information on attrition rates for participants involved in the studies; publication bias towards positive results; sample sizes are small. The majority of current studies, with the exception of Gherardini et al. (2018), only reported results of between 1-3 participants. From these small sample sizes, it is difficult to assess if the findings are generalisable to a larger population and thus if a co-design approach is scalable.
4) *Impact of devices on the user's day to day life.* Outcome measures reported have focused on standard assistive technology questionnaires, for example the QUEST 2.0 questionnaire. Such measures fail to capture any wider impact the device may have had on the user's life, nor do they provide any feedback about the user's experience of the co-design process. A mixed methods approach may provide greater insight to furthering the understanding and development of co-design methodologies.
5) *Device development timescales.* Studies do not report the timescales over which devices were designed and provided. A timely intervention was another barrier to using assistive technology (Howard et al., 2022a). Any process of designing and providing assistive technology needs to be done in a timely manner, otherwise they risk an individual's needs changing or the user not being compliance to the co-design process.
6) *Regulatory adherence.* Medical devices, including assistive technology, need to adhere to the relevant regional regulations. For example within the European

Union all devices provided, including custom-made devices, must legally adhere to the EU Medical Device Regulations (European Union, 2017). Only the methodology proposed by Gherardini et al. (2018) describe the development of device documentation within their process.

The provision of assistive technology also needs to be considered within the context of how devices are currently provided. Whilst many of the current studies look to include healthcare professionals as members of a multi-disciplinary group, none of them were conducted within current healthcare settings or services. To make customised assistive devices available it would seem rationale to try and integrate these co-design approaches within existing healthcare services. The integration of a co-design methodology into healthcare services will have implications for the future development of assistive devices and co-design methodologies.

Historically, healthcare professionals such as occupational and physio therapists have needed to modify and adapt existing assistive technology to fit the needs of their patients (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016). The current co-design literature would suggest having individuals who were competent and experienced with the use of CAD and 3D printing were crucial in the production of customised assistive devices. This poses the question if these groups of healthcare professionals could themselves manufacture custom assistive devices using CAD and 3D printing? Or are there other individuals who may be more suited to using these technologies? The next sub-chapter summarises the current literature around how 3D printing is used by healthcare professionals and within healthcare services currently.

3.4 3D printing in healthcare

Current trends in DIY practices and co-design methodologies made use of affordable, easy to use, low-scale manufacturing methods, for example 3D printing, to create customised assisted devices. Benefits of 3D printing commonly cited include: high-level of customisation in producing parts, high degree of design complexity, low weight, and an automated production process (Ngo et al., 2018; Wohlers, 2021). The rise of 3D printing has rapidly increased over the past 10-20 years, with small size desktop machines making the technology more accessible for use by industry and hobbyists. However, despite these advantages and the examples of it being used in both the DIY and co-design literature described previously, its widespread application clinically to create custom assistive devices has not been fully realised. This sub-chapter will seek to explore the barriers to why this is the case, first describing different applications of 3D printing used broadly across healthcare settings, before focusing on the use of 3D printing by healthcare therapists and how this may impact on providing customised assistive devices.

3.4.1 Current applications of 3D printing in healthcare

Within a healthcare environment the use of 3D printing has been explored. It has been used extensively in maxillofacial surgery, dentistry, and orthopaedics for manufacturing custom surgical guides, surgical models and custom implants (Banks, 2013; Bibb et al., 2009; Dawood et al., 2015; Harrysson et al., 2008; van der Zel et al., 2001). Research has also explored its application in creating specialist custom assistive devices, for example prosthetics, orthotics and wheelchair postural supports (Chen et al., 2016; Howard et al., 2020; Lunsford et al., 2016; Pallari, Dalgarno, & Woodburn, 2010). However, reported widespread clinical use in these areas is still limited. Reasons for this include concerns related to: the strength and safety of components produced by 3D printing, the lack of interface between design software and traditional clinical methods, the cost of 3D printing equipment and the lack of experience using them by clinicians (Chen et al., 2016).

A review by Lunsford et al. (2016) on the use of 3D printing in physical medicine and rehabilitation found only 2 of the 20 papers identified were not related to producing orthotics (11) or prostheses (7) (Lunsford et al., 2016). Of these two papers, one was describing a tactile visualisation tool and the other development of custom wheelchair push-rims. This indicates a lack of scientific research relating to the clinical application of 3D

printing for other types of custom assistive devices outside of the highly specialised areas of prostheses and orthotics. For example, creating upper-limb functional devices that were produced in the co-design studies described in the previous sub-chapter.

Therefore, instead of considering the specialised clinical services (prosthetics, orthotics, and specialist wheelchair seating) who historically have manufactured specialist devices, this sub-chapter will reflect on the use of 3D printing by healthcare therapists, for example occupational therapists and physiotherapists, who are common prescribers of a wide range of assistive technology. These healthcare therapists see a broad spectrum of medical diagnoses and have the capacity to reach a large number of users with varying abilities (McDonald et al., 2016). Occupational and physio therapists have often needed to modify and adapt existing assistive technology to better fit the needs of their patients (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016) However adaptions were often makeshift using improvised materials and as such solutions often lacked long-term durability and were not aesthetically pleasing (Aflatoony et al., 2021). The use of 3D printing could help create more robust and customised assistive technology in occupational and physiotherapy practices. The next section will summarise the current literature exploring the use of 3D printing by therapists to understand why it is not currently being used widespread by these professionals. This may help explain why co-design methodologies have not been tested previously in clinical settings.

3.4.2 Use of 3D printing by healthcare therapists.

This section will summarise the current literature around the use of 3D printing either by qualified or student healthcare therapists.

Buehler et al. (2016) explored the use of 3D printing for children in special education settings through observation of three different special educational schools/organisations (Buehler et al., 2016). At one site they looked to design a unique 3D printed hand grip and develop software that would easily automate this process for occupational therapists to use themselves. Findings indicated the occupational therapists preferred not to interact directly with 3D printing or the software. This was due to limited prior exposure and appropriate training in knowing how to use the 3D printer and time constraints in their clinical work. They additionally felt they lacked the time and skill set to learn the required CAD and 3D printing skills.

McDonald et al. (2016) examined the challenges and opportunities for 3D printing with physiotherapists (McDonald et al., 2016). An online survey of four physiotherapists revealed therapists concerns related to the safety and liability issues associated with designing and providing 3D printed assistive devices. The authors also ran an educational course with graduate level physiotherapy students on the use of 3D printing. The course set students the task of creating custom assistive devices based on clinical scenarios, for example a modified walking stick handle. Similar to the findings of Buehler et al. (2016), the students lacked the experience in using 3D printers and computational modelling software required to create devices. Feedback from the students indicated they lacked the required time to learn the necessary design skills, especially for creating complex computational models. They additionally felt uncomfortable in designing devices themselves as the devices would not have been rigorously tested compared to off-the-shelf products and as such would have been hesitant to prescribe any of the devices created.

Within a higher educational setting, Wagner et al. (2018) also looked to provide hands-on experience to occupational and physiotherapy students in 3D printing devices (Wagner et al., 2018). In this study students were only involved in making physical prototypes of the designs using common splinting and simple household materials. The prototypes created by the students were sent to an external engineering team to design the computer models for manufacturing by a 3D printer. Only 26 of the 39 devices designed by the students were able to be manufactured. This was primarily due to difficulties implementing the physical prototypes into 3D models suitable for 3D printing. The paper concluded that the students lacked the necessary skills to create appropriate designs that could be 3D printed successfully, due to a lack of knowledge about the considerations needed for 3D printing devices. The study only investigated 3D printing in an educational setting and as such none of the devices were tested in a real-world setting.

Hofmann et al. (2019) explored making custom assistive devices with occupational therapists across two different healthcare settings (Hofmann et al., 2019). They analysed the responses of four occupational therapists who worked with the researchers in the design and fabrication of three different devices. An iterative design approach was used to produce solutions, making use of CAD and 3D printing. Results revealed how the occupational therapists were not interested in using 3D printing and CAD technology as it poorly aligned with their current clinical practice. The therapists were used to a one attempt approach to providing devices. They did not like the iterative design process due to the length of time required and the associated costs for them and the patient. The authors observed how

occupational therapists preferred adapting devices physically during an appointment, rather than changing the design digitally on a computer. This indicated how digital design and manufacturing methods were poorly aligned with current occupational therapy practices.

However, Hofmann et al. (2019) only focused on the views of the occupational therapists and did not gather any feedback from the end user about the customised devices produced. It was thus inconclusive if the end-users preferred the 3D printed devices, or the solutions produced by the occupational therapists. The study also used the researchers as technical facilitators and did not seek to train the occupational therapists themselves in the use of 3D printing or CAD; this may have transformed their perception of the technology.

Schwartz et al. (2020) used student occupational therapists to produce customised pill boxes for 14 individuals, with each pill box having a unique design based on the end user's preference (Schwartz et al., 2020). The pill box designs were either modified from previous open-source designs or were designed from scratch using open-source design software by the student occupational therapists. The end users reported greater satisfaction using the custom pillboxes compared to an equivalent off-the-shelf pillbox. The paper only focused on pillboxes, a simple assistive device to design and manufacture. The authors concluded the complexity of designing other types of custom assistive devices was limited by the skill set of the occupational therapy students in using CAD software and 3D printers. The paper emphasised how empowering the end-user in the device selection process facilitated the end-user's compliance with using the final device.

Rasmussen et al. (2022) explored the feasibility of using 3D printing to produce custom assistive technology within an existing amyotrophic lateral sclerosis clinic (Rasmussen, Stewart, & Janes, 2022). The study used occupational therapists within the clinic, who were experienced in CAD and 3D printing, to design and develop devices for nine different individuals. Devices were developed by the occupational therapists based on the goals of the end user wanting to participate in a particular activity. Prior to issuing, devices were tested by one of the research team for safety, comfort, and function. A total of 20 out of the 34 device requests were able to be provided. Seven of device requests were only made after individuals had been provided with devices initially and as such the researchers did not have time to manufacture devices during this study. Seven of the requests were unable to be manufactured during the study due to the complexity of the request. The mean time for device delivery was 54.6 days.

This study demonstrated how some occupational therapists with experience in CAD and 3D printing were able to produce functional devices using these technologies (Rasmussen et al., 2022). However, the authors concluded more front-end learning in CAD would have enabled the therapists to use a full-featured CAD program which would likely have resulted in a more efficient design process and effective assistive device designs. The researchers also commented that one the main barriers to producing successful designs was being unable to see the participant perform the activity or use the object they needed to modify. More involvement of the end-user in the design process could help alleviate this.

This section has presented the current literature exploring the use and application of 3D printing by occupational and physiotherapists for the provision of assistive technology. The next section will summarise these findings and discuss in the context of the barriers to assistive technology.

3.4.3 Summary

In the current literature there is only a couple of studies where 3D printing has been used by occupational therapists to make custom assistive devices (Rasmussen et al., 2022; Schwartz et al., 2020). Whilst this shows it is possible, it is not clear how widespread these findings could be applied. Certainly, this contrasts with the findings from the other work, where healthcare therapists lacked the necessary training, expertise and confidence to produce devices using 3D printing (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016; Wagner et al., 2018). Although these studies themselves were limited in small sample sizes or made use of student therapists; the experience of students may reflect differently from that of qualified professionals. It could be the work by Schwartz et al. (2020) and Rasmussen et al. (2022) engaged with technically savvy, motivated occupational therapists who wanted to explore 3D printing. Or it reflects a change over time, with these two studies published most recently. In any case, the studies do appear to imply 3D printing is starting to become more accessible and more widely adopted by these professionals.

It is worth noting the conclusion by Schwartz et al. (2020) that the variability and complexity of solutions provided was limited by the current skill set of the student occupational therapists (Schwartz et al., 2020). Similarly Rasmussen et al. (2022) also concluded more learning was required on CAD to enable a more efficient and effective design process for therapists (Rasmussen et al., 2022). Especially compared to the custom assistive devices produced from the co-design methodologies summarised previously, the pillboxes produced

by Schwartz et al. (2020) would seem simpler and less complex. So, whilst healthcare therapists were able to make use of computer aided design and 3D printing, in terms of design complexity they would appear limited compared to those with more professional design and engineering experience and expertise.

In both cases it would be interesting to know the training received in CAD and 3D printing these therapists had prior to undertaking this work, and how these skills could be taught to other healthcare therapists. Results from Buehler et al. (2016) indicated therapists lacked the clinical time to learn the necessary skills to use 3D printers (Buehler et al., 2016); this relates to an already existing barrier to assistive technology regarding a lack of resources in the service provision of assistive technology (Howard et al., 2022a). As such this poses the question is it worth the resource investment currently to train therapists in such skills when healthcare services are already stretched for resources?

The answer to such a question, poses several other key questions:

- What level of skill, competency and training is required?
- What are the implications to healthcare services and the end-user of teaching therapists these skills in terms of quality of care and healthcare cost?
- And linked to this, what is the level of demand for such custom assistive devices?

Given the lack of evidence to these questions, currently it would not seem worthwhile to look at training healthcare therapists in CAD and 3D printing. Instead, it may be beneficial to make use of existing services that already design and manufacture custom assistive devices, albeit for different applications. For example, services such as protheses and specialist wheelchair services already make use of engineering expertise and small-scale manufacturing equipment to provide specialised custom assistive devices. However, access to these healthcare services is limited with strict eligibility criteria based on service commissioning and funding models. Often this is based on historical service models that have not changed with the opportunities presented by technological advances in CAD and manufacturing methods. Expanding such services may provide an avenue to increasing the range of custom assistive devices produced by healthcare services. The final section in this chapter will explore this idea further, summarising it in the context of the other approaches to custom assistive technology discussed in this chapter.

3.5 Summary

This chapter has explored the creation of custom assistive technology through three different approaches: DIY practices, co-designing devices with the end user and through healthcare therapists. In reviewing these approaches, links have been made to the barriers to accessing and using assistive technology previously identified.

DIY practices covers a vast range of different techniques and mechanisms, from the adaption of simple everyday objects, to making more complex devices through use of CAD, 3D printing and digital applications (García et al., 2021; Hofmann et al., 2016a; Hofmann et al., 2016b; Hook et al., 2014; Hurst & Tobias, 2011; Lewis & Leibrand, 2016; Marshall et al., 2019; Omer, 2016). The sense of community, whether this be in person makerspaces or online communities, has enabled the sharing of expertise, designs and, in the case of maker spaces, equipment to improve accessibility (Buehler et al., 2015; Dougherty, 2012; Layton et al., 2021; Omer, 2016). From this several DIY-AT communities have already grown, most noticeably the DIY-APS community and e-NABLE network described previously (Barnard et al., 2018; Kesavadev et al., 2020; Lewis & Leibrand, 2016; Parry-Hill et al., 2017; Rivard et al., 2021). The "*I designed it myself*" effect that individuals felt by making devices themselves also cannot be ignored, with implications for reducing stigmatising and promoting positive attitudes to using assistive technology (Braune et al., 2021; Buehler et al., 2015; Franke et al., 2010; García et al., 2021; Parry-Hill et al., 2017; Tanenbaum et al., 2013). DIY practices thus have obvious mechanisms for improving the access to and use of assistive technology with many applications already demonstrated, albeit on a small scale.

However, several issues do remain which were identified previously. How widely accessible is equipment, maker spaces and online communities to those who require assistive technology? How reliant are such techniques on the skill and expertise of the maker? Can these skills be taught and if so, how? What are the associated risks and benefits of such techniques and how aware are people of these risks? Issues also remain about when healthcare input may be required and liability around this. Given that individuals are already involved in such techniques themselves, one of the key questions is should healthcare services look to promote such approaches as self-management strategies? And secondly can this be done effectively and safely?

From DIY practice, this chapter reviewed a more structured methodology to the provision of custom assistive devices focusing on co-design. In this instance a designer worked within a multi-disciplinary team with the end-user to develop a solution (Sanders & Stappers, 2008).

Example frameworks of co-designing devices made use of iterative design cycles, where trialling prototypes and the end-user providing feedback were incorporated in the design process (De Couvreur & Goossens, 2011; Gherardini et al., 2018; Santos & Silveira, 2020). Tools such as CAD and 3D printing were commonly used due to low cost and enabling a high degree of customisation to devices. Studies reported high levels of satisfaction from the end users of producing custom assistive devices using the techniques (Day & Riley, 2018; Gherardini et al., 2018; Lee et al., 2019). However, a lack of long-term follow-up data, limitations in current evaluation methods and small sample sizes mean it is currently difficult to evaluate the feasibility of such approaches and the devices produced compared to the traditional prescription-based methods of assistive technology provision.. Additionally, a lack of information on the resources required, costs involved and a lack of application in a clinical setting further limits the current research around co-designing custom assistive devices.

Questions thus remained about how a co-design approach could fit into current healthcare services. Certainly, clinicians had some concerns about 3D printing and the processes used. Iterative design, and trial and error type approaches described by the e-NABLE network and Wagner et al. (2018) did not fit in well with current clinical practice (Hofmann et al., 2016a; Parry-Hill et al., 2017; Wagner et al., 2018). Therapists also had concerns about how to assess the safety of custom devices produced this way. Additionally, the skillset of the individuals needs to be considered, with such techniques heavily reliant on CAD and 3D printing. Research looking at how healthcare therapists could use 3D printing has indicated some of the challenges relating to the skill set, expertise and confidence in utilising such techniques (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016; Wagner et al., 2018). Although of note later work has successfully used occupational therapists to 3D print custom assistive devices (Rasmussen et al., 2022; Schwartz et al., 2020).

This research proposes to utilise a co-design methodology within current specialist healthcare services that routinely design and manufacture custom assistive devices. In such services, the role of designer in the co-design methodologies would be taken by the clinician, who would be experienced in not only the clinical skills but trained in digital design and manufacturing. These services are used to working within the standards and legislation required for the manufacturing of medical devices compared to healthcare therapists; this may lessen previous concerns relating to the safety of 3D printed devices. The opportunities presented by technological advances in CAD and manufacturing methods will be used to explore expansion opportunities for such services; this may increase the range of custom assistive devices produced by healthcare services and thus improve access to more

customised and suitable assistive technology. It is theorised such an approach will reduce barriers to assistive technology, improving usage and health outcomes for individuals living with chronic conditions.

It is against this context that the motivation for the research in the forthcoming chapters is undertaken – aiming to test and more closely investigate the degree to which co-design can be integrated into a current healthcare service for the provision of customised assistive devices and evaluate the wider utility of such an approach for future practice.

4 Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service: a service evaluation

This chapter explores the use of the previously described co-design methodology within a current NHS healthcare service to provide customised assistive devices. This will be through the evaluation of three case study examples. It seeks to identify the type of customised devices required, the impact providing such devices has on the user and the resources and costs associated with co-designing devices. A mixed-method evaluation is conducted of both the devices provided and of the process of co-designing process with the end user.

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4.1 Introduction

Assistive technology refers to "*any product either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing*" (pp.2229) (Khasnabis et al., 2015). The benefits of using assistive technology for the user include enhancing function and independence, improved safety, promoting social inclusion and increasing participation in education, employment, and society (Abrilahij & Boll, 2019; McNicholl et al., 2019). Providing the right assistive technology has the potential to reduce the burden of chronic conditions on the individuals, caregivers, healthcare services and wider society (Lansley, 2004; Madara Marasinghe, 2016; Mitzner et al., 2010; van Ommeren et al., 2018; World Health Organisation, 2018). However, despite these potential benefits of using assistive technology, to date its potential has not been fully realised.

A previous meta-synthesis identified 50 descriptive themes, grouped into 6 analytical themes, that were barriers to the provision and use of assistive technology for individuals with chronic conditions (Howard et al., 2022a). These themes, found to be common across different chronic health conditions and interlinked with each other, included: a lack of customisation in the design of assistive devices, a lack of end-user involvement in the design of assistive devices, a lack of patient involvement in decisions about their care and a lack of individualised care. One potential solution to overcoming the identified barriers is to increase the involvement of the end-user in the design and provision process (Alqahtani et al., 2019; Martin et al., 2011; Orejuela-Zapata et al., 2019; Robinson et al., 2013).

Co-design, or participatory design, is a design methodology which aims to include the end user in the design process through collaboration with the designer (Federici et al., 2013; Sanders & Stappers, 2008). A co-design approach can help empower the end-user by: encouraging them to input their knowledge and lived experiences into the design process; involving them in key decision making processes; and enabling them to provide feedback during the design process (Hakobyan et al., 2014; Vines et al., 2013).

Various previous studies have presented different co-design methodologies for the provision of assistive technology with the methodologies sharing many similarities: involvement of the end user throughout the design process; an iterative design approach with user feedback influencing the next design iteration; the use of physical prototypes to communicate ideas between the end-user and design team; and the bringing together of multiple personnel with unique expertise and experience into the process (De Couvreur & Goossens, 2011;

Gherardini et al., 2018; Santos & Silveira, 2020). Other studies have looked to utilise user feedback for the provision of bespoke hand orthotics and personalised pill boxes, tailored to an individual's needs (Day & Riley, 2018; Lee et al., 2019; Schwartz et al., 2020). Whilst Thorsen et al's (2019) further work built on the co-design concept by looking to train the end user in computer aided design software to enable them to be a maker of their own assistive technology (Thorsen et al., 2019).

From the current literature, several common shortcomings have been identified to evaluating the long-term use and feasibility of co-designing assistive technology:

1) The majority of studies report a lack of long-term follow up with the end-users to assess the satisfaction and compliance with the devices provided using a co-design methodology.
2) Studies do not report information about the resources involved in producing the devices, including costs, equipment, and personnel.
3) The majority of current studies only report case-studies involving between 1-3 participants. From these small sample sizes, it is difficult to assess if the findings are generalisable to a larger population.
4) No current work has reported qualitative data to assess the impact the devices have had on the user's day-to-day lives or the user's opinion on the co-design approach.
5) The reported studies do not specify timescales over which the devices were provided, so it is not clear if the design process took weeks, months, or years. This has potential implications for end-user compliance with the process and with the solutions provided.
6) The majority of studies do not mention the development of documentation to adhere to the relevant medical device regulations.

The co-design of assistive technology also needs to be considered within the context of where devices are currently provided; this is predominantly within healthcare settings. Schwartz et al. (2019) concluded the complexity of the devices they were able to provide was limited by the skillset of the student therapists (Schwartz et al., 2020). This raises a potential issue with traditional healthcare therapists not having the current expertise to produce customised devices using computational design and additive manufacturing, common tools used in the other studies. This may explain why none of the previous studies report being undertaken within a healthcare setting.

The current work aims to explore the use of co-design to provide customised assistive devices within a current healthcare service through an initial evaluation of three case studies. This evaluation took place in Swansea Rehabilitation Engineering Unit, a current UK National Healthcare Service, based in Morriston Hospital and part of Swansea Bay University Health Board. For this initial service evaluation, the main questions are threefold:

1) Is it possible to co-design assistive technology with people with chronic conditions within a health care setting?
2) What are participants experiences of the co-design process and what is the impact of the using the devices produced?
3) What are the costs involved in utilising a co-design approach?

This evaluation intends to help inform future service delivery and refine the methodology for future research studies around the use of co-design in the provision of customised assistive devices. The findings of this service evaluation add value to the existing literature by addressing some of the shortcomings previously identified. The methods used and findings are reported based on the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines (Appendix A: SQUIRE 2.0 checklist for Chapter 4) (Ogrinc et al., 2016).

4.2 Methodology

4.2.1 **Service context**

This work took place in Swansea Rehabilitation Engineering Unit, part of Swansea Bay University Health Board, UK. The department is certified to manufacture devices within the framework of ISO:13485, a quality management system for the provision of medical devices. All appointments and design work were conducted by JH, the first author of this paper, a Clinical Scientist working within the Rehabilitation Engineering Unit and PhD research student. The devices were developed between October 2020 to February 2021. As a result of the global COVID-19 pandemic all appointments and interactions with participants were conducted virtually using Attend Anywhere, a web-browser based video consultation software.

4.2.2 Participants

Participants were referred to the department by occupational therapists and physiotherapists working within Swansea Bay University Health Board. Participants had to be 18 years +, living with a long-term chronic health condition and residing in the community of Southwest Wales. Participants presented with a range of different medical conditions and challenges of daily living that they wanted to overcome, see Table 4-1.

*Table 4-1: Summary information of participants involved in the service evaluation. *International Classification of Diseases and Health Related Problems (ICD). **International Classification of Functioning, Disability and Health (ICF)*

Participant #	Age	Gender	Medical diagnosis	ICD* Code	Challenges of daily living identified	ICF** Code
001	30	F	Congenital birth defects affecting hands and feet	LD26.0&XK9J	Be able to tie up her own hair To be able to apply eyeliner herself	D5205 D5200
002	57	F	Amputation of middle three fingers of their right hand	NC59.20	Use and write with a pen in her right hand again Use a knife at the table to cut up food	D345 D550
003	62	F	Multiple sclerosis	8A40.2	Independently administer Sativex, an oral medication spray	D5702

4.2.3 **Ethical Considerations**

Service evaluations to gather the experiences of service users associated with the delivery of standard levels of care are characterised by minimal risk and are excluded from ethical review by research ethics committees in the United Kingdom (GAfREC 2.3.12). This evaluation was intended to gather the experiences of service users based on current provision of care in co-designing a customised assistive device. It did not involve a new treatment and participants were not randomised. All participants who were invited to participate in the evaluation provided both written and verbal consent to the treating clinician for their information to be shared as case-studies and included in this evaluation with any personal identifiable information anonymised (Appendix C: Consent form for service evaluation). All data was collected in accordance with the General Data Protection Regulation (GDPR) and information was anonymised prior to being shared with individuals not involved in the individual's standard level of care, for example anonymised prior to data analysis.

4.2.4 Materials

4.2.4.1 Equipment

This section provides an overview of the equipment used to produce the devices.

Computational models of the designs were created using a parametric computer aided design (CAD) software, Solidworks Premium 2016 x64 edition (Waltham, USA). The use of parametric design software enabled the size of the device to be easily edited and reconfigured based on a few key dimensions to create versions of different sizes. When manufactured, this enabled the user to test different sizes of a device, ensuring they could choose the best fit for them.

The devices were manufactured using a mixture of additive manufacturing and simple hand-held tools. Prior to manufacturing, parts produced by additive manufacturing were exported as a Stereolithography file from Solidworks and imported into a slicer software, PrusaSlicer V2.2.0 +win64 (Prague, Czech Republic). System pre-sets for shell thickness, layer height, infill percentage, infill pattern and print speeds were utilised to reduce the number of variables to be set during manufacturing. An Original Prusa i3 MK3S 3D printer, a fused deposition modelling (FDM) type machine, was used to manufacture the parts. The material selected for a device varied based on the part being produced, its intended function and the

stage of the design process. For example, initially parts were produced from Polylactic aid (PLA) due to its low cost and ease of printing to enable the user to feedback on the shape of the device. However, for final manufacture a tougher material, Polyethylene terephthalate glycol (PETG), was used to improve mechanical strength and reduce risk of failure of the device. Additional parts and accessories, for example foam liners, straps and fabric components were added using a range of simple hand-held tools.

4.2.4.2 Questionnaire measures

The two questionnaires used to explore the participant's experiences of the device they co-designed and its impact were the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) and the Psychosocial Impact of Assistive Devices Scale (PIADS) (Day, Jutai, & Campbell, 2002; Demers et al., 2002a) . QUEST 2.0 is a 12-item outcome measure that assesses the user's satisfaction with the assistive device and the service supplying the device (Demers et al., 2002a). For each item, the questionnaire uses a 5-point scale, 1 being not satisfied at all and 5 being very satisfied. Research has established the instrument has good internal consistency, moderate to substantial test-retest reliability and good construct validity (Demers et al., 2002a; Demers, Weiss-Lambrou, & Ska, 2000; Demers, Weiss-Lambrou, & Ska, 2002b). The items comprising the questionnaire are considered very important and relevant and the questionnaire has been shown to be a reliable and valid outcome measure of user satisfaction of assistive technology.

PIADS is a 26-item self-reported questionnaire to evaluate the effects of an assistive device on three sub-scales: competence, adaptability and self-esteem (Day et al., 2002). The individual is asked to read a list of phrases that describe how using the assistive device may have affected them. For each phrase, the individual rates the item using a 7-point scale, ranging from -3 (maximum negative impact) to +3 (maximum positive impact). Research has established that the instrument has good internal consistency, test-retest reliability, and construct validity (Jutai & Day, 2002). It is a responsive measure and sensitive to important variables such as the users clinical condition, device stigma, and functional features of the device, and thus can accurately reflect the self-described experiences of people who use assistive devices.

Both questionnaires were chosen as they are validated for use on different assistive devices and have been used in other previous studies evaluating co-designed assistive devices (Gherardini et al., 2018; Lee et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020).

4.2.4.3 Semi-structured interviews

Participants were invited by email prior to taking part in the interviews. Before the interview commenced, participants consented to take part in the interviews and for them to be audio-recorded. Interviews were conducted by the clinician involved in providing the devices, first author JH. This was chosen as the insight the clinician had on both the individual and the devices was important for gathering the feedback. The interviews were conducted using the video consultation software Attend Anywhere, with the participant at home and the interviewer in a private clinic room. No other individuals were present during the interviews and no repeat interviews were conducted. All interviews were audio-recorded and additionally the interviewer made notes to aid with the transcription and understanding after the interview. Interviews were conducted with all three participants and lasted between 30-40 minutes each. Initial interview questions asked were based around two main topics, with additional follow-up questions asked to gather further understanding based on the responses provided. The initial questions were agreed by all authors prior to conducting the interview and were as follows: '*What impact (if any) would you say the device has had on your day-to-day life?'; 'How have you found the service and being involved in the process of developing the devices? This includes your experience of virtual appointments and any suggestions for future improvements to the service'*.

4.2.5 Procedure

The process undertaken by participants is summarised in Figure 4-1.

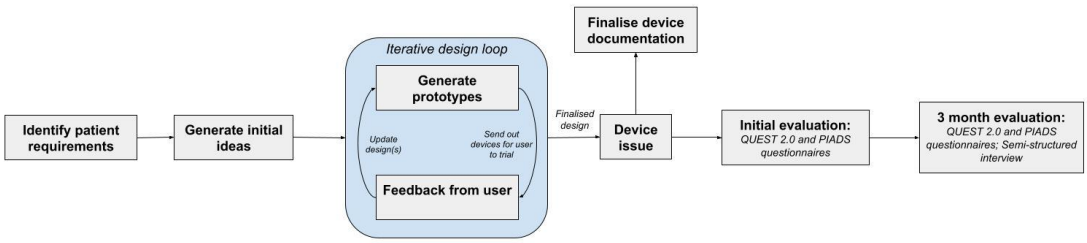


Figure 4-1: Overview of the process for participants involved within the study

1) *Identifying patient requirements*. The clinician gathered relevant background information and participants were asked to identify specific challenges of daily living they faced and wished to overcome.

2) *Generating initial ideas.* Design requirements were defined for the device(s) and design ideas generated through sketches and low-fidelity prototypes.
3) *Generating prototypes.* Functional prototypes were created using a mixture of CAD, additive manufacturing and handheld manufacturing tools. Prototypes were posted out for the participant to trial.
4) *Feedback from user.* Participants were encouraged to provide feedback about the design(s) including what they liked, disliked and suggestions for improvements.
5) *Device development - iterative design loop*. Feedback was used to implement design changes and produce further prototypes (step 3). Steps 3 & 4 formed an iterative loop of refining the design until a final design was reached. This took between 4 to 5 appointments and varied for each participant.
6) *Device issue.* The finished device was sent out to the participant, further training was provided on the use of the device and instructions for use issued. Technical files and risk management documentation for the device were completed.
7) *Initial Evaluation.* The QUEST 2.0 and PIADS questionnaires were sent out to the participants for each device provided. Participants completed the questionnaires at home.
8) *3-month evaluation*. Participants completed the QUEST 2.0 and PIADS questionnaires again for each device provided. Additionally, the participants were invited to take part in individual semi-structure interviews.

4.2.6 Data Analysis

4.2.6.1 Questionnaire analysis

Mean scores for satisfaction with each device and the service provided were calculated for each device from the QUEST 2.0 questionnaire. The device score was an average of eight items: dimensions, weight, durability, comfort, adjustment, safety, simplicity of use, effectiveness; whilst the service score was an average of four items: service deliverable, repairs and servicing, professional service and follow-up services. For the device and service scores, the difference between the scores at initial follow-up and at 3-month follow up were calculated.

For each device the mean score for the competence, adaptability and self-esteem were calculated from the PIADS questionnaire responses. The competence score was an average of 12 items: competence, adequacy, efficiency, productivity, usefulness, expertise,

capability, performance, skilfulness, independence, quality of life, confusion (reverse). The adaptability score is an average of 6 items: willingness to take chances, ability to participate, eagerness to try new things, ability to adapt to activities of daily living, ability to take advantage of opportunities, wellbeing. The self-esteem score is an average of 8 items: self-esteem, security, sense of power, embarrass (reverse), happiness, sense of control, frustration (reverse), self-confidence. For each sub-scale the difference between the scores at initial follow-up and 3-month follow up were calculated. Due to small sample size no further, statistical analysis was performed on the questionnaire data.

4.2.6.2 Qualitative analysis

Following the interviews, the audio files were transcribed by the interviewer for analysis. The semi-structured interview transcripts were analysed through reflexive thematic analysis to identify commonalities in the responses given amongst the three case studies. The process followed the six-step procedure to good Thematic Analysis described by Braun and Clarke (2006) (Braun & Clarke, 2006). Initially the author JH familiarised themselves with the transcript interviews (step 1). Quotes from the raw data were assigned initial codes inductively that closely related to the material and context (step 2). Codes were then grouped into potential themes (step 3), before being reviewed and refined such that quotes in each code were relevant and related to the theme assigned (step 4). No software was used in organising the codes. The themes were then reviewed by the other authors and each theme given a name (step 5). Finally, appropriate quotes that reflected each theme were selected (step 6). Frequencies for if a theme was identified in each participants transcript were calculated. The data was initially analysed by one coder only as multiple coders do not improve the accuracy of the coding process (Braun & Clarke, 2006). A review of the themes by the other authors, step 5, allowed for broader clinical and research experience to be incorporated into the thematic analysis. The thematic analysis of the data presented is a representation of the researchers understanding of the data based on their past clinical and research experience, and there involvement with the participants in designing the devices (Clarke & Braun, 2020). The qualitative data from the semi-structured interviews is reported following the Consolidated Criteria for Reporting Qualitative Studies (COREQ): 32-item checklist, Appendix B: COREQ checklist for Chapter 4 (Tong, Sainsbury, & Craig, 2007).

4.2.6.3 Cost analysis

For each participant the resources (time, money, material cost) required to produce the final device(s) were calculated. The time required for each visit and any subsequent changes to design were recorded and rounded to the nearest 5 minutes. The cost of the clinician's time was calculated by multiplying the time spent by the cost per hour of the clinician, £28.95/hr. This was based on the top increment of a band 7 clinician on the NHS pay scale as calculated at the time the case studies were conducted (September 2020).

4.3 Results

Our main service evaluation questions were threefold: 1) whether it was possible to co-design assistive technology with people with chronic conditions within a health care setting; 2) what were participants experiences of this process and using the devices produced and 3) what were the cost implications. Accordingly, the results section is structured around these questions.

4.3.1 Devices Produced

A total of 5 different devices were co-designed and provided to the three participants, see Figure 4-2. For participant 1: A grip holder to accommodate different household objects (A), including an eye-liner pencil, and a pull tight hair tie (B). For participant 2, a holder that straps onto the hand with attachment for different size knifes (C) and a finger attachment for supporting a pen between the little finger and thumb (D). For participant 3, a holder for the Sativex spray with a pull trigger mechanism (E). Each device was designed such that its dimensions could be easily changed and re-configured for a different user in the future if required.

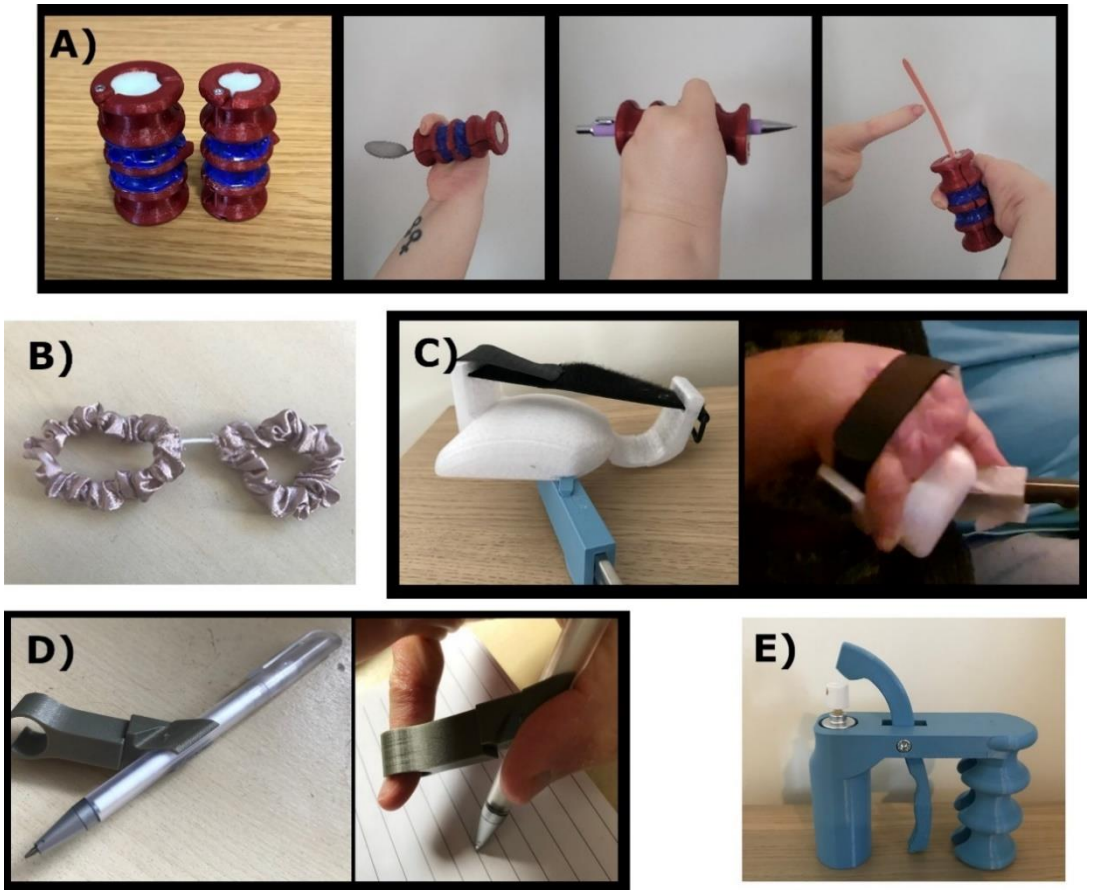


Figure 4-2: Devices produced for participants during the study.

A) Grip holder to hold various household objects being used by the participant.

B) Pull hair tie; as the individual pulls the left hair tie, the right hair tie tightens.

C) Knife holder device, strapped to participants hand.

D) Pen Holder; positioned on the little finger with support from the thumb.

E) Sativex spray holder with Sativex bottle in place.

Of the five devices issued, four of the devices were still being used daily 3 months after being issued. The one device no longer being used regularly was the pen holder for participant 2 who had regained sufficient function in her right hand that she was able to use a pen without the device.

4.3.2 Evaluation of devices and approach

A concurrent mixed-methods approach was chosen to evaluate the satisfaction with the devices and the process of providing the devices.

4.3.2.1 Questionnaire scores:

A summary of the results from the QUEST 2.0 questionnaire are shown in Table 4-2. The average device satisfaction for all devices was 4.8 initially and 5 at 3-months follow-up. The average satisfaction with the service was 5 initially and at 3-months follow up.

Table 4-2: Summary results from the QUEST 2.0 questionnaire for all three participants initially after being provided the results and 3-months post device issue. Participant 3 did not complete the QUEST 2.0 questionnaire at 3 months.

		After issuing device (Score) (0-5)		**3-month follow-up (Score) (0-5)**	
Participant	**Device**	**Assistive Device satisfaction**	**Service satisfaction**	**Assistive Device satisfaction**	**Service satisfaction**
001	Grip holder	5	5	5	5
	Hair tie	5	5	5	5
002	Knife holder	5	5	5	5
	Pen Holder	5	5	5	5
003	Sativex Spray	3.9	5	-	-

A summary of the results from the PIADS questionnaire are shown in Table 4-3. Across all devices, the average score was +2 for competence, +1.7 for adaptability and +2.2 for self-esteem initially. At 3 months follow-up the average for all three sub-scores increased to +3 for competence, +3 for adaptability and +2.8 for self-esteem.

Table 4-3: Summary of results from PIADS questionnaire for all three participants initially after being provided the results and 3-months post device issue. Participant 3 did not complete the PIADS questionnaire at 3 months.

		After issuing device (Score) (-3 to 3)			**3-month follow-up (Score) (-3 to 3)**		
Participant	**Device**	**Competence**	**Adaptability**	**Self-esteem**	**Competence**	**Adaptability**	**Self-esteem**
001	Grip holder	+ 1.9	+ 1.7	+ 1.9	+ 3.0	+ 3.0	+ 2.6
	Hair tie	+ 1.1	+ 1.2	+ 2.4	+ 2.8	+ 3.0	+ 2.6
002	Knife holder	+ 2.3	+ 1.8	+ 2.3	+ 3.0	+ 3.0	+ 3.0
	Pen Holder	+ 2.4	+ 2.0	+ 2.3	+ 3.0	+ 3.0	+ 3.0
003	Sativex Spray	+ 2.3	+ 1.7	+ 1.9	-	-	-
Mean	All Devices	+ 2.0	+ 1.68	+ 2.16	+ 2.95	+ 3.0	+ 2.8
Standard Deviation	All Devices	0.54	0.29	0.24	0.1	0.0	0.23

4.3.2.2 Qualitative feedback:

In total 11 themes were identified from the thematic analysis of the semi-structured interviews; 5 themes related to the impact of the device and 6 themes related to being

involved in the co-design process, see Figure 4-3. The themes, including quotations from the semi-structured interviews and frequency scores (n), are described below.

