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Extended Research Article

Social network intervention for loneliness and social isolation in a community setting: the PALS cluster-RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Background: Loneliness and social isolation are associated with adverse mental and physical health outcomes in adults. However, there is a lack of existing research on effective interventions and the contexts in which these could be implemented.

Primary objective: To assess the clinical and cost-effectiveness of a social network intervention compared to usual care among at-risk populations.

Design: A pragmatic, community-based, cluster randomised controlled trial with embedded health economic evaluation, process evaluation and qualitative study. Outcome assessments were conducted at baseline and at 3 and 6 months.

Setting: The study was conducted in collaboration with 44 community-based organisations in two regions in England.

Participants: Adults aged ≥ 18 years at risk of loneliness and social isolation.

Intervention: A facilitated social network tool ('project about loneliness and social networks'; PALS) designed to link people to opportunities for social involvement. First, participants map and reflect on personal social networks. Second, identification of local resources based on individual preferences, available support, and health and wellness needs.

Main outcome measures: The primary outcome was mental wellness at 6-month follow-up, measured by the Short Form questionnaire-12 items mental health component score (MCS). Secondary outcomes included the Short Form questionnaire-12 items Physical Health subscale, loneliness, social isolation, well-being and collective efficacy. Economic measures assessed the cost-effectiveness of the intervention in terms of costs, quality-adjusted life-years and net monetary benefits.

Results: We recruited 469 adults into the study, with 120 withdrawals (25.6%). The main trial results indicate little to no treatment effect of the intervention on either the primary or secondary outcomes compared to usual care. The within-trial economic evaluation found that PALS was inexpensive to deliver but there was no significant difference in quality-adjusted life-years, measures of well-being capability or costs, and the intervention did not lead to demonstrable cost-effectiveness in terms of net monetary benefits. The process evaluation found PALS to be acceptable to all types of community organisations, but low resource availability and capacity to sustain PALS was found across all community organisational contexts. Qualitative interviews (n = 20) highlighted that participants wanted to engage with meaningful social activities but barriers to doing so were psychological (i.e. confidence and competence) and practical (i.e. transport or cost).

Limitations: The timing of COVID-19 and associated restrictions (approximately splitting trial follow-up into thirds of pre-COVID, during the first lockdown, and following the trial reopening) meant its impact on the trial is difficult to assess. There were high levels of missing data (20–30% for most outcomes at 6 months), though methods to handle missing data did not change the conclusions of the trial.

Conclusions: Our findings do not provide strong evidence of the efficacy of the PALS social network intervention to address the complexities of loneliness and social isolation. Although the intervention was acceptable to participants and community organisations who hold the potential to deliver such an intervention, sustainability would require a networked approach between organisations to mitigate against the challenges found in each organisation.

Future work: Future interventions for loneliness would likely benefit from utilising a multistep approach providing tailored psychological, relational and social components.

Trial registration: This trial is registered as Current Controlled Trials ISRCTN19193075.

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Contents

List of tables

List of figures

List of supplementary material

Report Supplementary Material 1	PALS facilitator training guide

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/WTJH4379).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

A&E	accident and emergency
CEAC	cost-effectiveness acceptability curve
CENS	Collective Efficacy Network Scale
CFIR	Consolidated Framework for Implementation Research
CI	confidence interval
GENIE	Generating Engagement in Network Involvement
GP	general practitioner
ICC	intracluster correlation
ICECAP-A	ICEpop CAPability measure for Adults
iNMB	incremental net monetary benefit
MCS	mental health component score
NMB	net monetary benefit
PALS	project about loneliness and social networks (study name)
PCS	physical composite score
PPI	patient and public involvement
PSS	personal and social services
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
SAE	serious adverse event
SD	standard deviation
SF-12	Short Form questionnaire-12 items
SF-6D	Short Form questionnaire-6 Dimensions
TSC	Trial Steering Committee
WEMWBS	Warwick–Edinburgh Mental Well-Being Scale
WTP	willingness to pay
YFC	years of full capability
YSC	years of sufficient capability

Plain language summary

Loneliness is a negative feeling relating to desired level of social contact with others. Around 30% of the United Kingdom population experience loneliness. Feeling lonely and isolated has a negative impact on a person's emotional and physical health, but one way to tackle loneliness is through connecting with community resources which can help protect against loneliness.

