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

Authors:
Jonathan Howard [a, b*], Lorna H Tasker [b], Zoe Fisher [c, d], Jeremy Tree [a]

[a] *Department of Psychology, College of Human and Health Sciences, Swansea University, Swansea, United Kingdom*

[b] *Rehabilitation Engineering Unit, Swansea Bay University Health Board, Morriston Hospital, Swansea, United Kingdom*

[c] *Health and Wellbeing Academy, College of Human and Health Sciences, Swansea University, Swansea, United Kingdom*

[d] *Regional Neuropsychology and Community Brain Injury Service, Swansea Bay University Health Board, Morriston Hospital, Swansea, United Kingdom*

*Corresponding Author:
Jonathan Howard, Rehabilitation Engineering Unit, Morriston Hospital, Swansea, SA6 6NL, United Kingdom.
Email: Jonathan.Howard2@wales.nhs.uk

This is an Accepted Manuscript of an article published by Taylor & Francis in Disability and Rehabilitation: Assistive Technology on 15th April 2022, available at:
https://www.tandfonline.com/doi/full/10.1080/17483107.2022.2060355

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

Abstract

Introduction: Co-design involves engaging with the end-user in the design process and may help reduce the barriers to assistive technology use. Previous research has used co-design in the provision of assistive technology, but no research has looked at applying it within a healthcare setting. This service evaluation examines the use of co-design in providing customised assistive devices within a current UK healthcare based Rehabilitation Engineering department.

Methods: This evaluation reports on three case-studies. Individuals identified a range of challenges in daily living. The participants worked with the clinician in trialling prototypes and providing feedback to develop custom devices. A mixed-method approach of questionnaires and semi-structured interviews were used to evaluate the devices provided and the co-design approach. The resources required to provide the device were also calculated.

Results: Five different devices were developed which were able to overcome the challenges identified. Results indicated participants were satisfied with both the devices and service provided. Participants expressed other benefits including increased independence, increased positive emotions, and reduced mental load. Participants indicated they liked being involved in the design process and their feedback helped ensure the devices were customised to their needs.

Conclusions: The use of co-design was able to produce customised assistive device that met the needs of the individuals within a current healthcare service. Further work is required to assess the feasibility of utilising a co-design approach for the provision of other custom assistive technology in the future and explore if this can overcome the barriers to assistive technology use.

Key words: Assistive technology, custom assistive devices, Co-design, participatory design, user involvement

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"* [1]. 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 [2,3]. Providing the right assistive technology has the potential to reduce the burden of chronic conditions on the individuals, caregivers, healthcare services and wider society [4-8]. However, despite the 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 [9]. 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 [10-13] is to increase the involvement of the end-user in the design and provision process.

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 [14,15]. 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 [16,17].

Various previous studies have presented different co-design methodologies for the provision of assistive technology however, the methodologies share 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 [18-20]. 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 [21-23] . Whilst Thorsen et al. (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 [24].

From the current literature, we have identified several common shortcomings 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 [23]. 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 been 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, our 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 cost involved in utilising a co-design approach?

Through this evaluation we intend to help inform future service delivery and refine our methodology for future research studies around the use of co-design in the provision of customised assistive devices. We believe that 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 SQUIRE 2.0 guidelines [25].

Methodology

Service context:

This work took place in Swansea Rehabilitation Engineering Unit, part of Swansea Bay University Health Board. 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.

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 South West Wales. Participants presented with a range of different medical conditions and challenges of daily living that they wanted to overcome, Table 1.

Table 1: Summary information of participants involved in the study

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 eye-liner 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 again at the table to cut up food	D345 D550
003	62	F	Multiple Sclerosis	8A40.2	Independently administer Sativex, an oral medication spray	D5702

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). The participants who were invited to participate in the evaluation provided both written and verbal consent for their information to be shared as case-studies and included in this evaluation with any personal identifiable information anonymised.

Materials

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 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, 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.

Questionnaire measures: The two questionnaires used to explore participant's experiences of the device they co-designed and its impact were the Quebec User Evaluation of Satisfaction with Technical Aids (QUEST 2.0) and the Psychosocial Impact of Assistive Devices Scale (PIADS) [26,27] . QUEST 2.0 is a 12-item outcome measure that assesses the user satisfaction with the assistive device and the service supplying the device [26]. 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 [26,28,29]. 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 [27]. 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 [30]. It is a responsive measure and sensitive to important variables such as the user's 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 [19,20,22,23].

Semi-structured interviews: Participants were invited by email prior 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. 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 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 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 they 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'*.