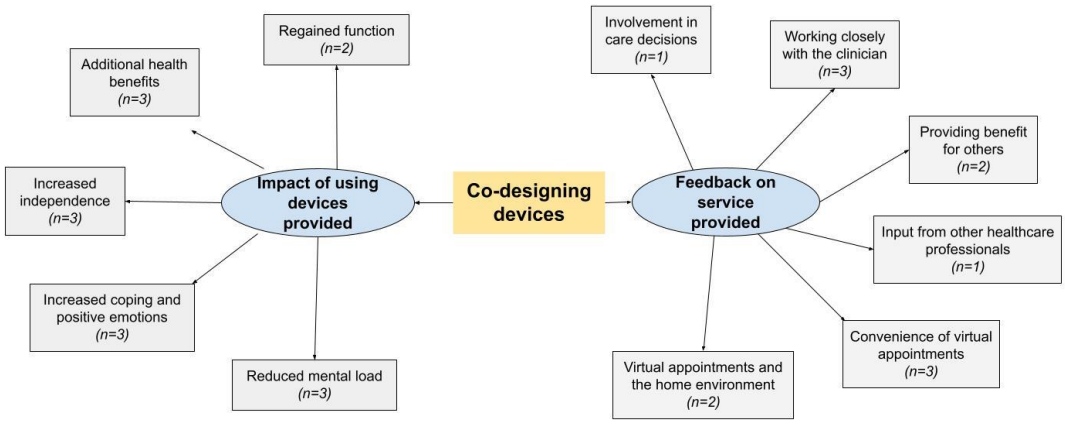


Figure 4-3: A summary of the themes identified from the participant's semi-structured interviews with the frequency (n) calculated.

Themes One-Five: Impact of using the device provided

Regained function (n=2): Participants found benefits of using the device not only in regaining function for the activities they had originally identified, but in some instances being able to use the devices for other activities as well.

P1: *"And then I use them [the grip holder] like on my knifes, my forks all of that type of stuff. Umm all my make-up, my make-up brushes, like my eye-pencil all of that type of stuff as well."*

P2: *"and I decided that that was going to be the garden knife now and now I put my thing on [knife holder] and I go outside and I split plants with it and cut string and I open boxes with it and all sorts of stuff, so it's not just, it's not just me sitting here at the table and eating a meal, its going out and doing stuff in the garden which I thought I would never ever be able to do again."*

Additional health benefits (n=3): Participants gained other benefits from using the devices including reduced pain, improvements in mental health and in the case of participant 2 a

rehabilitative benefit where she regained the function to use a pen again without the need for the pen-holder device.

P2: *"because honestly I swear, I am absolutely positive that if it wasn't for that [pen holder], I still would not be able to write with my right hand."*

Increased independence (n=3): All three participants had a feeling of increased independence in doing tasks and therefore made them feel less reliant and less of a burden on other members of the household. For example, participant 1 described how she was able to do more with her kids now, whereas previously she would have had to rely on her partner.

P1: *"… I didn't have to go like 'why don't you go ask [my partner], you know go and ask my partner, umm instead of me because I was like, because I was like 'yeah I can do that' and it was just like immediately … I don't have to think about waiting until [partner] has got 5 minutes to do it because I can do it. And it is just little things like that, it is nice."*

Increased coping and positive emotions (n=3). The theme of increased coping and positive emotions includes the participants feeling a sense of achievement, a sense of restoring loss function, improved confidence and a greater sense of control over their own decisions.

P3: *"it makes me feel… well more confident in general I suppose. Your confidence, your self-esteem, all these things make you feel just 'yes I can do it'."*

P1: *"but when it is something that has kind of been taken from you by pain and by degeneration it is, it's really difficult. So, getting that back, either by using a tool, it just, it just does give you that sense of like you haven't lost it anymore you know. You know longer have that sense of loss which really does make a difference."*

Reduced mental load (n=3): The final theme relating to the use of the devices was aspects related to reduced mental load that all three participants described. This included the reduced mental burden and anxiety of having to think about tasks. Participant 1 described a reduced mental burden and taking the pressure off doing tasks and provided an example of going to pay a cheque in at the bank:

P1: *"…one of the things I always dread is like you know when you have to go to the bank and sign something, or you have to go down and sign something? Because people will just pass you a pen and you're just like 'right here we go' and you've got to hope its big enough that you can balance it and I don't have to think about it, it's like a worry that I no longer have because I can just like chuck it in my thing [grip holder] and done, I don't have to worry about it."*

Themes Six - Eleven: Feedback on the service provided

Involvement in care decisions (n=1): This theme describes the importance that participants felt in being involved in decisions related to their care. Participant 1 described how she felt this was important as previously when she was younger, she felt excluded from conversations between parents, teachers, and healthcare professionals about what was best for her:

P1: *"and I was never included in those meetings and I was always used to think like 'why am I not being included, this is about me, this is literally about what's best for me and I'm not even included in these conversations and it was something I really had to fight for growing up was to be included in a conversation about my own disability and about what's best for me and what would be most helpful for me… Just having that open dialogue and being able to have that conversation I wish that more situations were like that, it is so important."*

Working closely with the clinician (n=3): Participants felt that close working was important in ensuring that the final device was suitable for their needs, as well as feeling valued by the time invested in creating a solution.

P1: *"Working one-on-one and being able to have this conversation is so, so important because how else are you going to be able to? You could come up with 50 different designs for different things and none of them would be suitable because you're just doing what you [the designer] think they need rather than having the conversation about what they [the end-user] think they need."*

P2: *"And for somebody to actually take the, take the time and make the effort to try and understand and to try and help is absolutely beyond umm, value. It really is umm, and it has gone an awful long way to umm, to making me feel human again."*

Providing benefit for others (n=2): By being involved in the process of designing assistive devices, both participants 2 and 3 felt a sense of happiness knowing that the devices may be able to benefit other individuals as well:

P3: *"Absolutely I did yeah. I would feel if I can do anything to enrich other people's lives then yes, I would love to be involved in it."*

Input from other healthcare professionals (n=1): Participant 1 felt there was a benefit of having input from other healthcare professionals and the insight they could help bring into the process:

P1: *"So I think having the collaboration between other departments and working with people who see people day in day out is also something that I think should definitely be maintained going forwards."*

Convenience of virtual appointments (n=3): All participants liked the use of virtual appointments during the process, as it reduced the need to travel to appointments and enabled the appointments to be at a time more convenient for them.

P2*: "I'm quite happy to do it virtually because for me, for me personally, I prefer this because it is an hour between me and Morriston [hospital where clinics would be based]. An hour in the car and you know we can get the same umm outcome without all that fuel being used."*

Virtual appointments and the home environment (n=2): Another aspect of the virtual appointments that the participants liked was being able to use and trial the equipment in their home environment as it gave them more time to trial the device and determine what worked for them compared to a clinical setting.

P1: *"Initially when I was picked it up, I was like 'that's great, that's fab' and I think if we had left the hospital, I think we would have left it like that. It wasn't until I got home and I was*

using it day in day out that I was like, actually I really need something to stick this too, something that's grippy on here to make that difference that so I can use it long term rather than short term and I don't think I would have necessarily figured that out in a 5 minute meeting in an office so you know."

4.3.3 **Cost Analysis**

The total cost of providing the devices for each participant is summarised in Table 4-4. Costs ranged from £581.93 to £1168.41, with an average cost of £520.72 per device. Material costs ranged from £12.88 to £61.07 and the average per device was £19.85. Material costs included 3D printing filament, nuts and bolts, elastic and all other components used in the development and design of the devices.

*Table 4-4: Total resources used to provide the final devices for each participant. * For participants 1 and 2, the resources are for providing 2 different devices.*

Participant	Clinicians time (hh:mm)	Cost of time	Material cost	3D printing time (hh:mm)	Total cost
001*	38:15	£1107.34	£61.07	53:00	£1168.41
002*	28:35	£827.97	£25.29	90:20	£853.26
003	18:55	£569.05	£12.88	37:45	£581.93
Total	85:45	£2504.36	£99.24	181:05	£2603.60
Average per participant	28:35	£834.79	£33.08	60:22	£867.87
Average per devices	17:09	£500.87	£19.85	36:13	£520.72

The cost of the materials for manufacturing the finished devices again is summarised in Table 4-5. The total cost, material cost plus the of the time spent by an individual to manufacture the item, varied between £3.41 for the pen holder and £22.81 for the grip holder.

Table 4-5: Costs and manufacturing time required to produce each of the final devices.

Device	Total material cost	Manufacturing time, person (hh:mm)	Manufacturing time, 3D printer (hh:mm)	Total Cost (£)
Hair tie (*Participant 1)*	£1.49	00:30	00:05	£11.19
Grip holder *(Participant 1)*	£3.41	01:00	04:00	£22.81
Pen holder (*Participant 2)*	£0.18	00:10	00:15	£3.41
Knife holder *(Participant 2)*	£2.38	00:30	04:00	£12.08
Sativex spray holder *(Participant 3)*	£3.45	00:10	08:00	£6.68

4.4 Discussion

This service evaluation explored the use of co-design to provide customised assistive devices within a current healthcare service based in Southwest Wales, UK. This work has demonstrated it is possible to co-design within the current structure and resources of a healthcare service. The devices were developed with the individuals over a 5-month period and all the devices complied with the relevant medical device regulations. Next, this work is discussed in the context of the initial aims of the service evaluation and reflect upon how this relates to some of the limitations in the literature previously identified.

4.4.1 **Impact of using the device**

The evaluation looked to explore the use of the devices by the user and any wider impact it had on their daily lives. Feedback gathered from both the QUEST 2.0 questionnaire, Table 4-2, and the semi-structured interviews indicated the participants were highly satisfied and felt great benefit from using the devices. The themes of 'additional health benefits' and 'increased independence', both indicate how the benefit went beyond simply using the device for the task originally identified by the participants. For example, participant 3 described how she was less reliant on her husband to administer the medication, whilst participant 1 described being able to do more for her children, which benefits the participant, her children, and her partner. The themes of 'increased coping and positive emotions' and 'reduced mental load' link to the improvements for all three participants in the sub-scale measures of the PIADS questionnaire: competences, adaptability, and self-esteem, Table 4-3. The feelings of achievement, confidence, reduced anxiety and safety were all described by participants; within the field of positive psychology these all have indications for improvements in overall health and wellbeing (Fisher et al., 2020). In future work it would be interesting to measure if a similar codesign approach has an impact on other important domains of wellbeing, for example improved social connection, improved connection with nature, balanced mind and health body (Fisher et al., 2020; Kemp et al., 2017; Mead et al., 2019). This could further evaluate if there are any wider benefits to an individual's life from providing the right assistive technology.

The use of a mixed-methods evaluation in this work has helped highlight the wider impact the devices have had on the individual's health and wellbeing, a factor not captured in previous co-design studies. It is important that outcomes related to assistive technology both

in healthcare settings and research reflect the potential wider impact providing the right device can have on health and wellbeing.

4.4.2 Use of Co-design

This evaluation sought to gain feedback on how the participants found the co-design process, an area not previously explored in the literature. Feedback obtained from the participants from both the semi-structured interviews and the QUEST 2.0 questionnaires highlighted satisfaction with the service provided, Table 4-2 & Figure 4-3. The theme 'working closely with the clinician' indicated how participants found the co-design process essential in being able to develop a device specific to their individual needs, as well as making them feel valued and listened to in their care. This was linked to the theme of 'involvement in care decisions', where participant one liked this process as she felt involved in decisions, whereas previously she had felt excluded from her own care. These themes reflect wider approaches to healthcare provision, for example co-production which identifies the individual as the expert in their own health and user-focused approaches which reinforces the role of the patient as the primary knower of their own needs (Realpe & Wallace, 2010; Scherer & Federici, 2017). Whilst it is not clear how much these results would be applicable to other situations, results certainly indicates that individuals are happy with greater involvement in their care and liked an individualised approach, factors previously identified as barriers in the service provision of assistive technology (Howard et al., 2022a).

4.4.3 Use of virtual appointments

This service evaluation was not intended as a robust evaluation of the use of virtual appointments. However, the sudden need to use virtual appointments due to the COVID-19 pandemic enabled the gathering of feedback from participants which may help shape future service provision and research methodologies. All three participants were positive about the use of virtual appointments with the theme of 'convenience of virtual appointments', highlighted how participants liked not having to travel to the appointments which saved time and fuel. Another benefit that participants liked was being able to trial the devices within their home environment, as they felt it gave them more time to use the device compared to a traditional clinical setting. These themes relate to previous barriers identified in the

literature around the service provision of assistive technology (Howard et al., 2022a). Virtual appointments could help reduce barriers around a lack of availability of local services with the reduced need to travel to appointments, and a lack of opportunity to trial equipment. Whilst the use of virtual appointments was out of necessity, the results from this evaluation indicate how future co-design processes could benefit from utilising virtual appointments.

4.4.4 **Resources used**

Whilst the average cost of the whole process was high, £520.72 per device, the costs of manufacturing the devices again were relatively low ranging from £3.41 to £22.48, Table 4-5. If the same devices could be reproduced for other individuals to overcome similar issues identified, this would help make the initial costs associated with co-designing the device more economical. Especially as the clinician's time would likely be reduced, the highest proportion of the cost in the production process, Table 4-4. For example, could other individuals with multiple sclerosis who are currently prescribed Sativex also use the Sativex holder? The use of such devices in a larger patient population will be the subject of future research.

In this work the main costs comprised the time taken to provide the device. For these case-studies, the devices were designed from scratch with few similarities in the devices produced. For a larger sample size, the time taken to produce a device may decrease due to both greater experience in designing such devices, the potential to draw on previous design experience and the use of parametric design features making devices easily customisable. From the three case-studies in this evaluation it is not clear if this will be the case and therefore further, larger trials are required to determine if the average time to produce a device changes.

The costs reported in this evaluation do not include the on-going departmental costs of providing the devices, for example is there any further follow-up with participants after they were issued the devices? What are the costs for repairing and replacement of devices and how regular may this be required? And what are the costs associated with further changes to the devices? A more longitudinal study is required to analyse the long-term costs of providing such devices. These costs could be compared to any potential cost savings associated with reduction in the user accessing other health and social care services.

4.4.5 **Limitations**

The conclusions are limited to the rehabilitation engineering service from which the data was collected as the process was unique to this service. However, findings are interpreted in line with other current research and theories and helps to identify avenues for further research and service development. Within this service evaluation methodology, a potential limitation was that the feedback was obtained from the same clinician who provided the device, this may have inflated the positive feedback provided. In this instance, the insight the clinician had on both the individual and devices were important for gathering the feedback. Upon reviewing by the authors, it was felt the feedback gathered was open and honest from all participants.

Another limitation was in the small sample size presented in this work. This produced limitations in the analyse of both the questionnaire data, with the sample size too small to perform meaningful statistical analysis, and in the qualitative data where it was unclear if data saturation was reached in identifying new relevant themes to the questions asked. This limits the generalisability of the data produced from this work. However, it was felt the sample size was sufficient for demonstrating in principle the use of co-design in a healthcare setting with outcomes that add value to the existing literature and help refine the methodology for future larger research studies.

4.5 Conclusion

This service evaluation demonstrates that it is possible to co-design within the current structure and resources of a healthcare service. This research outlines how this was done and the five customised assistive devices that were provided. The devices were able to functionally help the individual overcome the challenge they identified and also had further benefits for their independence, improved positive emotions and reduced mental load. Feedback from all three participants indicated they liked being involved in the co-design process and working closely with the clinician in this way. The resources used in providing the devices were also calculated. Whilst these initial findings show benefits for the individuals involved, further work is required with larger sample sizes to assess the effectiveness and feasibility of utilising a co-design approach for the provision of custom assistive technology in the future and exploring if this can help overcome some of the barriers to assistive technology use.

5 Co-designing personalised aids of daily living with users with chronic conditions: a feasibility study

This chapter aims to further evaluate the feasibility of co-designing within a current NHS healthcare service. Building on the methodology established in Chapter 4, this study seeks to co-design customised assistive devices with a larger sample size. Mixed-method analysis using questionnaires and semi-structured interviews are used to investigate the impact of the co-design intervention and the devices provided on the individuals. Additionally, any impact on healthcare services being accessed by individuals and on the help required by individuals to overcome challenges is investigated. Finally, the resources and costs involved in the co-design process are calculated.

5.1 Introduction

Activities of daily living describe a wide range of functional tasks an individual may do to independently care for themselves. However, the ability to perform such tasks may be hampered due to limitations as a result of acute and chronic conditions (Edemekong et al., 2022). The inability to perform such tasks can consequently lead to unsafe living conditions, poor quality of life and additional expenses for the individual, family and health and social care services through the need to access such services.

Assistive technology is one solution to help individuals overcome challenges associated with activities of daily living. Assistive technology refers to *"any product either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing"* (pp. 2229) (Khasnabis et al., 2015). However previous research has shown numerous barriers to individuals accessing and using assistive technology including: a lack of suitable devices being available, a lack of customisation of devices to the individual's needs, a lack of end-user involvement in the design process and a lack of user involvement within care decisions (Howard et al., 2022a; Phillips & Zhao, 1993).

Within healthcare service delivery, greater patient involvement in care decisions is increasingly viewed as a key fundamental part of safe, quality and person centred healthcare services (World Health Organisation, 2016). The UK National Health Service (NHS) Constitution recognises shared decision making between healthcare professionals and patients as a core feature of good healthcare, with recent guidelines from the National Institute for Health and Care Excellence (NICE) helping to facilitate this (Department of Health and Social Science, 2021; National Institute for Health and Care Excellence, 2021b). Shared decision making enables patients to choose the care that is right for them, based on evidence available and their own personal preferences, beliefs and values (National Institute for Health and Care Excellence, 2021b). Within the design of assistive technology, it is important to utilise the expertise, insight, and preference of end users to shape the design process and solutions produced (Aflatoony & Lee, 2020; McDonald et al., 2016). With the goal of improving the use of assistive technology, this research considers how to improve user involvement in the design and provision of assistive technology and explore this from a healthcare service provision perspective.

Co-design is a design methodology that engages the end user in the design process through collaboration with the designer by involving them in key decision-making processes and

enabling them to provide feedback during the design process (Hakobyan et al., 2014; Sanders & Stappers, 2008; Vines et al., 2013). It thus has similarities to the focus of shared decision making in healthcare. Co-design has been used in the provision of customised assistive devices including hand orthotics, devices to assist with upper limb function and pill boxes (Aflatoony et al., 2021; Day & Riley, 2018; De Couvreur & Goossens, 2011; García et al., 2021; Lee et al., 2019; Ragoo et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020; Thorsen et al., 2019). However, the chapter identified several limitations in the current literature to evaluate the feasibility of co-designing customised assistive technology: a lack of follow-up data, no reporting on resources required for the design process, small sample sizes and no reporting of any wider impact the devices may have had on the individual's lives (Howard et al., 2022b). Additionally, none of the studies were conducted in healthcare settings, the primary setting where assistive technology is issued. It is in this context this research seeks to co-design assistive devices.

Occupational and physiotherapists regularly prescribe assistive technology, modifying and adapting devices to better fit the needs of patients (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016). However adaptions are often makeshift, making use of improvised materials, lack long-term durability and are not aesthetically pleasing (Aflatoony et al., 2021). The majority of previous studies utilising a co-design approach make use of computer aided design (CAD) and additive manufacturing; more commonly referred to as 3D printing. Scientific literature investigating how healthcare therapists could use such technologies has found difficulties in implementing them due to individuals lacking training on the technology, limitations in time, and CAD and 3D printing not aligning well with current clinical practice (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016; Wagner et al., 2018). Schwartz et al. (2020) did produce custom pillboxes using student occupational therapists. However, the complexity of devices were limited by the skill-set of students in using CAD and 3D printers (Schwartz et al., 2020). Rasmussen et al. (2022) explored the use of 3D printing with an amyotrophic lateral sclerosis clinic to produce twenty aids of daily living for nine individuals (Rasmussen et al., 2022). The results supported the feasibility of using 3D printing within an existing multi-disciplinary clinic. However, their methodology was unclear if it focused on an iterative co-design approach involving the end user. Additionally, the authors report the devices were predominantly either pre-existing designs or modified designs from open-source platforms and thus were not novel devices designed from scratch. Limitations using CAD and 3D printers were again barriers to producing more complex designs

Our previous work looked to overcome the current limitations in the literature by exploring how a co-design approach could be used within an existing Rehabilitation Engineering healthcare service. The intervention was led by a clinical scientist with CAD and 3D manufacturing expertise (Howard et al., 2022b). Five unique devices were co-designed with three individuals. The research reported on the wider impact the devices had on the individuals' lives, as well as the resources required to produce the devices. This research demonstrated how a co-design approach could be used within a healthcare service to provide customised assistive technology. However due to only a small sample size, the feasibility of integrating into routine healthcare delivery could not be established.

This study seeks to build upon the previous case-study methodology by recruiting a larger sample size of participants with a range of chronic health conditions, co-designing bespoke devices with them, and evaluating the implications of this approach. The previous case-studies suggest that co-design can help produce customised devices that are able to overcome some of the barriers to assistive technology use previously identified (Howard et al., 2022a). Long-term it is hypothesised this will increase the use of assistive device, help support individuals to better self-manage their own health and wellbeing needs and thus reduce the need for input from other healthcare services.

To date, no other research has reported on the resources, costs, and timescales of co-designing assistive technology solutions in this way. The costs involved need to be considered against the potential short and long-term impacts on device usage, and the sequential benefits associated with this for individuals and healthcare services. The larger-sample size will help further assess the implications of co-designing within a healthcare setting as well as identify the range of novel assistive devices that could be produced to overcome challenges in daily living.

The current work aims to assess the feasibility of co-designing bespoke assistive devices with the end user within a healthcare setting through analysing the impact of the devices provided and the resources involved. Specifically, this research wants to:

- Record the range of different bespoke devices required by individuals with chronic health conditions to understand where future service need may be required.
- Evaluate the impact of the co-design process and the custom assistive devices provided through questionnaires and individual semi-structured interviews 3 months post the device being issued.
- Analyse the resources, costs and timescales involved in providing a device.

To explore the impact of the co-design intervention participants will be asked to complete questionnaires related to: the difficulty of completing a task (Individualised Prioritised Problem Assessment [IPPA]), wellbeing (Warwick-Edinburgh Mental Wellbeing Scale [WEMWBS]), device and service satisfaction (Quebec User Evaluation of Assistive Technology [QUEST 2.0]) and the psychosocial impact (Psychosocial Impact of Assistive Device Scale [PIADS]). The following null hypotheses will be used to test for any significant change:

1) There will be no significant change in the difficulty associated with completing task(s) as measured by the IPPA immediately after the intervention relative to baseline condition.
2) There will be no significant change in wellbeing scores as measured by WEMWBS immediately after and 3-months after the intervention relative to baseline condition.
3) There will be no change in device and service satisfaction and psychosocial impact as measured by the QUEST 2.0 and PIADS questionnaires respectively 3-months after the intervention relative to immediately after the intervention.

Qualitative semi-structured interviews will additionally be carried out to explore the participants experience of co-designing devices and the wider impact on their day to day lives. Through this study, this research intends to help inform future healthcare service delivery by providing a co-design framework that services can use for the provision of customised assistive devices. This will include an understanding of the challenges that can be overcome, the potential impact of the devices provided, and the cost, resources and equipment involved in utilising this approach. The methods used and findings are reported based on the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines (Ogrinc et al., 2016), available in Appendix M: SQUIRE 2.0 checklist for Chapter 5.

5.2 Methodology

5.2.1 Context

The study was conducted within Swansea Rehabilitation Engineering Unit, part of Swansea Bay University Health Board. The department is certified to manufacture custom medical devices within the framework of ISO: 13485, a quality management system for the design, manufacturing, and provision of medical device. The study was conducted between June 2021 and September 2022.

5.2.2 Recruitment

Participants were identified and referred into the study by healthcare professionals working within Swansea Bay University Health Board. Purposeful sampling was be used to identify potential participants, with the clinical judgement of the referring healthcare professionals used to identify who might be suitable and capable of engaging with the study. The study aimed to recruit between 12-15 participants, ensuring a larger sample size than previous work, allowing for a more robust analysis of results, whilst still being achievable within the time and resources restraint of the study. Participants were approached and recruited between June 2021 until February 2022.

5.2.2.1 Inclusion criteria

Individuals were eligible to participate if they met the following criteria: 1) Confirmed diagnosis of a long-term chronic condition; 2) Living in the community; 3) Aged eighteen years or older; 4) Ability to actively engage in the co-design process of the study design as determined by their treating clinician; 5) Currently under the care of healthcare services within Swansea Bay University Health Board; 6) At least three-month post injury/diagnosis at the point of recruitment allowing time for spontaneous recovery and for the person to become aware of their difficulties and the implications of this on their lives.

Participants were ineligible to partake in the study if they had receptive or expressive language difficulties, extremely low memory function, severe mental health or cognitive difficulties which would have precluded meaningful engagement in the study. Participants were also excluded if they were unable to provide informed consent.

5.2.3 Participants

Fifteen individuals consented to take part in the study, of which four withdrew from the study prior to completion. Reasons for withdrawal included becoming medically unwell during the study (n=1), no longer interested in taking part (n=1) and loss of contact with the participant (n=2).

The characteristics of the eleven remaining individuals are summarised in Table 5-1.

Table 5-1: Summary demographic information of participants

Demographic items		
Age, mean years (range)		49 (21-72)
Time since injury/ diagnosis, mean years (range)		10 (0-38)
		n
Sex	Male	7
	Female	4
Medical diagnosis	Cerebral ischaemic stroke	2
	Spastic unilateral cerebral palsy	1
	Secondary progressive multiple sclerosis	1
	Traumatic Brain Injury	2
	Left side hemiplegia	1
	Injury to hand muscle and tendon	1
	Thumb amputation	1
	Crush Injury to hand	1
	Burns injury leading to digit amputation	1
Living situation	Living alone	3
	Living with husband/wife	4
	Living with partner	1
	Living with parents	1
	Living with other relatives	1
	Living with others	1
Employment status	Employed (part or full-time)	6
	Retired	1
	Unemployed	4
Employment status changed due to injury (n=4)	Yes	3
	No	1
Time in education, mean years (range)		14 (11-20)

5.2.4 Ethical consideration

Ethical approval for this study was granted by the Wales 7 Research Ethics Committee (ref: 21/WA/0097) in April 2021. All participants voluntarily agreed to take part in this study and provided written informed consent prior to their involvement (Appendix D: Participant consent form and information sheet for feasibility study – Chapter 5) . Consent was reviewed at each appointment with the participant. The full IRAS ethics application form is available in Appendix E: IRAS application form for Feasibility study – Chapter 5

5.2.5 Equipment

The devices produced during this study were manufactured using a mixture of additive manufacturing and simple hand-held tools. Computational models of the designs were created using a parametric CAD software, Solidworks Premium 2016 x64 edition (Waltham, USA). Computational models were exported as a Stereolithography file from Solidworks and imported into a slicer software, ideaMaker V4.1.1.5050 (Irvine, USA), prior to manufacturing. System pre-sets for shell thickness, layer height, infill percentage, infill pattern and print speeds were utilised to reduce the number of variables to be set during manufacturing. Support material was added as deemed appropriate for each part. A Raise3D Pro2 3D printer, a fused deposition modelling (FDM) type machine, was used to manufacture the parts. The material selected for a device varied based on the part being produced, its intended function and the stage of the design process and included Polylactic acid (PLA), Thermoplastic polyurethane (TPU) and Polycarbonate (PC).

Additional parts and accessories, for example foam liners, straps and fabric components were added using a range of simple hand-held tools and adhesives.

5.2.6 Intervention

A mixture of face-to-face appointments and video appointments were used during the study. The type of appointment was selected based on the participant's ability to access video appointments, the preference of the participant and the local COVID-19 guidance at the time regarding face-to-face appointments. Video appointments were conducted using Attend Anywhere, a web-browser based video consultation software. Face-to-face appointments were conducted either within a clinic room at Morriston hospital, where Swansea

Rehabilitation Engineering Unit is based, or at the participants home. The location was chosen depending on the capability and availability of transport for the participant to travel to the hospital and the participant's preference.

A summary of the intervention to develop the devices is summarised in Figure 5-1. All the design work and appointments were conducted by JH, a male Clinical Scientist working with the Rehabilitation Engineering Unit and PhD research student (referred to as clinician in below text). In some instances, the referring healthcare professional joined the initial appointment to help facilitate identifying requirements for the custom assistive device(s).

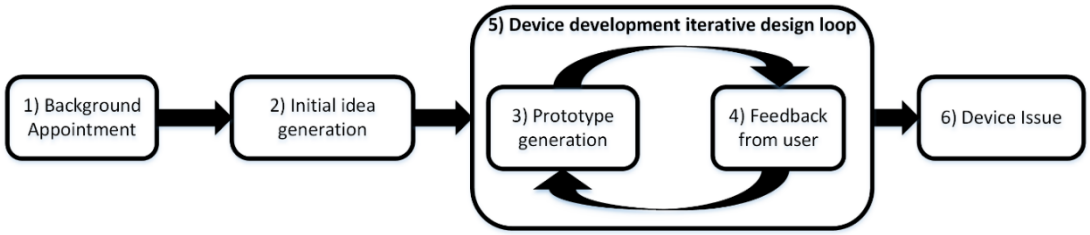


Figure 5-1: Flow diagram of co-design intervention for participants during the study.

1) Background appointment: The clinician gathered relevant medical and social background information from the participant. Participants were asked to identify challenge(s) in daily living they faced and wished to overcome. Measurements were taken of the participant's anatomy and relevant objects for the challenge(s) identified.
2) Initial idea generation: The clinician defined design requirements and generated design ideas through sketches and low fidelity prototypes.
3) Prototype generation: Functional prototypes were created using a mixture of CAD, additive manufacturing, and handheld manufacturing tools. These were provided to the participant to trial.
4) Feedback from user: The participant provided feedback on the prototype(s), included what they liked, did not like and suggestions for improvements.
5) Device development iterative design loop: Feedback from the participant was used to change the design(s) and produce further prototypes (step 3). Steps 3 and 4 formed an iterative loop, aiming to refine the design until a final design was reached. The number of iterations required to reach the final design varied.

6) Device issue: The final design was provided to the participant and further training provided as required. Technical files were completed for each device.

Some participants identified additional challenges during the co-design phase, stage 5, i.e. after the initial background appointment. In these instances, the generation of solutions went back to stage 2 and subsequent stages were followed.

5.2.7 Measures

Outcome measures included both standard questionnaires and semi-structured interviews. A summary of when the different outcome measures were completed is summarised in Figure 5-2.

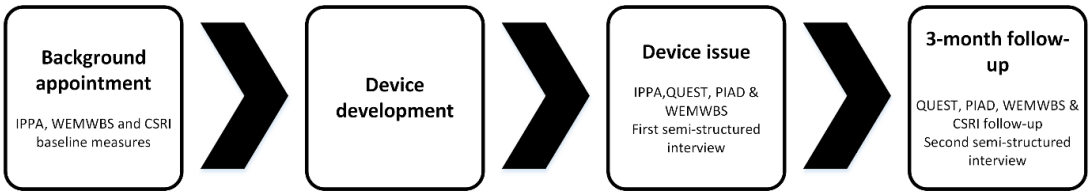


Figure 5-2: Summary of when outcome measures were completed during the study

5.2.7.1 Individually Prioritised Problem Assessment

The Individually Prioritised Problem Assessment (IPPA) is an instrument to assess the effectiveness of assistive technology provision in relation to overcoming problems the individual considers most relevant to them (Wessels et al., 2002). Initially the participant identifies up to seven problems/tasks. For each problem the participant assigns two scores, the importance, and the difficulty of the activity. Both scores are assigned using a 5-point Likert scale: 1 problem not important, to 5 problem most important and 1 problem not difficult, to 5 problem too difficult to perform. After being provided the device(s), the participant rates the difficulty score again.

The importance and difficulty scores are multiplied together, and an average score is calculated for all the problems the participant listed prior to and after receiving the device(s). The difference between the total IPPA score before and after provision of the assistive device(s) represents the effectiveness of the device(s), with a decrease in the score indicating

one or more of the problems has become easier. Changes in the IPPA score are consistent with changes in other scores, SIP68 and EuroQOL scores, and therefore IPPA has been validated to measure the change caused by assistive technology provision (Wessels et al., 2002). The IPPA has been used in previous work co-designing assistive devices (Thorsen et al., 2019). The questionnaire was completed by the clinician during the appointments with the participant.

5.2.7.2 Warwick-Edinburgh Mental Wellbeing Scale

The Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) is a 14-item questionnaire to evaluate changes in mental wellbeing. The questionnaire uses a 5-point scoring scale asking participants to describe their experience over the past 2 weeks of 14 different items, rating them from 1 (None of the time), to 5 (all of the time) (Tennant et al., 2007). The scores for each question are summed to calculate a total score out of 70, with higher scores indicating greater positive mental wellbeing. WEMWBS has proven to have high one week test-retest reliability (0.83) and internal consistency in adults in the general population (Cronbach's alpha = 0.91) (Tennant et al., 2007). The questionnaire was completed either during an appointment with the clinician or sent out for the participant to complete at home.

5.2.7.3 Client Service Receipt Inventory

The Client Service Receipt Inventory (CSRI) is a tool used to capture and record information on health and social care services accessed and resources used by study participants to help estimate the costs of services received (Beecham & Knapp, 2021). The CSRI asked participants what healthcare services they had accessed in the previous 3 months, any current help they received to overcome the challenges they faced, through both formal health and social care and informal carers, and current relevant medication. It was also used to capture relevant demographic information about the participants including information about any changes in employment and state benefits received. The questionnaire was completed by the researcher at the background and 3-month follow-up appointments, with participants required to recall information about healthcare services accessed.

5.2.7.4 Quebec User-Evaluation of Satisfaction with assistive Technology

The Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) is a 12-item outcome measure that assesses the user satisfaction with both the device and service provided in supplying the device. For each item, the questionnaire uses a 5-point scale, 1 being not satisfied at all and 5 being very satisfied (Demers et al., 2002b). The instrument has good internal consistency, moderate to substantial test-retest reliability and good construct validity (Demers et al., 2002a; Demers et al., 2000; Demers et al., 2002b). The questionnaire was posted out for the participant to complete at home.

Scores for the satisfaction with the device, the service provided, and an average total score were calculated for each device provided from the QUEST 2.0 questionnaire. The device score was calculated as the mean of eight items: dimensions, weight, durability, comfort, adjustment, safety, simplicity of use, effectiveness; whilst the service score was calculated as the mean of four items: service deliverable, repairs and servicing, professional services, and follow-up services. The total score was an average of all 12 items.

5.2.7.5 Psychosocial Impact of Assistive Devices Scale

The Psychosocial Impact of Assistive Devices Scale (PIADS) is a 26-item self-reported questionnaire to assess the effects of an assistive device on three sub-scales: competence, adaptability and self-esteem. The questionnaire uses a 7 point scale, ranging from -3 (maximum negative impact) to +3 (maximum positive impact) (Jutai & Day, 2002). The instrument has good test-retest reliability, internal consistency, and construct validity (Jutai & Day, 2002). The questionnaire was posted out for the participant to complete at home. Both the PIADS and QUEST 2.0 questionnaires have been used in previous studies co-designing assistive devices (Gherardini et al., 2018; Howard et al., 2022b; Lee et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020).

For each device the mean score for the competence, adaptability and self-esteem were calculated from the PIADS questionnaire responses. The competence score was the mean of 12 items: competence, adequacy, efficiency, productivity, usefulness, expertise, capability, performance, skilfulness, independence, quality of life, confusion (reverse). The adaptability score was the mean of 6 items: willingness to take chances, ability to participant, eagerness to try new things, ability to adapt to activities daily living, ability to take advantage of opportunities, wellbeing. The self-esteem score was the mean of 8 items: self-esteem,

security, sense of power, embarrassment (reverse), happiness, sense of control, frustration (reverse), self-confidence.

5.2.7.6 Semi-structured interviews

Participants were invited via either email or telephone to take part in the interviews. Before the interview commenced, participants consented to take part in the interviews and for them to be audio-recorded. Participants were assigned a unique numerical identifier prior to the interview to protect their identity. The clinician involved in providing the devices conducted all interviews, JH. This was chosen as the insight the clinician had on both the individual and the devices were important for gathering feedback. The interviews were conducted using a mixture of the video consultation software Attend Anywhere and telephone calls, based on the participant's capability to access the video consultation software. For the interviews, participants were at home and the interviewer in a private clinic room. No other individuals were present during the interviews.

All interviews were audio-recorded and additionally the interviewer made notes to aid with transcription and understanding after the interview. Interviews lasted between 3 and 29 minutes. Two interviews were conducted for each participant, one at initial device issue and one at 3-month post device issue. Discussions were semi-structured in nature and utilised open-ended questions, with follow-up queries asked to gather further understanding based on the responses provided. Different initial questions were used at the two appointments, but the same for all participants with questions framed around the impact the device(s) has had on the participants life, the participants involvement in the co-design process and how they would like to access such a service in the future. All co-authors agreed the initial questions prior to conducting the interviews. Audio files were transcribed orthographically, incorporating utterances, hesitations and repetitions and utilised grammatical correctness to ensure the true essence of the data were captured. Identifiable information relating to the participant, or any other individuals mentioned in the interviews, was anonymised to ensure confidentially.

5.2.7.7 Resources

The resources required to provide the device(s) for each participant were calculated. This included the clinicians time for appointments, travel, designing and manufacturing; the time

required for workshop technician to manufacture the devices; and the materials used. The cost of the clinician and workshop technician staff time was calculated by multiplying the time spent by the equivalent cost per hour of their time: £29.77/hr for clinician and £20.49/hr for workshop technician. These are based on top increment of a band 7 and band 5 based on the NHS pay scale as calculated at the time of the study finished and represent the cost to the healthcare service, e.g. pay/hr plus a 27% overhead cost to the health service. (September 2022). Additionally, the number of appointments and number of weeks between the initial appointment and final device being issued for each participant was summated.

5.2.8 Data analysis

A concurrent mixed methods approach to analysing the data was used.

5.2.8.1 Quantitative data analysis

The questionnaire data measures (IPPA, WEMWBS, QUEST 2.0 and PIADS) were subjected to statistical tests between the different time-points (baseline, initial follow-up and 3-month follow-up as appropriate). All the tests of significance used a significance level of 0.05. First data were assessed for normality using Shapiro-Wilk tests. If the data were normally distributed, parametric tests (paired sample t-tests, repeated measures ANOVA) were used to compare difference. For instances where the data were not normally distributed, non-parametric measures tests (Wilcoxon signed ranks tests) were used. Additionally descriptive statistics were calculated for all the questionnaire data.

5.2.8.2 Qualitative analysis

Interviews transcripts were analysed through reflexive thematic analysis following the six-step procedure to thematic analysis described by Braun and Clarke (2006) (Braun & Clarke, 2006). NVivo version 1.6.1 (January 2022) was used to aid thematic analysis. Stages 1-4 were conducted by JH only. First familiarisation with the interviews was undertaken through listening to the audio recordings and re-reading the transcripts (step 1). Quotes from the transcripts were then assigned initial codes inductively that closely related to the material and context (step 2). Codes were then grouped into potential themes (step 3), before being reviewed and refined to ensure quotes were relevant and related to the theme assigned (step 4). The themes were then reviewed by co-authors (supervisors) JT and ZF and named appropriately (step 5). Finally, quotes that reflected each theme were selected (step 6). A

frequency count for each theme identified in a participant's transcript were calculated. The data were initially analysed by one coder only as multiple coders do not improve the accuracy of the coding process (Braun & Clarke, 2006). A review of the themes by the other co-authors, step 5, allowed for broader clinical and research experience to be incorporated into the thematic analysis. The thematic analysis of the data presented is a representation of the researchers understanding of the data based on their past clinical and research experience, and there involvement with the participants in designing the devices (Clarke & Braun, 2020). The qualitative data from the semi-structured interviews are reported following the Consolidated Criteria for Reporting Qualitative Studies (COREQ): 32-item checklist, Appendix N: COREQ checklist for Chapter 5. (Tong et al., 2007).

5.3 Results

5.3.1 Challenges identified

A summary of the challenges identified are summarised in Table 5-2. Challenges ranged from wanting to help with specific tasks or objects, for example supporting an iPad in a specific position and orientation, to more broad descriptions of functional limitations, for example help with gripping and carrying a range of objects around the home. The challenges identified by the greatest number of participants related to eating or preparing food, whilst challenges related to personal care were identified the greatest number of times. Four of the challenges were identified after the initial appointment, i.e., during the co-design phase after the participant had trialled a solution, with three participants identifying these new challenges.

Table 5-2: Challenges in daily living identified by participants

Device to help with:	# Of participants who identified challenge	Total # of times challenge identified
Eating or preparing food	4	4
Personal Care	2	7
Dressing	3	4
Gripping & carrying objects	2	2
Rehabilitation exercises	1	1
Leisure activities	2	2
Housework	1	2
Un-doing padlock (for work)	1	1
Supporting iPad	1	1
	Total # challenges identified	24

5.3.2 Devices created

A total of nineteen devices were designed and issued across all the participant, equating for 79% of the challenges identified. A selection of the devices created can be seen in Figure 5-3. Challenges where no solution was provided were for personal care (1), dressing (2), leisure activities (1) and preparing food (1). In the case of preparing food, no solution was provided as a pre-existing off-the-shelf product was identified during the study. For ten of the

participants at least one solution was provided, but for one individual no solution was provided. Their data were not included in the outcome measure results as no follow-up data were gathered at initial or 3-month follow-up.

Of the devices provided, eighteen devices were still being used at the 3-month follow-up. The device not being used was the PlayStation controller adaption, Figure 5-3 L), as an alternative PlayStation controller adaption had been sourced online by the referring Occupational Therapist which was more suitable to the user's needs.

Figure 5-3: Selection of devices produced during the study:
A) Deodorant holder for to apply deodorant under both armpits for individual with Cerebral Palsy.
B) Hair curler holder for hemiplegic.
C) A hand support strapped to the patient's hand which supports use of a knife and spoon.
D) Adapted handles for using a mob and hoover for individual with amputated thumb.
E) Basket addition for a walking stick.
F) Fork adaption and device to help with pincer gripping objects for individual with multiple finger amputations.
G) A device to exercise and stretch the fingers to form a fist.
H) Finger caps with non-slip material to help with gripping thin materials.
I) A customised stand for supporting an iPad upright.
J) Device for helping an individual with hemiplegia to put earrings in; the device sits over the ear to help hold the earring whilst putting the back on the earring.
K) Adapted hair band for use by individual with hemiplegia.
L) Adaption to a play-station 4 controller to enable use one handed.

5.3.3 Quantitative outcomes

Shapiro-Wilk tests were carried out to assess whether the data were normally distributed prior to conducting inferential statistical analysis. If the data were not normally distributed, the narrative describing the descriptive statistics will refer to the median (Mdn) as opposed to the mean as the median is less affected by outliers and skewed data. In these instances, nonparametric tests will be used. Where the data being compared are normally distributed, the descriptive static narrative will describe the mean, and parametric tests will be used to compare means.