This study aimed to recruit people experiencing loneliness or isolation, working with community organisations around Southampton and Liverpool. Half of the people in the study were given access to a tool called PALS ('project about loneliness and social networks'), designed to map a person's social network and connect them to local community groups and activities.

We looked at the impact of PALS on mental health and other health outcomes, compared to 'usual care' for the organisation. We also looked at both quality of life and costs to see whether PALS offers value for money (i.e. is 'cost-effective'). We looked at how PALS was delivered, and interviewed participants about their experiences of loneliness.

We recruited 469 adults from 44 different organisations. Our findings show that it would be possible to sustain delivery of an intervention for loneliness in a community setting if organisations were able to work together to overcome resource issues.

However, we found that although acceptable, PALS did not 'work' to significantly impact on mental health or loneliness. PALS was cheap to deliver but we did not find evidence that it offers better value for money compared to usual care. We do not recommend it becomes national public health policy.

Participant interviews highlighted a link between loneliness and a lack of confidence and skills for building emotional connections with others. Connecting to new community activities was also impacted by social factors like availability in the local area and access to transport. Future interventions should include a multistep approach focused around these areas.

Scientific summary

Background and rationale

Social isolation is defined as a lack of social connections, contact or participation, while loneliness is a subjective psychological state where there is a discrepancy between desired and perceived levels of support or connectedness. Both social isolation and loneliness have been found to be associated with adverse mental and physical health outcomes. A potential mechanism for protecting against loneliness is to improve quality of interpersonal relationships and participation in social activities, as both social and emotional support from others is likely to be protective of the maintenance of health. Social network interventions have been shown to increase the uptake of new activities by connecting individuals to community resources, in addition to improving health outcomes. The current study was therefore designed to evaluate a social network intervention for loneliness, implemented outside of the formal healthcare setting, to connect people who are at risk of loneliness to others within their communities.

Aims and objectives

The aim of the study was to assess the clinical and cost-effectiveness of implementing a social network intervention [‘project about loneliness and social networks’ (PALS)] designed to link people at risk of social isolation and loneliness to community resources and activities.

Secondary objectives included exploration of the environmental and organisational factors that affected the integration and scalability of the intervention in local and organisational settings and exploration of participant experiences of loneliness in the context of building connections with important others and local communities.

Methods

The study design was a pragmatic, community-based, cluster randomised controlled trial with embedded health economic evaluation. A mixed-methods process evaluation included observations, interviews, a focus group and documentary analysis of relevant documents to assess the process of inducing, engaging and delivering the intervention. Concepts from the Consolidated Framework for Implementation Research were used to inform the analysis. Qualitative interviews were undertaken with participants with diverse demographic characteristics.

Inclusion criteria

To be eligible for enrolment in the study, participants had to be aged ≥ 18 years and be at risk of loneliness or social isolation. Participants were excluded if they were not living within a community setting, had any medical condition which impacted on their ability to take part, lacked sufficient capacity to consent, or had previously had access to the intervention.

Recruitment

The study identified and recruited community-based partner organisations to recruit participants and to deliver the intervention following bespoke study training. Participants were identified in line with the ordinary working practices (i.e. usual care) of the linked organisations. In total, participants were recruited from 44 community-based partner organisations.

Randomisation

A degree of flexibility was required in the study randomisation to ensure that it could be operationalised across all organisational contexts and potential facilitator–participant relationships. Therefore, it was set out that where possible, both facilitators and participants would be randomised within an organisation, and only facilitators randomised to the intervention group would be trained in how to deliver the intervention (to avoid contaminating the 'usual care' within that organisation). Four models of randomisation were outlined, where the model utilised was determined by whether it was possible to randomise the facilitator and whether there was an ongoing relationship between the facilitator and the participant.