Procedure

The process undertaken by each participant in this study is summarised in Figure 1.

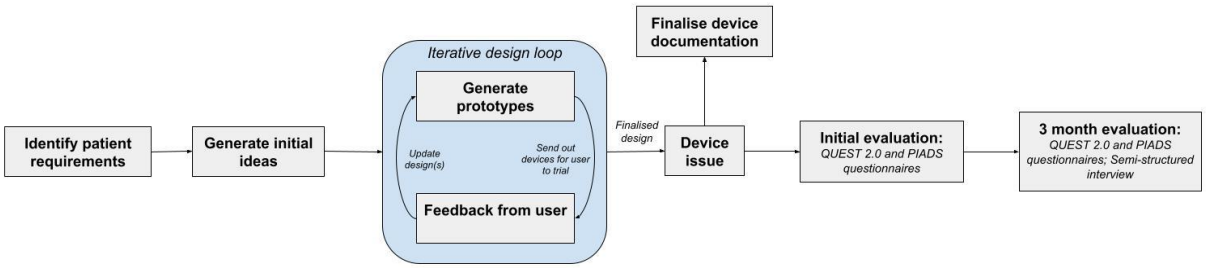

Figure 1: Overview of the process for participants involved within the study.

(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 or the device(s) and design ideas generated through sketches and low-fidelity prototypes.

(3) *Generating prototypes*. Functional prototypes were created using a mixture of Computer Aided Design (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.

Data Analysis

Questionnaire analysis

Average 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 services 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 response. 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 participant, eagerness to try new things, ability to adapt to ADL, 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.

Qualitative analysis

Following the interviews, the audio files were transcribed by the interviewer for analysis. The semi-structured interviews 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) [31]. 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 does not improve the accuracy of the coding process [31]. 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 [32]. The qualitative data from the semi-structured interviews is reported following the Consolidated Criteria for Reporting Qualitative Studies (COREQ): 32-item checklist [33].

Cost analysis

For each participant the resources (time, money, material cost) required to produce the final device 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 based on the NHS pay scale as calculated at time of case study (September 2020).

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 are participants experiences of this process and using the devices produced and 3) what are the cost implications. Accordingly, the results section is structured around these questions.

1. ***Devices Produced:*** A total of 5 different devices were co-designed and provided to the three participants, see Figure 2 A-E. 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.