5.3.3.1 Individually Prioritised Problem Assessment

Table 5-3: Descriptive statistics for the individually prioritised problem assessment questionnaire. Full data set available in Appendix F

	Baseline	***Initial Follow-up***
Valid (N)	10	10
Missing (N)	0	0
Mean	17.3	8.73
Median	16.7	9.75
Standard Deviation	4.09	3.56
Minimum	12.0	4.00
Maximum	25.0	16.0
Shapiro-Wilk	0.944	0.899
p-value of Shapiro-Wilk	0.593	0.216

Table 5-3 shows the descriptive statistics for the IPPA scores at baseline and initial follow-up. The mean score between baseline (17.3) and initial-follow-up (8.73) decreased by 8.57, a trend that supports the hypothesis that the provided devices would decrease the difficulty of completing tasks identified by individuals. The Shapiro-Wilk indicated the data were normally distributed (baseline $p = 0.593$, initial follow-up $p = 0.216$). A paired-sample t-test found the IPPA initial follow-up (mean = 8.73) to be significantly lower than the baseline (mean = 17.3) score; $t(9) = 7.58$, $p = <0.001$, with a large effect size, Cohen's $D = 2.399$. Results show the use of the custom assistive devices significantly lowered the difficulty of completing the tasks identified by individuals.

5.3.3.2 Warwick-Edinburgh Mental Wellbeing Scale

Nine individuals completed the WEMWBS scores, one individual opted out of wanting to complete the questionnaire.

Table 5-4: Descriptive statistics for the Warwick-Edinburgh Mental Wellbeing Scale questionnaire. Full data set available in Appendix G

	Baseline	***Initial Follow-up***	***3-month follow-up***
Valid (N)	9	9	9
Missing (N)	1	1	1
Mean	45.1	49.4	50.6
Median	44.0	50.0	55.0
Standard Deviation	6.45	8.29	9.95
Minimum	35.0	37.0	33.0
Maximum	55.0	60.0	63.0
Shapiro-Wilk	0.934	0.944	0.908
p-value of Shapiro-Wilk	0.516	0.620	0.304

Table 5-4 shows the descriptive statistics for the participants scores at each of the three time points (baseline, initial follow-up and 3-month-follow-up). Results show an increase in mean wellbeing scores for all the participants between the baseline, (45.1) and the initial (49.4) and 3-month follow-up (50.6). This trend supports the hypothesis that the intervention would increase wellbeing scores (as measured by WEMWBS).

The Shapiro-Wilk indicated the data were normally distributed (baseline p = 0.516, initial follow-up p =0.620, 3-month follow-up p=0.304). A one-way repeated measures ANOVA found no significant differences between the means at the three time points, F (2, 16) = 2.928, p = 0.083. Omega squared indicated the effect size to be small, ω^2 = 0.05 The participant's wellbeing as measured by WEMWBS did not significantly change over time.

5.3.3.3 Quebec User Evaluation of Satisfaction with assistive Technology

QUEST 2.0 scores were collected for 17 of the devices. For two devices, no scores were collected due to the similarity of the device with another device they had been provided and as such a single questionnaire was completed by the participant encompassing both devices.

Table 5-5: Descriptive statistics from QUEST 2.0 questionnaire across all devices provided initially and after 3 months of being provided the device. Full data set available in Appendix HE

	Device sub-scale		Service subscale		Total score	
	Initial	***3-month***	***Initial***	***3-month***	***Initial***	***3-month***
Valid (N)	17	17	17	17	17	17
Missing (N)	2	2	2	2	2	2
Mean	4.7	4.6	4.9	4.7	4.8	4.6
Median	4.9	4.8	5.0	5.0	4.9	4.8
Standard Deviation	0.48	0.43	0.17	0.4	0.32	0.40
Minimum	3.3	3.8	4.5	4.0	3.8	3.8
Maximum	5.0	5.0	5.0	5.0	5.0	5.0
Shapiro-Wilk	0.643	0.804	0.606	0.687	0.708	0.838
p-value of Shapiro-Wilk	<0.001	0.002	<0.001	<0.001	<0.001	0.007

Table 5-5 shows the descriptive statistics for the three scores calculated from the QUEST 2.0 questionnaire (device, service and total satisfaction scores) at initial and 3-month follow-up. The QUEST 2.0 scores ranged from 1 to 5, with 5 indicating high satisfaction. Results indicate participants were initially highly satisfied with the device (Mdn = 4.9) and service (Mdn = 5.0) provided. At the 3-month follow-up there was a small decrease in the device score (Mdn 4.8), but they still appeared highly satisfied with this and the service (Mdn = 5.0). An inspection of the results would suggest little change in satisfaction scores overtime. The Shapiro-Wilk test indicated the scores were not normally distributed.

A Wilcoxon signed-rank test showed no significant difference in device satisfaction subscale scores between the initial follow-up (Mdn = 4.9) compared to the 3-month follow-up (Mdn = 4.8), $z = 0.815$, $p = 0.444$. The effect size, as calculated by the rank-biserial correlation, was small, $r_s = 0.291$.

A Wilcoxon signed-rank test showed no significant difference in the service satisfaction subscale scores between the initial follow-up (Mdn = 5.0) compared to the 3-month follow-up (Mdn = 5.0), $z = 1.992$, $p = 0.058$. The effect size was large, $r_s = 0.905$.

A Wilcoxon signed-rank test showed no significant difference in the total satisfaction scores between the initial follow-up (Mdn = 4.9) compared to the 3-month follow-up (Mdn = 4.8), $z = 1.067$, $p = 0.306$. The effect size was medium, $r_s = 0.364$.

The satisfaction with using the device or with the service provided did not significantly change over time between initially and 3-months after being provided the device. Participants were highly satisfied with the devices and service provided.

5.3.3.4 Psychosocial Impact of Assistive Devices Scale

PIADS questionnaires were collected for 17 of the devices, following the same rational as per the QUEST 2.0 questionnaires.

Table 5-6: Descriptive statistics for PIADS questionnaire across all devices provided initially and after 3 months of being provided the device. Full data set available in Appendix I

	Competency		**Adaptability**		**Self-esteem**	
	Initial	***3-month***	***Initial***	***3-month***	***Initial***	***3-month***
Valid (N)	17	17	17	17	17	17
Missing (N)	2	2	2	2	2	2
Mean	+2.1	+1.9	+2.0	+1.9	+1.9	+1.6
Median	+2.0	+2.1	+2.3	+2.2	+2.1	+1.9
Standard Deviation	0.54	0.69	1.03	1.3	0.73	0.87
Minimum	+1.3	+0.6	-0.3	-1.0	+0.6	+0.3
Maximum	+2.9	+2.8	+3.0	+3.0	+2.9	+2.6
Shapiro-Wilk	0.931	0.917	0.824	0.777	0.94	0.863
p-value of Shapiro-Wilk	0.224	0.131	0.004	<0.001	0.324	0.017

Table 5-6 shows the descriptive statistics for the three sub-scale scores calculated from the PIADS questionnaire (competency, adaptability and self-esteem) at initial and 3-month follow-up. The PIADS scores ranged from -3 to +3, with +3 indicating maximum positive impact. Results indicate a positive impact in all three sub-scores initially, competency Mdn = +2.1, adaptability Mdn = +2.0 and self-esteem Mdn = +2.1. At the 3-month follow-up there was a small increase in the median competency score (Mdn = +2.2) and small decreases in adaptability (Mdn = +2.2) and self-esteem (Mdn = +1.9) scores. However, visual inspection suggests overall there was limited change in the scores between the two time points with scores indicating a positive psychosocial benefit from using the devices.

The Shapiro-Wilk test indicated the adaptability sub-scale scores, and the self-esteem 3-month follow-up scores were not normally distributed, and the competency sub-scale scores were normally distributed.

A paired-sample t-test showed no significant difference in competence scores between initial follow-up (mean = +2.1), compared to the 3-month follow-up (mean = +1.9) t (16) = 1.258, p = 0.227, with a medium effect size, Cohen's d = 0.305.

A Wilcoxon signed-rank test showed no significant difference in adaptability subscale scores between initial follow-up (Mdn = +2.3) compared to the 3-month follow-up (Mdn = +2.2), z = 1.111, p = 0.286, with a medium effect size, r_s = 0.379.

A Wilcoxon signed-rank test showed no significant difference in self-esteem subscale scores between the initial follow-up (Mdn = +2.1) compared to the 3-month follow-up (Mdn = +1.9); z = 1.138, p = 0.266, with a medium effect size, r_s = 0.324

The psychosocial impact of using the device did not significantly change over time from initial to 3-month follow-up. Using the customised assistive devices had a positive psychosocial effect.

5.3.3.5 Client Service Receipt Inventory

Of the seven individuals who were employed at the start of the study, two had changes in their employment during the study, one had changed job and one had to retire due to ill health. No participants reported any changes to the state benefits they received between baseline and 3-month follow-up data collection.

a) Healthcare services accessed

The contact participants had with healthcare services is summarised in Appendix J: Client Service Receipt Inventory - Contact with healthcare services. Of the 10 participants who completed the baseline and 3-month follow-up, seven had a decrease in the number of clinical appointments they attended, one saw no change and one had an increase in clinical appointments. One participant had no contact with any clinical services prior to or after receiving the device. The type of healthcare services accessed, and number of appointments differed amongst all the participants making summarising and further analysis of the data difficult.

b) Help with overcoming identified challenges.

The help participants received in overcoming the challenges in daily living they identified is summarised in: Appendix K: Client Service Receipt Inventory - Help received with challenges identified. Of the twenty-four challenges identified initially, help was received for fifteen of them. The biggest proportion of this was by informal carers/helpers in eleven instances, predominantly family members (eight challenges) but also friends (two challenges) and in one instance their partner. For one challenge help was provided by work colleagues and in another an NHS physiotherapist, who prescribed the exercises. For one individual, they paid professionals to do the tasks for them: hairdressing and painting nails. The frequency help was required varied from tasks that were done daily (seven), to other tasks requiring help only on a weekly (six) or monthly (two) basis.

At the 3-month follow-up, the number of tasks still requiring help had reduced from fifteen to four. Of these, help was now required daily twice and monthly twice. The main reduction had been in tasks requiring help from informal carers/helpers, reducing from eleven to three.

c) Medication

A summary of the medication, relevant to the challenges, is presented in: Appendix L: Client Service Receipt Inventory- Summary of medication. At baseline data collection five participants were not taking any medication, whilst others varied from one to seven different medications. Nine participants had no changes in their medication taken from baseline data collection to the 3-month follow-up and one participant had an increase in pain relief medication taken.

5.3.4 Qualitative analysis

A total of 17 semi-structured interviews were conducted, with 8 participants completing both the initial and 3-month follow-up interview, 1 participant completing 3-month follow-up interview only and 1 participant not completing either interview due to limited availability. The interviews lasted between 3 and 29 minutes, with an average time of 13 minutes.

A total of 34 descriptive themes, grouped in to 8 analytical themes were identified; a summary of the themes is shown in Figure 5-4. The themes, including quotations from the

semi-structured interviews and the frequency (n) if the theme was identified in one of the participant's interviews, are described below.

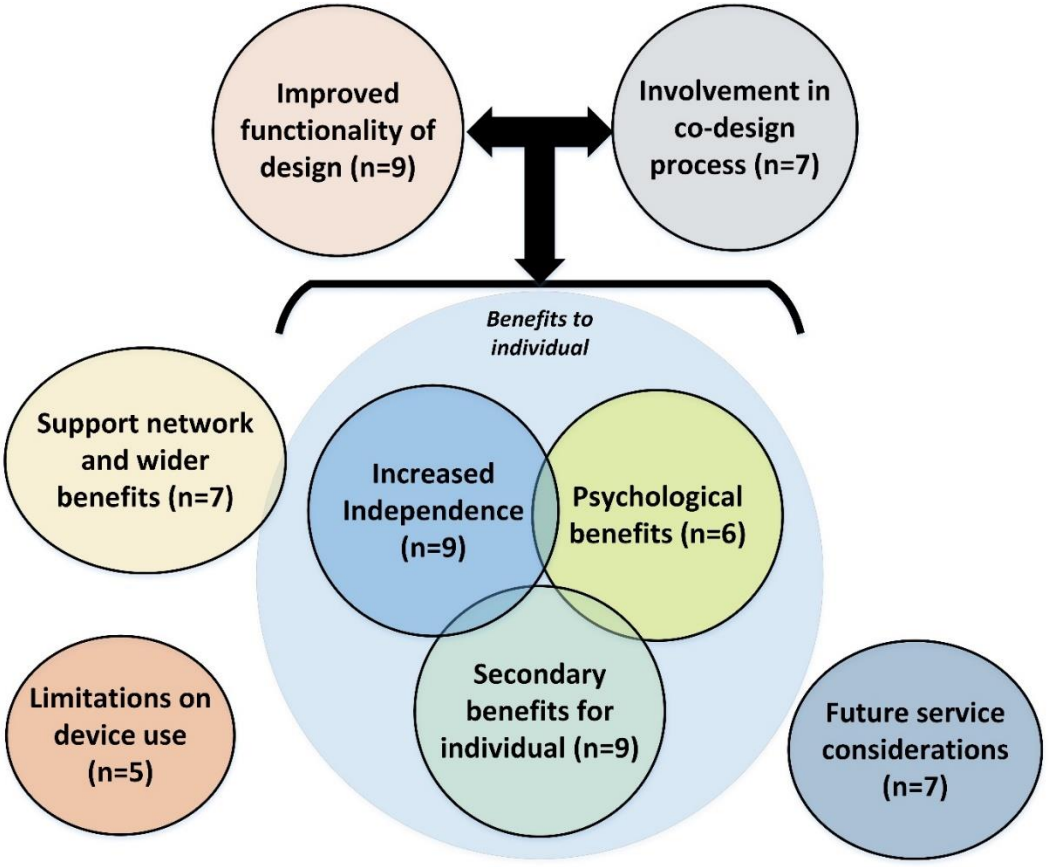


Figure 5-4: A summary of the analytical themes identified from semi-structured interviews, with the frequency (n) calculated.

5.3.4.1 Analytical theme 1: Involvement in co-design process (n=7)

This theme groups the descriptive themes related to feedback from individual about their involvement in co-designing the devices.

Evolution of design through co-designing (n=8): Participants described how the development of the designs during the co-design process enabled the final device to be customised to their needs. Participants were also able to trial the designs and provide feedback to enable modification of the design.

"…it [the device] was a bit too big for me and then you altered it and then we done that out. It was exactly altered for me with what you were doing as well." (Participant 10, hand support to aid using a knife)

Providing feedback into design process (n=7): Participants valued providing feedback into the co-design process, feeling involved in the process, being able to discuss the designs and agreeing changes to be made.

"I liked the idea of being able to input on this [the device] rather than say for example you just made it, and this is what we are going for. I liked the idea of being able to input on the way this was designed." (Participant 4, deodorant, and soap holder)

Listening to user's needs (n=6): Participants felt the clinician listened to what their needs were and the feedback they provided which developed an effective clinical relationship.

"Well like at the very beginning you asked what I wanted. What I thought I needed help with. It wasn't like, oh, well, I can do this and that kind of thing. It was what are you [the end user] struggling with." (Participant 2, hair curler holder, earring aid and adapted hair tie devices)

Individualised care (n=2): Participants placed importance in the intervention feeling individualised to their specific needs, instead of being given advice and/or equipment not suitable to their needs.

"… it's been really good working with you, working through it because you know actually being involved in the what works and what doesn't work, as opposed to it being prescriptive with someone saying "this is your situation, this is what you are getting". Whereas actually you don't know my situation, my situation is complex. Umm so it has yeah, it has made a big difference from that point of view." (Participant 8, iPad holder)

5.3.4.2 Analytical theme 2: Improved functionality of design (n= 9)

This analytical theme groups the descriptive themes about specific aspects of the design of the devices that participants felt met their needs.

Benefit over existing solution (n=5): Participants found the devices provided were of benefit over the existing solution they were having to use; these solutions included assistive devices, previous coping mechanisms and 'home-made' solutions.

"I was just remembering what, what I used to go through with the thing balancing over and everything and so I just put this [the device] on a lap tray on my lap and it works brilliantly, and I don't have to worry about whether it's going to topple over and whether I need to restack it and everything." (Participant 8, iPad holder)

Ease of use (n=5): The custom devices being easy to use impacted on the individual using the device to overcome the intended challenge. This included characteristics such as the comfort of the device and improved control in doing task through using the device.

"You know you pop it on. It was so simple and easy to use so." (Participant 3, device to exercise and stretch the fingers into a fist)

Ease of set-up (n=4): The ease of set-up of the custom device, including the portability of the device, impacted on the user's willingness and ability to use the device provided.

"Well, I don't have to give it so much time and thought to the set-up" (Participant 8, iPad holder)

Aesthetics of the device (n=3): The aesthetic characteristics of the device impacted on use, including how individuals liked they didn't look like medical devices and were discreet for them to use.

"… it [the device] looks the part, it looks just a bit of any kind of gadget that anyone carries in their pocket now a days" (Participant 7, pincer grip aid device and fork holder)

5.3.4.3 Analytical theme 3: Increased independence (n=9)

This analytical theme groups the descriptive themes related to increases in independence described by participants as a result of their involvement in the co-design intervention.

(Intervention includes both their involvement in the co-design process and the use of custom assistive device).

User able to overcome challenge (n=8): Through using the devices provided, participants had improved function in being able to overcome the challenge they originally identified, including how it made it easier to complete the task and how they had increased mastery in completing the task.

"Oh easier, because at least I can grip the mop now and the, and the hoover because I put my fingers through the hoops, the finger parts, and I can hold the cleaners." (Participant 10, hoover and mop grip aids)

Increased self-efficacy (n=6): Participants described improvements in feeling they were able to complete things themselves and the positive feelings associated with being more self-sufficient.

"It's just nice to be able to be ready and do it yourself kind of thing. It's just nice." (Participant 2, hair curler holder, earring aid and adapted hair tie devices)

Willingness to tackle other tasks (n=6): Participants felt able to try and overcome other day-to-day tasks and challenges, outside of the original challenges identified.

"I don't think there are many things I wouldn't tackle now, whereas before you would have been a little bit reluctant." (Participant 1, non-slip finger caps)

Encouraging individuals to problem solve themselves (n=4): Through involvement in the intervention, participants felt encouraged to adapt the way they used the devices to make it meet their own needs throughout the process, rather then it being a purely prescriptive process. This included how using the device helped educate the individuals to overcome the challenge they identified.

"It's [the device] kind of, I don't know. The way I hold it now it's kind of taught me how to do it." (Participant 2, in relation to the earring aid)

5.3.4.4 Analytical theme 4: Psychological benefits (n=6)

This analytical theme groups the descriptive themes related to the psychological benefits the users described from being involved in the co-design intervention.

Increased positive affect (n=5): The theme of increased positive affect includes increases in self-confidence, self-esteem, happiness and feeling more relaxed described by the participants.

"Yeah, it kind of gives me more confidence that, that I wouldn't have had, before, before I had these devices really." (Participant 4, deodorant and soap holder)

Overcoming sense of loss (n=5): Participants described how the intervention helped overcome a sense of loss they had from their chronic condition, restoring a more 'normal' life and having a greater feeling of self-identity.

"it's just you know really normal to have a knife and fork, a knife in the right hand and a fork in the left hand and umm it just seems, you know it just seems normal doesn't it." (Participant 5, hand support to aid using a knife and spoon)

Sense of achievement (n=4): This theme describes the sense of achievement felt by individuals in being able to complete tasks they had not been able to do prior to the intervention.

"You know if you went to do whatever task you were doing, you have a greater chance of completing it yourself without assistance, so you've got umm, you get self-pleasure then if that makes sense." (Participant 1, non-slip finger caps)

Reduced negative affect (n=4): The theme of decrease in negative affect includes reduced, stress, anxiety, frustration, and insecurity experienced by participants as a result of involvement in the intervention.

"And it used to really stress, well it was just, I am quite a positive person with my disability, but stupid things like that get to me. And I can do it now." (Participant 2, hair curler holder, earring aid and adapted hair tie devices)

5.3.4.5 Analytical theme 5: Secondary benefits for individual (n=9)

This analytical theme groups the descriptive themes related to the secondary health and wellbeing benefits (i.e. the wider ripple effects) of the intervention aside from the improved design use and psychological benefits described previously.

Increased connection to the community and environment (n=6): This theme describes how participants had a greater connection to the community, for example greater socializing with friends, eating out with friends and family, improvements in family life and increased time in nature.

"When your spirits are lifted it makes you want to 'oh it's a lovely day today let's go down to the beach or to the coast or go somewhere or do family things' rather than kind of like umm, chasing your tail trying to catch up with what you were able or what you were unable to do." (Participant 1, non-slip finger caps)

Improvement in quality of life (n=5): Participants suggested the intervention improved their overall quality of life, including making their day-to-day life easier.

"Ands, it improved, and it's improved my quality of life obviously you know," (Participant 7, fork holder and pincer grip aid)

Sourcing other solutions (n=4): Participants sourced their own solutions to problems, either looking to purchase commercial assistive devices or looking at other adaptions around the home using everyday objects to meet their needs.

"I can think about what other bits I might need that just put away rather than getting this from over here, and this from over here and lining it all up and you know trying to make do with things like that." (Participant 8, iPad holder)

Additional health benefits (n=3): The theme additional health benefit summarises some of the other secondary health benefits described by individuals related to regain function (rehabilitation), reduced pain and improvement in posture performing the tasks due to the intervention.

"I've regained feeling in my left middle finger, so I've got full feeling in that one. I've also got umm, intermittent feeling, it kind of goes numb and comes back on my index finger, so whether its umm, umm being going through a sort of umm, as if it's like training, or exercising them, they've kind of opened back up" (Participant 1, non-slip finger caps)

Changing attitudes to assistive devices (n=2): The final theme in this group describes how involvement in the intervention changed the attitudes of the participants to using assistive devices in the future.

"It's opened umm, it's opened my eyes totally that there are umm items or devices which are able to assist us in certain ways whereas probably before I had all of this, you would have thought these devices were for the more umm, the less capacitated people. Whereas you think sometimes you wouldn't assume that a relatively simple fix would make that much of an impact, but it's nice to be proved wrong that it does." (Participant 1, non-slip finger caps)

5.3.4.6 Analytical theme 6: Support network benefits (n=7)

This analytical theme groups the descriptive themes related to the benefits for both the immediate support network (family, friends etc.), but also the wider benefits for other individuals outside of this network.

Reduced burden on others (n=5): Individuals felt through the intervention they had become a reduced burden on other people, including family members and friends.

"Before you know I had to ask the wife to cut my meat and cut you know different umm parts of my food or whatever, and now I'm able to do it a bit more" (Participant 7, fork holder and pincer grip aid)

Changing the attitudes of others to assistive devices (n=3): This theme presents how participants had positive feedback about the device from other individuals and reduced feeling of being stigmatised by others through using the device provided.

"People who see me with it say, 'gosh what a good idea'." (Participant 8, iPad holder)

Re-using designs to help other individuals (n=3): Participants hoped other individuals would be able to benefit in the future from the designs being re-used for other individuals and the wider impact these designs could have.

"And they want advice and things, and they are like 'how do you do your hair?' It [the devices] could just help so many other people who don't think they can do it." (Participant 2, hair curler holder, earring aid and adapted hair tie)

5.3.4.7 Analytical theme 7: Future service considerations (n=7)

This analytical theme groups the descriptive themes related to feedback from participants if the intervention were to be implemented into future clinical services.

Timely process (n=6): Participants were happy with the time taken for the co-design process and in some instances were surprised how quickly the co-design process was for producing the final solution. This time enabled participants to trial out prototypes to enable them to work out what needed changing with the designs.

"You see, I thought it would have taken longer than it actually did, so I was pleasantly surprised it didn't take all that long." (Participant 5, hand support to aid using a knife and spoon)

More face-to-face appointments (n=3): Some participants suggested how going forward they would have preferred to have more face-to-face appointments instead of virtual appointments which were used by some individuals during this study.

"If it was a bit more involved, sometimes you possibly could be easier face to the face with the umm, with the patient to sort of see how, how you're using things." (Participant 1, non-slip finger caps)

Benefits of video conferencing (n=3): In contrast other participants expressed the benefits they felt in using the video conferencing software for this study. This included the reduce need to travel, the improved interactions over video and being able to have the appointment in their home environment.

"It saved me a lot of petrol, well diesel, and, but the result is the same effectively I mean you know." (Participant 3, device to exercise and stretch the fingers into a fist)

Broader access to service needed (n=2): Participants did not think they would be able to access a service providing these customised assistive devices due to their disability not being severe enough or not being recent enough.

"I thought it was only for umm people who were having recent, umm, you know serious operations, serious amputations and disability concerns" (Participant 7, fork holder and pincer grip aid)

Raising awareness of solutions (n=2): Participants expressed wanting to be made aware of the service and solutions in the future. Suggestions included being able to purchase these devices off-the-shelf, being able to find information/devices online and learning about the service through other healthcare services, for example GP surgery.

"That's what I would like if there was a little website, where you could just get these things in the future." (Participant 2, hair curler holder, earring aid and adapted hair tie devices)

*Involvement in group discussions (n=1): O*ne individual would have liked to have seen group discussions incorporated into the process as a way of learning from others with similar injuries.

"Group discussions with other people who have got similar injuries and umm perhaps they've got different gadgets from different people like you know." (Participant 7, fork holder and pincer grip aid)

5.3.4.8 Analytical theme 8: Limitations on device use (n=5)

This analytical theme groups the descriptive themes related to issues which were limiting the use of the device provided to its full potential.

Further modification required (n=3): Individuals expressed if they were to be involved in the intervention again, they had identified further modifications to the design through long-term use they would like rectified. This feedback was primarily captured at the 3-month follow-up interview.

"It's not too much of an issue, it's not too much of a problem it's just something I wished I had said if it could be slightly deeper, but you don't know until you try things though." (Participant 8, iPad holder)

Limited effectiveness using device (n=2): Individuals were only using their device a limited amount due to it being at the limit to what was effective for them, either due to rehabilitative gains or due to limitations in the device performing certain tasks.

"Umm I think it's probably diminished over this last month, 6 weeks I imagine because. Well mainly because obviously I got to a stage, which I think I said to you, I got to a stage where no matter what I did it sort of, it's kind of stabilised." (Participant 3, device to exercise and stretch the fingers into a fist)

Individual too busy to use (n=1): One individual had limited use of the device due to being too busy in other areas of their life to find the time to use the device frequently.

"Since I've last seen you, not very often I'm afraid I've been umm, it's been so bad, I've been busy and umm, I know it's no excuse but umm" (Participant 5, hand support to aid using a knife and spoon)

Uncomfortable to use for long periods (n=1): This final theme describes how one individual found the device uncomfortable to use for long periods of time and this anticipated discomfort limited their use of the device over which they hoped to be able to use the device for initially.

"I know it's going to ache after, afterwards, before I use it [the device]" (Participant 7, in relation to pincer grip aid)

5.3.5 Resources required

Table 5-7 summarises the time required, and costs associated with producing the devices. The total cost of providing a device varied from £165.64 to £688.53, with a mean cost of £352.00 per participant and £193.60 per device. The clinician's time equated for 86.5% of the total cost of the process, with an average time of 10 hours 14 minutes per participant spent interacting with the participant and designing the solutions.

*Table 5-7: Summary statistics of the resources required to produce the devices *Total of 20 devices produced; **Total of 11 participants*

	Clinician time (hh:mm)	Workshop support time (hh:mm)	3D Printing time (hh:mm)	Material cost	Clinician time cost	Workshop support time cost	Total cost
Total	112:35	14:50	858:50	£216.43	£ 3,351.61	£303.94	£3,871.97
Average per device*	05:37	00:44	42:56	£10.82	£167.58	£15.20	£193.60
Average per participant**	10:14	01:20	78:04	£19.68	£ 304.69	£27.63	£352.00
Standard deviation for participants	04:56	00:55	49:23	£10.92	£146.95	£19.03	£169.86
Range (min; max)	15:15 (5:05; 20:20)	2:30 (00:20; 2:50)	152:30 (2:40; 155:10)	£32.46 (£4.75; £37.21)	£453.99 (£151.33; £605.32)	£51.23 (£6.83; £58.06	£522.89 (£165.64; £688.53)

The number of appointments required to provide a device ranged from 2 to 6, with an average of 3.9 appointments and standard deviation of 1.4 across all participants. The average number of days between the initial appointment and a final solution being provided was 113 days (16.1 weeks), ranging from 32 days (4.6 weeks) to a maximum of 210 days (30 weeks) and a standard deviation of 61.3 days.

5.4 Discussion

5.4.1 Summary

This study aimed to look at the feasibility of co-designing customised assistive devices within a healthcare service through the impact of the co-design process, the devices created, and resources involved. A total of 11 participants were involved in the study, from which 19 devices were co-designed and 18 were being used at the 3-month follow-up. Devices were intended to overcome a range of challenges ranging from eating and preparing food, to personal care, housework, and leisure activities, and were provided for 79% of the challenges identified.

Quantitative analysis showed a significant decrease in the difficulty for individuals overcoming the challenges as measured by IPPA, in keeping with hypothesis one. There was no significant difference in wellbeing as measured by the WEMWBS before the intervention compared to after (initial and three-months), and on this basis hypothesis two can be rejected. QUEST 2.0 scores indicated high satisfaction with the device and service provided whilst PIADS scores indicated positive increases in competence, adaptability, and self-esteem from using the device provided. No significant changes in these scores over time were reported and on this basis hypothesis three can be rejected. Qualitative analysis generated thirty-four descriptive themes grouped into eight analytical themes that described the impact of the co-design intervention on participants, see Table 5-8. Results will now be interpreted in line with previous literature, discussing implications for the use of co-design within healthcare setting and research studies going forward.

It was not possible to distinguish if the results were due to the customised device, or the co-design process or due to a combination of both. The results are thus interpreted from the later viewpoint, using the analytical themes from the qualitative feedback to structure the discussion.

Table 5-8: Summary of analytical and descriptive themes

Analytical theme	**Descriptive themes**
Involvement in co-design process (n=7)	Evolution of design through co-designing (n=8) Providing feedback into design process (n=7) Listening to user's needs (n=6) Individualised care (n=2)
Improved Functionality of design (n=9)	Benefit over existing solution (n=5) Ease of use (n=5) Ease of set-up (n=4) Aesthetics of the device (n=3)
Increased Independence (n=9)	User able to overcome challenge (n=8) Increased self-efficacy (n=6) Willingness to tackle other tasks (n=6) Encouraging individuals to problem solve themselves (n=4)
Psychological benefits (n=6)	Increased positive affect (n=5) Overcoming sense of loss (n=5) Sense of achievement (n=4) Reduced negative affect (n=4)
Secondary benefits for individual (n=9)	Increased connection to the community and environment (n=6) Improvement in quality of life (n=5) Sourcing other solutions (n=4) Additional health benefits (n=3) Changing attitudes to assistive devices (n=2)
Support network benefits (n=7)	Reduced burden on others (n=5) Changing the attitudes of others to assistive devices (n=3) Re-using designs to help other individuals (n=3)
Future service considerations (n=7)	Timely process (n=6) More face-to-face appointments (n=3) Benefits of video conferencing (n=3) Broader access to service needed (n=2) Raising awareness of solutions (n=2) Involvement in group discussions (n=1)
Limitations on device use (n=5)	Further modification required (n=3) Limited effectiveness using device (n=2) Individual too busy to use (n=1) Uncomfortable to use for long periods (n=1)

5.4.2 Challenges identified and devices provided

Table 5-2 shows the wide range of challenges relating to daily living that were identified. The challenge(s) identified were very individual, based on what was important to each participant and their personal and social circumstances. The challenges were all associated with limitations in upper-limb function, ranging from very specific task-based problems, for

example applying roll-on deodorant, to more general problems, for example difficulty gripping thin objects. The focus on upper-limb functional challenges was similar to both the previous case-study work and other examples of co-designed devices in the literature (Aflatoony et al., 2021; Day & Riley, 2018; Gherardini et al., 2018; Howard et al., 2022b; Rasmussen et al., 2022; Thorsen et al., 2019). This may allude to a gap in the availability of current assistive devices for this patient population (either off-the-shelf equipment or via clinical services). Quantifying the un-met demand for custom assistive devices associated with upper-limb functional tasks requires further exploration and will be the subject of future work.

One outcome during the co-design process was that three participants identified further challenges after they had been shown or trialled a device already. Similar findings were previously reported by Rasmussen at al. (2022) (Rasmussen et al., 2022). This was due to initially individuals having limited awareness of the solutions that could be produced. Therefore, through their involvement in the co-design process, they increased their understanding of the types of solutions available. This encouraged them to think of other challenges assistive devices could help with and subsequently improved their independence in overcoming these challenges as well.

Raising the awareness of these types of solutions would therefore seem an important next step. The co-design methodology made use of CAD and 3D printing, similar to many other studies in this area (García et al., 2021; Gherardini et al., 2018; Rasmussen et al., 2022; Schwartz et al., 2020; Thorsen et al., 2019). Making both end-users and healthcare professionals aware of the increased possibilities these manufacturing technologies bring will encourage further challenges to be identified. This will help create a positive innovation spiral, where identifying new challenges will help develop further new innovative solutions. How to raise the awareness of the possibilities of these technologies in designing innovative customised assistive devices will be the subject of future work. Interestingly this relates back to the barriers to assistive technology use previously identified regarding a lack of awareness and information about assistive technology by both end-users and healthcare professionals (Howard et al., 2022a).

5.4.3 User involvement in the co-design process

It has been suggested co-design activities are a source of happiness which lead to engagement, fruitful relationships and a sense of accomplishment where the process of

making with the designer becomes a meaningful activity (De Couvreur et al., 2013). Results from this study certainly indicate high satisfaction with the co-design process, with high scores of 4.9 and 4.7 (out of 5) for service satisfaction at initial and 3-month follow-up respectively (see Table 5-5). These scores corresponded with the positive feedback from the qualitative analysis, with the co-design process. Participants felt engaged in the process by providing feedback into the design process, felt their needs were listened to through a good working relationship with the clinician and felt the care was individualised to their needs. These results indicate how the co-design methodology utilised as part of this study supported greater patient involvement in care decisions through shared decision making, in this instance the design of an assistive devices, ensuring a person-centred approach to healthcare service delivery. These support the aims of shared decisions making and patient centred care for the delivery of healthcare services set out by the WHO and UK NHS constitution (World Health Organisation, 2016) (Department of Health and Social Science, 2021)

What is unclear is to what extent the results are linked to the co-design process or if results are due to the customisation and improved design of devices. For example, would prescribing one of these newly developed devices have the same impact as being involved in its development? Does it make a difference if what is being prescribed has been previously co-designed for similar individuals? Does being involved in the development encourage the user to feel a sense of ownership over the device, impacting on use? And does the personal interaction with the clinician play a role in device use and the other psychological and wider benefits reported? The qualitative findings support how user-engagement helped ensure the devices provided were customised to meet an individual's needs. Thus, the other outcomes described are a causal effect of co-design improving the design and thus function of the devices; with the co-design process becoming a meaningful activity both in terms of the physical device and the psychological benefits.

5.4.4 Improved design of devices

One of the primary motivations for using co-design in this study was to improve the design of assistive technology through better customisation to the end-user's needs by making use of the expertise, insight and preferences of the end-user (Aflatoony & Lee, 2020; McDonald et al., 2016); a key barrier to assistive technology use previously identified(Howard et al., 2022a). Both the qualitative and questionnaire results indicate positive feedback about the

devices provided and thus the improved design of devices. Satisfaction scores showed no significant change over the 3-month period, indicating high levels of satisfaction with the device (4.6 out of 5 as measured by the QUEST 2.0) longer term, see Table 5-5. These results are comparable to previous co-design literature for customised assistive devices using QUEST 2.0 questionnaire with Gherardini et al. (2018), reporting device satisfaction scores of 4.76 and Schwartz et al. (2019), who reported that customised pill boxes produced an average device satisfaction score of 4.66 (Gherardini et al., 2018; Schwartz et al., 2020). Finally, the findings were comparable with own previous co-design work, where device satisfaction was rated as 5 out of 5 using the QUEST 2.0 questionnaire (Howard et al., 2022b). Qualitative feedback indicates aspects of the improved design participants liked including ease of use, ease of set-up, benefits over existing solutions and the aesthetics of the device. These themes were all previously identified as barriers to assistive technology use (Howard et al., 2022a), so it is interesting to note how specific characteristics of the design have been overcome through co-designing.

The qualitative themes 'user able to overcome challenge' and 'increased self-efficacy' are associated with improvements in overcoming the challenges identified by individuals through the use of the devices. This qualitative feedback is consistent with the significant reduction in the difficulty of completing the tasks recorded from the IPPA questionnaire, with analysis indicating this was a large effect, Cohen's D = 2.399. Results are consistent with other literature; Thorsen et al. (2019) reported a reduction in the IPPA score in their co-design study (Thorsen et al., 2019). The results show how co-designing has improved the design and use of the assistive devices provided in overcoming challenges in daily living, reducing the barriers related to the design and function of assistive technology previously identified (Howard et al., 2022a).

5.4.5 Psychological benefits

Supporting the psychological wellbeing of patients with chronic health conditions is vital. Psychological distress contributes to increase risk of premature mortality and an exacerbation of symptoms related to chronic conditions (Conversano, 2019; Russ et al., 2012). As such there is a need for healthcare interventions to manage the psychological distress, alongside the physical symptoms and limitations, for individuals living with chronic health conditions (Conversano, 2019).

Results from the PIADS questionnaire indicated an overall positive increase in psychosocial aspects related to using the devices (scale -3 to +3: competence +1.9, adaptability +1.9, and self-esteem +1.6 at 3-month follow-up). These results are consistent with other co-design literature, Gherardini et al (2018): competence +1.55, adaptability +1.81 and self-esteem +1.45, and the previous case study work undertaken in Chapter 4: competence +2.95, adaptability +3.0 and self-esteem +2.8 (Gherardini et al., 2018; Howard et al., 2022b).

Despite no significant difference being found in the WEMWBS scores, other results (PIADS and qualitative work) do suggest the role that co-designing customised devices can have in positively impacting on wellbeing for individuals. For instance, participants described increased positive affect, a sense of achievement and reductions in negative affect. These psychological benefits described are strongly linked to the concept of 'emotional balance' described by the GENIAL model of wellbeing (Kemp & Fisher, 2022; Mead et al., 2021). The GENIAL model describes how increases in positive emotions (positive affect and sense of achievement), coping (overcoming sense of loss) and an increased ability for individuals to manage negative emotions are linked to promoting more sustainable health and wellbeing behaviours in individuals, despite limitations bought about by chronic conditions. Research from the field of positive psychology further emphasises how positive affective psychological process can help with sustaining healthier behaviour changes (Van Cappellen et al., 2018); in this context this relates to both the continued use of the assistive devices provided and other secondary health benefits described. Results from this study illustrate how being involved in co-designing and using the devices creates a context for reducing psychological distress and enabling extrinsic psychological benefits, key determinants of wellbeing.

5.4.6 Increased independence and support network

The World Health Organisation recognises the role assistive technology can have in improving an individual's independence and reducing the need for formal health and care services and informal carers (World Health Organisation, 2018). Without assistive devices, people with chronic conditions are often excluded, isolated, and stuck in a poverty trap, increasing the impact of the condition on the person's life. This can in turn lead to negative spirals of ill-health further contributing to deteriorations in mental and physical health (Kemp et al., 2017). Qualitative results indicated the improvements in independence for individuals linked to their involvement in this study, see Table 5-8. This increased independence was not only for the challenges identified, but was also for other tasks, with participants indicating

increases in self-esteem and willingness for participants to tackle other tasks. It is hoped the increased independence, alongside the other benefits described (psychological and secondary), can reduce isolation and exclusion, providing opportunities for community integration and employment and thus promote positive spirals of healthy behaviours. Further work, with larger sample sizes is needed to assess this.

The increased independence evidenced did have a knock-on impact on the participants support network. Not only did participants feel they were less of a burden on others, which relates to reduce negative affect, but data collected from the CSRI showed that decreased help was required by informal carers (family members and friends) in completing tasks: Appendix K: Client Service Receipt Inventory - Help received with challenges identified. This could improve employment opportunities and reduce negative physical and psychological health outcomes associated with informal caregiving (Bauer & Sousa-Poza, 2015). The impact in improving the independence of the end-user and reducing the need for informal carers is evident from the results and corresponds to one of the primary benefits of using assistive technology described by WHO (World Health Organisation, 2018). Future work may consider the wider impact on informal carers of co-designing customised assistive devices.

5.4.7 Secondary benefits

Related to this increased independence, qualitative results indicated 'increased connection to the community and environment'. The theme described increased quality time with family and friends and increased social interactions, suggestive of improved social inclusion through use of the devices. This connectedness with community and environment is also a key aspect of the GENIAL wellbeing model (Kemp & Fisher, 2022; Mead et al., 2021). This again demonstrates how co-designing customised assistive devices can link to improving wellbeing. Given this link it would be interesting to explore other aspects of wellbeing co-designing devices may help with. For instance, could it improve positive health behaviours by promoting opportunities for physical exercise, healthier eating and/or improved sleep? These factors would be worth considering in future research studies. Nevertheless, in relation to established key determinants of wellbeing (Seligman, 2011), results show how co-design creates a context for facilitating positive emotions, engagement, relationships, meaning and achievement.

Another secondary benefit identified was that individuals were sourcing other solutions to challenges and problem solving themselves, and thus were involved in a personal innovation

process. Similar findings were also reported by Thorsen et al. (2019) when investigating co-designing and co-making assistive devices (Thorsen et al., 2019). Therefore, by getting individuals with chronic conditions to think about solutions, through trialling and providing feedback about designs, it would appear to initiate 'creative' thinking for them to be able to overcome other challenges. These themes are linked to improved independence and psychological benefits described and are suggestive of individuals better self-managing their own health. Promoting self-management is widely established as being important for improving health and wellbeing outcomes for individuals with chronic conditions and reducing burden on healthcare services (Dineen-Griffin et al., 2019; Ekman et al., 2011; Jordan et al., 2008). Garcia et al. (2021) previously concluded how user involvement in the design process promoted their self-management through educating and empowering individuals (García et al., 2021). Findings from this research support this with individuals not only able to manage their own needs better through using the assistive devices but were also looking for other solutions.