Intervention

The social network 'Generating Engagement in Network Involvement' (GENIE) intervention was modified for use in the context of loneliness and social isolation. A trained facilitator (from a lay or professional background) guided the recipient through the process. There are three key stages in delivering the intervention. This starts with the development of a visual representation (i.e. map) of a person's existing personal community. It then works towards exploring their preferences and the leveraging of actual or potentially available community resources. This process is coproduced, and the user has ownership of the network map. Finally, links to locally available resources and activities are achieved by focusing on individual preferences.

Outcomes

The primary outcome of the trial was mental wellness at 6-month follow-up as measured by the Short Form questionnaire-12 items mental health component score (SF-12 MCS). Secondary outcomes included physical health, loneliness, social isolation, social support and collective efficacy. Economic outcomes assessed quality of life (Short Form questionnaire-6 Dimensions), capability well-being [ICEpop CAPability measure for Adults (ICECAP-A)], resource use and engagement with new activities.

All participants completed baseline data collection upon entry into the study. At 3 and 6 months after enrolment into the study, participants were sent follow-up assessments.

Data management and analysis

The sample size calculation was based on the primary analysis of the comparison of intervention and usual care on SF-12 MCS at 6 months, assuming that a 4-point difference detected on the SF-12 would be clinically meaningful. It was assumed that each facilitator would be able to recruit 12 participants, and a 15% dropout was accounted for, resulting in a recruitment target of 335 people. Following the COVID-19 pandemic, the overall target sample size was adjusted to reflect the loss to follow-up due to the pandemic. The complete cases target sample size was not changed (i.e. 335 people), but a total of 453 was the overall target (assuming that loss to follow-up post pandemic would be 15%). The statistical and health economics analysis plan was agreed prior to final analysis.

Results

In total, 469 participants were recruited into the study and completed baseline assessments. The median age of participants who took part in the trial was 65 years, with participant ages ranging across the life course from 19 to 95 years. A total of 330 participants were female (70.4%), and 433 participants were of white ethnicity (92.3%). Approximately half of participants in the trial lived alone (*n* = 242, 51.6%). Of the 469 participants, 227 were allocated to the control group and 242 to the intervention group. The results for both 3- and 6-month analyses provided no indication to support a meaningful treatment effect of the intervention on the primary outcome. Evidence also indicated no meaningful treatment effect of the intervention on any of the secondary outcomes. The within-trial economic evaluation found that PALS was inexpensive to deliver but there was no difference in quality-adjusted life-years (QALYs), measures of well-being capability or costs. Net monetary benefits were small and close to zero, suggesting the approaches are near-equivocal at all threshold values of willingness to pay per QALY. There was no demonstrable benefit of PALS in terms of cost-effectiveness from a public sector perspective.

Process evaluation

A typology of community organisations was developed to portray the complexities experienced when implementing in open systems like community contexts. The typology categorised organisations as existing on a continuum from fully professionalised organisations, to aspirational community, voluntary and social enterprises, and finally non-professionalised community-based groups. Within each organisation, the implementation was shaped by 'service user needs', 'workforce' and 'organisational structure' but in different ways. No single context was found to possess all the facets necessary for implementation; a networked approach that connects the facets of reach and delivery is likely to help facilitate intervention delivery in each setting and thus support sustainability. In the context of loneliness and social isolation, the environment of austerity negatively affects organisational capacity in numerous and interacting ways. Of particular note was the precarious nature of many community organisations, which are continuously seeking financial investment to secure their own survival in addition to facing increasing pressures and demands for scarce resources.

Qualitative study

Twenty participants were interviewed about their experiences of loneliness. The qualitative findings highlighted that it is not an absence of people but an absence of emotional connections that leads to feelings of loneliness. Participants indicated a desire to increase social participation and develop new links to local community activities; however, several barriers were identified. At an individual level, some participants lacked the confidence and social skills to engage in new activities, and some felt that additional support for attending new places would be beneficial. Others identified how social and structural aspects of the community made it difficult to widen social contact where, for example, local resources did not exist and there was no accessible or affordable means to travel. These results indicate that interventions would likely benefit from several interacting components, tailored to individual need and social circumstance.