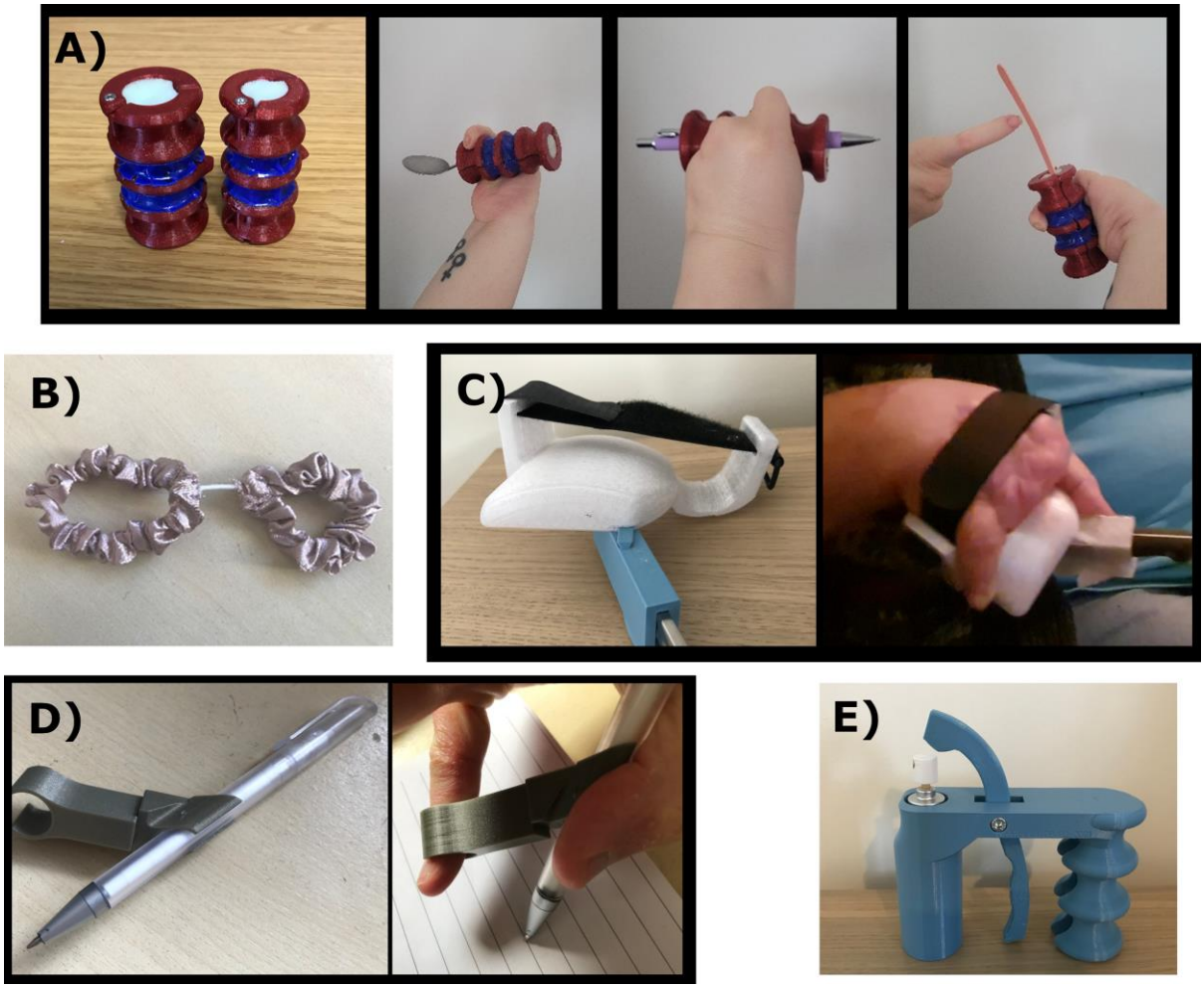

Figure 2: Devices produced for participants during the study.

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 at the 3 months after being issued the device. The one device no longer being used regularly was the pen holder for participant 2 who had regained sufficient function in her right hand she was able to use a pen again without the device.

2. Evaluation of devices and approach: A mixed-methods approach was chosen to evaluate the satisfaction with the devices produced and the process of providing the devices.

***Questionnaire scores*:** A summary of the results from the QUEST questionnaire are shown in table 3. 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 3: Summary results from the QUEST questionnaire for all three participants initially after being provided the results and 3-months post device issue. Participant 3 did not complete the QUEST questionnaire at 3 months follow-up.

Participant	**Device**	**After issuing device (Score) (0-5)**		**3-month follow-up (Score) (0-5)**	
		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. 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: 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 follow-up.

Participant	Device	After issuing device (Score) (-3 to 3)			3-month follow-up (Score) (-3 to 3)		
		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	1.68	2.16	2.95	3	2.8
Standard Deviation	All Devices	0.54	0.29	0.24	0.1	0	0.23

Qualitative feedback: In total 11 themes were identified from 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, figure 3. The themes, including quotations from the semi-structured interviews and frequency scores (n), are described below.

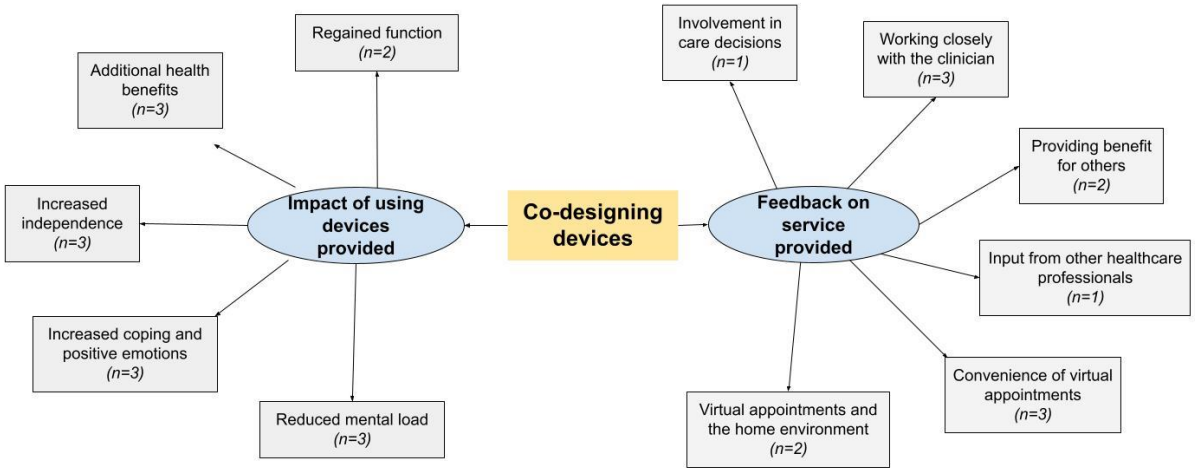

Figure 3: A summary of themes identified from the participant's semi-structured interviews with the frequency (n) calculated.