Individuals sourcing solutions may also be an indication of increased awareness of assistive technology and a changing attitude of individuals to using assistive devices. De Couvreur et al. (2011) similarly concluded involving the end-user in the design process reduced stigmatisation and changed their attitudes to using assistive devices (De Couvreur & Goossens, 2011). Qualitative results also indicate how the devices changed the attitudes of others to assistive devices. Interestingly a negative attitude towards using assistive technology by both the individual and the support network were all previously identified as barriers to assistive technology use (Howard et al., 2022a). Findings thus indicate how co-designing devices creates a context for improving wellbeing, better self-management of health, increasing awareness of solutions and positively changes attitudes towards using assistive devices.

5.4.8 Future service considerations

Results indicate an un-met need currently in the availability of assistive devices to meet individuals needs and thus a need for future healthcare services to co-design solutions to meet this need. Participants were very positive about the need for this in the future with qualitative feedback indicating aspects to consider. This section should be interpreted in accordance that feedback was low in frequency and was not necessarily common across participants.

Interestingly, the theme timely intervention indicated how participants were overall happy about the time period it took to produce the final devices, which was on average 16.1 weeks. Participants liked having sufficient time to trial the designs, enabling them to give more effective feedback. It was a positive that the time to produce a device did not impact on compliance with the co-design process or was a barrier to using the devices provided.

Feedback about the type of appointments varied. Whilst some individuals were positive about video conferencing, other participants felt that face-to-face appointments may have been more beneficial. Apart from the previous co-design research study from Chapter 4, where overall feedback was positive about the use of video appointments (Howard et al., 2022b), no other study co-designing assistive devices has used video-appointments. Going forward, encompassing a hybrid approach would seem logical, enabling patients' choice over appointment types that could vary at different stages of the co-design process. Future services also need to take into account the need to review and make further modifications to devices. At the 3-month follow-up, some participants identified issues with the devices which on occasions were limiting their use. This is reflective of a barrier to assistive technology previously identified relating to a lack of follow-up support (Howard et al., 2022a) and was a limitation in the methodology of the current study that should be considered in the design of future research studies. Encouraging individuals to pro-actively contact healthcare services when issues occur, rather than waiting for review appointments, would also help identify issues, refine solutions quickly and limit negative consequences of using an ineffective device.

The themes raising awareness of solutions is applicable to both the devices produced and the healthcare service. This also reflects the barriers to assistive technology previously identified about a lack of awareness about products and services available (Howard et al., 2022a). Linked to this is the theme describing broader access to service. Participants thought they would be unable to access a service due to their disability not being 'severe' enough. Future services need to ensure they are inclusive to individuals with a range of disabilities with information being accessible to those who would benefit from using the service. Results have revealed several considerations for future services related to the type of appointments, follow-up requirements, information and awareness and ensuring equitable access to services.

5.4.9 Resources required to provide devices

The need to consider the resources involved in co-designing customised assistive devices is important for analysing the cost versus patient benefit for healthcare services. Results indicate an improvement in the efficiency of co-designing devices compared to the previous work in Chapter 4. In the previous work the average clinician's time taken per device and per participant were 17 hours 9 minutes and 28 hours 35 minutes respectively (Howard et al., 2022b). Within this study the average clinician's time per device and per participant both decreased, 5 hours 37 minutes per device and 10 hours 14 minutes per participant, a near 3-fold decrease, see Table 5-7. These reductions are partly due to greater experience with co-designing devices within this study, due to being able to re-use and adapt some of the previous designs, and due to the simplicity of some of the solutions required. No other previous co-design literature reported the resources and costs involved and thus it is not possible to compare these results to any other work.

A large variation was seen in the time required between different participants. The total range in time required per participant was 15 hours 15 minutes, and the standard deviation was 4 hours 56 minutes. This variation is also reflected in the in number of appointments required, ranging from 2 to 6, evidencing how in some instances it took several iterations to reach the final solution. This variation was owing to differing levels of complexity in the challenges identified and the differing personal and social circumstances of the participants. It is important that future co-design methodologies recognise the variation in the time and number of appointments required to produce devices.

A reduction in time led to a subsequent reduction in cost. The total cost per device in this study was £193.60, compared to £529.72 in the previous cast-study work in Chapter 4 (Howard et al., 2022b). The biggest contributor to this cost was still the cost of the clinician's time, equating for 86.6% of the total cost. Reducing the clinician's time, for example through the further re-using of designs, would make the process more cost effective. However, it should be balanced against the importance of the human interactions within the co-design process and the need for customisation in the design. For instance, the qualitative feedback from participants indicated the importance of the personal interaction and feeling listened too within the co-design process. Future research will consider ways to improve cost-efficiency, whilst maintaining a personalised approach to co-designing devices. It will also look to further understand the key factors related to the improvement in efficiencies observed associated with the clinician's experience and refinement of the co-design process.

5.4.10 Limitations

The validity of the conclusion drawn from the quantitative aspect of the study is limited as a function of the small sample size. However, this is offset by the mixed methods approach with qualitative findings adding a rich narrative to the data which is critical to better understanding the impact of co-designing customised devices. Moreover, the research aimed to investigate whether reported everyday problems could be overcome by co-designing solutions within a health care context and so one outcome from the results is the devices themselves.

Another limitation is that the heterogeneous sample limited the interpretation of the results from the CRSI data about the healthcare services accessed. The healthcare services accessed varied amongst participants which, alongside the small sample size, made it difficult to draw any similarities or conclusions from the data. Additionally, it was difficult to distinguish if changes were due to the co-design intervention or other external factors. Results are included in the Appendix to enable readers to interpret themselves, Appendix J: Client Service Receipt Inventory - Contact with healthcare services. A larger sample size and longer follow-up time in the future would enable more meaningful conclusions to be drawn from contact with healthcare services data. The data reported may also be usefully included in future meta-analyses that explore the cost effectiveness of this approach.

There was also no control group to compare the results too in this study. However, due to the individualised approach of the study design with unique devices being produced for individual's unique context, it would be impossible to have an unbiased, similar control group for comparison. Additionally, the feedback gathered from participants through using a mixed-method analysis helped to establish how results related to aspects of the co-design process. Instead, in the future it would be more pragmatic to use a multiple baseline approach with each individual acts as their own control to understand changes in outcomes prior to and after the co-design intervention and track long-term outcomes.

It could be argued that another limitation was that the co-design work and the follow-up outcome measures were conducted by a single individual, JH. This could have introduced positive bias in the responses provided by participants. However, it was decided the same individual would conduct both parts due to the insight they had about the devices which facilitated the semi-structured interviews. The qualitative feedback corresponded with

questionnaire scores and the final analysis of the qualitative data was conducted by a selection of the co-authors to reduce bias.

5.5 Conclusion

This study aimed to explore the feasibility of co-designing customised assistive devices within a current healthcare setting by evaluating the impact of the co-design process and the resources required. Devices were provided for 19 out of 24 challenges of daily living identified by individuals with a range of chronic health conditions. The impact of the co-design intervention went beyond providing a customised device to meet an individual's needs, with the co-design process and improved design facilitating other outcomes for the individual related to physical and mental wellbeing. The outcomes have been discussed in relation to theoretical models of wellbeing, indicating the potential long-term benefit for the individual and others. An analysis of the resources involved show a decrease compared to previous work. With increasing scale and experience, for example being able to re-use designs, the co-design process could therefore become an efficient and cost-effective process. Further scaling will also help produce more innovative customisable solutions, causing a positive innovation spiral in the development of new solutions other individuals can subsequently use and customise. Findings from this work support the use of co-design for producing customised assistive devices in improving health and wellbeing and reducing the barriers individuals face in accessing and using assistive technology. Further work is required to evaluate these findings for a larger sample size, exploring further opportunities to improve the resource and cost efficiency of the co-design process.

6 Can a previously co-designed device be used by others? A service evaluation of the use of the Sativex spray holder for individuals with multiple sclerosis

This chapter looks to expand on the work of Chapter 4 by exploring whether one of the devices previously developed through the co-design approach, the Sativex spray holder, can be re-used by other individuals. The Sativex spray holder is prescribed to other individuals with multiple sclerosis who have similar assistive device needs. This chapter seeks to understand mechanisms that could make the co-design process more cost-effective by reducing the time required to initially design a custom assistive device. The resources required and satisfaction with the devices provided are analysed.

At the time of submission, this chapter is currently under peer-review for publication in the Journal of Disability and Rehabilitation: Assistive Technology under the title:

"*Can a previously co-designed device be used by others? A service evaluation of the use of the Sativex spray holder for individuals with multiple sclerosis*".

6.1 Introduction

The management of chronic health conditions pose a key challenge to health and social care services, with healthcare costs associated with chronic health conditions taking up the largest proportion of healthcare expenditure (Centers for Disease Control and Prevention, 2022; Department of Health, 2012; Holman, 2020; Hutt & Rosen, 2005). Enabling people to better self-manage their own health and wellbeing could help reduce this burden; assistive technology has an important role to play in this (World Health Organisation, 2018). Providing the right assistive technology has the potential to reduce the burden on the individual, their family and health and social care services (Lansley, 2004; Madara Marasinghe, 2016; Mitzner et al., 2010; van Ommeren et al., 2018; World Health Organisation, 2018). However, a lack of customisation and user involvement in the design and provision process are among many of the key barriers to using assistive technology (Howard et al., 2022a; Phillips & Zhao, 1993).

Previous work has looked to improve the customisation of assistive devices by involving the end user in key decision making processes and encouraging them to provide feedback during the design of their own assistive devices, a methodology known as co-design (Federici et al., 2013; Sanders & Stappers, 2008). Example devices have included hand orthotics, pill boxes and devices to assist with upper limb functional tasks (Aflatoony et al., 2021; Day & Riley, 2018; De Couvreur & Goossens, 2011; Lee et al., 2019; Ragoo et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020; Thorsen et al., 2019). However several shortcomings currently exist in the literature including a lack of information about the resources involved in co-designing devices, a lack of long-term follow-up and the majority of studies having small sample sizes (Howard et al., 2022b).

To address this first shortcoming, a service-evaluation was conducted for three individuals to explore the use of co-design within a current healthcare setting to provide custom assistive devices, Chapter 4 (Howard et al., 2022b). In total five custom and novel devices were created specific to the challenges identified by the individuals. Improvements in independence, positive emotions and reduced mental load were among many of the benefits reported by the individuals through long-term use of the devices. This work demonstrated an advantage of utilising a co-design approach in helping to produce innovative assistive devices that met the bespoke needs of the end user. However, the process for producing these devices was initially labour intensive, with an average of around 17 hours spent by the clinician in designing and delivering a device; this time accounted for 96% of the total cost of providing the device. The majority of this time was spent on designing the devices, rather

than interacting with the end-user. As such if the same devices could be utilised by other individuals, with less time spent designing the device, the whole co-design process may be substantially more cost effective. This could provide secondary benefits for integrating co-design methodologies to enable customisation of assistive devices into healthcare services beyond the benefits to the initial user. Exploring if other individuals can use a previously co-designed device forms the basis of the current work.

There are a couple of recent examples of where this approach could have been used in the literature. Gherardini et al. (2018) co-designed nine different assistive devices for nine individuals with hand pathologies (Gherardini et al., 2018). The authors used parametric design software to enable key features of the designs, for example the shape and size, to be configurable to meet the needs of different individuals. However, the study did not report the extent to which designs were configured to other people's needs and how many individuals used each of the devices produced. Schwartz et al. (2019) produced different designed pill boxes that were tailored to the preference of fourteen individuals (Schwartz et al., 2020). They found the complexity of the customisation they were able to do was limited by the skill set of the student occupational therapists. This study only looked at the customisation of a pre-existing commercial product and did not explore customisation of a novel co-designed assistive device. In all previous cases in the literature, no further follow up work is reported exploring how previously co-designed devices could be re-used and modified to meet the needs of other individuals. Such an approach could strike a balance between the ability to create bespoke designs tailored to an individual needs against a cost-effective healthcare service model.

This work intends to address these current shortcomings by further exploring the use of one of the devices previously co-designed in the service evaluation, Howard et al. (2022) (Howard et al., 2022b). The device chosen was a holder for helping an individual administer the oral medication Sativex themselves, see Figure 6-1, which is referred to ongoing as the Sativex spray holder. This device was chosen as Sativex is prescribed to other individuals with multiple sclerosis. It was hypothesised others may similarly struggle with independently administering Sativex themselves due to limitations in hand strength and dexterity, common symptoms of multiple sclerosis. Sativex (delta-9-tetrahydrocannabinol combined with cannabidiol) is an oral medication currently recommended in the UK to treat moderate to severe spasticity in adults with multiple sclerosis (National Institute for Health and Care Excellence, 2021a). Individuals are prescribed between 2 and 12 sprays per day to help manage symptoms. The medication is administered by spraying underneath the tongue or

to the inside of the left or right cheek (Multiple Sclerosis Trust, 2021). Prior to the previous case-study work in Chapter 4, no assistive device existed that could help individuals administer Sativex.

The Sativex spray holder is designed to enable the user to squeeze the trigger with both hands to compress the top of the spray bottle, rather than having to compress the top of the spray between their index finger and thumb. In the initial service evaluation, this enabled the user to administer the spray independently, rather than having to rely on their spouse. Through investigating if other individuals could benefit from using the Sativex spray holder, this work seeks to understand if there are any secondary benefits of co-designing assistive devices within a healthcare service.

Figure 6-1: Sativex spray holder previously developed (Howard et al., 2022b)

Specifically, this work aims to evaluate the service provision of the novel Sativex Spray holder provided to other individuals currently prescribed the Sativex medication. To achieve this, two questions are considered:

1) Are other individuals able to use the Sativex spray holder or is further customisation required to enable individuals to use the device?
2) If customisation is required, what type of customisation is required and what are the costs and resources involved in making these modifications?

In line with previous work, a co-design approach was adopted to providing and modifying devices to meet the end-user needs. Questionnaires will be used to capture the satisfaction and impact of using the device and the recourses involved will be recorded. This evaluation intends to inform healthcare service delivery and refine future research methodologies around the use of co-design for the provision of custom assistive devices.

6.2 Methodology

6.2.1 Service context

This service evaluation was conducted in Swansea Rehabilitation Engineering Unit, a department within Swansea Bay University Health Board, a UK National Health Service (NHS). All appointments and design work was conducted by JH, the first author of this paper, a Clinical Scientist working in the Rehabilitation Engineering Unit and PhD research student. Devices were manufactured under the department's quality management system, certified to ISO:13485, for the manufacture and provision of medical devices. The evaluation took place between June and August 2022.

6.2.2 **Participants**

Individuals were referred into the department by a consultant in Rehabilitation Medicine working within Swansea Bay University Health Board. Individuals had to be 18 years +, have a diagnosis of multiple sclerosis, and be currently prescribed Sativex. Individuals were sent an information sheet explaining the previously developed Sativex spray holder and were invited to contact the referring Rehabilitation Medicine Consultant if they would like to trial the device. Six individuals indicated they would be interested of which five continued to the stage of trialling the Sativex spray holder. Table 6-1 shows the demographic information of the participants who were included in the service evaluation, including information related to challenges they experienced independently administering the Sativex medication.

Table 6-1: Summary demographic information of participants

Gender	**Female = 3; Male = 2**
Age (years)	Mean = 50; Standard Deviation = 6.44; Range = 43 – 60; Median = 50
Years since MS diagnosis	Mean = 15.8; Standard Deviation = 4.71; Range = 8 – 20; Median = 18
Number of times individual administers Sativex per day:	Mean = 5.6; Standard Deviation = 2.61; Range = 2 – 9; Median = 5
Number of months prescribed Sativex	Mean = 12.4; Standard Deviation = 2.61; Range = 8-14; Median = 14
Currently able to administer independently?	Yes = 1; No = 3; Occasionally = 1
Who currently helps deliver the spray if not able to administer independently:	Family = 3; Carers = 1

6.2.3 Ethical Considerations

Service evaluations to gather the experiences of service users associated with the delivery of standard levels of care are characterised by minimal risk and are excluded from ethical review by research ethics committees in the United Kingdom (GAfREC 2.3.12). This evaluation was intended to gather the experiences of service users based on current provision of care in co-designing a customised assistive device. It did not involve a new treatment and participants were not randomised. The participants who were invited to participate in the evaluation provided verbal consent for their information to be shared and included in this evaluation with all personal identifiable information anonymised, (Appendix C: Consent form for service evaluation). All participants valued the opportunity to take part in all aspects of the process outlined below and provide feedback on the intervention to help improve future service delivery. All data was collected in accordance with the General Data Protection Regulation (GDPR) and information was anonymised prior to being shared with individuals not involved in the individual's standard level of care, for example anonymised prior to data analysis.

6.2.4 Materials

This section provides an overview of the equipment used to produce the devices. The tools used reflect the equipment available and the expertise of the clinician in using the equipment available within the healthcare service where this evaluation was conducted.

3D computational models of devices were created and edited using a parametric CAD software, Solidworks Premium 2016 x64 edition (Waltham, USA). Prior to manufacturing, parts were exported as a Stereolithography file from Solidworks and imported into the slicer software ideaMaker v4.1.1, Raise3D Technologies Inc. (Irvine, USA). The parameters for the slicer software were: number of shells: 4; layer height: 0.2mm; infill percentage: 25%; infill pattern: gyroid and a raft was added to prevent warping on the print bed. These settings were chosen as they provided a good surface finish, appropriate mechanical strength whilst minimising weight and manufacturing time. A Raise 3D Pro2 printer, a fused deposition modelling (FDM) type machine, was used to manufacture the parts. Parts were manufactured from Polycarbonate due to its superior strength and impact resistance

compared to lower-cost materials, for example PLA which is commonly used for prototyping parts with additive manufacturing.

6.2.5 Procedure: Devise provision

All appointments with the participants were conducted virtually using a web-based video consultation software, Attend Anywhere. Devices were posted out for the participants to trial and use at home. A summary of the process is provided in Figure 6-2.

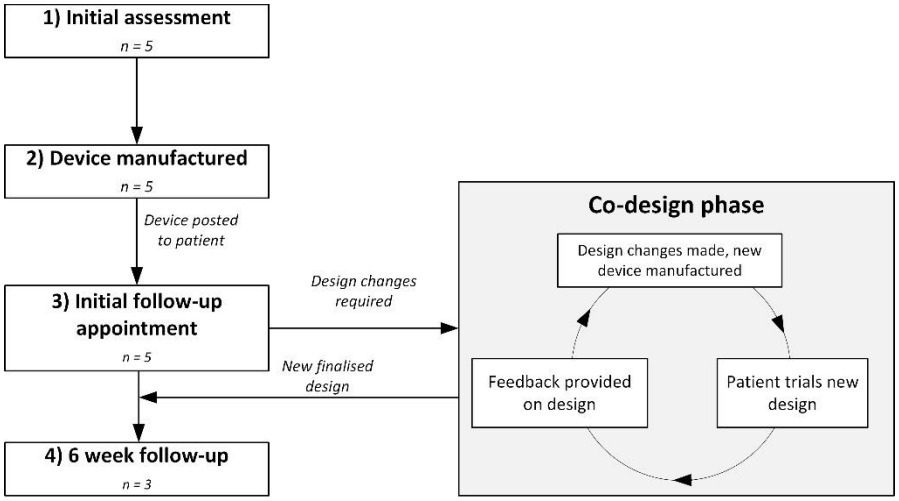


Figure 6-2: Summary of process for providing Sativex Spray holder, n represents number of participants at each stage.

1) Initial assessment: Clinician gathered relevant medical history, identified the reasons the individual was struggling to use the Sativex independently and assessed suitability for trialling the device. If suitable, training was provided on the use of the Sativex spray holder previously created (see Figure 6-1).
2) Device manufacture: The Sativex spray holder was manufactured and posted out for the participant to trial at home; instructions for use were provided.
3) Initial follow-up appointment: Clinician reviewed the use of the Sativex spray holder with the participant. The individual indicated if they were happy with the design of the device, or if any further changes were required
    a. Co-design phase: If a participant indicated changes were required, feedback from them was used to implement design changes and produce new prototype(s). These prototype(s) were posted for the participant to

trial from which further feedback was gathered and changes made. This formed an iterative design cycle until a final solution was reached.

4) 6-week follow-up appointment: Clinician reviewed use of the Sativex spray holder with the participant to understand if any further changes required after longer-term use. If changes were required, the same process as above (3a) was followed to develop a solution.

6.2.6 Evaluation

The evaluation of the Sativex spray holder took two forms: 1) Feedback from the end users on the impact and satisfaction of the device and 2) an evaluation of the resources required to provide the devices.

6.2.6.1 Feedback on device use

Feedback was obtained via two standard assistive technology questionnaires, the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) and the Psychosocial Impact of Assistive Devices Scale (PIADS). Both questionnaires were chosen as they are validated for use on different assistive devices and have been used in other previous studies evaluating co-designed assistive devices (Gherardini et al., 2018; Howard et al., 2022b; Lee et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020). Questionnaires were sent out for participants to complete at home at least 6 weeks after being provided the device.

QUEST 2.0 is a 12-item outcome measure that assesses the user's satisfaction with the assistive device and service supplying the device (Demers et al., 2002a). For each item, the questionnaire uses a 5-point Likert scale, 1 being not satisfied at all and 5 being very satisfied. Research has established the instrument has good internal consistency, moderate to substantial test-retest reliability and good construct validity (Demers et al., 2002a; Demers et al., 2000; Demers et al., 2002b). Average scores for satisfaction with the device and the service provided were calculated for each participant from the QUEST 2.0 questionnaire. The device score was an average of eight items: dimensions, weight, durability, comfort, adjustment, safety, simplicity of use, effectiveness; whilst the service score was an average of four items: service deliverable, repairs and servicing, professional service and follow-up services.

PIADS is a 26-item self-reported questionnaire to evaluate the effects of an assistive device on three sub-scales: competence, adaptability and self-esteem (Day et al., 2002). The individual is asked to read a list of phrases that describe how using the assistive device may have affected them. For each phrase, the individual rates the items using a 7-point scale, ranging from -3 (maximum negative impact) to +3 (maximum positive impact). Research has established that the instrument has good internal consistency, test-retest reliability, and construct validity (Jutai & Day, 2002). For each participant the mean score for the competence, adaptability and self-esteem were calculated from the PIADS questionnaire response. The competence score was an average of 12 items: competence, adequacy, efficiency, productivity, usefulness, expertise, capability, performance, skilfulness, independence, quality of life and confusion (reverse scored). The adaptability score is an average of 6 items: willingness to take chances, ability to participate, eagerness to try new things, ability to adapt to activities of daily living, ability to take advantage of opportunities, wellbeing. The self-esteem score is an average of 8 items: self-esteem, security, sense of power, embarrassment (reverse scored), happiness, sense of control, frustration (reverse scored) and self-confidence.

6.2.6.2 Resource evaluation

For each participant the resources (time, money, material cost) required to produce the device and any subsequent changes to the design were calculated. The time was split between two groups, clinician's time and workshop support time. The clinician's time included all appointments with participants, writing notes and making any changes to the design. The workshop support time was for setting up the 3D printer, manufacturing and post-processing of the devices. Times were recorded and rounded to the nearest 5 minutes. The cost of this time was calculated by multiplying the time spent by the cost per hour of the two groups, £29.76/hr for clinician's time, band 7, and £20.49/hr for workshop support time, band 5. Both costs were calculated at top of banding based on the NHS pay scale and represent the cost to the healthcare service, e.g. pay/hr plus a 27% overhead cost to the health service. These represent the costs at the time this evaluation was undertaken, July 2022.

6.2.7 Data Analysis

Descriptive statistics were calculated across all participants for both questionnaires. Due to the small sample size no further, statistical analysis was performed on the data.

6.3 Results

6.3.1 Use and modification of device

Three out of the five participants had been using the device for more than 8 weeks at the time of the evaluation: 1 participant for 11 months, 1 participant for 9 months and 1 participant for 8 weeks. Of the three participants, only one required further customisation to the device, Figure 6-3. Further customisation was required due to them struggling to wrap their hand around the back handle and squeeze the trigger at the same time; this was in part due to limited finger extension caused by connective tissue disease. The individual suggested removing the back section to enable them to hold the front with one hand and pull the trigger with the other hand, without the back handle being in the way. The other alteration was an increase in the length of the trigger, to reduce the force required to push the trigger.

Figure 6-3: Modified Sativex spray holder

Of the two participants who did not use the device, the reasons for abandonment were due to them being unable to operate the device. One individual struggled to use the device due to tremors in their hands and another due to insufficient hand strength to operate the spray mechanism. In both instances, modified designs were trialled, but the individuals found it easier to get assistance from another individual to administer the Sativex rather than use the device.

6.3.2 Evaluation of device

Questionnaires were completed by the three participants who were using the device for more than 8 weeks. A summary of the results from the QUEST 2.0 questionnaires are shown in Table 6-2. For each item, the questionnaires use a 5-point scale (1 being not satisfied and 5 being very satisfied). The average device satisfaction score was 4.6, ranging from 3.9 to 5.0, and the average service satisfaction score was 4.7. Overall, the average total score was 4.6.

Table 6-2: Summary of results from the QUEST 2.0 questionnaire for the three individuals using the device long-term.

Participant no.	Assistive device subscale score	Service subscale score	Total score
001	5.0	5.0	5.0
002	5.0	5.0	5.0
003	3.9	4	3.9
Mean	4.6	4.7	4.6
Standard Deviation	0.65	0.57	0.63

A summary of the results from the PIADS questionnaires are shown in Table 6-3. For each item the individual rates the items using a 7-point scale, ranging from -3 (maximum negative impact) to +3 (maximum positive impact).

Table 6-3: Summary of results from the PIADS questionnaire from the three individuals using the device long-term.

Participant	Competence	Adaptability	Self-esteem
001	+3.0	+3.0	+3.0
002	+2.3	+1.5	+3.0
003	+0.3	+0.3	0.0
Mean	+1.9	+1.6	+2.0
Standard Deviation	1.4	1.3	1.7

Across all three individuals, increases in competence and adaptability scores were reported from using the device, ranging from +0.3 to + 3.0 for both scores. For the self-esteem an increase was indicated in two of the three individuals, with the third indicating no change. Overall, there was an average increase in all three scores: +1.9 competence; +1.6 adaptability; +2.0 self-esteem.

6.3.3 Resource analysis

The total cost of providing the Sativex holder for each individual is summarised in Table 6-4.

Table 6-4: Summary of resources used to provide devices for all five individuals involved in the trial.

Participant	Clinicians Time (hh:mm)	Workshop support time (hh:mm)	3D printing time (hh:mm)	Cost of clinician's time	Cost of workshop time	Material cost	Total cost
001	01:30	00:20	17:30	£44.66	£6.83	£6.91	£58.40
002	02:45	00:35	29:40	£81.87	£11.95	£12.32	£106.14
003	01:05	0:10	17:30	£32.25	£3.42	£6.91	£42.58
004	03:05	00:35	33:00	£91.79	£11.95	£10.53	£114.27
005	01:30	00:35	37:30	£44.66	£11.95	£12.32	£71.73
Total	9:55	02:15	135:10	£295.22	£46.10	£51.79	£393.11
Mean	01:59	00:27	27:02	£59.04	£9.22	£10.36	£78.62
StD	00:52	00:11	09:08	£26.10	£3.93	£3.55	£30.76

The time taken to provide a device ranged from 1 hour 5 minutes to 3 hours 5 minutes, with the total costs ranging from £42.58 to £114.27. The range was due to the time spent making customisations to the design, for participants 2 and 4 the clinician spent the most time trialling different modifications to the design, whilst participants 1 and 3 required no further modifications. The mean clinicians time to provide the device was 1 hour 59 minutes, with a mean cost of £78.62. The highest proportion of this cost was due to the clinician's time, equating for 75% of the total cost of providing the five devices.

6.4 Discussion

This service evaluation explored the wider use of a previously co-designed device by other individuals to explore any secondary benefits of co-designing devices within a healthcare service. Of the five individuals who trialled the device, three were using it long-term representing a 60% success rate. Of the three individuals using the device longer-term, one required further modification. The results from the questionnaires and the resource analysis will now be discussed in the wider context of previous co-design work and the implications for co-designing assistive devices within healthcare settings going forward.

6.4.1 Questionnaire feedback

Scores from the QUEST 2.0 questionnaire indicate high levels of satisfaction with both the Sativex spray holder (4.6 out of 5), and the service provided (4.7 out of 5), Table 6-2. Compared to the previous co-design in Chapter 4 work where average device and service satisfaction scores were both 5 at 3-month follow-up, the scores from this service evaluation show a small decrease in both sub-scale scores (Howard et al., 2022b). Scores from the PIADS questionnaire indicate improvements in competence (mean +1.9 out of a maximum positive increase of +3.0) and adaptability (mean +1.6) for all three individuals and self-esteem (mean +2.0) for two individuals from using the devices, see Table 6-3. Similar to the QUEST 2.0 questionnaire, the scores are lower compared to the 3 month follow-up scores from the previous co-design study in Chapter 4: +2.95 for competence, +3 for adaptability and + 2.8 for self-esteem (Howard et al., 2022b). The scores from PIADS within this study also showed greater variation between the three participants across all three sub-scale scores, indicating how the different individuals perceived the impact of the Sativex spray holder.

Although these differences are negligible, they may reflect the different methodology of this work. Whereas in the previous case study work participants were asked to identify the challenge(s) most important to them and devices were then specifically co-designed to meet these needs, in this work the participants were provided with an already designed device. Thus, if administering the Sativex was of varying importance to individuals, this may reflect the variations in PIADS scores reported, particularly for participant 3. This reflects how the importance and preference of overcoming the challenge may vary across different individuals and could be based on individual's personality, their personal and social circumstances. For instance, some individuals are happy to ask for help when they struggle

to do things. Whilst others may find this distressing as they place a high value on being independent and not feeling a burden on others. Finally, some individuals may have no one they can ask for help routinely. Matching these individual preferences is important in ensuring appropriate assistive devices are provided and used; the user-centred co-design approach supports this. Future work should look to incorporate how to capture an individual's importance and preference to help ensure an appropriate match between the assistive technology and the individuals' needs.

Despite the differences in scores, overall, the results do indicate a positive response from using the Sativex spray holder for the three individuals who were using the device long-term and thus show how a previously co-designed device can be provided to other individuals.

6.4.2 Customisation of Sativex spray holder

Customisation of the Sativex spray holder was explored within this work in the context that a lack of customisation was previously identified as a barrier to assistive technology use (Howard et al., 2022a). One of the three individuals using the device longer-term required modifications, Figure 6-3. In keeping with the co-design methodology, the end user had involvement in modifying the device to meet their needs. The newly modified Sativex spray holder could provide a new alternative design to trial with other individuals and further research could look at comparing the two designs in a larger sample. However, it is worth noting that in two instances despite further customisation being trialled, it was not possible to adapt the Sativex spray holder to become usable.

These results show that whilst in some instances further customisation was not required, being able to modify the design was beneficial for one individual in making the device usable for them. This supports the need to have design and manufacturing facilities and expertise embedded within healthcare services to enable novel customisable assistive devices to be available close to the point of care based on the needs of the end users. This second step of modifying the previous design would not have been possible without having access to the design initially developed from the first co-design development stage. This emphasises the importance in co-designing with the end-users initially to produce novel solutions.

Although the sample size is small, these findings indicate how further customisation is required to meet the needs of different individuals. Whilst co-designing can be used to produce novel bespoke solutions to meet the needs of the individuals, as demonstrated in

previous literature (Aflatoony et al., 2021; Day & Riley, 2018; De Couvreur & Goossens, 2011; Lee et al., 2019; Ragoo et al., 2019; Santos & Silveira, 2020; Schwartz et al., 2020; Thorsen et al., 2019), it is also important to reflect ways the newly created devices can be further deployed to meet the needs of others. Further work is required to explore if other co-designed devices can be similarly re-deployed and modified to meet the needs of others in a safe, efficient, and cost-effective way. Additionally further work is also required to explore the wider utility of the Sativex spray holder.

6.4.3 Resources

It is striking that if one compares the baseline of the previous case study work, where the average clinicians time was 17 hours 9 minutes to provide a device (Howard et al., 2022a), compared to this current study, average clinicians time of just 1 hour 59 minutes, Table 6-4. There were similar reductions in the material cost and 3D printing time required compared to the previous case-study work which reflected an overall reduction in costs associated with the co-design process. The average previous design process costs were £520.72 compared to £78.62 for the current work (i.e., a 6-fold decrease). The results show how some of the costs associated with co-designing devices initially could be offset by re-using and modifying devices to meet the need of others. Even when customisation was required, the time and cost of customisation still represented a fraction of the overall costs in producing the devices in the first instance. These findings support the legacy use of bespoke co-designed assistive devices to meet other end user needs as a key aspect of making the co-design process more cost effective going forward.

6.4.4 Implications for co-designing

This work shows an evolution of the initial co-design process and how it could be integrated into healthcare services. An initial solution developed to help one individual, administering the medication Sativex, has been scaled up and shown to benefit others. Through working with the prescribers of the Sativex medication, and they subsequently asking their patients if they similarly struggled to administer the medication, additional individuals were able to benefit from the originally developed device. Thus, the device has helped overcome a wider problem in administering the medication that was beyond that of the initial individual who the device was initially developed for. The approach still stayed true to the co-design process

by enabling the further customisation of devices to meet an individual needs. This model for co-designing customised devices that are able to be scaled-up and used to benefit other individuals provides a novel approach to providing assistive devices within a healthcare setting. This study represents a significant contribution to the literature around co-designing customised assistive devices Expanding on previous co-designing methodologies that have produced devices from scratch, to instead look at co-modification– where individuals are involved with designers and/or clinicians in modifying previous designs to meet their individual needs in a more resource efficient process.

6.4.5 Limitations

The conclusions from this work are limited to the Rehabilitation Engineering service from which the data were collected, as the process was somewhat unique to this service. However, findings from this service evaluation are interpreted in the context of other current research and help identify avenues for further research and service development. Within the service evaluation, one limitation is the sample size. This limits the ability to perform meaningful statistical analysis on the data set and limits the generalisability of the results to a wider population. However, the findings add significant context to the literature around the utility of co-design, and the current work has a similar sample size to previous co-design studies. A further limitation in the design of the study was the level of customisation able to be provided, limited by the equipment, materials, and expertise available within the Rehabilitation Engineering service. It is possible more complex solutions could have been developed to enable the two individuals who were not able to use the device to use it, however this was not further explored. The current study specifically sought to focus on simple modifications to the design/shape only. Finally, the findings are limited in that only the wider use of a single device was investigated and therefore it is not known if these findings would be applicable to other co-designed bespoke devices, although the findings thus far are encouraging. Nonetheless, it is possible some co-designed assistive devices are so specific to an individual's needs that use by other individuals would not be appropriate.

6.5 Conclusions

This service evaluation has shown how a previously co-designed device was able to be re-used and modified to meet the need of other individuals. The Sativex spray holder was provided to five individuals with multiple sclerosis who had similar requirements to the initial individual the device was designed for, unable to independently administer the Sativex medication. Three of the five individuals who trialled the Sativex spray holder were using it long-term at the time of the evaluation, with further customisation of the device required for one individual. Modification was required to the holder and trigger part of the devices. The resources required to modify the device were low compared to the initial time spent designing the device in previous work. The three individuals who were using the device long-term were satisfied with both the device and service produced, with on average improvements to adaptability, competence, and self-esteem. This work provides an important example of the means by which previously co-designed devices can be further deployed and modified to meet the needs of other similarly placed individuals. That is there are wider secondary benefits to the initial process of co-designing such bespoke devices, both with respect to the outcomes for other patients and the overall costs to healthcare services long-term. In effect this work demonstrates the potential *legacy* of co-designed products, notwithstanding the typical benefits around long-term utilisation of assistive technology in the sphere of healthcare.

7 Conclusions and future work

7.1 Introduction

This thesis has investigated the role of user-involvement in the design of customised assistive devices to improve health and wellbeing for individuals living with chronic health conditions. This has entailed conducting a meta-synthesis and literature review, and three empirical studies investigating the use of co-design to produce customised assistive devices. The research has been sequential, with findings from the initial chapters defining the design and conduct of subsequent chapters.

No previous work had looked to integrate a co-design methodology into an existing health care service to make customised assistive devices. This research has thus added significant new knowledge to the current scientific literature in relation to this. This final chapter will summarise the main findings from each chapter. It will then discuss the findings in the context of reducing the barriers to assistive technology use, improving health and wellbeing outcomes, implications for healthcare services and the current co-design literature. Finally, this chapter will review the main aims and objectives of this thesis, provide recommendations for further research and summarise the main contributions of this work to the scientific literature

7.2 Summary of chapters

The research was organised into seven chapters, with Chapter 1 being the introduction followed by five subsequent research chapters with the following objectives:

1. T Identify the current barriers to accessing and using assistive technology for people living with chronic health conditions (Chapter 2)
2. Identify the current evidence gaps related to increasing end-user involvement in the design and provision of customised assistive devices through reviewing the current scientific literature. (Chapter 3)
3. Investigate if co-design can be implemented within a current healthcare service to provide customised assistive devices for individuals with a range of chronic health conditions (Chapter 4 & 5)
4. Evaluate the impact for the individuals and the implications for healthcare services of providing customised assistive devices using this co-design method through mixed methods analysis of questionnaire and semi-structured interviews (Chapter 4 & 5)
5. Investigate if a previously co-designed devices can be re-used to meet the needs of other individuals through provision of the Sativex spray holder. (Chapter 6)

This section will summarise the key outcomes from each chapter.

7.2.1 Chapter 2: Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review

In Chapter two, a meta-synthesis was conducted to identify why people living with chronic health conditions do not have access to and use assistive technology (Howard et al., 2022a). A systematic literature search of five scientific databases was conducted to identify relevant qualitative studies. The inclusion criterion were trans-diagnostic including studies with different chronic conditions to identify if barriers were shared across different health populations. A total of forty studies were included in the synthesis, with thematic analysis

conducted to identify barriers to assistive technology within the studies. The methodological quality of the studies was evaluated using the Critical Appraisal Skills Programme checklist for qualitative research.

Fifty-one descriptive themes were identified grouped into six analytical themes:

- Societal barriers to assistive technology use
- Awareness and information of assistive technology
- The service provision of assistive technology

  The design and function of assistive technology
- Psychological barriers to assistive technology use
- The influence of the support network in accessing and using assistive technology

The barriers were found to be common across different health conditions and interconnected. Interventions aimed at improving the use of assistive technology should therefore consider the role of multiple barriers instead of targeting only one specific issue, for example the design and function of devices only. In discussing ways to reduce these barriers, ideas from multiple disciplines were drawn upon to propose avenues for future research.

Greater involvement of the end-user in both the design and provision process of assistive technology were identified as important in the acceptance and use of assistive technology. This reflects a move away from the traditional acute medical model of care, where individuals are seen as passive recipients of care, to a co-productive approach. In this instance clinicians (or designers in relation to improving design) would work collaboratively with the end-user to provide more appropriate solutions matched to the needs deemed most important to them. This can include the provision of off-the-shelf equipment, the use of and adaption of everyday items (for example as described by the term 'bricolage' (Greenhalgh et al., 2013)) and the design and customisation of new assistive devices.

Future research opportunities were identified including how to improve end-user input into the design and provision process to enable more patient specific solutions, how to effectively disseminate accessible information about assistive technology to the end-users, the lack of evidence around assistive technology, and how to tackle wider issues, for example social

stigma. Investigating the first of these points underpinned the remaining research presented in this thesis.

7.2.2 Chapter 3: Customisation of assistive technology: A review of the literature

Chapter three presented a summary of the scientific literature related to user-involvement and customisation of assistive devices and was split into three sub-chapters. The first sub-chapter focused on the end-user themselves making solutions by summarising the current literature around DIY practices related to assistive devices. The second sub-chapter focused on the end-user inputting into the design process through working with designers, co-designing. The third sub-chapter looked to summarise why these techniques were not commonplace in current healthcare settings by looking at the use of digital design and manufacturing techniques by healthcare professionals.

The first sub-chapter explored how DIY practices were being used by individuals to create assistive technology. This ranged from the adaption of everyday household objects to making more complex devices utilising computer aided design, 3D printing and the 'hacking' of medical devices to create digital apps (García et al., 2021; Hofmann et al., 2016a; Hofmann et al., 2016b; Hook et al., 2014; Hurst & Tobias, 2011; Lewis & Leibrand, 2016; Marshall et al., 2019; Omer, 2016). This sub-chapter described how specific DIY-AT communities have been formed, for example the DIY-APS community and e-NABLE network, that shared blue-prints and designs, and formed a community to help and support others (Barnard et al., 2018; Kesavadev et al., 2020; Lewis & Leibrand, 2016; Parry-Hill et al., 2017; Rivard et al., 2021). Individuals were also sharing designs using online platforms synonymous with DIY communities, for example thingiverse.com, although such websites were not specifically focused on DIY-AT solutions (Buehler et al., 2015).

Whilst there was evidence of DIY practices being used to create assistive technology, what was not apparent was how currently widespread such techniques were being used, by whom, how accessible they were, and what skills and expertise were required. It was also not known if current results were biased by individuals with sufficient free time and resource to engage in these practices relatively risk free. Additionally, it was not clear the scope that individuals who needed assistive technology were interested in and felt comfortable making devices independently or preferred to have support from healthcare and/or design professionals? In theory, scaling DIY practices could ultimately lead to true 'self-management' strategies where individuals are self-sufficient in making and maintaining their

own assistive devices, reducing need for healthcare service input completely. However, currently there are significant gaps in the literature to understand the accessibility, level of interest and longer-term risk and benefits of DIY practices.

The next sub-chapter reviewed the use of co-design to produce assistive technology, specifically focusing on the co-design of custom assistive devices. Reviewing the methodology of four key studies identified similarities in the literature: an iterative design process to create solutions, the use of physical prototypes as a communication tool between end-user and designer and the use of multi-disciplinary teams (Aflatoony et al., 2021; De Couvreur & Goossens, 2011; Gherardini et al., 2018; Santos & Silveira, 2020). The use of digital design and manufacturing tools, for example 3D printing, was also common in several of the methodologies to enable customisation and manufacturing of designs at a small scale. Additional studies also utilised some level of user-input in the design process to produce novel hand orthotics to perform functional tasks such as playing a French horn, using a pen, using cutlery and playing pool (Day & Riley, 2018; Lee et al., 2019; Ragoo et al., 2019). Finally, one further study investigated evolving the methodology from co-designing to co-making by training the end user in digital design and manufacturing techniques, although was unsuccessful in its single case study example (Thorsen et al., 2019).