Conclusions

On the basis of evidence collected in this trial, PALS should not be implemented in a community setting. The findings from this study highlight the difficulties of delivering interventions in communities, and show no evidence of a significant impact on participant mental health, physical health or other outcomes (including loneliness and isolation).

Our work suggests that further intervention development work addressing individual, relational and social aspects of loneliness would be beneficial. Future work should also explore the commissioning context and funding arrangements (e.g. local authority, community organisations).

Trial registration

This trial is registered as Current Controlled Trials ISRCTN19193075.

Funding

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Chapter 1 Introduction

Loneliness and social isolation: the problem

Social isolation is defined as a lack of social connections, contact or participation, while loneliness is a subjective psychological state where there is a discrepancy between desired and perceived levels of support or connectedness.[1,2] Loneliness and social isolation are estimated to affect about 30% of the adult population in the UK,[3] and the impact of loneliness and isolation on well-being and health has been identified as a major public health problem.[4,5] Loneliness and social isolation are associated with poor physical and mental health outcomes,[6,7] reduced quality of life (QoL) across key points in the life course,[8,9] and poorer physiological outcomes such as raised blood pressure and increased health-risk behaviours (e.g. being excessively sedentary).[10] The impact on mortality is estimated to exceed that of major risk factors such as obesity and cigarette smoking, with a 50% higher risk compared with socially integrated participants.[11–13] Increased prevalence rates of loneliness have been identified in older people, minority communities and those with long-term mental or physical health conditions, who are significantly more isolated than those in good health.[14–16] Significant social and economic costs of loneliness are also associated with raised demand and use of health services, including increased general practitioner (GP) appointments, emergency hospital admittance and premature social care use.[17–19]

Factors influencing loneliness and social isolation include ageing, socioeconomic deprivation,[5] multimorbidities and stigma. The limitations of long-term conditions contribute to increased social isolation and feelings of loneliness.[20,21] Loss of employment through retirement or ill health can have a detrimental impact on social status and connections with others.[22] Reduced social contact and participation and widowhood are identified as additional risk factors[5,23] because they add barriers to sociability, creating a negative impact on QoL[24,25] and possible reinforcement of serious and sustained health-related risk-taking.[26]

Social factors to prevent or reduce loneliness and social isolation

Although the causes and drivers of loneliness and isolation are varied, social and emotional support from others is likely to be protective of the maintenance of health.[27] Interventions providing social and emotional support, such as befriending,[28] and targeting and enhancing self-worth appear to be more effective than those that do not.[27] While there are benefits to taking an individualised approach to loneliness and social isolation (e.g. psychological interventions to tackle maladaptive cognitions),[29] evidence suggests that improving the quality of interpersonal relationships and participation in social activities may be key to tackling the impact of loneliness.[5] Increasing social interactions and the number of people who can be relied on is associated with reduced levels of distress,[30] by making available strategies for action and facilitating emotional and instrumental support.[31,32] Connecting with community resources may be another strategy to protect against loneliness for those who are most at risk.[5,31] Using everyday public spaces can benefit both well-being and social relations, as connecting with community groups, voluntary organisations and neighbourhood contexts has been shown to play a role in the formation of social ties facilitated by proximity between individuals leading to friendships or relationships.[33] Furthermore, there is evidence that social network interventions can significantly improve health outcomes and QoL and increase the uptake of new activities.[34,35] A diverse and supportive network has been shown to reduce health service costs.[36] A recent National Institute for Health and Care Excellence quality standard recommends the navigation of older vulnerable people to community activities as a means of preventing loneliness in older people.[31] In line with this, there is a logical argument for introducing, implementing and assessing a social network intervention outside of the formal healthcare setting to connect people who are at risk of loneliness to others.