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 and 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 feelings of a sense of achievement, a sense of restoring loss function, improved confidence and more a 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, for example participant 1 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."

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 conversation' 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."

3. Cost Analysis

The total cost of providing the devices for each participant ranged is summarised in table 5. 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 5: 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	Clinician 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 reproducing the finished devices provided to the participants is summarised in table 6. 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 6: 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

General Discussion

This evaluation explored the use of co-design to provide customised assistive devices within a current healthcare service based in South West Wales, UK. In this work we have 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, we shall discuss this work 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.

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 questionnaires, table 3, 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 from using the device went beyond simply using 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 measure of the PIADS questionnaire: competences, adaptability, and self-esteem, table 4. 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 improvement in overall health and wellbeing [34]. 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 and balanced mind and health body [34-36]. This could further evaluate if there are any wider benefits to an individuals life from providing the right assistive technology.

The use of a mixed-methods evaluation approach 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.

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 questionnaires highlighted satisfaction with the service provided, table 3. The theme of '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, where previously she had felt excluded from her own care. These themes reflect wider approaches, for example co-production which identifies the individuals as the expert in their own health and user-driven approaches which reinforces the role of the user as the primary knower of their own needs [37,38]. Whilst it is not clear how much these results would be applicable to other situations, it certainly indicates that individuals are happy with greater involvement in their care and liked an individualised approach to their care, factors previously identified as barriers in the service provision of assistive technology [9].

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 us to gather 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 and savings in 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 [9]. 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 effectively. Whilst the use of virtual appointments was out of necessity initially, the results from this evaluation may indicate how future co-design processes could benefit from utilizing virtual appointments.

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 6. 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 cost in the production process, Table 5. 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 designs 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 any further follow-up required after the participants were issued the device? 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.

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 was 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 our methodology for future larger research studies.

Conclusion

This service evaluation demonstrates that it is possible to co-design within the current structure and resources of a healthcare service. This paper 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, but 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.

Acknowledgements

The authors would like to thank all three participants for agreeing to take part in this service evaluation.

Conflict of interest

The authors report no conflicts of interest

References

1. Khasnabis C, Mirza Z, Maclachlan M. Opening the GATE to inclusion for people with disabilities. The Lancet. 2015;386(10010):2229-2230.
2. McNicholl A, Casey H, Desmond D, et al. The impact of assistive technology use for students with disabilities in higher education: a systematic review. Disabil Rehabil Assist Technol. 2019 Jul 23:1-14.
3. Abrilahij A, Boll T. A Qualitative Metasynthesis of Reasons for the Use or Nonuse of Assistive Technologies in the Aging Population. GeroPsych. 2019;32(2):79-92.
4. Mitzner TL, Boron JB, Fausset CB, et al. Older Adults Talk Technology: Technology Usage and Attitudes. Comput Human Behav. 2010 Nov 1;26(6):1710-1721.
5. Madara Marasinghe K. Assistive technologies in reducing caregiver burden among informal caregivers of older adults: a systematic review. Disabil Rehabil Assist Technol. 2016;11(5):353-60.
6. van Ommeren AL, Smulders LC, Prange-Lasonder GB, et al. Assistive Technology for the Upper Extremities After Stroke: Systematic Review of Users' Needs. JMIR Rehabil Assist Technol. 2018 Nov 29;5(2):e10510.
7. Lansley P. Can adapting the homes of older people and providing assistive technology pay its way? Age and Ageing. 2004;33(6):571-576.
8. World Health Organisation. Assistive Technology: World Health Organisation; 2018 [cited 2019 03 November]. Available from: https://www.who.int/news-room/fact-sheets/detail/assistive-technology
9. Howard J, Fisher Z, Kemp AH, et al. Exploring the barriers to using assistive technology for individuals with chronic conditions: a meta-synthesis review. Disability and Rehabilitation: Assistive Technology. 2020:1-19.
10. Martin JK, Martin LG, Stumbo NJ, et al. The impact of consumer involvement on satisfaction with and use of assistive technology. Disabil Rehabil Assist Technol. 2011;6(3):225-42.
11. Robinson L, Gibson G, Kingston A, et al. Assistive technologies in caring for the oldest old: a review of current practice and future directions. Aging Health. 2013;9(4):365-375.
12. Orejuela-Zapata JF, Rodriguez S, Ramirez GL. Self-Help Devices for Quadriplegic Population: A Systematic Literature Review. IEEE Trans Neural Syst Rehabil Eng. 2019 Apr;27(4):692-701.
13. Alqahtani S, Joseph J, Dicianno B, et al. Stakeholder perspectives on research and development priorities for mobility assistive-technology: a literature review. Disabil Rehabil Assist Technol. 2019 Sep 19:1-15.
14. Sanders EBN, Stappers PJ. Co-creation and the new landscapes of design. CoDesign. 2008 2008/03/01;4(1):5-18.
15. Federici S, Borsci S, Kurosu M, et al. Computer Systems Experiences of Users with and without Disabilities: An Evaluation Guide for Professionals. 2013.
16. Vines J, Clarke R, Wright P, et al. Configuring participation: on how we involve people in design. Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; Paris, France: Association for Computing Machinery; 2013. p. 429–438.
17. Hakobyan L, Lumsden J, O'Sullivan D. Older Adults with AMD as Co-Designers of an Assistive Mobile Application. International Journal of Mobile Human Computer Interaction. 2014;6(1):54-70.
18. De Couvreur L, Goossens R. Design for (every)one: co-creation as a bridge between universal design and rehabilitation engineering. CoDesign. 2011 2011/06/01;7(2):107-121.
19. Santos AVF, Silveira ZC. AT-d8sign: methodology to support development of assistive devices focused on user-centered design and 3D technologies. Journal of the Brazilian Society of Mechanical Sciences and Engineering. 2020 2020/04/26;42(5):260.