Through this review several shortcomings were identified in the current literature related to co-designing custom assistive devices including:

1) A lack of long-term follow-up with users
2) No reporting of the resources and associated costs of designing and proving devices
3) Methodological limitations in the studies related to small sample sizes, no information on attrition rates and no control groups.
4) Limitation in the outcome measures used which fail to capture the wider impact using the device had on the user's day to day life
5) No data about the timescale over which devices were created.
6) Limited information about compliance to any regulatory standards for the manufacturing and provision of medical devices

Additionally, no previous studies had looked to integrate the co-design methodology into existing healthcare services to make these custom assistive devices available within the current set-up of assistive technology provision. Many questions remained regarding the feasibility and impact of such approaches. For instance, what healthcare professionals and

services would be best suited to applying the co-design methodology techniques? To apply such techniques, it seemed essential that individuals would need to be competent in using digital design and 3D printing techniques.

The final sub-chapter reviewed the current evidence around this question by exploring the use of 3D printing by healthcare professionals, initially focusing on occupational therapists and physiotherapists (common prescribers and adapters of assistive technology). There was overall a lack of literature around this topic, with one study conducted in a school, three using student therapists in a higher education setting and only two within current healthcare clinics. Early studies indicated that therapists had concerns about the skills, knowledge and confidence required to utilise such techniques as well as concerns about assessing the safety of devices produced (Buehler et al., 2016; Hofmann et al., 2019; McDonald et al., 2016; Wagner et al., 2018). However, two later studies, Schwartz et al. (2020) and Rasmussen et al. (2022), did successfully use 3D printing to produce customised devices, although in the former case only simple custom pill boxes (Rasmussen et al., 2022; Schwartz et al., 2020). This could represent a culture shift into more acceptance of these technologies by therapists within healthcare settings, however there is overall a lack of literature currently to support this.

Instead of seeking to train therapists in these techniques at this time, it was proposed it would be more effective to utilise existing healthcare services and professionals who are already familiar with designing customised assistive devices. Albeit different types of devices compared to those manufactured in the previous co-design literature. This could expand the range of customised assistive devices provided by healthcare services, making access to such devices and services more inclusive. Co-designing within healthcare services can help ensure devices are more customised to the user's needs by enabling the end-user to have a greater input into the design and provision process. Investigating the use and evaluating the impact of co-designing within a current healthcare service was the foundation for the remaining empirical studies.

7.2.3 Chapter 4: Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service: a service evaluation

This chapter aimed to investigate the feasibility of co-designing within a current NHS Rehabilitation Engineering service as well as exploring the impact and cost effectiveness of this approach (Howard et al., 2022b). Three case-studies were conducted and evaluated. Across the three individuals, five challenges in daily living were identified, with each challenge unique to the individual's personal and social circumstances. An iterative design approach was used to produce the devices, with the individual's trialling prototypes and providing feedback to ensure the devices met their needs. Devices were manufactured using digital design and manufacturing tools, predominantly 3D printing. A mixed-method methodology evaluated the devices provided and the co-design process, whilst the resources required to provide the devices were also calculated.

Four of the five customised devices provided were still being used after 3-months. The one device not being used was the pen holder because it was no longer required as the individual had regained sufficient function through using the device. Results from the QUEST 2.0 questionnaires indicated high satisfaction with the device and service provided initially and at 3-month follow-up. Results from the PIADS questionnaires indicated improvements in self-esteem, adaptability, and competence through using the devices. The questionnaire results corresponded to qualitative feedback from semi-structured interviews. Themes indicated improvement in independence, improved position emotions and reduced mental load. Feedback about the co-design approach indicated participants liked being involved in the design process, working closely with the clinician, feeling listened too and being able to input their ideas into the solutions they were going to use. Participants additionally liked the use of video-appointments, with it being convenient, it saved on travel and enabled users to trial the device at home in their own time.

In terms of the resources, the average cost per device was £520.72. The majority of this cost, 96%, was associated with the clinician's time with the material cost relatively low. Therefore, the re-production costs in manufacturing the final designs again were low, ranging from £3.41 to £22.48. It was identified that reducing the clinician's time in the co-design process would make the whole process more cost-effective. This study was limited by the small sample size, limiting both the analyses of the data and generalisability of the results. However, it did demonstrate the proof of principle in co-designing customised assistive

devices within a healthcare setting. It also revealed some of the wider health and wellbeing benefits associated with customising assistive devices, beyond that of the functional use of the device to overcome a particular challenge. The methodology developed and mixed-method analysis used in this chapter was subsequently used in Chapter 5 for a larger sample size. One of the devices developed (the Sativex spray holder) was also re-used in Chapter 6 for investigating the wider use and utility of a novel co-designed device.

7.2.4 Chapter 5: Co-designing personalised aids of daily living with users with chronic conditions: a feasibility study

Chapter five built upon the methodology developed and outcomes from Chapter 4. This study aimed to co-design customised assistive devices for a larger sample size, evaluating the impact of co-designing on both device use and the wider impact on the participant's lives. A mixed-method analysis was conducted utilising questionnaires and semi-structured interviews. This study calculated the costs and resources involved in co-designing devices and measured any reduction in health and social care services accessed and any reduction in informal care. A trans-diagnostic inclusion criterion was used to include individuals with different health conditions and different challenges in daily living.

Twenty-four challenges were identified across eleven individuals. Challenges were identified for a range of tasks including eating and preparing food, personal care, gripping and carrying objects, housework, and leisure activities. Nineteen devices were provided initially with eighteen still being used at 3-month follow up. For one participant, no solution was provided. Results indicated significant changes in lowering the difficulty of completing a task through using the device for the individuals. A positive trend in increasing wellbeing scores over time was recorded, although this was not a significant change. Results also indicated high levels of satisfaction with the device and service provided and improvement in competence, adaptability, and self-esteem. No significant changes in these outcome measures were recorded between initial and 3-month follow up indicating long-term satisfaction and use of the devices provided.

The number of tasks that participants required assistance with reduced from fifteen to four after being provided a device; this was predominantly a reduction in help required by informal carers to complete tasks (family and friends). Results indicated a reduction in the healthcare services being accessed by participants, however the small sample size, the

variation in sample characteristics and the short follow-up period limited any meaningful conclusions being made from these data. Additionally, only one participant showed any changes in medication taken between baseline and 3-month follow-up data collection.

Qualitative feedback corresponded with the other outcome measures, with participants positive about being involved in the co-design process (providing feedback, listening to user's needs, individualised care) and an improvement in functionality of the designs produced (ease of use, ease of set-up, aesthetics, and benefit over existing solutions). It was not possible to distinguish if the benefits were due to co-designing the devices, or due to the improved design of the devices produced. However, the co-design intervention was considered to be causal to ensuring the device met the user's needs and thus contributed to the other impacts described. Impacts for the individual included increased independence (overcome challenges, increase self-efficacy, willingness to tackle other tasks), psychological benefits (increase positive affect, sense of achievement, overcoming sense of loss, and reduced negative affect) and the secondary benefits for the individual (increased connection to community/nature, quality of life, sourcing other solutions, additional health benefits and changing attitudes). These benefits were discussed in terms of theoretical wellbeing models and self-management, showing the link between co-designing custom assistive devices and improvements in health and wellbeing for individuals. The impact for the support network was also described alongside future service considerations and factors which were limiting device usage, including further modifications being required after longer-term use.

The time and resources required to produce a device were also calculated. The average clinician's time per participant was 5 hours 37 per device, with associated costs of £193.60. This represented a near 3-fold decrease compared to the previous case-study work (Chapter 4), although the cost of the clinician's time still accounted for 86% of the total cost. The reason for reducing in time this was due to increased experience producing solutions and being able to re-use and modify previous solutions. However, per participant, there was a large degree of variation in the time required, ranging from 5 hours 5 minutes to 20 hours 20 minutes. This was also present in the number of appointments, ranging from two to six appointments, and the number of days from initial assessment to final solution ranging from 32 days to 210 days. This variation was due to differing levels of complexity of challenges identified, if any previous designs had been created, as well as the individual preferences of the participants.

This chapter conducted a mixed-method analysis evaluating the implications of co-designing within healthcare services. Results were positive about the co-design process and indicated overall improvements in the design of devices being suited to the individual's needs, and improvements in health and wellbeing outcomes for individuals. Results also suggested improvements in efficiency of co-designing through experience and re-using/modifying previous designs. The study was limited by the sample size and the follow-up period of only three months. However, the findings provide a meaningful contribution to the literature around the use of co-design to produce customised assistive devices within current healthcare settings, identifying future areas for research and service development.

7.2.5 Chapter 6: Can a previously co-designed device be used by others? A service evaluation of the use of the Sativex spray holder for individuals with multiple sclerosis

As part of exploring the secondary benefits of co-designing beyond that of the initial user, Chapter six explored the re-usability of the previously developed Sativex spray holder for other individuals with multiple sclerosis. There were no previous examples in the scientific literature investigating this. The chapter considered two questions:

1) Were other individuals able to use the Sativex spray holder or was further customisation required?
2) What were the resources associated with providing the device and making further customisations to the design?

Five individuals trialled the device to help them independently administer the Sativex medication. A co-design approach was adopted to the provision of the device, with individuals encouraged to feedback about the design to enable modifications to be made. Modifications were made to the designs using CAD prior to manufacturing using 3D printing. The assistive technology questionnaires, QUEST 2.0 and PIADS, were used to evaluate the satisfaction and impact of the device. The resources required to provide the devices were also recorded.

Of the five individuals who trialled the device, three were using the device long term with one requiring further modification to the design to meet their needs. This represented a 60% success rate in re-using the device. Results from the QUEST 2.0 questionnaires indicated high satisfaction with the device and service provided, whilst results from the PIADS

questionnaires indicated improvements in competence, adaptability, and self-esteem. These results were more varied and lower compared to the initial case-study work (Chapter 4), perhaps owing to the importance that the individual's put on this challenge. The mean cost of providing a device, including modifications, was £78.62 across the five participants and represented a 6-fold decrease in the costs compared to the initial case-study work. The main reason was a reduction in the clinician's time required to provide a device, decreasing from approximately 17 hours in the initial case-study to 2 hours for this study. This evidenced how re-using the device improved the time and thus cost-efficiency associated with co-designing devices.

This chapter discussed the implications of these findings more widely for co-designing within healthcare services. From initially co-designing 'novel' devices to meet an individual's needs (Chapter 4), this work demonstrated how devices could be scaled up to benefit other individuals whilst at the same time off setting some of the high costs associated with initially designing the device. By keeping the design and manufacturing 'in-house' (in the healthcare service), it was easy to customise the device as required to meet the needs of individuals and thus still embodying an individualised, user-centred approach. Future co-design work should consider the way in which devices can be further deployed and modified to meet the needs of others.

This chapter was limited by a small sample size which restricted the ability to perform meaningful statistical analysis and the generalisability of the results. Another limitation was the extent to which the findings may be applicable to other co-designed custom assistive devices. For instance, some devices may be so specific to an individual's needs that use by other individuals would not be appropriate. Nevertheless, results showed how a previously co-designed device could be re-used and modified to meet the needs of other individuals, improving the cost efficiency of the co-design process. This demonstrated the secondary benefits associated with co-designing devices within healthcare services beyond the initial user through re-using designs and adds further weight to the feasibility and utility of the co-design approach being used in healthcare services.

This section has summarised the key findings from the Chapters of the thesis. The next sections will now discuss the findings from these chapters in the context of reducing the barriers to assistive technology use, improving health and wellbeing outcomes, implications for healthcare services and the current co-design literature.

7.3 Overcoming barriers to assistive technology

This section will discuss the results from the three co-design empirical chapters in relation to overcoming the barriers to assistive technology access and use identified in Chapter 2 (the main themes are represented pictorially in Figure 7-1 below for convenience). Whilst some of the barriers are directly linked to the results, other barriers are more indirectly linked and are discussed to demonstrate some of the potential wider benefits in co-designing solutions. In discussing these findings, it is acknowledged that the sample sizes of the studies were small and thus the evidence and discussion is not conclusive. Further work is clearly required to further evaluate the impact of co-designing to reduce these barriers.

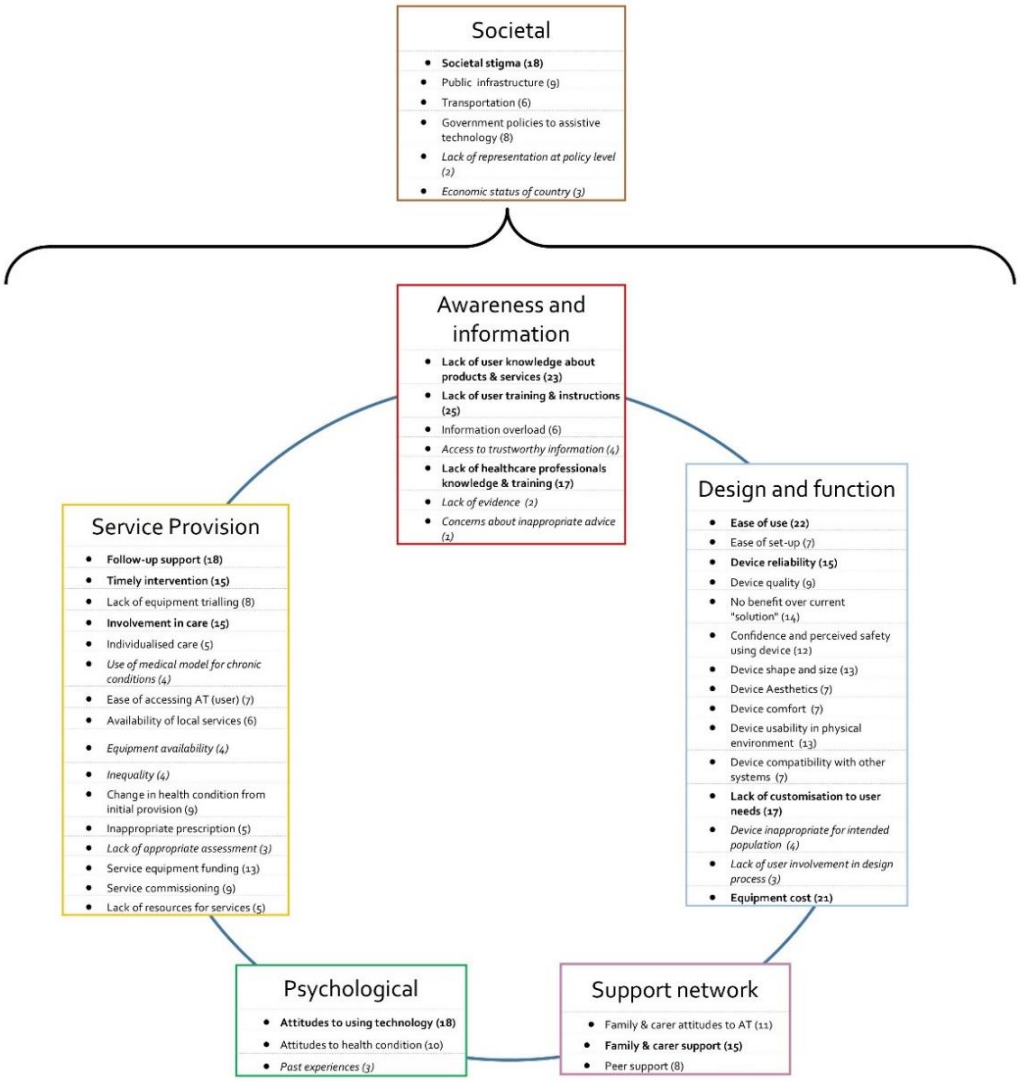


Figure 7-1: The summary of analytical and descriptive themes relating to the barriers to assistive technology identified in Chapter 2 (Howard et al., 2022a).

7.3.1 Design and function of assistive technology

One of the primary rationales for investigating co-design was to help ensure the design of assistive devices met the end user's needs, through increasing the user-involvement in the design process (Alqahtani et al., 2019; Martin et al., 2011; Orejuela-Zapata et al., 2019; Robinson et al., 2013). This research utilised a one-to-one approach to design devices for instances when no current off-the-shelf products were available that could meet an individual's needs. Devices were *customised to meet the user's need*s, ensuring the device fitted into the unique personal, social, and wider-environmental context of individuals. These different contexts are important as described by the biopsychosocial models of disability (ICF) and wellbeing (GENIAL) (Kemp et al., 2017; Mead et al., 2019; World Health Organisation, 2001). Through customisation, this ensured the device was *appropriate for the intended population*; in this work the intended population was the individual end user. The co-design methodology also ensured that the user was *involved in the design process*. Results from the QUEST 2.0 questionnaires indicted high satisfaction with the service, whilst qualitative feedback in Chapters 4 and 5 described how participants valued providing feedback into the design process and felt their opinions were listened too.

Feedback from participants showed how co-designing improved specific aspects of the design including: *ease of use, ease of set-up, shape and size of device, aesthetics, and comfort*. Feedback also indicated how the devices were *beneficial over existing solutions.* The longer-term use of the devices also seemed to imply individuals were *confident with the safety of the device*s *provided,* as otherwise devices would have likely been abandoned*.* Further follow-up is required to assess characteristics such as the *reliability* and *quality* of the devices provided over time. Additionally, it is not possible to comment on overcoming the barriers of *usability in physical environment* and *compatibility with other systems* as there is no specific feedback from participants related to this; this demonstrates how not all the barriers identified are relevant for all devices.

Whilst the co-design process to develop solutions, could be perceived as costly from the healthcare service prospective, in terms of manufacturing the same device again the costs were relatively small as calculated in Chapter 4 and demonstrated in Chapter 6; this could help reduce the barrier associated with *equipment cost.*

7.3.2 Service provision

Another aim of co-designing devices was to ensure the end user was *involved in their care* and, by working-one-to-one with the end-user, creating an *individualised approach to care*. Qualitative feedback in Chapters 4 and 5 indicated this was achieved. Participants were overwhelmingly positive about working closely with the clinician to design solutions and described how important it was that designs were tailored to their specific needs. The methodology involved iteratively designing solutions, with the design evolving during the co-design process. This enabled the user to *trial equipment* in a 'real-world' environment (e.g., at the participant's home) and helped make sure the '*prescription',* or in this instance the device provided*, was appropriate to their needs.* The success in producing solutions also indicated the *assessment process was appropriate* in identifying the participants individual needs. Conducting the design and manufacturing within healthcare service ensured *equipment was available* as required. All three of the empirical chapters recorded the time taken to provide a device. Qualitative feedback indicated participants felt it was a *timely intervention* and was not a barrier to device use in this instance.

To help reduce *inequality* in accessing services in the future, a trans-diagnostic inclusion criterion for recruiting participants was used to create evidence to support trans-diagnostic services and define eligibility criteria. Results indicated how co-designing customised devices was successful across a range of different health conditions for a range of different challenges. Future services need to consider how those who need customised devices can *easily access the service,* including the awareness and information needs. The co-design methodology has taken a holistic approach to caring for people, focusing on the individualised requirements that people need to support themselves and be independent long-term. As such this methodology moved away from the *medical model for the care of chronic conditions* that simply looks to 'fix' short term problems. Whilst the studies were limited to Southwest Wales, the use of video appointments within the co-design process reduced the need for participants to travel to appointments. The use of video appointments going forward could therefore reduce the need for services to be *available more locally*; although it is important to note how feedback in Chapter 5 indicated some participants still preferred face-to-face appointments.

Results from Chapter 5 showed that some participants identified further design modifications associated with longer-term use of the devices, this implies the need for future services to include *follow-up support* as part of the ongoing provision process. Due to time

and resource constraints, providing long-term follow-up support was beyond the scope of the research. Following up will also help identify any changes required to devices due to *changes in an individual's health condition from initial provision*. Wherton et al. (2015) suggest that assistive technology provision must cease to be a one-off technical event and instead be an ongoing process (Wherton et al., 2015). It is important that future healthcare services include follow-up support to facilitate this.

One key outcome from the research was an estimation of the resources and costs involved in co-designing customised assistive devices. This was to provide an indication of the *funding* and *resources* required for future healthcare services. Unfortunately, there is no evidence available for comparison of the costs associated with providing an off-the-shelf solution compared to the co-design process developed in this research. It is worth noting, the co-design process was for when there was no off-the-shelf product available, and as such comparison with either a completely inappropriate product or no service at all may be of limited value. Additional research is required to evaluate the on-going and long-term costs associated with providing and maintaining devices, for example repairs, additional modifications, and replacement of devices. It is hoped results from this research will help with the *commissioning* of future services, although larger trials and more evidence is required to support this.

7.3.3 Awareness and information

Through being involved in the design and development process, meeting with the clinician and trialling prototypes, end-users were *trained on how to use* the devices. In the case of the Sativex device holder trial, Chapter 6, training was provided by the clinician over a video call and an instruction leaflet issued. Results from the qualitative feedback in Chapter 5, 'sourcing other solutions', indicates an *increase knowledge* of individuals in looking for assistive technology products themselves, be it either off-the-shelf products or home-made solutions. This is an interesting secondary outcome how co-designing could increase knowledge and awareness of individuals about other products and services. One future consideration is how to make individuals aware of the novel assistive devices produced and future services. For instance, how do individuals want to find information about services and products? Could for example, designs be shared online to improve awareness and knowledge, either commercially available or freely available on websites associated with DIY practices and communities such as thingiverse.com? And what are the implications of this? How to

overcome the awareness and information barriers in relation to co-designing customised assistive devices at a larger scale needs consideration in future research.

The barrier about the *knowledge that healthcare professionals* had about assistive technology was not assessed during this thesis. However, the dissemination of this research aims to make healthcare professionals more aware of the increased opportunities for creating customised assistive devices associated with utilising digital design and 3D printing. What I do reflect on personally is that through being involved in this research and running the studies, I have increased my own knowledge of assistive technology available. Therefore, co-designing solutions could increase the knowledge of the healthcare professionals involved. Consequently, further consideration is needed about the *knowledge, skills and training required for other healthcare professionals* to undertake this co-design approach to enable scaling and wider use of this process in healthcare services.

The results from the studies have either been published or are due to be published (Howard et al., 2022a; Howard et al., 2022b). It is thus hoped this adds *further evidence* around the benefits of using assistive technology and of co-designing solutions. The results not only focused on the use of the devices, but also looked to incorporate the wider impact on the individual's day-to-day life. For instance, qualitative results from Chapters 4 and 5, were closely linked to theoretical wellbeing models.

7.3.4 Psychological

Results from chapters 4, 5 and 6 show satisfaction with the devices provided and indicate a *positive attitude* from participants to using the devices. This may cross-over to positive attitudes about using other assistive devices, with some evidence to suggest participants looked at sourcing other solutions as discussed previously. The outcomes of reduce stigmatisation and changing attitudes towards assistive technology use were also previously reported by De Couvreur et al. (2011) in relation to user-input in the design process (De Couvreur & Goossens, 2011). It may have also been influenced by the sense of engagement and ownership over the devices by being involved, similar to the "I designed it myself effect" described by Franke et al. (2010), and evidenced as a motivation for DIY practices (Braune et al., 2021; Buehler et al., 2015; Franke et al., 2010; García et al., 2021; Parry-Hill et al., 2017; Tanenbaum et al., 2013). In future work it would be interesting to research the influence of these aspects further.

The barrier '*attitudes to health condition'* related to individuals needing to be willing to accept the realities of their health condition and thus have the motivation to want to use assistive technology. In these studies, participants were accepting of the co-design process and willing to engage in the participatory design process to co-construct solutions to the challenges they identified. However, it is unclear if individuals were already motivated to do this, or if the design and outcomes of the co-design process meant they were interested to initially be involved and engage. It remains unclear if the co-design process had any impact on the individual's attitudes to their health condition from this research.

For the theme *negative past experiences*, it is unclear if any negative previous experiences may have impacted on the results. Nonetheless, it is hoped that the positive experience participants had in co-designing solutions will influence future use of other assistive technology. Further work is required to follow-up on this. However, for individuals involved where a solution was not provided there is the potential it impacted on their future acceptance of assistive technology. It is unknown if this may be positive or negative and may vary depending on the individual and their expectations. It is important to ensure the provision process remains a positive experience, even when not successful, in the future.

7.3.5 Support network

This work did not specifically measure the attitudes of the support network (family, friends or carers) to the devices provided. However, one of the qualitative themes from Chapter 5, 'changing the attitudes of others to assistive devices', did indicate how other people were positively remarking about the devices. The co-designed devices (linked to improvements in the design, function and aesthetics) may therefore have *improved the attitudes of the support network* to using assistive devices.

Linked to this is the theme *family and carer support*. This related to the need for family/carers to help support an individual to use a device. In all three studies, many of the challenges individuals identified required help from their support network. Results showed through using the devices provided, the level of support required reduced. This was evident from qualitative feedback in the initial case study work (Chapter 4) and CRSI data in the feasibility study (Chapter 5), which recorded the change in help required for the specific tasks. Finally, in the Sativex trial (Chapter 6) of those using the device longer-term, all were now able to administer the spray independently. The need for family and carer support had thus decreased. This reduced need to support individuals may subsequently also impact on the

previous theme, improving the attitudes of the support network to using assistive technology.

The *peer support* theme was linked to individuals wanting to gather information about assistive technology from those already using devices. This current research focused on a one-to-one approach and did not facilitate this. Feedback from one participant in the feasibility study (Chapter 5) did mention about group discussions as a future service consideration, which may help facilitate peer support. Making the designs available on an online digital platform may also help facilitate this. This could follow a similar model to either the thingiverse.com or ATchat.com websites discussed in the DIY-AT literature review (Chapter 3) to grow a community of co-designed customisable assistive technology solutions (Buehler et al., 2015; Layton et al., 2021). Future work should consider the requirements to facilitate both face-to-face and online peer support, the desire for this amongst individuals and methods to ensure devices are still safe, efficient, and effective.

7.3.6 Societal

The last analytical theme was societal barriers. Overcoming the barriers associated with this theme was not the primary goal of this research. Certainly, themes such as improving *public infrastructure* and *transportation* were not considered in this work in relation to assistive technology use. Although by conducting research within an accessible healthcare setting, the research looked to ensure these were not barriers to participation for the participants in the co-design research undertaken. Nor has the research considered *government policy* or the *lack of representation at policy level* of AT users. Whilst the evidence produced may help influence policy in the future, this would be long-term with more evidence and research required. Long-term, the devices may have influence on *societal stigma* through improving the design and function of devices, however this was not measured. Finally, the theme *economic status of country* reflected that in less economically developed countries, funding for assistive technology was not a priority due to widespread poverty. This research again did not consider this. The research was undertaken in the UK, of a high-economic status, and therefore it is unknown how the devices, co-design intervention and results may be applicable and transferable to less economically developed countries.

This research has helped both directly and indirectly reduce barriers to assistive technology use. Whilst the main benefits have been focused on the design and function of assistive devices and the healthcare service provision, an effect has also been seen in the analytical themes related to awareness and information, psychology and support network. The findings from the thesis support the use of co-design to reduce the barriers to assistive technology access and use. The next section will discuss the findings in relation to the effects on individual's health and wellbeing, healthcare services and how findings relate to limitations in the current co-design literature.

7.4 Effects on individual wellbeing, healthcare services and co-design research

This section will provide a short summary of how results from this research relate to three themes discussed in the introduction: 1) encouraging individuals to self-manage their own health; 2) improving health and wellbeing for individual's living with chronic health conditions; 3) creating more sustainable, effective healthcare services for managing chronic health conditions. Finally, the results will be summarised in the context of user-involvement in the design process related to the current co-design literature and the evidence gaps identified in Chapter 3.

7.4.1 Influence on self-management

Enabling individuals living with chronic conditions to self-manage their own health is important to reduce the burden of chronic conditions on healthcare services (Dineen-Griffin et al., 2019; Ekman et al., 2011; Jordan et al., 2008). Self-management describes "*an individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition" (pp.177)* (Barlow et al., 2002). This next section will discuss the impact from the current research around self-managing.

A consistent theme from the results was the increase in independence for the end users. Through using the assistive devices provided, the participants were able to overcome the challenges in daily living they had previously encountered. This directly helped the individuals with managing the physical limitations inherent with living with a chronic condition, but also facilitated psychosocial benefits as well (discussed in more detail in the next section). The improved independence was not only in overcoming the initial challenge identified. In Chapters 4 and 5, results from qualitative feedback indicated how devices were used for other tasks, participants were more willing to tackle other tasks, and participants tried to solve problems for themselves. Additionally, use of the Sativex spray holder described in Chapter 4 and 6, enabled individuals' greater control in taking the Sativex medication, thus helping them to better manage their symptoms associated with multiple sclerosis.

Further evidence from Chapter 5 indicated how some individuals looked to source other solutions (both assistive technology and 'home-made' solutions) to overcome challenges

themselves. These implied individuals were looking to find alternative ways to manage their own health. The use and adaption of home-made object corresponds to literature previously discussed around 'bricolage', described in relation to telehealth and dementia (Gibson et al., 2019; Greenhalgh et al., 2013). Similarly Thorsen et al. (2019) also reported that in their co-design/co-maker case study, the individual had looked to adapt solutions themselves (Thorsen et al., 2019). The findings from this thesis would support previous research that user involvement in the design process promotes their self-management through educating and empowering individuals (García et al., 2021). Further research is required to establish the extent of this longer-term and links back to the DIY practices discussed in Chapter 3. It would be interesting to investigate how to further enable individuals to create and source solutions themselves within future co-design methodologies as a way of initiating and promoting self-management.

Another aspect of self-management is enabling individuals to be more active collaborators in their care (Dineen-Griffin et al., 2019; Jordan et al., 2008). This research aimed to achieve this through involving the end-user in the design and decision-making processes (Chapters 4 and 5) and in the modifications of designs (Chapter 6). This enabled the end-user to input their own knowledge and preference into decisions about how devices were developed from them and links back to the theme of co-production in healthcare (Realpe & Wallace, 2010). Qualitative results from both Chapters 4 and 5 described how participants valued providing feedback into the design process, being involved in decisions, working closely with the clinician, and feeling listened to. This feedback correlated with high satisfaction scores for the service provided reported in the QUEST 2.0 questionnaires in Chapters 4, 5 and 6. Results show how co-designing devices with individuals helped them become more active collaborators in their care with individuals very satisfied with this level of involvement.

This section has summarised how co-designing customised assistive devices has helped individuals to self-managing their own health needs. This has been through the physical use of the devices provided and wider benefits related to improved independence and sourcing their own solutions. Co-designing additionally helped individuals to be more active collaborators in their care, inputting their own experiences and preferences to make decisions related to the development of devices. The next section will summarise the findings from this thesis in relation to the impact on individual health and wellbeing.

7.4.2 Impact on individual health and wellbeing

Healthcare models for chronic conditions need to shift away from looking to 'fix' problems and instead focus on promoting health and wellbeing for individuals to live 'well' with their chronic conditions (Kemp et al., 2022). One model that aimed to facilitate this was the GENIAL wellbeing model (Kemp et al., 2017; Kemp & Fisher, 2022; Mead et al., 2021). This biopsychosocial model described wellbeing as a multi-faceted entity for the individual, community and the environment related to emotional balance, promoting healthy bodies, personal relationships, connectedness to communities and the natural environment. This next section will summarise how results from the empirical studies relate to these aspects of wellbeing.

7.4.2.1 Emotional balance

Results from all three empirical chapters have demonstrated the psychological benefit of providing customised assistive devices and involving the user in co-designing such devices. Results from the PIADS questionnaires indicated increases in competence, adaptability, and self-esteem. This correlated in Chapters 4 and 5 with qualitative feedback gathered. Themes included increases in positive affect (confidence, happiness, self-esteem, sense of control), a sense of achievement, and reduction in negative affect (stress, anxiety, frustration). Additionally, themes also described overcoming a sense of loss, leading to feelings of a more normal life and greater self-identity. All these relates to the theme of emotional balance, indicating the psychological benefits from co-designing devices. Positive affective psychological experiences are also key to sustaining new healthier behaviour changes (Van Cappellen et al., 2018). In the context of this research, the positive psychological experiences relate to both the use of the assistive devices provided, but also more widely to other aspects of healthy behaviours. Results from this research support how co-designing assistive devices reduces psychological distress and provides positive psychological experiences, key determinants of emotional balance and wellbeing.

7.4.2.2 Promoting healthy bodies

Results showed some of the benefits related to healthy bodies. Participants were more able to overcome the challenges identified with improvements in regaining function and a reduction in the physical limitation due to their chronic condition. Additionally, some

participants in Chapters 4 and 5 described other benefits including the rehabilitative benefits from using the device, reductions in pain. In the case of the Sativex spray holder in Chapter 4, the increased control of being able to take medication reduced spasticity and pain and had other benefits including increased sense of control and safety (related to emotional balance). It was not measured if similar benefits were described by participants in Chapter 6 for the Sativex spray holder, but certainly participants were more able to administer the medication themselves.

Healthy body also relates to healthy diet, physical activity and quality of sleep. These outcomes were not measured or reported in any of the current studies, however, are potential secondary benefits. For instance, participants in Chapter 5 described increased time in nature, perhaps resulting in increased physical exercise. In both Chapters 4 and 5 several of the devices were intended to help with eating and preparing food, this could have indirectly improved diet. And improvements related to emotional balance described previously (reduction in anxiety and frustration) could lead to improved quality of sleep. Whilst the results from this research were inconclusive on these aspect, future research could look to include measuring these outcomes.

7.4.2.3 Personal relationships

The key personal relationship impacted by this research was that between the participants and their close family members and friends (the support network). Participants described how they felt they were a reduced burden on others by being able to do things themselves. This corresponded to results from the CSRI outcome measure, that showed decreases in the help required for challenges in Chapter 5. Qualitative feedback from both Chapters 4 and 5 also indicated increased opportunities to spend increased quality time with family and socialising opportunities. For example, participant 1 in Chapter 4 described how she could interact more with her children now, rather than having to wait for her partner. Outcomes from the research support improvements in personal relationships by co-designing and providing more effective customised devices. Future research could investigate this further from the family member/friend perspective (for example Family Reported Outcome Measures) to evaluate the secondary benefits for other individuals.

7.4.2.4 Connectedness to communities and natural environment

Closely linked to the theme of personal relationships is connectedness to communities and the natural environment. Whilst none of the devices in the study were directly associated with increasing participation in communities or the natural environment, qualitative results from Chapter 5 did indicate this as a secondary benefit described in the theme: *increased connection to the community and environment*. This theme described greater socialising opportunities with friends, opportunities to eat out and spend more time in nature. This secondary benefit was linked to the improved design of the devices provided, for instance making it easier to do a task so having more free time, as well as the psychological benefits, for example increased confidence. One of the challenges where a device was unable to be provided in Chapter 5 was to help with cycling. This again would be linked to both physical exercise (healthy bodies) and connection to the natural environment. The technical skills and time required to produce a solution were unfortunately beyond what was achievable in the current studies. Whilst results related to this aspect of wellbeing were less frequently reported compared to the other aspects discussed previously, results do suggest how co-designing customised devices does have potential to impact on connection to communities and the natural environment. It would be interesting for future outcome measures to quantify any of these wider secondary benefits.

This section has illustrated how being involved in co-designing and using devices creates a context for enabling emotional balance, promoting healthy bodies, improve personal relationships and enable connection to nature and communities. Thus, co-designing devices can help facilitate some of the key determinants of wellbeing for individuals living with chronic conditions. The next section will now discuss the implications of co-designing for making more effective and sustainable healthcare services.

7.4.3 Implications for healthcare services

The need to create more sustainable and effective healthcare services to manage chronic health conditions was considered in the introduction. An ageing population and an increasing prevalence of chronic health conditions, means global health expenditure is predicted to increase correlating to an increased burden on healthcare services (Foreman et al., 2018; World Health Organisation and World Bank, 2011). This section will summarise the findings

of the research in relation to the implications for healthcare services and identify further research opportunities.

Greater user-involvement in care is recognised as increasingly important for the management of chronic conditions by healthcare services (Department of Health, 2012; Welsh Government, 2018). As discussed in the previous self-management section, the co-design methodology supported this with positive feedback from participants about the process of being involved in co-designing devices. The co-design methodology helped ensure that devices were provided depending on what mattered to the end-user, looked to create solutions with users and encouraged inter-personal relationships between the user and the clinician to support the use of devices. These aspects were all highlighted as quality principles in the ARCHIE framework for telehealth and telecare provision (Greenhalgh et al., 2015) and, as identified in Chapter 2, were more widely appropriate to other areas of assistive technology provision (Howard et al., 2022a). The ARCHIE framework additionally identified the need to integrate methods of knowledge sharing between individual and services; this has not been addressed in the current research, but knowledge sharing could help facilitate improving the efficiency and scaling up the co-design approach in the future.

One consideration for future research and healthcare services is what impact will scaling-up of the co-design process have on the individualised approach that participants liked? The sample size of the current research was small, making an individualised approach easy to manage and implement. It is unknown if this individualised aspect of the process will still be sustainable and feasible with scaling up of this work. Further research is required to evaluate this for future healthcare service provision.

One interesting finding from the research was that scaling-up is unlikely to be necessarily associated with linear increases in costs. Results from Chapters 5 and 6 have shown how scaling up the co-design process, with increased experience and re-using of previous designs, reduced the costs associated with co-designing devices, compared to results from Chapter 4. Chapter 6 especially evidenced the secondary benefits of initially co-designing within a healthcare service. The novel Sativex spray holder was able to be re-used and modified to meet the needs of other individuals, with large time and cost reductions associated with this. This certainly gives an indication of how future healthcare services could co-design devices in an efficient and cost-effective manner. However, there needs to be a fine balance between the cost-effectiveness associated with re-using and providing ‘standardised’ devices against the benefits associated with involving the end user in the co-design process. A hybrid of these

two aspects (cost-effective and personalised approach), which is individualised and flexible is most likely required. Results presented in the thesis, give an indication of how co-designing customised assistive devices can meet both of these demands.

In relation to the impact on other healthcare and social services, results from Chapter 5 are inconclusive as to whether there was any reduction in access to formal health and social care services because of the research. Whilst there may appear to be some reductions, the methodological limitations of this study (small sample size, lack of long-term follow-up), mean it was difficult to compare data across the participants and draw meaningful conclusions. Similarly, there was no meaningful change in the medications taken by participants. Feedback from participants in Chapters 4 and 5 did identify additional health benefits from using the devices, for example reduced pain and regained function. This could have longer-term impacts on medication being taken and healthcare services being accessed than was able to be measured in the methodologies of the current studies. Future studies should look to include longer-term follow-up.

The final consideration for healthcare services is how to scale up and integrate this into current and future service provision. By undertaking the research within a current healthcare service, the research has shown how the skills and equipment are already in place to co-design customised assistive devices similar to the ones produced in this study. This work, however, did not consider other types of devices (for example electrical or digital solutions) as this was outside the skillset of the researcher. Future work could look to investigate the provision of these devices, including identifying the skills and equipment required to create these devices. Another consideration was all of the current research was conducted by a single individual. Therefore, there is a need to establish the training requirements for others to undertake this work to scale-up the co-design process. There is also a need to consider how the process could potentially be used by other healthcare professions, for example occupational therapists, considering the barriers identified in the literature review in Chapter 3. Finally, as discussed previously, there is a need to ensure access, awareness and information about any future healthcare service is available to individuals who would most benefit from accessing such a service.

This section has summarised how co-designing customised assistive devices in healthcare settings helps to facilitate user involvement in care and design decisions and promotes an individualised approach to care. Through re-using and modifying designs, the co-design process can be cost-effective and still maintain a personalised approach to care. Further work

is required to assess the scalability and long-term implications for healthcare services. The next section will discuss the findings in relation to the literature around co-designing customised assistive devices.

7.4.4 Implications for co-designing customised assistive devices

This section will summarise this research in relation to the current scientific literature around co-designing customised assistive devices. The shortcomings in the literature identified in Chapter 3 will be revisited as well as discussing the additional contributions to the literature this research has made.

The majority of previous studies lacked any long-term follow up data to assess if devices were being used after initial provision of the device. Chapters 4 and 5 conducted 3-month follow-up data collection, whilst in Chapter 6 participants had been using the Satviex spray holder for 11 months, 9 months and 8 weeks. It is acknowledged further follow-up work is required beyond that initial 3-month period in Chapters 4 and 5 and this follow-up was shorter than the 6-months reported by Gherardini et al. (2018) and Thorsen et al. (2019) (Gherardini et al., 2018; Thorsen et al., 2019). This will help establish some of the longer-term impacts for the individual and healthcare services. However, results from the research support that co-designing enables long-term use of assistive devices.

Previous research reported limited information about the resources involved in co-designing solutions. This research reported this in all three studies and as previously discussed, showed reductions in costs associated with scaling-up the co-design process. The results therefore provide a significant contribution around the resources involved in co-designing solutions. Linked to this was the timescale over which devices were provided. Results from Chapter 5 reported the average number of appointments and days it took to provide a device to individuals. Feedback indicated participants were happy with the time it took to provide devices. Recording the resources and time taken should be included in other co-design research to enable comparison of results for different methodologies. It is acknowledged long-term costs associated with providing devices were not recorded, for example due to repair, future modifications and replacing devices, and this should be incorporated into future research.

Previous literature also had methodological limitations. For example, no information on attrition rates, positive publication bias and small sample sizes. Chapter 5 reported attrition

rates for the research study (15 recruited with 11 involved in co-designing devices) and both Chapters 5 and 6 report instances where devices were not used, and the co-design process was unsuccessful in producing a solution. The research conducted still had a small sample size but was comparable to other co-design research. It is intended that the findings, and experience gained from this research, will be used to conduct larger co-design trials in the future to access the scalability and long-term impacts.

Another methodological limitation was that the outcome measures used in previous research only reported standard assistive technology questionnaires. Chapters 4 and 5 incorporated a mixed-method analysis to provide greater insight into the impact the device had on the user's day to day life as well as an understanding of the user's experience of the co-design methodology. This mixed-method approach was instrumental in linking the research with improved health and wellbeing outcomes based on theoretical models. Future research should similarly look to incorporate this analysis and look to develop more Patient Reported Outcome Measures (PROMs) focused on measuring the impact of co-designing assistive devices in relation to these theoretical models and Patient Reported Experience Measures (PREMs) to gather information on the quality of the patient's healthcare experience within a co-design process.

With the exception of Gherardini et al. (2018) (Gherardini et al., 2018), no previous research described the development of documentation to meet regulatory compliance. Developing documentation was included in the methodology for all the current studies and was recorded as part of the resources required to produce devices. The work was undertaken within an NHS Rehabilitation Engineering service that was accredited to a quality management system (ISO-13485) for the manufacturing of medical devices. This ensured the devices provided were in compliance with the regulatory requirements for custom-made medical devices.