Changes to the societal and research context since the project commenced

The COVID-19 pandemic and its associated lockdowns were found to have a detrimental effect on social isolation, loneliness and general mental health. The social isolation experienced due to the restrictions was found to exacerbate loneliness and poor mental health that existed before the pandemic.[37] Groups at risk of loneliness during COVID-19 included individuals living alone, individuals experiencing emotional regulation difficulties and young people, although perceived social support was found to be a protective factor.[38] Thus, although opportunities to engage with community activities will have reduced to some degree during the varying restrictions, an intervention that is able to encourage reflection on social networks and boost readiness to engage in community activity could still provide benefit.

Study aims and objectives

Aims

The main aim of the study was to assess the clinical and cost-effectiveness of the social network intervention for loneliness and social isolation compared to a wait-list control within a community setting among at-risk populations. A secondary aim was to understand implementation in the context of different organisations that work in community environments.

Objectives

Primary objectives

- To assess the effectiveness of the 'project about loneliness and social networks' (PALS) intervention compared to usual care on mental health at 6 months.

Secondary objectives

- To assess the feasibility of the study based on recruitment and retention during an internal pilot phase.
- To determine the effect of the PALS intervention compared to usual care on loneliness, social isolation, physical health, engagement, depression, anxiety, self-efficacy and QoL.
- To explore people's experiences of using PALS, how the intervention impacts on loneliness and isolation, and the mechanisms by which participants enact change.
- To explore environmental and organisational factors that impact the integration and scalability of PALS in local and organisational settings.

Economic objectives

- To establish whether the use of PALS within a community setting is cost-effective.

Structure of report

Chapter 2 provides an overview of the intervention used within this study. In addition, information regarding the specific adaptations to the intervention delivery will be outlined; this includes those made prior to the commencement of the study and throughout. Information regarding the facilitation training is also outlined here.

Chapter 3 reports on the methods and results pertaining to the main PALS randomised controlled trial (RCT), including both statistical and health economic analysis.

Chapter 4 presents the process evaluation exploring the pre-implementation and implementation arrangements, focusing specifically on the different organisational and local contexts. Reflections on the intervention delivery are provided here.

Chapter 5 presents the qualitative participant interview data exploring their experiences of loneliness in the context of building connections with personal communities.

Finally, *Chapter 6* discusses the study findings, limitations and implications for future research.

Chapter 2 The intervention

The GENIE intervention

The Generating Engagement in Network Involvement (GENIE) intervention was developed in the context of self-management support for long-term conditions. It was built on a body of knowledge concerning the mechanisms and properties of social networks and their beneficial health outcomes.[35,39,40] GENIE is a facilitated web-based tool designed to generate a visual representation (i.e. map) of self-described social networks and improve people's ability to navigate and negotiate local support and resources. This process is coproduced, and the user has ownership of the network map and links to locally available resources and activities, achieved by focusing on individual preferences. A trained facilitator (from a lay or professional background) guides the recipient through the process. The focus of the intervention is to assess and mobilise existing or future ties relevant to maintaining wellness, within the everyday context of living life. This starts with the development of a visual representation (i.e. map) of a person's existing personal community. It then works towards exploring their preferences and the leveraging of actual or potentially available community resources. The contact between the participant and the intervention facilitator was, on average, 1 hour long. There were three main stages in the intervention:

1. Network mapping

Firstly, the concentric circles technique was used to gain insight into the recipient's personal community by building a visual representation of current social network ties and support.[35] Using this technique, the participant was placed at the centre of the network map, with three concentric circles around this central position. The facilitator and participant then explored the people, places and things most important to the person in their everyday life. Those identified as most important were placed in the inner circle; the next circle represents those that are important but less so than the first, and the same again for the third circle. These circles created a visual representation of the personal community but required the facilitator to encourage the participant to think about why and how some people and resources might be more or less important to them. This was then progressed to further map the people and groups who could potentially provide extended support.[35] An overview of the completed network was provided to check that the network map accurately represented their situation.