20. Gherardini F, Mascia MT, Bettelli V, et al. A Co-Design Method for the Additive Manufacturing of Customised Assistive Devices for Hand Pathologies. Journal of Integrated Design and Process Science. 2018;22:21-37.
21. Day SJ, Riley SP. Utilising three-dimensional printing techniques when providing unique assistive devices: A case report. Prosthet Orthot Int. 2018 Feb;42(1):45-49.
22. Lee KH, Kim DK, Cha YH, et al. Personalized assistive device manufactured by 3D modelling and printing techniques. Disabil Rehabil Assist Technol. 2019 Jul;14(5):526-531.
23. Schwartz JK, Fermin A, Fine K, et al. Methodology and feasibility of a 3D printed assistive technology intervention. Disabil Rehabil Assist Technol. 2020 Feb;15(2):141-147.
24. Thorsen R, Bortot F, Caracciolo A. From patient to maker - a case study of co-designing an assistive device using 3D printing. Assist Technol. 2019 Jul 16:1-7.
25. Ogrinc G, Davies L, Goodman D, et al. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2016 Dec;25(12):986-992.
26. Demers L, Monette M, Lapierre Y, et al. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disability Rehabilitation. 2002 Jan 10-Feb 15;24(1-3):21-30.
27. Day H, Jutai J, Campbell KA. Development of a scale to measure the psychosocial impact of assistive devices: lessons learned and the road ahead. Disabil Rehabil. 2002 Jan 10-Feb 15;24(1-3):31-7.
28. Demers L, Weiss-Lambrou R, Ska B. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 20): An overview of recent progress. Technology and Disability. 2002 01/01;14.
29. Demers L, Weiss-Lambrou R, Ska B. Item analysis of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST). Assistive Technology. 2000;12(2):96-105.
30. Jutai J, Day H. Psychosocial Impact of Assistive devices Scale (PIADS). Technology and Disability. 2002 01/01;14:107-111.
31. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006 2006/01/01;3(2):77-101.
32. Clarke V, Braun V. Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. Counselling and Psychotherapy Research. 2020 10/18;21.
33. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007 Dec;19(6):349-57.
34. Fisher Z, Galloghly E, Boglo E, et al. Emotion, Wellbeing and the Neurological Disorders. Reference Module in Neuroscience and Biobehavioral Psychology: Elsevier; 2020.
35. Kemp A, Arias JA, Fisher Z. Social Ties, Health and Wellbeing: A Literature Review and Model. In: Ibáñez A., Sedeño L., A. G, editors. Neuroscience and Social Science: The Missing Link: Springer; 2017.
36. Mead J, Fisher Z, Lowri W, et al. Rethinking wellbeing: Toward a more ethical science of wellbeing that considers current and future generations. Authorea. 2019.
37. Realpe A, Wallace LM. What is co-production? : Foundation TH; 2010.
38. Scherer MJ, Federici S. Assistive Techology Assessment Handbook. 2nd ed. Boca Raton: CRC Press; 2017.