It was also identified that no previous research had been undertaken within healthcare services. This research was conducted in a current healthcare service utilising the equipment of the Rehabilitation Engineering Department and the skill set of the researcher, a Clinical Scientist. This factor helped with the recruiting of individuals with different health conditions, via signposting and receiving referrals from a range of services. It also helped ensure compliance to the regulations, as discussed above, and ensure findings were more applicable for integration into future healthcare services. It could have also potentially impacted on the interaction with the participants, perhaps making participants feel more

comfortable they were talking to a qualified healthcare professional within a clinical setting. The influence of this last point may need consideration for future studies.

Finally, this research conducted sequential studies exploring co-design, with Chapters 5 and 6 developing from Chapter 4. This meant that the devices produced, and the experience gained from the first chapter influenced the results from the later chapters. This helped to evaluate the longer-term implications of co-designing devices and the cost-effectiveness gains through experience and re-using designs. This was not considered in any other previous co-design literature. Chapter 6 especially demonstrated the secondary benefits of co-designing devices; establishing how to scale the use of the device through re-using and modifying to benefit other individuals, reducing the costs associated with the long, initial process of co-designing devices. The findings from this research provide a significant contribution to the literature in respect to these aspects.

7.4.5 Summary

The section has summarised the findings from this research in relation to key concepts of self-management, health and wellbeing, implications for healthcare services and co-designing assistive devices. The research supports how the co-design methodology helps to empower individuals to self-manage their own health. It has shown how outcomes are related to established models of wellbeing, indicating how co-design can help facilitate positive wellbeing behaviours despite the limitations bought about by living with chronic conditions. It has discussed the implications for providing quality, patient centred healthcare services for the delivery of assistive technology, including considerations for scaling up and future healthcare service delivery utilising co-design. Finally, it has summarised how the research adds knowledge to the gaps in the current co-design literature. The next and final section will summarise a co-design service model blueprint, review the initial aims and objectives of the thesis, identify areas for future research and summarise the key contributions of this thesis to the scientific literature.

7.5 Summary

This section will present a summary of co-design service model blueprint based on the findings from this thesis, it will review the initial aims and objectives of the thesis, identify areas for further research and finally summarise the key contributions of the thesis to the scientific literature.

7.5.1 Co-designing assistive devices service model blueprint.

To summarise the findings from this thesis, Figure 7-2 presents a model service blueprint based on the study design and findings from this research for the co-design of assistive devices within a clinical service. The terminology “personalised aids of daily living” is used to reflect the devices created within the research conducted which have focused on tasks for daily living, instead of the term assistive devices which covers a broad range of different devices. The framework combines the methodologies from both chapters 5 and 6. The design idea generation and identification stage including a ‘search’ of previous designs to enable the re-use and modification of previous designs, as per the methodology tested for a single device in Chapter 6. It is acknowledged that in some instances the searching and therefore use of a previous design may not require any iterations to the design, at which point the iterative co-design phase described will be short. It is included as a single pathway at this stage with further testing required to identify other devices where co-modification may be more appropriate compared to co-design.

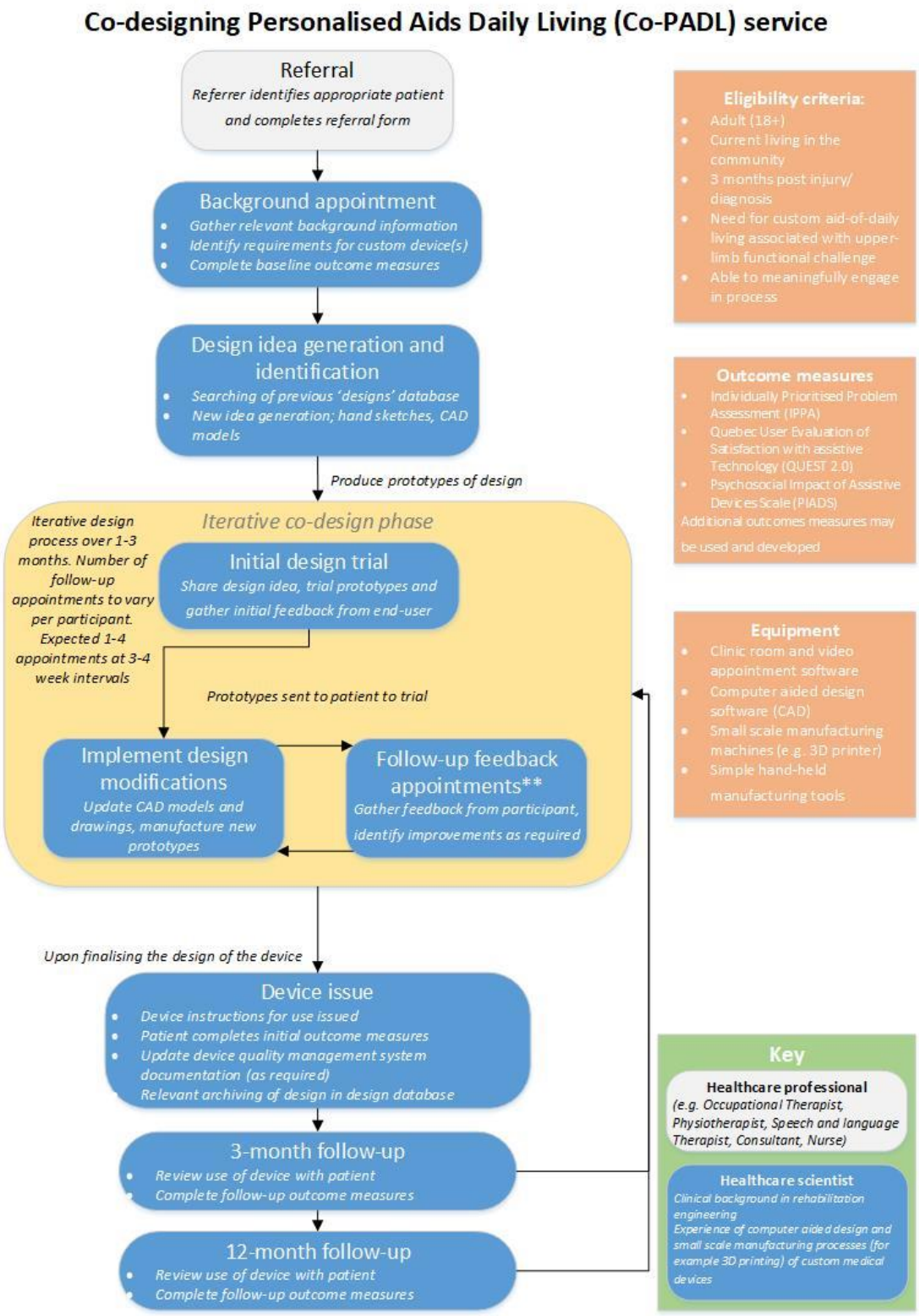


Figure 7-2: Blueprint of co-design clinical service to produce personalised aids of daily living.

Additional work is still required to look at the design, testing and feasibility of this 'design' database included within the process. This database will include designs that can be re-used

and modified by healthcare professionals. It is intended such designs will be produced in such a standardised way that reconfiguring them will be quick and easy process for different individuals and across different hospital sites. This database will be of importance to enable efficient scalability of the co-design process from the initial hospital service to other national and international settings. Further testing of this concept is required to investigate how to standardise designs and enable other healthcare professionals to use and modify previous designs.

The current proposal contains three main outcome measures used within the thesis and consistent with previous research, however additional outcome measures may look to be included. As discussed previously, additional PROMs and PREMS may be developed which better measure outcomes associated with co-designing assistive device which may be added to the service blueprint as developed. Outcome measures that measure mental wellbeing, for instance WEMWBS used in Chapter 5, or quality of life, for example the EQ-5D-L, may also wish to be included as part of evaluating the health outcomes from delivering such a service in the future.

The current proposal, based on the research methodologies presented, has identified the role of a healthcare scientist with a background in rehabilitation engineering as the principal personal in the process. Results showed how this individual could take the role of clinician and designer within the co-design process; different from several previous co-design methodologies who split the role of therapist and designer. It is acknowledged that other healthcare professionals may be able to fulfil some of the roles of the healthcare scientist, for example follow-up appointments with patients, and may in the future be able to be more involved with the searching, design, and modification of devices. This will require further work to explore the role other healthcare professionals could take within this process.

The proposed eligibility criteria were based on the eligibility criteria used in the current work. However, it is acknowledged this may be able to be expanded. For instance:

- How the co-design process would work for children and adolescents (<18)
- How the co-design process may be able to be adapted for those with cognitive or learning difficulties where meaningful engagement in the process may be more difficult.
- How the process may be able to be adapted to for those within an acute hospital setting, instead of community-based patients.

Further research is required to test and refine the proposed service methodology with these populations/settings; however, each can be used to expand upon the service blueprint presented.

7.5.2 Aims and objectives

This thesis aimed to improve the access to and use of assistive technology for individuals living with chronic health conditions through involving individuals in the design and development of customised assistive devices. To answer the main aim of the research, five objectives were identified for this thesis. Each objective will now be revisited in turn, discussing how the current research has met each objective before finally discussing how the main aim of the thesis was achieved.

1) Identify the current barriers to accessing and using assistive technology for individuals living with chronic health conditions.

This objective was achieved through conducting a meta-synthesis of the current scientific literature within Chapter 2. The meta-synthesis presented a clear summary of the common barrier's individuals with a range of different chronic conditions face in accessing and using assistive technology, identifying how barriers were common across different health conditions.

2) Identify the current evidence gaps related to increasing end-user involvement in the design and provision of customised assistive devices through reviewing the current scientific literature.

This objective was achieved through the literature review conducted in Chapter 3. The chapter reviewed three methodologies to increase user involvement in the design and provision of custom assistive devices: DIY practices, co-design methodologies and current use of small-scale design and manufacturing technologies within healthcare settings. The chapter summarised current limitations in the evidence around these methodologies and thus identified further research opportunities applicable for both the current research thesis and other researchers working within the field of assistive technology.

3) Investigate if co-design can be implemented within a current healthcare service to provide customised assistive devices for individuals with a range of chronic health conditions.

This objective was achieved through the service evaluation and research trial conducted in chapters 4 and 5 respectively. The results demonstrated that co-design could be used to provide custom assistive devices within a current NHS healthcare service, utilising the individuals and equipment currently present in such a service. The co-design methodology was successful in providing a wide range of assistive devices for different upper-limb functional tasks for individuals with different chronic health conditions. From the findings of this research, a service blueprint has been developed for further implementation and testing of co-designing customised assistive devices within healthcare services.

4) Evaluate the impact for the individual and the implications for healthcare services of providing customised assistive devices using the co-design method through mixed methods analysis of questionnaires and semi-structured interviews.

This objective was achieved through the service evaluation and research trial conducted in chapters 4 and 5 respectively. A mixture of standard assistive technology questionnaires, health questionnaires and semi-structured interviews were used to evaluate the impact. For the individuals, results showed a positive use of the assistive devices long term, with implications for improvement in physical and mental health and wellbeing, as previously discussed. For healthcare services, results presented an indication for the resources and costs involved in such a process. Results from Chapter 5 also looked to measure any reduction in healthcare services being accessed, although further work is required for this with a larger sample size and longer-term follow-up. The mixed-methods analysis completed within this thesis to evaluate the wider impact of providing customised assistive devices, with a focus on health and wellbeing, was beyond that captured in any previous research within this research area and represents a significant contribution to the scientific literature.

5) Investigate if a previously co-designed device can be re-used to meet the need of other individuals through provision of the Sativex spray holder.

This objective was achieved through the service evaluation conducted in Chapter 6. The results demonstrated the Sativex spray holder was successfully able to be used long-term for other individuals with similar needs to the individual who the device was originally designed. The chapter demonstrated how the device could also be modified to meet an individual's needs and summarised the service costs involved within the provision and modification process. It thus demonstrated that previously co-designed devices can be re-used and modified within a resource efficient process to meet the needs of others.

In summary this thesis aimed to improve the access to and use of assistive technology for individuals living with chronic health conditions through involving individuals in the design and development of customised assistive devices.

This thesis has successfully improved the access and use for those individuals involved within the research, producing novel assistive devices for which individuals for previously there were no solutions available. Therefore, for this small population of adults with chronic health conditions the long-term use of assistive technology has been improved. More widely, the results from this thesis provide a framework for further implementation of the co-design methodology within healthcare services to further improve the access and use of such assistive devices. Key areas for future research that expand upon these findings have been identified and are presented below. Further work is required to build upon the initial positive results from this finding about how user-involvement in the design can improve access to and use of assistive technology. The initial aim of the research has been achieved in the context of what was achievable within this thesis.

7.5.3 Recommendations for future work

This section will summarise a number of key recommendations for future work to expand upon the findings of this thesis.

Recommendation 1: Investigate the wider demand for customised assistive devices, including exploring opportunities to co-design other types of assistive technology, for example electronic and digital solutions.

One aspect not measured within this research is the current and future demand for such customised assistive devices. This was due to the design of the research studies conducted focusing on evaluating the co-design methodology and thus limited by small sample sizes. The devices created were also focused on simple, mechanical, physical devices due to the skill set and experience of the researcher. It thus did not consider any electronic or digital solutions, the challenges such devices could be designed to overcome and if co-design could be used to produce these types of devices. Future research is thus required to assess the wider demand for customised assistive devices and the range of solutions required.

Recommendation 2: Evaluate the long-term implications for individuals of co-designing devices with them, investigating the long-term use of devices, impact on health and wellbeing and any changes to accessing health and social care services.

The exploratory nature of the research studies within the time and resources available limited the follow-up period with participants to assess the long-term impact of co-designing devices. Additionally, the small sample sizes limited some of the statistical analysis undertaken. Future research is required to: (a) record if devices are still being used long-term after the study, for example 1 year after, (b) if there are any other changes in health and wellbeing, for instance are the improvements previously summarised sustained long-term or do outcomes return to pre-intervention levels and (c) assess if there any long-term changes in health and social care services accessed by participants. A larger clinical trial, with a longer follow-up period, is thus required to evaluate the long-term implications of co-designing customised assistive devices across a larger sample. This will help assess the healthcare 'value' of co-designing customised assistive devices.

Recommendation 3: Evaluate the long-term costs for healthcare services related to the on-going costs required to support individuals' and their customised assistive devices.

One methodological limitation of the current research was that it only recorded resources up to the point of final device provision and did not look at the long-term costs. This was partly due to the limited long-term follow-up associated with the research studies (as discussed above). However, the provision of assistive technology does not stop at the point of delivery of a product/device and should include follow-up, reviewing of patients and replacing devices. Further research is therefore required to record the on-going costs to healthcare services associated with co-designing customised assistive devices, including further modifications to designs, the repair and replacement costs and long-term follow-up. This should be incorporated into larger clinical trials as discussed previously.

Recommendation 4: Investigate approaches to further improve the efficiency of the co-design process to help with the wider scaling-up of the co-design methodology, including the further use of digital design and manufacturing technologies.

Results have indicated the reduction in costs associated with re-using and modifying designs and the efficiency gains through greater experience of co-designing devices. However,

results from the feasibility study (Chapter 5) still show how a significant proportion of the cost (86%), was associated with the cost of the clinician's time in providing devices. Whilst some of this time was for clinical appointments that would not necessarily want to be any shorter, a proportion of this time was spent in the design and manufacturing process (e.g. not with patients). There is the potential for digital design and manufacturing to further improve the efficiency of this part of the co-design process. For example, through utilising modular and parametric designs and enabling designs to be easily digitally shared and modified between different individuals and services through a digital database of designs. Future work is required to identify and evaluate tools related to digital design and manufacturing that could further improve the efficiency and reduce the costs of the co-design process.

Recommendation 5: Evaluate the co-design process across different services, geographical locations and by different healthcare professionals to refine the blueprint for future co-design assistive technology healthcare services.

This research has been limited in being conducted by a single individual in a single healthcare service setting. It is thus not clear the extent to which the co-design methodology could be used by other healthcare professionals and if results were dependent on the knowledge of the researcher. Similarly, how well this methodology relates to other healthcare services and other geographical locations has not been considered within the current research. It would be anticipated that other individuals with similar clinical experience to the researcher (e.g. rehabilitation engineer/clinical scientist), would be able to follow and apply the co-design methodology, however further evidence is required to evaluate this. Further research is thus required to test the use of the co-design service model blueprint proposed in Section 7.5.1 by other healthcare professionals both within and external to the healthcare service where this was conducted. This will help refine the service blueprint for co-designing customised assistive by healthcare services, improving access to such a service.

7.5.4 Contributions to knowledge:

This final section summarises the key contributions to the scientific literature resulting from this thesis. A total of six key contributions have been made to the scientific literature, based on previous identified shortcomings in previous research:

- This research has identified the barriers individuals face in accessing and using assistive technology, identifying how barriers were common across a range of different chronic health conditions.
- This research has identified research opportunities based on shortcomings in the current literature related to the customisation of custom devices, including relating to DIY practices and the co-design of custom assistive devices.
- This research has tested and evaluated the use of co-design to produce custom assistive devices within a current healthcare setting, evaluating the wider impact on the individual's health and wellbeing through conducting mixed-method analysis. The research has reported on the resources required to co-design customised assistive devices within a healthcare setting, exploring how re-using of devices and greater experience can reduce associated costs. This research has explored how previously co-designed devices can be re-used and easily modified to meet the needs of other individuals.
- Finally, this thesis has presented a service blueprint for the further implementation of co-designing custom assistive devices within a healthcare setting which can be implemented within other healthcare services.

8 Appendices

8.1 Appendix A: SQUIRE 2.0 checklist for Chapter 4

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) checklist for Chapter 4. Accessed from: Ogrinc G, Davies L, Goodman D, Batalden PB, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. BMJ Quality and Safety. 2016 Volume 25, Issue 12: pp. 986 – 992. (Ogrinc et al., 2016).

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	✓
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	n/a n/a *Article abstract not included in thesis*

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	✓
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	✓
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	✓
6. Specific aims	Purpose of the project and of this report	✓
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	✓
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	✓ ✓
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	✓ -
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	✓ ✓ ✓
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	✓ ✓
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	✓

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project	–
	b. Details of the process measures and outcome	✓
	c. Contextual elements that interacted with the intervention(s)	–
	d. Observed associations between outcomes, interventions, and relevant contextual elements	–
	e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	✓
	f. Details about missing data	✓
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims	✓
	b. Particular strengths of the project	✓
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes	✓
	b. Comparison of results with findings from other publications	✓
	c. Impact of the project on people and systems	✓
	d. Reasons for any differences between observed and anticipated outcomes, including the influence of context	–
	e. Costs and strategic trade-offs, including opportunity costs	✓
16. Limitations	a. Limits to the generalizability of the work	✓
	b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	✓
	c. Efforts made to minimize and adjust for limitations	✓
17. Conclusions	a. Usefulness of the work	✓
	b. Sustainability	✓
	c. Potential for spread to other contexts	✓
	d. Implications for practice and for further study in the field	✓
	e. Suggested next steps	✓
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	✓

8.2 Appendix B: COREQ checklist for Chapter 4

The Consolidated Criteria for Reporting Qualitative Studies (COREQ): 32-item checklist for the qualitative data from the semi-structured interviews is reported in Chapter 4. The checklist was developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357 (Tong et al., 2007).

No.	Item	Description	Page number
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	**98**
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	**96**
3.	Occupation	What was their occupation at the time of the study?	**96**
4.	Gender	Was the researcher male or female?	**96**
5.	Experience and training	What experience or training did the researcher have?	**96**
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	**98-99**
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? *E.g. Personal goals, reasons for doing the research*	**96,98-99**
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *E.g. Bias, assumptions, reasons and interests in the research topic*	**96**
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and theory	What methodological orientation was stated to underpin the study? *E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	**101**
Participant selection			
10.	Sampling	How were participants selected? *E.g. purposive, convenience, consecutive, snowball*	**98-99**
11.	Method of approach	How were participants approached? *E.g. face-to-face, telephone, mail, email*	**98**
12.	Sample size	How many participants were in the study?	**96**
13.	Non-participation	How many people refused to participate or dropped out? What were the reasons for this?	**N/a**
Setting			
14.	Setting of data collection	Where was the data collected? *E.g. home, clinic, workplace*	**99**
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	**99**

16.	Description of sample	What are the important characteristics of the sample? *E.g. demographic data, date*	**96**
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	**99**
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	**99**
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	**99**
20.	Field notes	Were field notes made during and/or after the interview or focus group?	**99**
21.	Duration	What was the duration of the interviews or focus group?	**99**
22.	Data saturation	Was data saturation discussed?	**115**
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	**N/a**
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	**101**
25.	Description of the coding tree	Did authors provide a description of the coding tree?	**106**
26.	Derivation of themes	Were themes identified in advance or derived from the data?	**101**
27.	Software	What software, if applicable, was used to manage the data?	**101**
28.	Participant checking	Did participants provide feedback on the findings?	**N/a**
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *E.g. Participant number*	**106-110**
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	**106-110**
31.	Clarity of major themes	Were major themes clearly presented in the findings?	**106-110**
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	**106-110**

8.3 Appendix C: Consent form for service evaluation

Swansea University
Prifysgol Abertawe

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

Patient Consent Form

Name of Clinician: Jonathan Howard

Please initial box

1. I confirm that I have read and understand the information sheet provided "Co-designing personalised aids of daily living (version 1). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care being affected. ☐
3. I understand that individual interviews for the purpose of evaluating the service provided will be audio recorded. ☐

We are looking to use the results from this work for the following purposes:

i) Publication of this work in scientific journals, presentations conferences and as part of a PhD thesis submission to further expand on the scientific body of evidence in this field.
ii) Use for teaching and training purposes for healthcare staff, public engagement events and university teaching
iii) To illustrate the types of work we are doing for the purpose of growing and promoting this type of work for the benefit of other patients.

For these purposes we may wish to use certain information relevant to your medical and social history to give context to our results. However all personal identifiable information, for example your name, will be anonymised.

4. I understand that relevant medical information may be used for the purposes of this work and agree for this information to be used for the purposes stated. ☐

Optional

We may wish to use photographs and video recordings to document this work. Where possible all videos and photos will be taken without revealing your identify by not showing your face. However this may not always be possible and it may mean that you become recognisable. You do not have to give permission to be videoed or photographed and doing so will not impact on your involvement in this research.

5. I understand I may be recognisable from any videos and photos taken. ☐
6. I give my permission for video recordings and photography to be used for the purposes stated above. ☐

7. I agree to take part in the service evaluation. ☐

Name of Patient (Please Print)

.....

Signature of Patient ..... Date .....

Date 16/09/2020 Version One Author: Jonathan Howard

8.4 Appendix D: Participant consent form and information sheet for feasibility study – Chapter 5

Swansea University
Prifysgol Abertawe

Participant Consent Form

Research Title: Co-designing personalised aids of daily living with users with chronic conditions: a feasibility study

Name of Chief Investigator: Professor Jeremy Tree (Swansea University)

Please initial box

1. I confirm that I have read and understand the information sheet dated: 06/04/2020, version 3.0 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant information from my medical records will be shared with the research team where it relates to details about the use of assistive technology. I give permission for this information to be shared. ☐
4. I understand that videos recordings and/or photographs may be taken and stored as part of my clinical record and I may be recognisable from the video recordings or photographs taken. ☐
5. I understand that individual interviews for the purpose of evaluating the study will be audio recorded. ☐
6. I agree to take part in the study. ☐

Name of Participant (Please Print)

……

Date…… Signature……

Name of healthcare professional taking consent

……

Date…… Signature……

Profession ……

OPTIONAL:

Following completing of the study we are able to send you a summary of the findings from this study. Please circle if you would like a summary sent to you.

YES NO

If YES please circle to indicate preference for email or postal address

Email address OR Postal Address

OPTIONAL: - This section is optional and your response will not impact your involvement in this research or any present or future care

I give permission for video recordings and photographs to be used for the following purposes and understand I will be anonymised, such that I am not identifiable, for these uses:

i) Publication of this work in scientific journals, presentations at conferences and as part of a PhD thesis submission. ☐

ii) For teaching and training purposes for healthcare staff, public engagement events and university teaching ☐

iii) To illustrate the types of work we are doing for the purpose of promoting this type of work for the benefit of other patients. ☐

Name of Participant (Please Print)

.....

Date..... Signature.....

Swansea University
Prifysgol Abertawe

Participant Information Sheet: Co-designing personalised aids of daily living, a feasibility study

This is a student project being led by Jonathan Howard; funded by Swansea University and hosted by Swansea Bay University Health Board's Rehabilitation Engineering department.

Swansea University and the psychology department would like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you to help you decide whether or not you would like to take part and to answer any questions you may have. We'd suggest this should take about 20 minutes. Please feel free to talk to others about the study if you wish. The first part of the participant information sheet tells you the purpose of the study and what will happen if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear.

Introduction: We are looking to explore solutions for individuals who need more personalised assistive devices to overcome challenges they face in daily life. We are primarily looking at simple, low tech solutions that will act as aids of daily living. If you chose to be involved we will ask you to meet with the researcher over a number of appointments. In the appointments we will ask you about day-to-day difficulties you experience and together we can think and develop device ideas to help meet your needs. Through this work we are looking to explore a range of personalised assistive technology solutions that are required and how we could go about providing such devices in the future.

This study forms part of a wider research PhD exploring the ways more personalised assistive technology solutions can be provided to improve independence, health and wellbeing. Jonathan Howard is the principal investigator for this study. He is currently undertaking a PhD funded by Swansea University and works as a Clinical Scientist in the Rehabilitation Engineering at Swansea Bay University Health Board. The work is being overseen by Professor Jeremy Tree (chief investigator, Department of Psychology, Swansea University), Dr Zoe Fisher (Consultant Clinical Psychologist, Community Brain Injury Service, Swansea Bay Health Board), Dr Lorna Tasker (Consultant Clinical Scientist, Rehabilitation Engineering Department, Swansea Bay Health Board) and Dr Mark Bowtell (Principal Clinical Scientist, Rehabilitation Engineering Department, Swansea Bay Health Board).

What is the purpose of this study?: This study seeks to assess the feasibility of co-designing assistive technology devices with the end-user. Specifically, we want to:

a) Explore the range of different custom assistive devices that are required by people that are not currently available.
b) Evaluate the methods used for designing and providing the devices and seek how we can improve these processes for the future.
c) Evaluate the long-term implications of using the customised assistive devices provided.

Your input in this study will help inform the design of future research studies and NHS services. This helps us ensure that our NHS services are designed and run to meet the needs of those accessing and

using the services. Before we tell you more about the study, we will briefly explain a few terms that you will need to be familiar with to understand whether you would like to take part in our research study.

What is assistive technology?: Assistive technology refers to both physical products and digital applications whose main purpose is to maintain or improve an individual's everyday abilities, promoting independence and wellbeing. Assistive technology refers to a wider range of products from complex high-tech devices to very simple accessories and devices.

In this study we will be primarily focusing on simple, low-tech physical devices. At this stage we are unable to provide any more specific detail about the types of devices we will produce as part of this work is to explore the types of devices required. Examples could include devices for eating & drinking, taking medication, dressing, personal hygiene and other daily activities and hobbies you are interested in.

What is co-design?: Co-design is a method used in the design of products, where the person who will be ultimately be using a device works alongside the designer to create a product that works for them.

In this study, we will invite you to work with the researcher to help design your own device that will hopefully be able to overcome challenges you face in daily living. We hope the device can help make you more independent or increase participation. Specially we want your input in:

- Describing the challenges you face to help identify where an assistive device may be needed
- Involvement in defining the requirements for the device.
- Involvement in the decision making processes for the design, testing out different design ideas and providing feedback on the design in order for improvements to be made
- A final evaluation of the device.

Why have I been invited to take part?: You have been invited to participate because you have been identified by one of your healthcare providers as someone who may benefit from a customised device and have shown interest in participating.

What will happen to me if I take part and what will I have to do:? The diagram below (Figure One) is a guide to what will happen if you decide to take part. If you would like to consider taking part, your healthcare professional will pass your contact details onto the principal investigator, Jonathan Howard, who will then contact you to arrange a convenient time to go through this information sheet and confirm if you would like to take part in this study.

We expect your involvement to last 3-4 months and will involve a series of 4-6 appointments over this time frame. The appointments should last between 30 minutes to 1 hour. However the exact number and length of your involvement may vary depending on the complexity of the work, for example it may take less time or it may take more time.

Three months following the final appointment we will arrange a follow-up with you to gain feedback about the solution provided and how you found the involvement in this work. This follow-up will be audio recorded and transcribed. All personal and identifiable information that could identify you will be removed during the transcribing process. Photographs or video may also be taken.

Figure One: A guide to what will happen to you if you decide to take part.

Invitation: You will be invited to take part in the study by your healthcare provider. You will be provided the information sheet (this document) for you to read to consider if you would like to participate. You'll be asked to consent for your contact details to be passed onto the principal investigator.
↓
Arrange appointment: The principal investigator will contact you to arrange the initial appointment.
↓
Appointment 1: (Information and consent) 1 week
Questions and consent: The researcher will go over the participant information form and answer any questions you have about this study. You will then be asked to give your consent by completing the consent form if you are happy to participate in this study. This will take approximately 30 minutes.
↓
Appointment 2: (initial assessment) 1 week
Initial assessment: The researcher will ask you to explain about your medical and social history, daily routine, challenges in daily living and any current/previous solutions used. This will be used to explore ideas about the type of custom device that may be required. Additional healthcare professionals may be invited to participate in this appointment if you wish.
↓
Appointment 3: (Initial design ideas) 1-2 week later
Discussion: You will help the researcher to discuss initial design thoughts and ideas, look at simple design sketches and prototypes ideas. You will be asked to provide feedback on these ideas in order for the researcher to further refine the design ideas and generate prototypes. This will be an interactive discussion session where the researcher is wanting to capture your input and ideas. This appointment will take approximately 1 hour. Following on from the appointment the researcher will generate further design ideas, create computer models, and manufacture different prototypes for you to try.
↓
Appointments 4-6: (Trial and refinement) at 2-3 week intervals
Discussion: During this series of appointments the researcher will provide different designs for you to trial out. You will be able to provide feedback on the different designs and how they could be improved upon. The researcher will use your feedback to make changes to the design for you to trial again. These appointments are expected to last approximately 30-60 minutes. ***The exact number of appointments is likely to vary here for each individual.***
↓
Appointment 7: (Device issue) 2 weeks later
Training: Once the design has been refined to a level you and the researcher are happy with, a final solution will be manufactured. The researcher will provide any necessary training and any instructions for safe usage of the final device and answer any questions you have. This will take approximately 30 minutes.
↓
Initial feedback: The researcher will be seeking to capture your initial feedback on the final device provided. The researcher will provide you with two questionnaires to complete. The researcher will also ask you to complete a semi-structured interview; this will be audio recorded. This will take around 30 minutes.
↓
Appointment 8: (Feedback session) 3 months later
Feedback: The researcher will conduct a second semi-structured interview with you to obtain your feedback on the solution provided and how you found the process. You will also be asked to complete the two questionnaires again. This appointment will take approximately 1 hour, and the semi-structured interview will be audio recorded for analysing by the researcher after the session.

Where will the visits take place?: Due to COVID-19, where possible the majority of appointments will occur virtually using a video consultation programme called Attend Anywhere. Information on how to access an appointment through this will be provided when you are invited to your first appointment. To use Attend Anywhere you require a device with internet connectivity, this can be a computer, laptop, smart phone or tablet device. We may also use other online video conferencing programmes for example Microsoft Teams. If these are used, information will be provided to you on how to access these prior to any video calls taking place.

The researcher will mainly contact you using telephone or email to arrange appointments and is able to use whichever method you prefer. You may occasionally be required to send measurements and/or pictures to the researcher to help with the design of the device. During the study devices will be mailed out for you to trial. Training and/or instructions will be provided on how to use the device prior to it being sent out.

It is possible that during the study a face-to-face appointment may be required to assist in the design of the device. Face-to-face appointments are entirely optional and will occur at a place of your choosing; either at your home or in a fully accessible clinic room in the Specialist Rehabilitation Centre at Morriston Hospital, Swansea. All COVID-19 precautions will be followed by the researcher, following the latest guidance from Welsh Government and Swansea Bay University Health Board's guidance. Additional detail will be provided by the researcher prior to any face-to-face appointments. Unfortunately, we will not be able to reimburse you for any travel expenses as a result of attending any face-to-face appointments related to your involvement in this study.

Will a solution definitely be provided?: Unfortunately we cannot guarantee that a solution will be provided to you. This may be because we lack the resources, equipment or expertise to provide an appropriate solution. Whilst we hope this does not occur, it will form an important outcome of this study in defining our current limitations. If this proves to be the case we will work with you to provide the best possible solution with the resources available to us and we hope you still gain some benefit from being involved in this study.

What if I change my mind about what I need during the study?: This is perfectly acceptable and in part will be expected to happen as you work with the researcher and learn more about the type of devices that are possible. In such instances the researcher will discuss these ideas further and, if possible, look to incorporate into the solution(s) provided. However, in some instances this may not be possible if for example a challenge is identified near the end of the study or depending on the resources available.

What happens to devices after the end of the study? After the end of the study you are able to keep and use the device(s) that have been designed for you. The researcher will do their best to support you if you have any queries of issues for a short period following the issue of the device. However, due to limitation of the study's funding this may not be possible.

Unfortunately, long-term replacement devices will not able to issued due to limitations in current service provision. If successful, it is hoped the results from this study may help support a service being able to provide personalised assistive devices in the future.

Will taking part affect my standard care? No, taking part in this study will not impact on any standard care and treatment you are currently or will receive in the future from any other healthcare service.

Confidentiality

Across all aspects of the study your information will be kept strictly confidential. However, there are some instances when a member of the research team who is collecting data might have to break confidentiality. For instance, if a participant discloses information which indicates they may be a risk to themselves or to others, or any information is disclosed about someone else who may be a risk to the safety of someone else. Where possible, you will be informed if confidentiality needs to be broken. Table One gives examples when confidentiality would need to be broken and who might be informed.

Table 1: Examples when confidentiality would need to be broken and who might be informed.

Type of Disclosure	Who might be informed
Malpractice by staff	Senior manager in the relevant health board/ University and study sponsor when appropriate
Potential risk of harm to self	General Practitioner
Potential risk of harm to others	Social Service/ police

What will happen to the results of the study?: It is hoped that the results of the study will be published in a scientific journal. You will not be identified in any report or publication related to this study. We may include some images of any devices produced, but you will not be identifiable from any images. If you wish to receive a summary of the results then you can either complete the part of the consent form or contact the principal investigator who will be able to share this with you.

Do I have to take part?: It is entirely up to you to decide to join the study. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This will not affect the standard of your current or future care. If you do not want to take part for any reason, this is no problem at all and has no implications for you whatsoever.

What are the benefits of this research: A benefit of being involved in the study is an opportunity to contribute to research designed to improve future service provision. The potential benefit for you is the opportunity to use a new device intended to help you overcome a challenge you face. However, it should be made clear that the study is being carried out to find out if this new method is helpful and effective, although it may not be.

What are the possible disadvantages and risk of taking part: Taking part in the research will involve your time to engage and interact with the researcher to provide feedback during the design and development of any device. It will also require some time to complete the questionnaire and interviews

following a device being issued to you. We have tried to keep the number of assessment tools to the minimum needed to answer our research questions.

Any device provided to you for trialling are prototypes, and whilst they have been designed following good-engineering practice to minimise the risk, there is a potential for minor injury if the device is mis-used outside the use recommended by the researcher.

During the appointments and feedback sessions, some of the questions may be sensitive or upsetting for you to answer. The majority of questions you can expect should be typical of any medical appointment, for example questions about your medical background. In addition, we will look to gather demographic information, to characterise who is involved in the study, and questions in relation to healthcare services you have recently accessed. This information helps us to understand any changes in the healthcare resources you access prior to and after involvement in the study.

If any question or topic is upsetting you can either discuss with the researcher at the time, arrange a subsequent appointment to discuss or the researcher can refer you on to other healthcare professionals to provide support. All interactions will involve a qualified healthcare professional and as such any information you share will be kept and stored in strict confidence (except in exceptional circumstances described above).

How will we use information about you? We will need to use information from you for this research project. This will include your name, age, NHS number, contact details and medical diagnosis. People will use this information to do the research or to check your records to make sure the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Personal data will be stored on a password protected database in accordance with General Data Protection Regulations and Good Clinical Practice Guidelines. On this database your name will be cross referenced with a unique research number. This information will be stored on the secure NHS network at Swansea Bay University Health board.

Anonymised data: The remainder of the information collected about you during the study (notes, questionnaire data and interview data) will contain only your research code and not your name. This fully anonymised data will be stored on secure NHS network at Swansea Bay Health board and a copy will be emailed to members of the research team at Swansea University for analysis and write up. Anonymised electronic data will be stored on Swansea University network.

Interview data: The semi-structure interviews at the end of the study will be audio recorded. This data will be stored on a secure NHS network at Swansea Bay Health Board and deleted from the device it was recorded on. The audio recordings will be transcribed by a member of the research team. Once the data has been transcribed we will delete the audio recordings. In the final write up of the study we will use direct quotations from the semi-structure interviews. However, no information will be included that could identify you

Storage of the data when the study has ended: All records of your name or personal information held by the health board regarding your involvement in the study will be destroyed 5 years after the study has ended. The anonymous data will be stored electronically for 5 years before being deleted. Fully anonymized data held at Swansea University will be deleted after 10 years.

What are your choices about how your information is used: You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used? You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/
- Our GDPR leaflet available from Jonathan Howard, principal investigator
- https://www.swansea.ac.uk/about-us/compliance/data-protection/

What will happen if I don't carry on with the study?: Participating in this study is entirely voluntary and you can stop being part of the study at any time, without giving a reason. If you decide to withdraw or do not wish to be involved in this study it is important to understand this will not affect the level of care you are receiving currently or in the future.

Who is organising and funding the study?: Swansea University is sponsoring this study and is being run in collaboration with healthcare professionals from Swansea Bay University Health Board.

What if there is a problem: If you have a concern or wish to make a complain about any aspect of the study, please contact the following:

For data issues: The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data, and can be contacted at the Vice Chancellors Office: dataprotection@swansea.ac.uk. Your personal data will be processed for the purposes outlined in this information sheet.

For health issues please contact the health watchdog:

SBU Community Health Council
First Floor, Cimla Hospital, Neath , SA11 3SU
Tel: 01639 683490 http://www.wales.nhs.uk/sitesplus/902/home

For management issues contact the head of the College of Human and Health Sciences, Keith Lloyd, at Swansea University at: meddean@swansea.ac.uk

Alternatively you can contact Professor Jeremy Tree (chief investigator) at Swansea University (01792 602908 or j.tree@swansea.ac.uk)

Swansea University
Prifysgol Abertawe

Who has reviewed the study: All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Wales Research Ethics Committee 7.

Further information and contact details: For further information about this study, please contact Jonathan Howard (Principal Investigator) at:

01792 703609
[redacted]

Rehabilitation Engineering Unit
Specialist Rehabilitation Centre
Morriston Hospital
Swansea
SA6 6NL

8.5 Appendix E: IRAS application form for Feasibility study – Chapter 5

IRAS Form | Reference: 21/WA/0097 | IRAS Version 5.19

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Co-designing personalised assistive technology

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(•) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a UKCA/CE UKNI/CE Mark, or a UKCA/CE UKNI/CE marked device which has been modified or will be used outside its intended purposes?

(•) Yes ( ) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(•) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(•) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(•) No

Date: 03/03/2021 | 1 | 266195/1487926/37/600

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ○ England
- ○ Scotland
- ◉ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):

The student will be Principal investigator in the project for the fulfillment of a PhD with Swansea University.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(●) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Integrated Research Application System
Application Form for Other clinical trial or investigation

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Co-designing personalised assistive technology

Please complete these details after you have booked the REC application for review.

REC Name:
Wales REC 7

REC Reference Number:
21/WA/0097

Submission date:
03/03/2021

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Co-designing personalised aids of daily living with users with chronic conditions - a feasibility study

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Mr	Jonathan	Howard

Address [redacted]

Post Code

E-mail

Telephone

Fax

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:

Doctorate in Philosophy - Ph.D (Psychology)

Name of educational establishment:
Swansea University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Jeremy	Tree
Address	Room 725, Vivian Building, Department of Psychology Singleton Park, Singleton Swansea		
Post Code	SA2 8PP		
E-mail	J.Tree@swansea.ac.uk		
Telephone	01792602908		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Jonathan Howard	☑ Professor Jeremy Tree

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Jeremy	Tree
Post	Professor of Neuropsychology and Director of Research (College of Human and Health Sciences)		
Qualifications	PhD, MSc, BA Hons		
ORCID ID	0000 0001 6000 8125		
Employer	Swansea University		
Work Address	Psychology Department, Vivian Tower Singleton Campus, Singleton Park Swansea		
Post Code	SA2 8PP		
Work E-mail	j.tree@swansea.ac.uk		

* Personal E-mail
Work Telephone 01792602908
* Personal Telephone/Mobile
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

Title	Forename/Initials	Surname
	Paola	Griffiths

Address [redacted]
Post Code
E-mail
Telephone
Fax

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	RIO 008-21
Protocol Version:	V2
Protocol Date:	26/02/2021
Funder's reference number (enter the reference number or state not applicable):	Not applicable
Project website:	

Registry reference number(s):
The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):
ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Assistive technology is an important tool in helping people maintain independence, allowing them to actively participate in education, work, and society. If maximised to its full potential there would be significant health and wellbeing benefits for individuals, reduced reliance on formal health and social care services and reduced healthcare costs. However, current equipment is often unsuitable in meeting an individual's needs. Previous review work by the research team highlighted issues with the design, function, and service provision of assistive technology as barriers to its use. Two specific barriers, a lack of equipment customisation and a lack of end-user involvement in the provision process, are the focus of this work.
This research aims to assess a new method that provides personalised assistive technology to individuals. The method will actively engage participants to input into the design of their own assistive device(s) to help them overcome their challenges of daily living. This method will help enable the device to be customized to their needs, a process known as co-design. Participants will be recruited from Swansea Bay University Health Board with a range of long-term physical health conditions whose current needs are unable to be met by current standard and off-the-shelf assistive technology solutions.
Participants will be involved in up to 6 interactive sessions spread over 3 months with the researcher. In the initial session the researcher will work with the participants to identify challenges in daily living for the device to overcome. In subsequent sessions, the researcher will design different solutions for the participant to try and feedback on, enabling the design to be adapted to the participants needs. Finally, the participants will evaluate the device provided through questionnaires and individual semi-structured interviews. This feedback will help assess the effectiveness of co-design and its feasibility to be incorporated into future NHS services.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

PURPOSE AND DESIGN OF STUDY:
A previous meta-synthesis was conducted to summarise the barriers to accessing and using assistive technology. Amongst the barriers identified were a lack of customisation of devices to an individuals needs, lack of end-user involvement in the design process of assistive devices and a patients not being involved in decisions about their care. The design of this study looks to address these barriers by asking the participants what challenges are most important to them and then continuously involving them in the development of the assistive device. The methodology aligns with co-production strategies for involving and empowering patients to make decisions about their own care. The study design builds upon three previous case-study examples run by the researcher involving co-designing aids of daily living. The previous case study participants were referred into the Rehabilitation Engineering Unit. Experience gained by the researcher and feedback from participants during the case-studies was used to refine the design of the current study. This study differs from the previous case-study examples by:
- Looking to actively recruit from a range of different services within the local Health Board to assess the broad range of challenges that different individuals identify and if a co-designed device can overcome these challenges. Previous case-studies involved participants referred into the Rehabilitation Engineering Unit, however using this recruitment strategy would provide insufficient numbers for this study.
- Recruiting a larger sample size to evaluate the co-design methodology. To date, there is no published scientific literature reporting the use of co-design for the sample size selected. A larger sample size will help provide a more accurate reflection of the cost and resources required to co-design within a healthcare setting to help assess the feasibility of this method of working for future healthcare services.
- Follow-up assessment with participants to assess the potential impact of the device has had on overcoming the challenges and on their overall health and wellbeing. This will use a mixture of standardised questionnaire measures and qualitative semi-structured interviews.