2. A preference questionnaire

This part of the intervention included questions developed to elucidate people's preferences for activities or resources related to support.[41] In order to simplify links to community-based activities and support the preference stage, the tool was designed to closely align to the user's values and interests. Suggestions for health-related activities included social groups or activities, exercise or weight loss groups and things like hobby groups; support for independent living, volunteering opportunities and educational courses were included.

3. Linking individuals to prioritised and valued activities and resources

The items in the preference questionnaire were linked to a pre-created database where local organisations and resources were categorised. This was populated in the first instance using pre-existing city and county council directories and databases, and then supplemented with study partner resources and ad hoc information that became available to the research team. The tool then linked preferences with the user's postcode to identify local, relevant activities and resources. Immediate feedback was provided in the form of a Google-generated map which included the local activities and groups they had indicated an interest in. Subsequently, participants were provided with a paper copy of their social network map and a list of relevant local activities, along with the contact details of when and where the activities were taking place.

The paper copies were important as they provided participants with a document they could refer back to when they felt ready and could be used by the facilitator when planning, with the participant, who in the social network might be able to accompany or assist with attending an activity.

During the 3-month contact, the network map was revisited; participants' current support networks were discussed; and any new connections were incorporated, along with updates to existing relationships. The preference questionnaire was repeated, and additional relevant local activities were identified. Facilitators would discuss the activities with the participants and ascertain whether the participant had attended any activities. If they had not attended, the conversation would explore why not; for example, some participants might have decided they were no longer interested in a group or activity. Alternatively, participants might have experienced barriers to access, so the conversation could explore these barriers and potential ways to overcome them where appropriate.

Further information regarding the development of the GENIE intervention can be found in *Appendix 1*.

Adapting and using GENIE in the context of loneliness

Theoretical background of the intervention relevant to the study

The theoretical underpinning of PALS was derived from implementation theory of a social network intervention designed to promote self-management for those living with long-term conditions through promoting the uptake of available and underused collective support.[42] The key mechanism for this is hypothesised to be through enhancing people's ability to navigate and negotiate the support available within the personal social network and extending this support by engaging with local groups and organisations. Individual motivation and behaviour change are viewed as being likely to be enhanced by developing and implementing strategies for engaging social networks and local support to provide people with access to wider resources.[36,43,44]

The specific mechanisms for the workability of the intervention include the following:

- Opportunities for individual change are a result of relationships, based on degrees of commitment and choice, and accessed through social interaction. These have the capacity to promote autonomy and control in mobilising resources.
- Network navigation (identifying who should be contacted to make decisions or provide help to access previously unused resources and prioritising access to some ties while abandoning others), negotiation within networks (reshaping relationships, roles, expectations, and terms of engagement and communication between and by network members) and building collective efficacy (developing shared perceptions and capacity aimed at successful management through shared efforts and objectives) are the three processes implicated in mobilising network support.
- Mapping and reflection on personal network membership and support results in a process of positive disruption which opens up the potential for reconstructing possibilities differently from current practice.
- The facilitation process is supported by a perceived lack of status difference (between the participant and the facilitator). This assists with engagement through the constructive discussion of support and preferences for activities. Having a reliable background database provides a method for delivering tailored preferences to support participant action planning.[35]

In terms of the focus on loneliness in PALS, additional concepts of social network connectivity were drawn upon to help understand how a social network intervention might influence people's experience of loneliness in community settings. The properties of networks focused specifically around the following:

- The support role of social networks tends to expand in line with increasing need.[36]
- Participation in community organisations is associated with better physical and mental health in those who are more deprived.[45]
- Contact with diverse groups and individuals renders more support than restricted networks.[46]

- Weak ties are distributed, sporadic and fleeting but are less liable to loss over time than stronger ties because they respond to limited demands and offer reciprocity with other people.[47]
- Meaningful ties include links to valued activities such as music and hobbies.[48]

In relation to loneliness, we drew on the ideas that:

- Social ties 'provide sociability, support, information, a sense of belonging and social identity'.[49]
- At an individual level, increasing 'cognitive social capital' is associated with cooperative behaviour – the trust and reciprocity between people.[50]
- Social isolation and loneliness are linked to the disruption, flow and loss of the benefits of everyday social capital embedded in social networks.[51] Thus, in order to ameliorate loneliness, a sense of community belonging can be facilitated through social capital resource distribution (i.e. the leveraging of support and access to resources and activities), building reciprocity and trust.[52]

Creative engagement with non-traditional informal providers of wellness management (such as through accessing locally available community groups and activities) offers an alternative opportunity to address health and social needs in an increasingly resource-stretched NHS. In this study, we set out to determine whether implementing a social network intervention in a community setting is effective at reducing loneliness and social isolation.

Adapting the intervention for PALS

The intervention and approach were designed to be generic and thus of use not only to people with long-term physical and mental health problems as per the initial development. Given the accumulating evidence highlighting the links between loneliness and social isolation and poorer mental and physical health, and the evidence suggesting improving relationships is a potential avenue for tackling loneliness, we hypothesised that this social network intervention may also be appropriate for those who were isolated and lonely.

Some small modifications of the original intervention were needed to adapt it to be a suitable intervention focused on loneliness and social isolation. These included:

- Additional age categories were added in the initial filter questions (linked to the database) to include and differentiate between older participants. These were broken down into 66–75, 75–85 and 86+ years old (compared with the previous single category of 66+ years).
- As it was likely that not all participants would have a health condition, one question was changed from 'your health conditions' to 'any health conditions'.
- An additional question was added to the preference questionnaire to include resources linked to 'pets and contact with animals', as evidence indicates this is an important source of support for some people and especially relevant to those who are lonely or isolated.[53]
- Refinement of training (see *Refinement of PALS facilitator training throughout the project*).

Prior to starting the project, the intervention database was manually populated over approximately 120 hours, to include local activities and support resources in the locations the project intended to recruit from. It was intended that the PALS database would be continually updated throughout the life of the project whenever new resources were identified by partner organisations or the research team; this occurred on a very ad hoc basis in the initial stages of the project set-up. For ease of reading, we will subsequently refer to the intervention as the 'PALS intervention/PALS' throughout this report.

Adaptations to intervention delivery throughout the project

It was planned that the intervention would be delivered to intervention group participants at baseline and again at 3 months (during the follow-up visit). The 3-month follow-up repeated the intervention and allowed participants to create an updated map and reflect on any changes to their social network and revisit relevant community groups or activities. During the pandemic, many participants were confined to their homes; therefore, the delivery of the 3-month follow-up was conducted over the telephone. This process consisted of the facilitator and participant reflecting on the baseline map and discussing any changes. The preference questions were used to identify groups or activities with an online presence and to help elicit the types of activities the participant may choose in the future once in-person activities had resumed. In cases where the partner organisation had adapted in-person activities to fit with the restrictions imposed by the pandemic, these were conveyed to the participant whenever specific interests were matched.

Development of PALS facilitator training

The aim of the PALS facilitator training was to equip personnel from partner organisations with the resources, confidence and knowledge to be able to successfully deliver PALS in the community. The training was designed to be delivered face to face in a classroom environment over the course of a half day. The training covered five main areas:

- Intervention overview – what is PALS and how does it work (delivery 45 minutes).
- Study procedures and research practicalities (delivery 45 minutes).
- Interactive session – online PALS demonstration, pair work to test out PALS with a partner and group discussion (delivery 45 minutes).
- Adding resources to the PALS database and inputting data into the trial database – this portion of the training and requirement for facilitators was removed due to informational overload (see *Refinement of PALS facilitator training throughout the project* for further information) (delivery 30 minutes).
- What is good intervention facilitation – including suggestions and prompts (delivery 30 minutes).

After the session, facilitators were provided with an 80-page facilitator training guide booklet that covered all training topics in further detail (see *Report Supplementary Material 1* for a copy of the facilitator training guide). The PALS research team provided ongoing support to partner organisations and facilitators for the duration of their involvement with the project. The PALS research team would conduct telephone conversations with staff/facilitators to discuss emerging challenges and offer support and assistance with project implementation, recruitment and facilitation. For example, if an organisation faced challenges due to limited staff capacity, the researchers could offer to attend groups/activities to promote the project and enhance participant recruitment efforts.