With the ongoing COVID-19 pandemic, the design of the research reflects the need to limit face-to-face contact as much as possible. Therefore, the use of virtual video consultants will predominantly be used for all appointments with the participant. Previous case-study work used virtual appointments for all appointment with participants. Feedback from the case studies indicated participants liked the virtual appointments as it:
- Reduced face-to-face contact, especially with concerns over COVID-19 and wanting to avoid travelling to a hospital for appointments
- Avoided the need for excess travel by participant.
- Enabled appointments to be arranged at a more convenient time for them, with less time required for appointment/travel to appointment.

RECRUITMENT
Participants will initially be approached by a member of their current clinical team and asked if they would be interested in taking part in the study. At this stage they will be provided with the participant information leaflet to go through with a member of their clinical team.
If they would like to consider taking part, they will consent for a member of their clinical team to pass on their contact details over to the principal investigator. Only limited contact details will be passed over to the principal investigator. Participants will be given at least 1 week prior to meeting with the principal investigator to go through the information and decide if they would like to take part.
It is clearly stated in both the participation information and consent form that their participation is voluntary, and they are free to withdraw at any time without consequence.

INCLUSION/EXCLUSION CRITERIA
Clear inclusion and exclusion criteria have been developed so that clinicians can appropriately identify and approach potential patients with information regarding the study and can do so with reasonable confidence that the individual will meet the criteria for inclusion. Importantly, one inclusion criteria is that potential participants must not have significant communication, behavioural or cognitive impairments to such a degree that it would prevent them from engaging in the study. This will minimise the risk of distress associated with being unable to engage in the study.

An inclusion criteria of at least three-month post injury/diagnosis at the point of recruitment was used to allow time for spontaneous recovery and for the person to become aware of the challenges they face and the implications of this on their lives. Less than three months, a device is unable to be provided in a reasonable time frame such that the individuals goals and challenges are likely to change. This could lead to distress for the individual if a device is no longer suitable to meet their changing needs.

A purposeful broad criterion is chosen with regard to different health conditions. Previous case-study work we have conducted has already shown the co-design methodology can be applied to a wide range of health conditions (previous: congenital birth defects, traumatic injury to hand resulting in amputation of fingers, multiple sclerosis). The study is designed to work with the individual and the individual challenges they face, this is largely independent of an individual's health condition. Thus targeting specific health condition(s) would limit the aims of the study in assessing the range of different devices required and provide unnecessary bias and inequality in the study design and results.

CONSENT
Participants will be excluded from the study if they are unable to provide informed consent. Participants' capacity to remain in the study will be monitored throughout the different stages of the study by the principal investigator. This ensures that all participants can fully consent to participation and can decide to withdraw at any point.

All consent will be sought by the principal investigator, a registered clinical scientist, who routinely takes consent as part of their clinical practise.

RISK, BURDEN & BENEFITS

Harm to participants through incorrect usage of device: Devices will be designed to meet a particular need/function and if the device is used outside of the intended scope of the device it has potential to cause harm to the participant or other individuals. Instructions and training will be provided on the correct usage of the device prior to any device being sent out to the participant. Feedback from the participant will help reduce the risk of incorrect use.

Harm to participant through device failure during expected use: Devices may fail even during expected usage due to issues with the device design, manufacturing process, storage or transportation. Device failure may cause minor injury/harm, loss of confidence and distress. This risk is highly unlikely with all devices being manufactured according to the Quality Management System of the Rehabilitation Engineering Unit (working toward ISO 13485 certification).

This includes appropriate risk assessment and risk management strategies for each device produced relating to the design, manufacturing, storage and use of devices. Where appropriate bench testing and computational simulation may be used to help assess mechanical strength of devices and reduce risk of failure.
All devices will be designed and developed by the researcher following good engineering practise. The principal investigator is a clinical scientist with experience in designing and manufacturing bespoke assistive devices. Device concepts will be tested by the researcher prior to sending any device to participants. All devices will be quality checked prior to sending out to participants.

There is a risk that a solution will not be able to be provided to a participant due to complexity of the solution required, resources available or expertise available to produce a device. This is likely to lead to inconvenience and potential distress for the participant. This risk is clearly explained within the participant information sheet and all participants agree to this prior to undertaking the study. In an instance where a solution is not able to be produced, the researcher will work with the participant to provide a best possible compromise. Additionally, involvement in the study could still help the participant identify new and innovative ways to manage their own health, even without a device being provided.
To manage expectations and help the participants understand the types of devices that could be provided, example images from previous case-study work are included in the participant information sheet.

The focus of the study is on simple, mechanical devices assistive devices aimed to assist with activities of daily living, however the exact design and function of these devices cannot be known prior to starting the study. This is because the devices are developed based on the needs identified by participants. The quality management system will provide governance over the type of devices able to be produced and provided.
Any solutions requiring electronic components or software solutions will not be developed as part of this study as they fall outside the remit of the Rehabilitation Engineering Unit and outside of the experience and competence of the research team. If this type of solution is required, it will be explained to the participants this is outside the scope of the current research. This will be recorded and forms an important outcome of the study in identifying the limitations in current services, facilities and personnel in providing custom devices that meet the end-user needs. The researcher will continue to work with the participant to explore if any alternative solutions can be developed.

The majority of questions asked during the appointments and during the semi-structured interviews will be typically expected during any routine medical appointment, for example medical background. However there is potential that some of the questions asked during the appointments or interviews may be upsetting and cause distress to the participants. Prior notice of this possibility is documented in the participant information sheet. In these instances, the participant will have an opportunity to talk to the researcher in confidence either during the appointment or at an alternative time after the appointment. The researcher is a qualified healthcare professional. Additionally, there will be an opportunity to discuss with a member of their current clinical team.
If serious cause for concern is observed, appropriate action may include liaising with a participant's GP. A participant's consent will always be obtained before involving members of their proximal support network, unless this is not practical and there is an imminent risk of serious harm to them. In a crisis situation the researcher will notify the patients GP in accordance with clinical governance procedures.

Benefits of being involved in the study include an opportunity for the participants contribute to help create new devices that can help both themselves and potentially other future service users to overcome challenges they face in daily living. This includes increased independence and autonomy and subsequent impact on health and wellbeing. From the previous case studies, participants described how:
"For the first time [post injury] she was able to sit at the table and feel like an adult again" - a knife holder that is supported on the participants hands.
"It has been a life-saver in being able for me to help my child with their school work [for home schooling]" - a large handle which helps the participant hold pens, pencils and other household objects.
Additionally, participants can feel value in being involved in research that could help shape future service provision in the NHS.

MEDICAL DEVICES DEVELOPED FOR USE IN STUDY
The Rehabilitation Engineering Unit will lead and take responsibility for the development and provision of the devices used within this study. Devices will be manufactured under the Quality Management System of the Rehabilitation Engineering Unit (working towards ISO 13845 certification) under the UK regulations on medical devices for the in-house manufacturing of medical devices by a health institution. For this study devices will be classified as custom-made for the individual. All devices will be used 'in-house', for the use of patients within the health institution of Swansea Bay University Health Board only, and as such will not be classed as being "put on the market" (sold or transferred to another legal entity/healthcare institution). No commercial exploitation is foreseen for devices developed in this study. As the device is to be used in-house and will not be commercialised, a notification to the MHRA is not required for devices manufactured as part of this study.
This follows the guidance for 'clinical investigations and healthcare establishments' published by the MHRA and 'Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in

both cases, for use within the same health institution', January 2021, published by the Institute of Physics and Engineering in Medicine (IPEM).

All devices will be manufactured according to best engineering and clinical practise in accordance with the quality management system.

CONFIDENTIALITY
Only a single database will include patient identifiable information, and this will be stored on the secure NHS network at Swansea Bay University Health Board. This database will be password protected and the password only know to three individuals: the principal investigator and the head and deputy head of the Rehabilitation Engineering Unit. Therefore, outside of the current care team, only these three individuals will have access to personal identifiable information about participants involved in the study. The principal investigator will collate the personal information and assign the unique research number to the participants. The head and deputy head of the Rehabilitation Engineering Unit will only access the personal information in the instance the principal investigator is absent.
Medical notes and research project data, may be accessed by authorised individuals from the Sponsor, regulatory authorities or host NHS site for monitoring and auditing purposes. This is made clear on the participant information sheet.

All data stored about research participants in relation to this study, for example notes, device designs and outcome measures (questionnaire data, transcribed interviews) will only state the unique reference number assigned to the participant and will not include the individual's name. The patient will not be identifiable from any of this data. Consent forms will be stored in the patient's clinical notes. Only fully anonymised data will be sent via email to Swansea University for analysis. All audio-recordings produced during the semi-structured interviews will be transcribed and anonymised.

All patient identifiable information stored in the NHS (with the exception of entries in clinical notes) will be destroyed within 5 years of the start of the study. Fully anonymised data stored at Swansea University will be destroyed after 10 years, in adherence to university policy.

In accordance with GDPR guidelines a section will be added to the patient information form outlining what choices the patients have regarding how their research data is used. Participant information sheets will also clearly explain the limits of confidentiality and instances where this may have to be broken.

CONFLICT OF INTEREST
It is not anticipated that any conflict of interest will exist between research interests and the duty of care for the individual. The study has been designed based around current provision of care and as such is intended to be in the best interest of the participant.

At the end of the study the participant will be able to keep and use the device(s) that have been provided to them. Support from the Rehabilitation Engineering Unit will be provided for up to 1 year following the device being issued to the participant.
Unfortunately, after one year, the long-term replacement of devices will not be able to be supported due to limitations in current service provision. This information is clearly stated in the participant information sheet. Depending on the results of this study, it is hoped this study can help support justification for a service able to provide such devices in the future.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology

- [x] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [x] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

Aim: Evaluate the feasibility of using co-design to provide bespoke assistive devices with services users to overcome their challenges of daily living.

Objectives:
- Record the range of different bespoke devices required by service users with a range of (physical) chronic conditions.
- Analyse the resources, costs and time-scales for providing a satisfactory device to the participants.
- Assess the participants use and satisfaction with the assistive device provided through questionnaire and individual interviews 3 months post the device being issued.
- Evaluate the use of co-design for providing bespoke assistive technology through individual interviews with participants about the method used within this study.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

n/a

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

In the UK it is estimated that at least 30% of the population live with one or more chronic long-term health conditions. Expenditure attributed to chronic conditions has now overtaken spending on acute medical conditions (Department of Health 2012). Traditionally healthcare systems have focused on acute medical models and interventions that assume a disease is curable (Keller and Gregory Carroll 1994). For chronic conditions however, this goal is seldom possible. Instead, chronic conditions must be managed to enhance functional status, minimise distressing symptoms, prolong life through secondary interventions and enhance quality of life through care of the whole person (Grumbach 2003).

In this context we consider the role of assistive technology to assist in promoting positive self-management strategies for individuals with chronic conditions to facilitate more sustainable methods of healthcare delivery. Assistive technology refers to "any product either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing" (Khasnabis, Mirza, and Maclachlan 2015). Assistive technology can support an individual to self-manage, reducing the need for formal and informal care and enhancing health and wellbeing in individuals living with chronic conditions (Mechling 2007; Whitehead and Seaton 2016; van Ommeren et al. 2018; O'Neill and Gillespie 2014).

However, despite the potential benefits of using assistive technology, to date its full potential has not been fully realised. Cited abandonment rates for assistive technology range between 20-70% (Scherer 2014; Phillips and Zhao 1993; Martin et al. 2011; Sugawara et al. 2018). We previously conducted a meta-synthesis to identify the barriers to acquiring and using assistive technology and if these were common across different chronic conditions (Howard et al. 2020). Our findings identified 50 descriptive themes common across the different health conditions which were grouped into six analytical themes. The analytical themes are presented below:
- Societal barriers
- Awareness and information about assistive technology
- Service provision of assistive technology
- Design and function of assistive technology
- Psychological barriers
- Support network

One common barrier with the design and function of assistive technology was the lack of customisation to the user's needs (Howard et al. 2020). This meant characteristics such as shape, size, aesthetics, comfort, usability and ease of set up were not suitable for an individual's needs. One suggested solution to this is to increase the involvement of the

end-user in the design and decision making processes for the provision of assistive technology (Martin et al. 2011; Robinson et al. 2013; Orejuela-Zapata, Rodriguez, and Ramirez 2019; Alqahtani et al. 2019). Similarly within the analytical theme of service provision, a lack of patient involvement in their care and a lack of individualised care were identified as barriers to assistive technology use. It is theorised the application of co-design and co-production techniques could help overcome some of the barriers to assistive technology use.

Co-design, or participatory design, is a design methodology which actively involves the end user in the design process through collaboration with the designer (Sanders and Stappers 2008). A co-design approach can help empower the end-user through encouraging them to input their knowledge and lived experiences into the design process, involving them in key decision making processes and enabling them to provide feedback during the design process (Vines et al. 2013; Hakobyan, Lumsden, and O'Sullivan 2014). Capturing the user's intrinsic knowledge helps innovation in the design process by establishing a mutual understanding of the user's challenges (Hakobyan, Lumsden, and O'Sullivan 2014; Wu, Richards, and Baecker 2004; De Couvreur et al. 2013; Moody 2015). This in theory means that co-design improves the chance the final design will meet the user needs, thus improving the use of the assistive device.

Co-design methodologies for designing bespoke assistive technology have previously been reported in the literature. This has included the design of devices for hand orthotics, devices to provide upper limb function and pill boxes (De Couvreur and Goossens 2011; Santos and Silveira 2020; Day and Riley 2018; Schwartz et al. 2020; Lee et al. 2019; Ragoo et al. 2019; Thorsen, Bortot, and Caracciolo 2019). However, the majority of these studies only report on a small number of case studies, ranging from 1 – 3 participants, did not always conduct any follow-up work to evaluate the devices and did not consider the regulatory requirements for providing the device. Gherardini et al. do report on a larger sample size of 8 participants, and provide some initial feedback using standard questionnaires, after 6 months (Gherardini et al. 2018). However, there is no report of the resource costs of conducting the co-design process or the time frame over which devices are created. This additional information is clearly key in understanding the feasibility of utilising a co-design approach within a healthcare setting. Additionally no qualitative feedback is gathered in any previous work. Qualitative feedback can provide a wider understanding of the impact of the device on the individual and capture more personal and meaningful information, which is beyond the scope of standard questionnaires – as a consequence we feel a mixed methods approach is the best means of furthering our understanding and development of the co-design methodology.

Previously, we have conducted three case studies using a co-design approach to provide novel custom assistive device solutions specific to each participant's individual requirements and needs. Participants whose current needs were unable to be met by off-the-shelf equipment, were referred into the Rehabilitation Engineering Unit, Morriston Hospital, Swansea. From these case-studies, a wide range of devices were produced that assisted the participants with: taking prescribed medication, writing, eating and self-care. Participants chose devices to enable them to be more independent; this had implications for improved individual health and wellbeing.
The case studies demonstrated that a co-design approach, where the participant was inputting ideas and feedback into the design process, could be used within a healthcare setting to provide customised assistive technology; however due to only a small sample size, the long-term feasibility of such an approach has not been established.

Why is this research needed:
The current study looks to build upon the co-design methodology established within the case-study examples by utilising co-design for a larger sample size of participants. Our previous case-studies suggest that co-design can help produce customised devices that are able to overcome some of the barriers to assistive technology usage previously identified. Long-term it is hypothesised this will increase the usage of the assistive device, help support individual's to better self-manage their own health and wellbeing needs and thus reduce the need for input from other healthcare services.

To date, no research has been conducted analysing the resources, costs and time-scales of co-designing assistive technology solutions in this way. Additionally the costs involved need to be considered against the potential short and long-term impacts on device usage, satisfaction and the health and wellbeing benefits for the individual that a co-design device could provide. Current research on co-design has focused on a single or a small number of case-studies, no study as yet has reported co-designing different custom devices for a larger sample size. A larger-sample size will help assess the feasibility of co-design within a clinical environment as well as investigating the types and range of new, novel assistive devices that could be produced.

This current study aims to address some of the current limitations in the research regarding the application of co-design in producing bespoke assistive devices. This work is essential for a) informing future service provision of assistive technology, b) identifying methods to overcome the barriers to assistive technology c) identifying new and novel assistive technology solutions through working with the end-user, d) ensuring our work is embedded in and embody the principles of co-production and partnership working in the healthcare sector e) lay foundations for a more effective and sustainable model of healthcare for those living with chronic conditions in Wales where services meet the needs of the user.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

PARTICIPANTS:
12-15 individuals will be recruited to take part in this study. Individuals will be identified by members of their current healthcare team. Participants will be living in the community and currently be under the care of Swansea Bay University Health Board.

Participants will be included in the trial if:
- They have a long-term physical or health condition
- Living in the community and be at least 3 months post injury/diagnosis. This is to allow time for the person to adapt to their new living environment and become aware of difficulties they face and implications of injury/diagnosis has on their health.
- Ability and willingness to actively engage in a co-design process, including:
- Able to meaning engage in verbal dialogue to communicate their needs and feedback
- Insight into their condition to understand their needs
- Able to retain information between sessions
- Aged eighteen years or older

Participants will be unable to be included if:
- They have communication/memory/cognitive difficulties that may prevent them engaging meaningfully in the process
- They are not able to provide informed consent.

A purposeful broad criteria is chosen with regard to different health conditions. Previous case-study work we have conducted has already shown the co-design methodology can be applied to a wide range of health conditions (previous: congenital birth defects, traumatic injury to hand resulting in amputation of fingers, multiple sclerosis). The study is designed to work with the individual and the individual challenges they face, this is largely independent of an individual's health condition. Thus, targeting specific health condition(s) would limit the aims of the study in assessing the range of different devices required and provide unnecessary bias and inequality in the study design and results. Finally, our previous meta-synthesis also highlighted that barriers to assistive technology are common across different health conditions. We are therefore looking if similar approaches can be effective across different health conditions to overcoming these barriers.

SETTING:
Due to COVID-19 pandemic, where possible the majority of appointments with occur virtually using a video consultation programme called Attend Anywhere. This will include assessing eligibility and gaining consent, initial assessment, follow-up appointments and the semi-structured interviews. Information on how to access an appointment through this will be provided to participants when they are invited to their first appointment.

Between appointments, the researcher will contact participants using telephone or email to arrange subsequent appointments. During the study, any devices for the participant to trial will be posted out to them. Training and/or instructions will be provided on how to use the device prior to it being sent out.
It is possible that during the study a face-to-face appointment may be required to assist in the design of the device. Face-to-face appointments are optional for the participant and will occur at a place of their choosing; either at their home or in a fully accessible clinic room in the Specialist Rehabilitation Centre at Morriston Hospital, Swansea. All COVID-19 precautions will be followed by the researcher, following the latest guidance from Swansea Bay University Health Board. Additional details for the appointment will be provided to the participant prior to any face-to-face appointments. For all face-to-face appointments the researcher will adhere to all the current guidance for PPE and social distancing at the time to maximise the safety for the participant and researcher.

PROCEDURE:
1. Referral: Potential participants will be identified by a healthcare professional from their current care team and asked whether they would like to participate in the study. Potential participants will be provided with the participant information sheet and asked to consent if they would like their details to be referred onto the principal investigator.

1.1 Arrange appointment: The principal investigator will telephone the potential participant to arrange an appointment to discuss their involvement in the research and gain consent. The consent form will be sent out to the participant (email or posted, depending on preference of participant).

2. Consent and eligibility [Virtual appointment]: The principal investigator will go through the participant information sheet with the participant and answer any questions they have about the study. The researcher will check they are eligible to take part in the study. If the participant is happy to be involved, they will be asked to sign the consent form and return it back to the researcher (either by email or posting back).

3. Initial assessment [Virtual appointment]: Through discussion with the participant, the researcher will gather relevant information to help identify their assistive technology needs. This will include information about their medical history and social context, likes and dislikes, current and any previous solutions used and challenges they faces in daily living. For each challenge identified, participants will be asked to score 1-5 about how important the challenge is to them and how difficult it is. This is for the Individually Prioritised Problem Assessment (IPPA) base-line measure. The researcher will complete the Client Service Receipt Inventory base-line measure with the participant to capture demographic information, information on heathcare services accessed in the previous 3 months and medication being taken.

4. Follow-up appointments, approximately 3-5 [Predominantly virtually, with face-to-face only if required]: In subsequent appointments the participant will meet with the researcher to discuss design ideas, provide feedback and agree on design changes for the devices(s) provided by the researcher to the participant. The participant will be asked to describe what they like/dislike about the current design and what changes they would make. The researcher may show design prototypes over video call to demonstrate how a device will work and to help facilitate gathering feedback. Following the appointment, the researcher will make design alterations, manufacture designs and post prototypes out for the participant to try. Appointments will be 2-3 weeks apart.
Previous case-studies showed the number of follow-up appointments varied for each individual depending on: the challenges identified, the complexity of the design, the level of feedback from the participant. As such a set number of follow-up appointments may limit the ability to produce a satisfactory final solution for the participant.

5. Device issue: Once the design has been refined to a level the participant and researcher are happy with, a final solution will be manufactured. The device will be sent out to the participant and the researcher will meet virtually with the participant to provide any necessary training and instructions for safe usage of the device.

6. Outcome measures [Virtually, same appointment as above]: The researcher will explain and go through the three different questionnaires being used as outcome measures for the study. The participant will be asked to score 1-5 the difficulty they now find the previously identified challenges (from initial assessment). For the two other measures, QUEST and PIADS [explained below], the researcher will either email or post out the questionnaires to the participant, preference of participant. Participants will be asked to complete and send back (email/post) once completed. Participants will be invited to complete the first of the semi-structured interviews with the resercher to obtain feedback on the co-design process and the device provided. Prior to beginning the interview, participants will be reminded it will be audio-recorded. If required, an additional appointment can be arranged to help the participant complete the questionnaires.

7.Three month follow-up feedback [Virtual appointment]: Participants will be invited to again complete and return the two questionnaires, QUEST and PIADS, to the researcher. Participants will complete the follow-up CSRI with the researcher. Participants will also be invited to undertake the second semi-structured interview to obtain feedback on the long-term use of device provided. Prior to beginning the interview, participants will be reminded it will be audio-recorded. Upon completion of the interview the participants involvement in the study will finish. Participants will be advised to contact the Rehabilitation Engineering Unit with any issues with their devices or further queriers about the research.

Feedback from current service users who were involved in the case-study helped feedback into the design of the current study. They liked being involved in the design process and being able to give feedback at each stage so the device could be customised to their needs. They also liked the use of virtual appointments for the process as it:
- Reduced face-to-face contact, especially with concerns over COVID-19 and wanting to avoid travelling to a hospital for appointments
- Avoided the need for excess travel by participant.
- Enabled appointments to be arranged at a more convenient time for them, with less time required for appointment/travel to appointment.
Finally the majority of them were happy to be contacted by email for arranging appointments as it enabled them to respond at a time convenient to them.

MEASURES:
Individually Prioritised Problem Assessment (IPPA) is an instrument to assess the effectiveness of assistive technology provision in relation to activities the individual considers most relevant. The participant can select up to 7 problems they experience in everyday life. For each problem the participant assigns two scores, one for the importance of the activity and the second for the difficulty. Both scores are assigned using a 5 point scale: 1 not important to 5 most important and 1 not difficult to 5 too difficult to perform. The importance and difficulty score are multiplied together, and an average score is calculated for all of the problems the participant listed. The assessment is completed at the beginning of the participants involvement in the study and after being issued the device(s) (Wessels et al. 2002).

Quebec User Evaluation of Satisfaction with Technical Aids (QUEST 2.0) is a 12-item outcome measure that assesses the user's satisfaction with both the device and service provided in supplying the device. For each item of the questionnaire, a 5-point scale is used, 1 being not satisfied at all and 5 being very satisfied (Demers, Weiss-Lambrou, and Ska 2002).

Psychosocial Impact of Assistive Devices Scale (PIADS) is a 26-item self-reported questionnaire to assess the effects of an assistive device on three sub-scales: competence, adaptability and self-esteem. For each item of the questionnaire, a 7-point scale is used, ranging from -3 (maximum negative impact) to 3 (maximum positive impact) (Jutai and Day 2002).

Client Service Receipt Inventory (CSRI) is a tool used to capture and record information on health and social care services and resources used by study participants to help estimate the costs of services received (Beecham and Knapp 2021). It will be used to calculate the economic cost benefits associated with the study. The CSRI will be completed at the initial assessment and again at the 3-month follow-up assessment; asking participants what healthcare services they have accessed in the previous 3 months and medications they are taking relevant to the health condition and challenges of daily living identified. It will also capture demographic information about the participants, including any changes as a result of participating in this study.

Qualitative feedback: Semi-structured questions will be used in individual interviews to facilitate a better understanding of:
- Any impact the device(s) provided has had on the participants life
- Identify components of the co-design methodology that participants like and dislike and how it could be improved in the future.
- If co-design has helped overcome any of the barriers to accessing and using assistive technology

A theory-driven topic guide has been developed to form the basis of the semi-structured interviews, with reference to the consolidated criteria for reporting qualitative research (COREQ). The topic guide for semi-structured interviews will be flexible and may be revised throughout the data collection process, consistent with established guidelines (Charmaz, 2014).
Two different topic guides have been developed, one for the semi-structured interview after initial device issue and one for the 3-month follow up. The first semi-structured interview focuses on initial device use and feedback on the co-design process; this information may be difficult for the participant to recall at the three-month follow-up appointment. The second interview captures feedback following longer term use of the device.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Feedback from current service users of the Rehabilitation Engineering Unit (Swansea Bay) who were involved in previous case-study work have helped feedback into the design of the current study. This has included how to conduct the interactive parts of the co-design feedback sessions.

Service users liked being involved in the design stages of the study and being able to give feedback at each stage so the device could be customised to their needs. They also liked the use of virtual appointments for the process as it:
- Reduced face-to-face contact, especially with concerns over COVID-19 and wanting to avoid travelling to a hospital for appointments
- Avoided the need for excess travel by participant.
- Enabled appointments to be arranged at a more convenient time for them, with less time required for appointment/travel to appointment.

Finally the majority of them were happy to be contacted by email for arranging appointments as it enabled them to respond at a time convenient to them.

The participant information sheet and participant consent form have both been reviewed by service users, with their feedback being used to help make the information sheet more accessible and easier for potential participants to understand. Sections regarding what happens to participants during the study and what happens if they change their priorities during the study were added and amended based on feedback.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [x] Congenital Disorders
- [x] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [x] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [x] Musculoskeletal
- [x] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [x] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 75	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

- Confirmed diagnosis of a long-term chronic condition
- Living in the community
- Age eighteen years or older
- Ability to actively engage in a co-design process, as determined by the referring clinician, including:

o Sufficient comprehension of language to engage in meaningful verbal dialogue with the researcher.
o Sufficient insight into their condition such that they understand their needs.
o Sufficient ability to communicate their needs.
o Sufficient ability to retain information between sessions
- Currently under the care of healthcare services within Swansea Bay University Health Board
- At least three-month post injury/diagnosis at the point of recruitment allowing time for spontaneous recovery and for the person to become aware of their difficulties and the implications of this on their lives

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

- Receptive or expressive language difficulties, or extremely low memory function that may preclude people from engaging meaningfully
- Medically unstable, severe mental health or cognitive difficulties which may preclude meaningful engagement in the study.
- Not able to provide informed consent

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Identification of participant	1	0	20 minutes	Current member of participants healthcare team based at Moriston Hospital
Seeking informed consent	1	0	20 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Questionnaire One: Individually Prioritised Problem Assessment (IPPA)	2	0	5 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Client Service Reciept Inventory	2	0	20 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Questionnaire Two: Quebec User Evaluation of Satisfaction with Technical Aids (QUEST 2.0)	2	0	5-10 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Questionnaire Three: Psychosocial Impact of Assistive Devices Scale (PIADS)	2	0	5-10 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Semi-structured interviews	2	0	30-45 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be*

received as routine clinical care outside of the research.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Initial assessment: Gather patient history and identify requirements for customised assistive device	1	0	40 - 60 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Feedback and follow-up appointments: Participant provides feedback to the researcher on the designed device and discuss design changes	3-5	0	30 - 45 minutes	Jonathan Howard (principal investigator). This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)
Device issue: Final training and instructions provided to participant by researcher on use of device.	1	0	30 minutes	Jonathan Howard (principal investigator. This will take place either virtually, using video consultation software, or in person at Morriston Hospital (Swansea Bay University Health Board)

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ◉ No

A21. How long do you expect each participant to be in the study in total?

It is expected that participants will be involved within the study for between 6-7 months. This will depend on the type and complexity of the device(s) to be produced. This time frame is split into:
- 3-4 months for the design and provision of device
- 3 months for follow-up after the device has been issued to the participant.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Harm to participants through incorrect usage of device: Devices will be designed to meet a particular need/function and if the device is used outside of the intended scope of the device it has potential to cause harm to the participant or other individuals. Instructions and training will be provided on the correct usage of the device prior to any device being sent out to the participant. Feedback from the participant will help reduce the risk of incorrect use.

Harm to participant through device failure during expected use: Devices may fail even during expected usage due to issues with the device design, manufacturing process, storage or transportation. Device failure may cause minor injury/harm, loss of confidence and distress. This risk is highly unlikely with all devices being manufactured according to the Quality Management System of the Rehabilitation Engineering Unit (working toward ISO 13485 certification). This includes appropriate risk assessment and risk management strategies for each device produced relating to the design, manufacturing, storage and use of devices. Where appropriate bench testing and computational simulation may be used to help assess mechanical strength of devices and reduce risk of failure. All devices will be designed and developed by the researcher following good engineering practise. The principal investigator is a clinical scientist with experience in designing and manufacturing bespoke assistive devices. Device concepts will be tested by the researcher prior to sending any device to participants. All devices will be quality checked prior to sending out to participants.

There is a risk that a solution will not be able to be provided to a participant due to complexity of the solution required, resources available or expertise available to produce a device. This is likely to lead to inconvenience and potential distress for the participant. This risk is clearly explained within the participant information sheet and all participants agree to this prior to undertaking the study. In an instance where a solution is not able to be produced, the researcher will work with the participant to provide a best possible compromise. Additionally, involvement in the study could still help the participant identify new and innovative ways to manage their own health, even without a device being provided.
To manage expectations and help the participants understand the types of devices that could be provided, example images from previous case-study work are included in the participant information sheet.

The focus of the study is on simple, mechanical devices assistive devices aimed to assist with activities of daily living, however the exact design and function of these devices cannot be known prior to starting the study. This is because the devices are developed based on the needs identified by participants. The quality management system will provide governance over the type of devices able to be produced and provided.
Any solutions requiring electronic components or software solutions will not be developed as part of this study as they fall outside the remit of the Rehabilitation Engineering Unit and outside of the experience and competence of the research team. If this type of solution is required, it will be explained to the participants this is outside the scope of the current research. This will be recorded and forms an important outcome of the study in identifying the limitations in current services, facilities and personnel in providing custom devices that meet the end-user needs. The researcher will continue to work with the participant to explore if any alternative solutions can be developed.

The majority of questions asked during the appointments and during the semi-structured interviews will be typically expected during any routine medical appointment, for example medical background. However there is potential that some of the questions asked during the appointments or interviews may be upsetting and cause distress to the participants. Prior notice of this possibility is documented in the participant information sheet. In these instances, the participant will have an opportunity to talk to the researcher in confidence either during the appointment or at an alternative time after the appointment. The researcher is a qualified healthcare professional. Additionally, there will be an opportunity to discuss with a member of their current clinical team.
If serious cause for concern is observed, appropriate action may include liaising with a participant's GP. A participant's consent will always be obtained before involving members of their proximal support network, unless this is not practical and there is an imminent risk of serious harm to them. In a crisis situation the researcher will notify the patients GP in accordance with clinical governance procedures.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

During the appointments, responding to the questionnaires or during the semi-structured interviews questions may be asked that could potentially be sensitive or upsetting to participants. Prior notice of this possibility will be documented in the participant information sheet. Participants will have the opportunity to discuss any concerns they have during or after completing the questionnaires or interviews. They will be informed from the start of their right to stop at any time during this process. However, the majority of questions asked will be typically expected during routine medical appointments.

Any topics that participants find upsetting during an appointment will be addressed by the reasercher during the appointment if possible, or in confidence afterwards. (If a patient remains upset following discussions with the researcher the PI for the study will be informed and the participant will be offered an appointment with a member of the clinical team.) In a crisis situation the researcher will notifiy the patients GP in accordance with clinical governance procedures.

The limits of confidentiality will be made explicitly clear on the information sheet and when these will need to be breached.

A24. What is the potential for benefit to research participants?

Benefits of being involved in the study include an opportunity for the participants contribute to help create new devices that can help both themselves and potentially other future service users to overcome challenges they face in daily living. This includes increased independence and autonomy and subsequent impact on health and wellbeing. From the previous case studies, participants described how:

"For the first time [post injury] she was able to sit at the table and feel like an adult again" - a knife holder that is supported on the participants hands.

"It has been a life-saver in being able for me to help my child with their school work [for home schooling]" - a large handle which helps the participant hold pens, pencils and other household objects.

Additionally, participants can feel value in being involved in research that could help shape future service provision in the NHS.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

At the end of the study the participant will be able to keep and use the device(s) that have been provided to them. Support from the Rehabilitation Engineering Unit will be provided for up to 1 year following the device being issued to the participant. This information is made clear in the participant information sheet.

Unfortunately, after one year, the long-term replacement of devices will not be able to be supported due to limitations in current service provision. If successful, it is hoped the results from this study can help support justification for a service able to provide such devices in the future

A26. What are the potential risks for the researchers themselves? *(if any)*

Home visit to participants: In the event that a face-to-face visit is required and it is agreed to occur at the participants home, there is a potential risk to the researcher. For home visits the researcher will use Rehabilitation Engineering Unit departmental vehicles installed which are installed with Quartix tracking systems. Additionally they will check in with the head of department prior to and after the visit. The researcher is well accustomed to lone working in the community as part of their current clinical role. For all face-to-face appointments the researcher will adhere to all the current guidance for PPE and social distancing at the time to maximise the safety for the participant and researcher.

Use of equipment/machinery to manufacture devices: The inappropriate use of machinery used in the manufacture of devices has a potential risk of injury to the researcher. The researcher will only use equipment they are competent and qualified to use, having completed the necessary training as per the quality management system of the Rehabilitation Engineering Unit.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Participants will be identified and referred into the study by healthcare professionals working within Swansea Bay University Health Board. This will include potentially recruiting from the following outpatient and community departments:
- Burns and Plastics
- Multiple Sclerosis Team
- Traumatic Brain Injury Service
- Rehabilitation Engineering Unit
- Artificial Limb and Appliance Centre

Potential participants will be identified and initially approached by members of their current clinical care team. They will provide the participant with the participant information sheet.

If to participant is happy to participate, their contact information, medical diagnosis and a brief summary of main challenges they face relating to activities of daily living will be sent onto the principal investigator. The participant will consent for this information to be passed on. This information will be passed on via a standardized referral form which a member of the participant's clinical team will complete. Potential participants will then meet with the principal investigator to determine eligibility for the study and, if eligible, provide informed consent.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◯ Yes ◉ No

Please give details below:
Potential participants will be identified by their current clinical care team who will seek consent from the participant for their information to be passed onto the research team. Only limited personal information will be initially provided to the research team to enable the principal investigator to screen potential participants.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◯ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential participants will be first approached by a member of their current clinical team.
Clinicians will approach participants either during a routine scheduled appointment or will contact them via telephone to discuss the study and ask participants if they would like to be involved.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ◯ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Participants will meet with the principal investigator to initially provide consent. The principal investigator is a qualified healthcare professional. No participants will be included in the study if they do not have the required capacity or decision-making abilities to make an informed decision. The opinion of the referrer, a member of the participant's current clinical team, will be sought regarding if the participant has the required capacity and decision-making abilities to make an informed decision.

Participants will be contacted via telephone to arrange a virtual appointment to discuss participation in the study. The consent form will be sent out to the participant via post and/or email depending on the preference of the participant. During the appointment, the researcher will restate the aim of the study and outline what participation will involve, going through the participation information sheet. The researcher will ensure that the patient fully understands the information presented in the participant information form and consent form. Family members of the patient will be invited to participate in the appointment and receive information regarding the study if the participant so wishes.

Participants who wish to be involved in the study will be asked to read and sign the consent form provided and then return to the researcher by either mailing to the Rehabilitation Engineering Unit or scanning and emailing the form directly to the researcher.

At the beginning of every appointment with the researcher, the researcher will check the participant is still happy continue taking part in the study as per good clinical practise.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Following the initial provision of study information, potential participants will have at least one week to consider if they would like to participate in the study. After being provided the information, the principal investigator will contact the participant to arrange an opportunity to talk about the research with them; this appointment will be at least 1 week after initially being given the patient information sheet.
Additionally the participant will be able to discuss their involvement in the research with a member of their current clinical team and will be encouraged to discuss with family members and friends about their involvement in the research study.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

○ Yes
○ No
◉ Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?
The involvement of potential participants in research prior to recruitment will not be known to the researcher. However, each case would be judged on its merit and on whether involvement in current/previous research projects would impact upon involvement within the present study.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

Previous clinical experience indicates the likelihood an interpreter will be required is relatively low. However, should this be required the researcher will discuss with the referring clinician about current arrangements for routine clinical appointments. Support will be sought from the health board's R&D department in adherence to local health board policies if a translator is required.

Those with significant communication difficulties or comprehension of language such that they are unable to effectively communicate their needs will be unable to be included in the study and will not meet the inclusion criteria.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

All participants will be provided with the opportunity to receive correspondence, the participant information sheet and consent form in Welsh.

Previous experience indicates the use of the English language only will not be a significant barrier to participants, as no requests purporting to the use of Welsh language have been made by similar populations previously. Support will be sought from the health board's R&D department in adherence to local health board policies if the provision of the study in Welsh is required.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

Should relevant information surface during the research project, the principal investigator will discuss the information with the chief investigator and other members of the researh team to co-ordinate a plan to ensure participants are made aware of this information. For example, whether or not the researcher should contact a participant directly, or if it would be more appropriate for a member of their care team to contact them, will be discussed and will depend on the nature of the information in question.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◉ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

◯ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◯ The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◯ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Once participants have completed the study all data will have been anonymised and will be stored accordingly - before completion participants have the right to withdraw at any time and all data will be destroyed.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☑ Laptop computers

Further details:

Electronic transfer of data will occur between referrer and principal investigator. Emails will be sent and received from personal NHS email addresses and not generic accounts. Emails will be kept for 7 years as per NHS Wales 7-year retention policy

Use of personal address, postcodes, email and telephone numbers will be required to contact participants and send out devices for them to trial. Contact via email will be from the researchers personal NHS email account only. Items to be sent will have to include personal addresses and postcodes. No information regarding the research study will be included on the external mail packaging.

For quotes obtained during the semi-structured interviews, no quote will be published that identifies participants. A two-digit code will be used within any publications to report individual quotes, this is typical scientific practise for this type of research

NHS iPads and computers will be used to record audio data during the semi-structured interviews. These devices are appropriately networked, such that the audio files can be uploaded directly to the NHS servers and not stored on the iPad/computer. Audio files will be stored on the secure NHS network. The audio data will be transcribed and anonymised by the researcher on the NHS network prior to being sent externally to Swansea University.

Personal data included on paper referral and consent forms will be stored in a locked filing cabinet located in the Rehabilitation Engineering Unit.

Personal identifiable information will be stored on a password protected database, stored on the secure NHS network at Swansea Bay University Health Board. Access to this database will be through NHS computers and NHS laptops only. The password to the database will be known by the principal investigator and head and deputy head of the Rehabilitation Engineering Unit only.

NHS laptops have an authentication pin prior to logging onto the computer. Additionally, access to the NHS network via an NHS laptop when working off-site involves logging into the VPN (virtual private network) via a 2 step-verification process.

A37. Please describe the physical security arrangements for storage of personal data during the study?

The database linking each participant to their unique research number will be stored on the secure NHS network at Swansea Bay University Health Board and will be password protected. The password will be known only to the principal investigator and the head and deputy head of Rehabilitation Engineering Unit (both members of research team). The database will never be stored on any device and paper copies are not required.

Any paper records related to the study will be kept in a locked filing cabinet at the Rehabilitation Engineering Unit, Swansea Bay University Health Board. Access to the Rehabilitation Engineering Unit is via swipe-card and passcode protected doors. The data will be retained for 5 years in line with health board guidelines, before being destroyed.

Audio-recordings and transcription data relating to the qualitative research component will be stored on password-protected documents on a secure NHS network at Swansea Bay. No personal patient information will be stored on iPads or laptop devices.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Each participant will be assigned a numerical identifier code. This code helps to maintain participants anonymity throughout the research study. Any subsequent data relating to the participant, including notes, design/drawings and outcome data will only reference the participants unique identifier code. Data stored relating to the study outcomes will be separate from the main personal identifiable data. Adherence to the NHS code of conduct will be followed.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The principal investigator and the head and deputy head of the Rehabilitation Engineering Unit will have access to the participant's personal data during the study. The referrer, a current member of the participants care team, will send the referral form containing participants personal data to the principal investigator. Upon receipt the principal investigator will enter the participant personal data into a password protected database stored on the secure NHS network at Swansea Bay University Health Board. The participant will be assigned a unique research number; this research number will be used for any subsequent documentation and results (e.g. questionnaire data) stored relating to the study. Information about access to personal data is clearly outlined in the participant information sheet and consent forms.

The principal investigator will need to know participants personal data to enable them to contact the participant

(telephone, email) and send out devices for them to trial. Only the principal investigator and the head and deputy head of Rehabilitation Engineering Unit will know the password to the participant database. The head and deputy head of Rehabilitation Engineering Unit are required to know this password to access participant contact information only in the result of long-term absence of the principal investigator impacting on the study conduct. Both the head and deputy head are members of the research team.

Medical notes and research project data, may be accessed by authorised individuals from the Sponsor, regulatory authorities or host NHS site for monitoring and auditing purposes.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be analysed at Swansea University (at the Psychology Department) and Swansea Bay University Health Board (In the Rehabilitation Engineering Unit and Brain Injury Service).

Swansea University Psychology Department: by Jonathan Howard (PhD student, principal investigator) and Professor Jeremy Tree (PhD supervisor, chief investigator)

Swansea Bay University Health Board: by Dr Lorna Tasker (Consultant Clinical Scientist) at the Rehabilitation Engineering Unit and Dr Zoe Fisher (Consultant Clinical Psychologist) at the Brain Injury Department.

Data for analysis will be fully anonymised prior to being transferred using the participants unique research number.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title	Forename/Initials	Surname
Mr	Jonathan	Howard

Post	[redacted]
Qualifications	
Work Address	
Post Code	
Work Email	
Work Telephone	
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10

Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The database linking a persons name with their research number will be kept on an NHS secure network at Swansea Bay Health Board. It will remain on the network and deleted 5 years after the study has ended.

Any paper documents, for example consent forms, will be stored in a locked filling at the Rehabilitation Engineering Unit and destroyed after 5 years.

Fully anonymised data will be stored on an NHS computer and deleted after 5 years.

Fully anonymised stored at Swansea University will be deleted after 10 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The UK Policy Framework for Health and Social Care Research sets out the principle of making information about research publicly available. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

○ Yes ◉ No

Please give details, or justify if not registering the research.
This study forms part of an educational project (PhD) and thus the study will be published as part of the publication of the PhD thesis.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No personal data that will connect an individual to the study will be published.

All information provided in any scientific journals will use the standard numerical code (e.g., case 01) to refer to the participants in a manner that preserves anonymity - and all information provided specific to the individual will be very broad such that a specific individual will not be identifiable. Participants will be informed on the patient information sheet that direct quotes from semi-structured interviews may be used in the write up, but that they cannot be identified from this information.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
Participants have the option of receiving written feedback detailing a summary of the research. They can indicate their preference to receive a summary of the results on the participant consent form.
Participants will be provided with the researcher's contact details should they wish to discuss anything further. If appropriate, findings may also be communicated on the local NHS health boards website and if so, participants will be informed of how to access this information at the web address.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The study has been reviewed by PhD supervisor, academics and clinicians based at Swansea University and Swansea Bay University Health Board that have past experience in conducting trials in healthcare settings. These include Professor Jeremy Tree (Psychology, Swansea University), Dr Zoe Fisher (Consultant Clinical Psychologist, Brain Injury Unit) and Dr Lorna Tasker (Consultant Clinical Scientist, Rehabilitation Engineering Unit).

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☑ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Professor	Jeremy	Tree
Department	Department of Psychology		
Institution	Swansea Univeristy		
Work Address	Room 725, Vivian Building, Department of Psychology		
	Singleton Park, Singleton		
	Swansea		
Post Code	SA2 8PP		
Telephone	01792602908		
Fax			
Mobile			
E-mail	J.Tree@swansea.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

There will be two different outcomes for this study. The first set (captured via questionnaire and qualitative semi-structured interviews) will assess the satisfaction of the participants with the device, process and the impact it has had on their life. The second outcome will be to assess the health economic analysis of the process by estimating associated costs and calculating economic savings through any reduction in contact with health and social care services, medications being taken or changes to participants employment/benefits status.

Individually Prioritised Problem Assessment (IPPA) is an instrument to assess the effectiveness of assistive technology provision in relation to activities the individual considers most relevant. The participant can select up to 7 problems they experience in everyday life. For each problem the participant assigns two scores, one for the importance of the activity and the second for the difficulty. Both scores are assigned using a 5 point Likert scale: 1 not

important to 5 most important and 1 not difficult to 5 too difficult to perform. The importance and difficulty score are multiplied together and an average score is calculated for all of the problems the participant listed. The assessment is completed at the beginning of the participants involvement in the study and after being issued the device(s) (Wessels et al. 2002).

Quebec User Evaluation of Satisfaction with Technical Aids (QUEST 2.0) is a 12-item outcome measure that assesses the user satisfaction with both the device and service provided in supply the device. For each item, the questionnaire uses a 5 point scale, 1 being not satisfied at all and 5 being very satisfied (Demers, Weiss-Lambrou, and Ska 2002).

Psychosocial Impact of Assistive Devices Scale (PIADS) is a 26-item self-reported questionnaire to assess the effects of an assistive device on three sub-scales: competence, adaptability and self-esteem. The questionnaire uses a 7 point scale, ranging from -3 (maximum negative impact) to 3 (maximum positive impact) (Jutai and Day 2002).

Qualitative measures: Semi-structured questions will be used in individual interviews to facilitate a better understanding of:
- Any impact the assistive device(s) has had on the participants life
- Identify components of the co-design methodology that participants like and dislike and how it could be improved in the future.
- If co-design has helped overcome any of the barriers to accessing and using assistive technology

A theory-driven topic guide has been developed to form the basis of semi-structured interviews, with reference to the consolidated criteria for reporting qualitative research (COREQ). The topic guide for semi-structured interviews will be flexible and may be revised throughout the data collection process, consistent with established guidelines (Charmaz, 2014).Two different topic guides have been developed, one for the semi-structured interview after initial device issue and one for the 3-month follow up. The first semi-structured interview focuses on initial device use and feedback on the co-design process; this information may be difficult for the participant to recall at the three-month follow-up appointment. The second interview captures feedback following longer term use of the device.

HEALTH ECONOMIC ANALYSIS:
We will test the feasibility of applying co-design to produce personalised assistive devices.
Client Service Receipt Inventory (CSRI) is a tool used to capture and record information on health and social care services and resources used by study participants to help estimate the costs of services received (Beecham and Knapp 2021). It will be used to calculate the economic cost benefits associated with the study. The CSRI is to be completed at the initial assessment and again at the 3-month follow-up assessment; asking participants what healthcare services they have accessed in the previous 3 months relevant to the health condition and challenges of daily living identified.
Data from the CSRI will be used to compare the services accessed, assistance from formal and informal carers, changes to employment, and any relevant changes to medication due to involvement in the study. A comparison of the 3-months prior to the initial assessment and 3-month follow-up appointment will be used to evaluate potential cost savings associated with the provision of a more personalised assistive device.
Additionally, for each participant an estimate of the resources used and costs involved will be calculated. Costs will be calculated based on the number of person-hours required to engage participant and produce device, manufacturing time and material cost of all components required to produce the final device. This will include time for each appointment with the participant, time spent developing and changing the design, and time to create documentation required to comply with quality management system.

A58. What are the secondary outcome measures? *(if any)*

There are no secondary outcome measures for this study.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 15
Total international sample size (including UK):
Total in European Economic Area:

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

12 – 15 participants will be recruited to take part in this study. Based on previous case-study work, this sample size was selected as:
- Will provide insight into the different types and range of challenges that are important to different individuals
- Larger sample size than any previous co-design study currently published in the literature, enabling a larger sample to evaluate the effectiveness of using co-design.
- It was deemed viable to complete within the time-scale and the resources available in this study.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Quantitative Questionnaire data: Analysis will focus on descriptive statistics of the results from the IPPA, QUEST and PIADS questionnaires. The data will be used to evaluate the satisfaction of the user with the device and service provided and the impact it has had on an individual's life. It is hypothesised the IPPA will improve post device issue compared to at initial assessment. Comparison of the QUEST and PIADS questionnaire results immediately post device issue and at 3 month follow up with help to evaluate the long term satisfaction with the device provided.

Qualitative semi-structured interviews: Thematic analysis of the semi-structured interview transcripts will be used to identify commonalities in the responses given amongst the participants. Thematic analysis will follow the process described by Braun and Clarke (2006) (Braun and Clarke 2006). Initially the researcher will familiarise themselves with the transcript interviews. Next, the data set will be systematically coded, with codes collated inductively into potential themes. Each theme will be checked in relation to the coded extracts and the entire data set to ensure a true representation of the data set. Finally, each theme will be named and defined. The themes will be reviewed by the research supervisory team to validate it is a fair representation of the data set.

Health economic analysis: We will test the feasibility of applying co-design to produce personalised assistive devices. Data from the CSRI will be used to compare the services accessed, assistance from formal and informal carers, changes to employment, and any relevant changes to medication due to involvement in the study. A comparison of the 3-months prior to the initial assessment and 3-month follow-up appointment will be used to evaluate potential cost savings associated with the provision of a more personalised assistive device.
Additionally, for each participant an estimate of the resources used and costs involved will be calculated. Costs will be calculated based on the number of person-hours required to engage participant and produce device, manufacturing time and material cost of all components required to produce the final device. This will include time for each appointment with the participant, time spent developing and changing the design, and time to create documentation required to comply with quality management system. Cost of clinician time will be based on top of band on the NHS pay scale and calculated at time of study (April 2021).

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname
Post	[redacted]
Qualifications	
Employer	
Work Address	

Post Code
Telephone
Fax
Mobile
Work Email

[redacted]

Title Forename/Initials Surname

[redacted]

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

Title Forename/Initials Surname

[redacted]

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ◯ NHS or HSC care organisation
- ◉ Academic
- ◯ Pharmaceutical industry
- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)

Commercial status: Non-Commercial

◯ Other

If Other, please specify:

Contact person

Name of organisation Swansea University

Given name [redacted]
Family name
Address
Town/city
Post code
Country
Telephone
Fax
E-mail

A65. Has external funding for the research been secured?

Please tick at least one check box.

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname

[redacted]

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 05/04/2021
Planned end date: 30/09/2022
Total duration:
Years: 1 Months: 5 Days: 26

A71-1. Is this study?

- (●) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

( ) Yes (●) No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- [ ] NHS organisations in England
- [x] NHS organisations in Wales 1
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland

- ☐ GP practices in England
- ☐ GP practices in Wales
- ☐ GP practices in Scotland
- ☐ GP practices in Northern Ireland
- ☐ Joint health and social care agencies (eg community mental health teams)
- ☐ Local authorities
- ☐ Phase 1 trial units
- ☐ Prison establishments
- ☐ Probation areas
- ☐ Independent (private or voluntary sector) organisations
- ☐ Educational establishments
- ☐ Independent research units
- ☐ Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

Swansea University as sponsor periodically operates a risk based audit programme on research being undertaken. Monthly meetings within the supervisory research team will be used to monitor the conduct of the research and ensure compliance the protocol.

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

Not applicable, interim data will not be collected for the trial.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

The principle investigator is bound by their professional registration as a clinical scientist and therefore any research would be electively stopped if serious concerns are raised regarding the intervention or any other aspect of the study. For example this might include the non-compliance of the quality of equipment being manufactured and provided by the Rehabilitation Engineering Unit. The sponsor and local health board R&D representatives would be included in all discussion regarding concerns.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the

sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Swansea University has in force a Public Liability Policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Swansea University have the necessary insurance to indemnify for harm to participants arising from the design of the research

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The NHS indemnity scheme will meet the potential legal liability of investigators arising from harm to participants in the conduct of the research.

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ◉ No

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

Part B: Section 2

A. General information

Information in this sub-section will be included in applications to the Research Ethics Committee and NHS R & D offices at the research sites.

1. Is the manufacturer (or other organisation responsible for developing the device) the same organisation named as lead sponsor for this study?

◯ Yes ◉ No

If No, please give details of the manufacturer or other organisation responsible for developing the device below:

Organisation
Address

Post Code
Country
Telephone
Fax
Mobile
E-mail

[redacted]

2. Details of the medical devices to be used in the study

Name of the manufacturer:	Rehabilitation Engineering Unit
Manufacturer's trade name for the device:	Bespoke assistive device
Device identification name and/or number:	
Name:	N/a
Number:	N/a
Generic name of device and principal intended use(s):	Device(s) will be designed and developed as part of the study depending on the individual needs of participants involved in the study. It is not possible to name the type and/or intended use of the devices prior to starting the study as this will depend on the participants recruited and the needs they identify.
Length of time since device came into use:	N/a

3-1. Further details of the purpose of the study

Does the study involve:

◉ Investigation of a new medical device
◯ Investigation of new implantable material
◯ Use of an existing product outside the terms of its UKCA/CE UKNI/CE marked intended purpose
◯ Use of a modified product

◯ Use of an existing product within its UKCA/CE UKNI/CE marked intended purpose

3-2. Please give further details below including the following:

Description of any new device, materials, method of use or operation with a summary of the intended purpose.

Not known prior to recruitment of participants.

The Rehabilitation Engineering Unit will lead and take responsibility for the development and provision of the devices used within this study. Devices will be manufactured under the Quality Management System of the Rehabilitation Engineering Unit (working towards ISO 13845 certification) under the UK regulations on medical devices for the in-house manufacturing of medical devices by a health institution. For this study devices will be classified as custom-made for the individual. All devices will be used 'in-house', for the use of patients within the health institution of Swansea Bay University Health Board only, and as such will not be classed as being "put on the market" (sold or transferred to another legal entity/healthcare institution). No commercial exploitation is foreseen for devices developed in this study. As the device is to be used in-house and will not be commercialised, a notification to the MHRA is not required for devices manufactured as part of this study.
This follows the guidance for 'clinical investigations and healthcare establishments' published by the MHRA and 'Best-practice guidance for the in-house manufacture of medical devices and non-medical devices, including software in both cases, for use within the same health institution', January 2021, guidance published by the Institute of Physics and Engineering in Medicine (IPEM).

All devices will be manufactured according to best engineering and clinical practise in accordance with the quality management system.

Composition of any new implantable materials, including summary of biocompatibility findings from studies to date.

None of the device designed will be implantable.

A summary of any modifications to UKCA/CE UKNI/CE marked devices.

See above regarding manufacture of new devices

A summary of any proposed changes to the UKCA/CE UKNI/CE marked intended purpose.

See above regarding manufacture of new devices

For all products with UKCA/CE UKNI/CE mark please attach instructions for use.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site Organisation name: [redacted] Address: [redacted] Post Code: [redacted] Country: [redacted]	Forename: [redacted] Middle name: [redacted] Family name: [redacted] Email: [redacted] Qualification (MD...): [redacted] Country: [redacted]
IN2	○ NHS/HSC Site ◉ Non-NHS/HSC Site Institution name: Swansea University Department name: Psychology Department Street address: Singleton Campus, Singleton Town/city: Swanea Post Code: SA2 88PP Country: United Kingdom	Forename: Jonathan Middle name: Family name: Howard Email: [redacted] Qualification (MD...): MSc - Clinical Science (Rehabilitation Engineering) MEng - Mechanical Engineering Country: United Kingdom

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.
10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.
12. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
13. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Prof Jeremy Tree on 03/03/2021 14:38.

Job Title/Post:

Organisation:

Email:

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by [redacted] on 03/03/2021 14:52.

Job Title/Post: [redacted]

Organisation:

Email:

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Prof Jeremy Tree on 03/03/2021 14:38.

Job Title/Post:

Organisation:

Email:

8.6 Appendix F: Individually Prioritised Problem Assessment raw scores

Raw scores for Individually Prioritised Problem Assessment questionnaire completed by participants in Chapter 5.

Participant #	Baseline	Initial Follow-up
001	12	4
002	15.4	7.2
003	20	10
004	14.8	9.5
005	16	10
006	25	10
007	17.3	10.3
008	12	4
009	20	16
010	20.3	6.3
Mean	17.3	8.7
StD	4.1	3.6

8.7 Appendix G: Warwick-Edinburgh Mental Wellbeing Scale raw scores

Raw scores for Warwick-Edinburgh Mental Wellbeing Scale questionnaire completed by participants in Chapter 5. Participant 3 chose not to complete the questionnaire

Participant #	Baseline	Initial Follow-up	3-month follow-up
001	43	60	58
002	55	56	63
003	-	-	-
004	54	54	57
005	44	58	55
006	39	37	33
007	48	44	48
008	35	47	49
009	44	50	55
010	44	39	37
Mean	45.1	49.4	50.6
StD	6.45	8.28	9.95

8.8 Appendix H: Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) raw scores

Raw scores for Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) completed by participants in Chapter 5.

Participant #	**001**		**002**			**003**		**004**		**005**	**006**	**007**		**008**	**009**	**010**	
	Initial follow-up																
Device name	Non-slip fingertips	Hair tie	Hair curler holder	Earring helper	Nail varnish holder	Finger exercise tool	Deodorant holder	Soap holder	Clothes clip	Knife holder	Basket holder	Fork holder	Pincer grip	iPad stand	PlayStation controller	Mop/ hoover grip	Knife holder
Device subscale	5.0	4.4	4.9	3.8	4.9	5.0	5.0	4.9	4.9	4.8	4.7	5.0	5.0	4.8	3.3	4.8	4.8
Service subscale	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	4.5	4.5	4.8	4.8	5.0	4.8	5.0	5.0
Total	5.0	4.6	4.9	4.2	4.9	5.0	5.0	4.9	4.9	4.7	4.7	4.9	4.9	4.8	3.8	4.8	4.8
	3-month follow-up																
Device name	Non-slip fingertips	Hair tie	Hair curler holder	Earring helper	Nail varnish holder	Finger exercise tool	Deodorant holder	Soap holder	Clothes clip	Knife holder	Basket holder	Fork holder	Pincer grip	iPad stand	PlayStation controller	Mop/ hoover grip	Knife holder
Device subscale	5.0	4.1	4.8	4.3	4.9	5.0	5.0	5.0	4.9	4.0	4.7	3.9	3.8	4.9	5.0	4.8	4.6
Service subscale	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	4.2	4.5	4.0	4.0	5.0	5.0	4.3	4.3
Total	5.0	4.4	4.8	4.5	4.9	5.0	5.0	5.0	4.9	4.1	4.7	3.9	3.8	4.9	5.0	4.6	4.5

8.9 Appendix I: Psychosocial Impact of Assistive Devices Scale raw scores

Raw scores for Psychosocial Impact of Assistive Devices Scale (PIADS) completed by participants in Chapter 5.

Participant #	001		002		003		004		005	006	007		008	009	010	
	Initial follow-up															
Device name	Non-slip fingertips	Hair tie	Hair curler holder	Earring helper	Nail varnish holder	Finger exercise tool	Deodorant holder	Soap holder	Clothes clip	Knife holder	Basket holder	Fork holder	Pincer grip	iPad stand	PlayStation controller	Mop/ hoover grip	Knife holder
Competence	+2.4	+1.4	+2.0	+2.2	+2.2	+1.7	+2.8	+2.9	+2.8	+1.9	+1.6	2.6	+2.8	+2.0	+1.3	+2.0	+1.4
Adaptability	+3.0	+2.2	+3.0	+2.7	+2.3	+1.0	+2.2	+1.7	+2.7	+2.0	+3.0	2.7	+2.7	+2.5	+1.3	-0.2	-0.3
Self-esteem	+2.4	+1.4	+2.1	+2.1	+2.1	+1.0	+2.8	+2.8	+2.9	+1.5	+0.6	2.4	+2.5	+1.8	+1.0	+1.4	+0.9
	3-month follow-up															
Device name	Non-slip fingertips	Hair tie	Hair curler holder	Earring helper	Nail varnish holder	Finger exercise tool	Deodorant holder	Soap holder	Clothes clip	Knife holder	Basket holder	Fork holder	Pincer grip	iPad stand	PlayStation controller	Mop/ hoover grip	Knife holder
Competence	+2.8	+2.1	+2.6	+2.5	+2.7	+1.3	+2.4	+2.4	+2.3	+1.7	+1.7	1.7	+1.3	+2.3	+1.5	+0.6	+0.6
Adaptability	+3.0	+2.8	+2.5	+2.7	+1.8	+0.8	+2.2	+2.2	+2.0	+0.8	+3.0	2.7	+2.7	+2.7	+2.0	-1.0	-1.0
Self-esteem	+2.6	+2.1	+1.5	+2.3	+2.1	+0.6	+2.6	+2.6	+2.6	+1.4	+0.5	1.0	+0.6	+2.5	+1.9	+0.3	+0.6

8.10 Appendix J: Client Service Receipt Inventory - Contact with healthcare services

Summary data of contact participants had with healthcare services 3-months prior to and 3-months after being provided customised devices. Data collected using Client Service Receipt Inventory (CRSI) for participants in Chapter 5.

	Baseline data collection				3-month follow-up data collection			
Participant #	**Healthcare service accessed**	**# of appointments over last 3 months**	**Location**	**Average contact time (mins)**	**Healthcare service accessed**	**# of appointments over last 3 months**	**Location**	**Average contact time (mins)**
001	GP	6	GP Surgery	30	Cardiac department (doctor)	2	Hospital	30
	Occupational therapist	1	Hospital	30	Cardiac department (Nurse)	2	Hospital	30
002	Physiotherapist (private)	6	Hospital	60	Physiotherapist (private)	6	Hospital	60
003	Consultant	2	Hospital	20	*No contact with any healthcare services*			
	Occupational therapist	5	Hospital	60				
	Physiotherapy	5	Video call	60				
004	Occupational therapist	1	Hospital	40	*No contact with any healthcare services*			
005	Occupational therapist	3	Telephone	30	Nurse Practitioner	2	GP Surgery	15
	Prosthetist	2	Hospital	30				
	Psychologist	1	Hospital	60				
	Nurse	1	Hospital	30				
006	Occupational therapist	3	Home visit	30	*No contact with any healthcare services*			
007	*No contact with any healthcare services*				*No contact with any healthcare services*			
008	Consultant medical	2	Hospital	30	GP (Primary care)	3	GP surgery	20
	Occupational therapist	4	Video call	30	Occupational Therapist	6	Home	60
	Neuropsychologist	6	Video call	60	Neuropsychologist	6	Video call	60
009	Occupational therapist	12	Hospital	60	Occupational therapist	8	Home	60
	Physiotherapist	12	Home visit	60	Gardening Group	4	Hospital	60
	Music therapy sessions	6	Hospital	60				
010	Occupational therapist	2	Hospital	60	Diabetes nurse	1	Hospital	30
	Physiotherapist	1	Hospital	60	GP	1	GP surgery	20

8.11 Appendix K: Client Service Receipt Inventory - Help received with challenges identified

Summary data of help participants received with overcoming challenges of daily living they identified prior to and 3-months after being provided customised the devices. Data collected using Client Service Receipt Inventory (CRSI) in Chapter 5.

		Baseline data collection				3-month follow-up data collection			
Participant #	**Challenge**	**Sector**	**Occurrence frequency**	**Average contact time per occurrence (mins)**	**Other information**	**Sector**	**Occurrence frequency**	**Average contact time per occurrence (mins)**	**Other information**
001	Opening packets	Informal carer/helper (Family)	Daily	10		Family	Monthly	5	
002	Tying up hair	-	-	-	Unable to do and no help received				No help required
	Curling hair	Private hairdresser	Weekly	60	Cost per appointment: £10				No help required
	Putting in earrings	Informal carer/helper (Friends)	Weekly	10					No help required
	Painting fingernails	Pay for nail technician	Weekly	60	~£50 per month				No help required
	Getting out the bath				No help, struggles to do				No help, struggles to do
003	Finger stretching (exercise)	NHS physiotherapist	Monthly	60	*Given exercises to do at home*				No help required
004	Applying deodorant	Informal carer/helper (Family)	Daily	3					No help required
	Buttoning up trousers	Informal carer/helper (Family)	Daily	10					No help required - sourced elastic banded trousers
	Applying soap in bath	Informal carer/helper (Family)	Weekly	10					No help required
	Keeping jacket falling off when walking	Informal carer/helper (family)	Weekly	5					No help required
005	Using knife	-	-	-	Unable to use and no help received				No help required
	Unlocking padlock	Work colleagues	Monthly	15		Work colleagues	Monthly	15	
006	Carrying objects	Informal carer/helper (partner)	Daily	20		Informal carer/helper (partner)	Monthly	5	
007	Dressing (buttons and zips)	Informal carer/helper (Family)	Daily	10		Informal carer/helper (Family)	Daily	5	

	Holding fork	-	-	-	No help currently, adapt to use in other hand				No help required
	Cycling (holding handlebars)				No help currently, struggles to do				No help, struggles to do
008	Support for positioning an iPad	Informal carer/helper (Friend)	Weekly	10					No help required
009	Playing PlayStation	-	-	-	Unable to use				No help required
	Chopping food	Informal carer/helper (Family)	Daily	120	*Does not do anymore*	Informal carer/helper (Family)	Daily	120	
010	Using knife	Informal carer/helper (Family)	Daily	10					No help required
	Hoovering & mopping	-	-	-	No help currently				No help required
	Wringing out dish cloth	-	-	-	Unable to do				No help required

8.12 Appendix L: Client Service Receipt Inventory- Summary of medication

Summary data of medication taken by participants prior to and 3-months after being provided customised the devices. Data collected using Client Service Receipt Inventory (CRSI) in Chapter 5.

	Baseline data collection				3-month follow-up data collection			
Participant	**Name of Drug**	**Indication**	**Daily Dose**	**State if none**	**Any changes (Y/N)**	**Change in medication**	**Current daily does**	**End date (if stopped)**
001	-	-	-	No medication	No			
002	-	-	-	No medication	No			
003	-	-	-	No medication	No			
004	Topiramate	Seizure	150mg		No			
	Carbamazepine	Seizure	1200mg		No			
005	-	-	-	No medication	No			
006	Gabapentin	Epilepsy	100mg		No			
	Clopidogrel	Anti-platelet	-		No			
	Baclofen	Spasticity management	10mg		No			
	Lorazepam	Anxiety	1 tablet		No			
	Clonazepam	Seizures	1 tablet		No			
	Fluvastatin	hypercholesterolemia	40mg		No			
	Folic Acid		-		No			
007	-	-	-	No medication	No			
008	Gabapentin	Epilepsy	*Not known*		No			
	Amitriptyline	Pain relief	*Not known*		No			
	Paracetamol/ ibuprofen	Pain relief	When needed		No			
009	Levetiracetam	Epilepsy	1000mg		No			
010	Amitriptyline	Pain relief	20mg		Yes	Increased	30mg	

8.13 Appendix M: SQUIRE 2.0 checklist for Chapter 5

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) checklist for Chapter 5. Accessed from: Ogrinc G, Davies L, Goodman D, Batalden PB, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. BMJ Quality and Safety. 2016 Volume 25, Issue 12: pp. 986 – 992. (Ogrinc et al., 2016).

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	✓
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	n/a n/a

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	✓
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	✓
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	✓
6. Specific aims	Purpose of the project and of this report	✓
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	✓
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	✓ ✓
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	✓ -
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	✓ ✓ ✓
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	✓ ✓
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	✓

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project	–
	b. Details of the process measures and outcome	✓
	c. Contextual elements that interacted with the intervention(s)	–
	d. Observed associations between outcomes, interventions, and relevant contextual elements	–
	e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	✓
	f. Details about missing data	✓
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims	✓
	b. Particular strengths of the project	✓
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes	✓
	b. Comparison of results with findings from other publications	✓
	c. Impact of the project on people and systems	✓
	d. Reasons for any differences between observed and anticipated outcomes, including the influence of context	✓
	e. Costs and strategic trade-offs, including opportunity costs	✓
16. Limitations	a. Limits to the generalizability of the work	✓
	b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	✓
	c. Efforts made to minimize and adjust for limitations	✓
17. Conclusions	a. Usefulness of the work	✓
	b. Sustainability	✓
	c. Potential for spread to other contexts	✓
	d. Implications for practice and for further study in the field	✓
	e. Suggested next steps	✓
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	✓

8.14 Appendix N: COREQ checklist for Chapter 5

The Consolidated Criteria for Reporting Qualitative Studies (COREQ): 32-item checklist for the qualitative data from the semi-structured interviews is reported in Chapter 5. The checklist was developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357 (Tong et al., 2007)

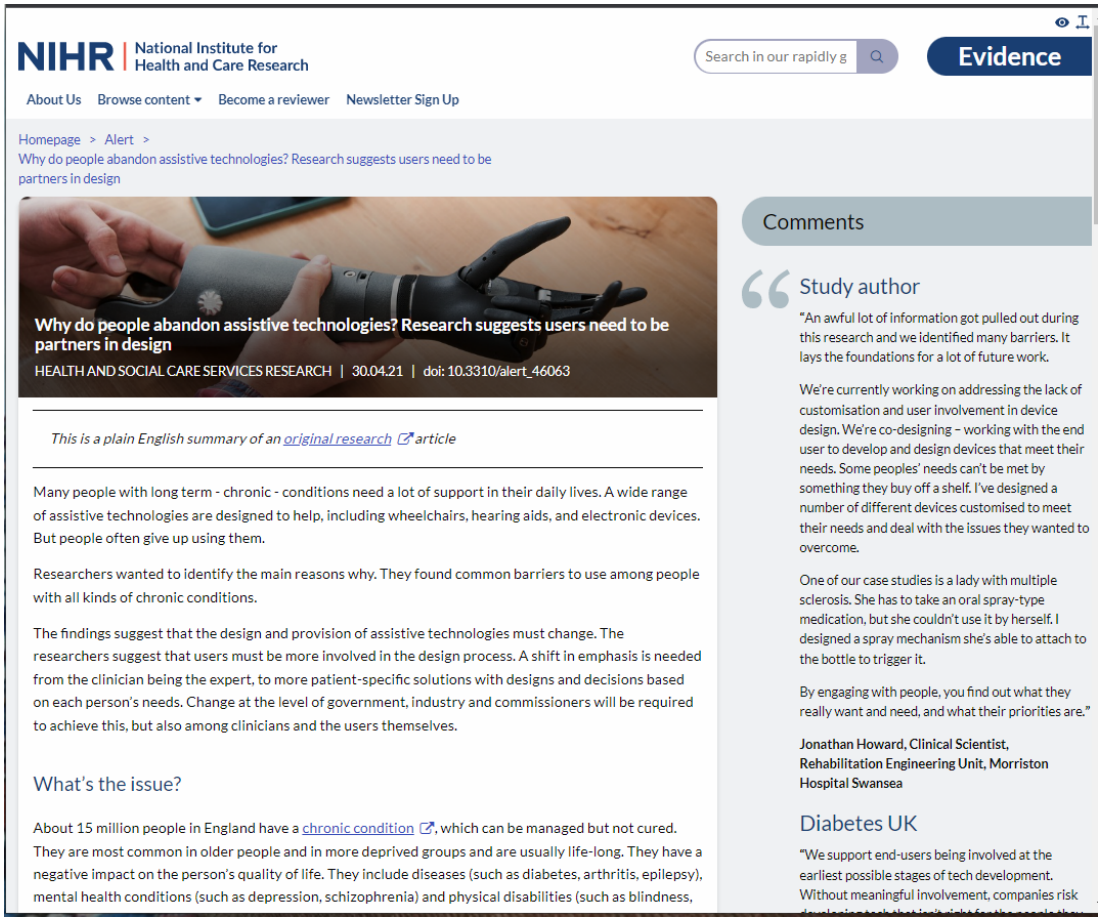
No.	Item	Description	Page number
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	**130**
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	**126**
3.	Occupation	What was their occupation at the time of the study?	**126**
4.	Gender	Was the researcher male or female?	**126**
5.	Experience and training	What experience or training did the researcher have?	**126**
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	**123**
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? *E.g. Personal goals, reasons for doing the research*	**124**
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? *E.g. Bias, assumptions, reasons and interests in the research topic*	**130**
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and theory	What methodological orientation was stated to underpin the study? *E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	**130**
Participant selection			
10.	Sampling	How were participants selected? *E.g. purposive, convenience, consecutive, snowball*	**123**
11.	Method of approach	How were participants approached? *E.g. face-to-face, telephone, mail, email*	**123**
12.	Sample size	How many participants were in the study?	**123 - 124**
13.	Non-participation	How many people refused to participate or dropped out? What were the reasons for this?	**124**
Setting			
14.	Setting of data collection	Where was the data collected? *E.g. home, clinic, workplace*	**130**
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	**130**

16.	Description of sample	What are the important characteristics of the sample? *E.g. demographic data, date*	**124**
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	**130**
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	**130**
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	**130**
20.	Field notes	Were field notes made during and/or after the interview or focus group?	**130**
21.	Duration	What was the duration of the interviews or focus group?	**130**
22.	Data saturation	Was data saturation discussed?	**162**
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	**N/a**
Domain 3: analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	**131-132**
25.	Description of the coding tree	Did authors provide a description of the coding tree?	**141, 153**
26.	Derivation of themes	Were themes identified in advance or derived from the data?	**131-132**
27.	Software	What software, if applicable, was used to manage the data?	**131-132**
28.	Participant checking	Did participants provide feedback on the findings?	**N/a**
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? *E.g. Participant number*	**141-151**
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	**141-151**
31.	Clarity of major themes	Were major themes clearly presented in the findings?	**141-151**
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	**141-151**

8.15 Appendix O: NIHR summary article of barriers to assistive technology

The National Institute for Health and Care Research (NIHR) produced a plain English summary of the barriers to assistive technology published article in Chapter 3. The article produced by NIHR intends to widen the scope and make scientific findings more accessible to the general public. The full web-link the article is provided below (Accessed 09/12/2022)

https://evidence.nihr.ac.uk/alert/why-people-abandon-assistive-technologies-research-suggests-users-become-partners-in-design-users/



NIHR | National Institute for Health and Care Research

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Evidence

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Homepage > Alert >
Why do people abandon assistive technologies? Research suggests users need to be partners in design

Why do people abandon assistive technologies? Research suggests users need to be partners in design

HEALTH AND SOCIAL CARE SERVICES RESEARCH | 30.04.21 | doi: 10.3310/alert_46063

This is a plain English summary of an original research article

Many people with long term - chronic - conditions need a lot of support in their daily lives. A wide range of assistive technologies are designed to help, including wheelchairs, hearing aids, and electronic devices. But people often give up using them.

Researchers wanted to identify the main reasons why. They found common barriers to use among people with all kinds of chronic conditions.

The findings suggest that the design and provision of assistive technologies must change. The researchers suggest that users must be more involved in the design process. A shift in emphasis is needed from the clinician being the expert, to more patient-specific solutions with designs and decisions based on each person's needs. Change at the level of government, industry and commissioners will be required to achieve this, but also among clinicians and the users themselves.

What's the issue?

About 15 million people in England have a chronic condition, which can be managed but not cured. They are most common in older people and in more deprived groups and are usually life-long. They have a negative impact on the person's quality of life. They include diseases (such as diabetes, arthritis, epilepsy), mental health conditions (such as depression, schizophrenia) and physical disabilities (such as blindness,

Comments

Study author

"An awful lot of information got pulled out during this research and we identified many barriers. It lays the foundations for a lot of future work.

We're currently working on addressing the lack of customisation and user involvement in device design. We're co-designing – working with the end user to develop and design devices that meet their needs. Some peoples' needs can't be met by something they buy off a shelf. I've designed a number of different devices customised to meet their needs and deal with the issues they wanted to overcome.

One of our case studies is a lady with multiple sclerosis. She has to take an oral spray-type medication, but she couldn't use it by herself. I designed a spray mechanism she's able to attach to the bottle to trigger it.

By engaging with people, you find out what they really want and need, and what their priorities are."

Jonathan Howard, Clinical Scientist, Rehabilitation Engineering Unit, Morriston Hospital Swansea

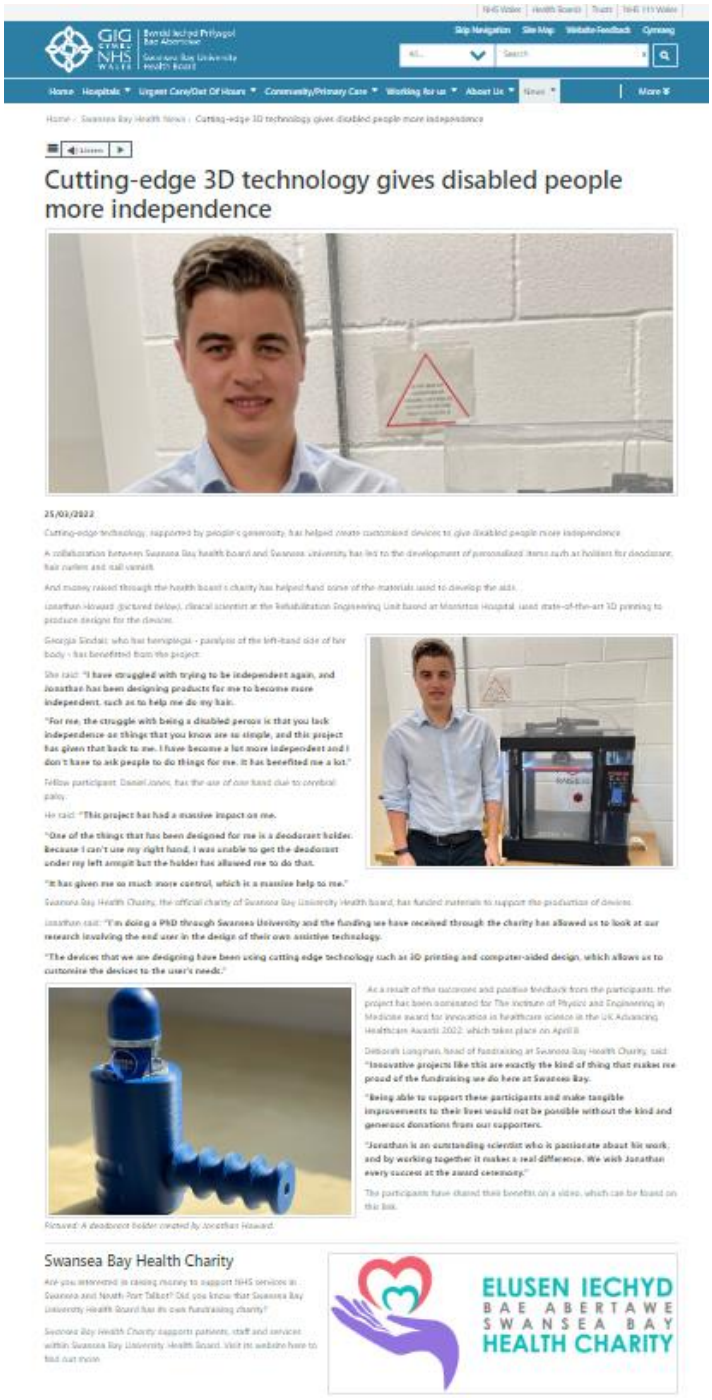
Diabetes UK

"We support end-users being involved at the earliest possible stages of tech development. Without meaningful involvement, companies risk

8.16 Appendix P: Swansea Bay University Health Board news article

Swansea Bay University Health Board produced a news article for the work around co-designing assistive devices with individuals (Chapters 4-6). (Accessed 09/12/2022)

https://sbuhb.nhs.wales/news/swansea-bay-health-news/cutting-edge-3d-technology-gives-disabled-people-more-independence/



GIG CYMRU NHS WALES

Cutting-edge 3D technology gives disabled people more independence

25/03/2022

"I have struggled with trying to be independent again, and Jonathan has been designing products for me to become more independent, such as to help me do my hair.

"For me, the struggle with being a disabled person is that you lack independence on things that you know are so simple, and this project has given that back to me. I have become a lot more independent and I don't have to ask people to do things for me. It has benefited me a lot."

He said: "This project has had a massive impact on me.

"One of the things that has been designed for me is a deodorant holder. Because I can't use my right hand, I was unable to get the deodorant under my left armpit but the holder has allowed me to do that.

"It has given me so much more control, which is a massive help to me."

Jonathan said: "I'm doing a PhD through Swansea University and the funding we have received through the charity has allowed us to look at our research involving the end user in the design of their own assistive technology.

"The devices that we are designing have been using cutting edge technology such as 3D printing and computer-aided design, which allows us to customise the devices to the user's needs."

Pictured: A deodorant holder created by Jonathan Howard.

"Innovative projects like this are exactly the kind of thing that makes me proud of the fundraising we do here at Swansea Bay.

"Being able to support these participants and make tangible improvements to their lives would not be possible without the kind and generous donations from our supporters.

"Jonathan is an outstanding scientist who is passionate about his work, and by working together it makes a real difference. We wish Jonathan every success at the award ceremony."

Swansea Bay Health Charity

ELUSEN IECHYD BAE ABERTAWE SWANSEA BAY HEALTH CHARITY

9 Glossary

Assistive Technology

Any product either specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their wellbeing (Khasnabis et al., 2015). This includes both physical devices and software applications.

Assistive devices

In this thesis the term assistive device is used to describe a sub-category of assistive technology related to physical devices: for example, wheelchairs, prosthetics, communication aids and aids for daily living.

Additive Manufacturing

The building of a physical object layer-by-layer through a series of cross-sectional slices, typically derived from a 3D digital model. Additive manufacturing is an umbrella term that describes a range of different manufacturing techniques, although is most commonly referred to as 3D printing. *Within this thesis additive manufacturing and 3D printing will be used interchangeably, it will predominantly use 3D printing as the more colloquial term.*

Computer aided design

The use of computer-based software to aid in the creation, modification or optimisation of a design. It can be used to create 2D drawings, or 3D models of a design for manufacturing.

Digital Design and Manufacturing

A term to group techniques associated with computer aided design and additive manufacturing.

Co-design

Co-design, or participatory design, is a design methodology that seeks to actively involve the end user of a product in the design process through collaboration with the designer (Sanders & Stappers, 2008).

Co-production

A person-centred approach where patients are placed in equal partnership with healthcare professionals for managing their own health and wellbeing and making decisions about their care (Realpe & Wallace, 2010).

Self-management

An individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition (Barlow et al., 2002).

GENIAL wellbeing model

A biopsychosocial model that describes wellbeing as a multi-faceted entity for the individual, community and the environment related to emotional balance, healthy bodies, personal relationships, connectiveness to communities and the natural environment. (Kemp et al., 2017; Kemp & Fisher, 2022; Mead et al., 2021).

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