Refinement of PALS facilitator training throughout the project

Initially, two PALS researchers delivered group training sessions; it was thought that group training would be time-efficient and cost-effective while providing an opportunity for partners to network and learn about how PALS would be implemented within the different services/community projects. Early feedback from initial partner organisations identified that the starting point for organisations was not uniform. For example, facilitators who were not as comfortable using information and communications technology needed additional support during these sessions. In addition, the training helped identify potential pre-implementation arrangements and this varied considerably between organisations. Consequently, researchers delivered the facilitator training ‘in-house’ at the community organisation office/location at a time and date that was convenient for the facilitators. The individual organisation training sessions were easier to arrange as organisations could provide researchers with their availability without having to wait to see if the same date was also convenient for multiple organisations. These training sessions were often smaller and provided an opportunity for facilitators to try the intervention with their colleagues and the researchers.

Although included in the initial training package, it was decided based on feedback that training facilitators to enter information into the intervention database and trial management database would be removed. Instead this would be done by the researchers as it was too time-consuming for facilitators and would detract from the delivery of the intervention (by bogging them down in administration). A workaround was devised: facilitators were able to e-mail the study team with any relevant activities that needed including in the database and these would be added in. This approach added current and relevant resources to the intervention database from the grassroots up while at the same time enabling community organisations to feel more intrinsically involved in the ongoing development of the intervention. PALS refresher training was also offered to all organisations, and was accepted by several, especially in instances where initial training had been delivered but organisations were not ready to start recruitment.

Southampton site-specific arrangements

In August 2018, the team in Southampton moved towards implementing a pre-training meeting and a post-training meeting to sandwich the training session, following several training sessions where facilitators attending the training came knowing very little about the study, which impeded the training session. The pre-training meeting attempted to bring together several individuals within the organisation, including potential facilitators, their line managers, the contacts to the study team and senior managers within the organisation. This meeting was an opportunity to explore the necessary pre-implementation arrangements – that is, how PALS would work within the organisation – with all potential collaborators present to ensure that all potential facilitators had a basic understanding of the PALS project and their potential role and involvement. It also helped to identify potential barriers or misunderstandings so that the study team were able to quickly pre-emptively identify solutions and ensure all individuals understood and agreed to these. The post-training meeting provided an opportunity to recap on any training issues and to discuss how the facilitator role would be incorporated into current roles/workstreams; at this point organisations were then able to begin participant identification and recruitment. It was felt that this was not necessary or appropriate in Liverpool, where the researcher followed up the facilitators with a phone call post training.

In addition, the GENIE intervention was commissioned by Southampton City Council in 2017. A separate (but linked) study mapped the implementation (led by JE and EJ) and meetings were held with the GENIE and PALS teams to ensure there was no organisational overlap. However, to ensure there was no potential contamination to the PALS study, a criterion was set out to exclude any individuals from the study who had previously engaged with the GENIE intervention.

Unplanned adaptations to PALS training and delivery during the COVID-19 pandemic

The COVID-19 pandemic

Recruitment into the project was paused from March 2020 due to the outbreak of the COVID-19 pandemic; this project pause lasted approximately 8 months. In October 2020, it was agreed that the study could prepare to begin 'slow recruitment' (i.e. to test the feasibility of restarting recruitment), and participant entry into the study resumed in November 2020. From this point forwards, we will describe these periods as pre pause (i.e. everything before March 2020), the study pause (March–November 2020) and post restart (i.e. everything after November 2020).

PALS facilitator training

Due to the changing nature of national COVID-19 restrictions and guidance, coupled with the ongoing risk to facilitators and the study team, all training was delivered through an online platform [Microsoft Teams® (Microsoft Corporation, Redmond, WA, USA) or Zoom® (Zoom Video Communications, San Jose, CA, USA)] post restart. The training was adapted using the original PALS training and covered similar topics (study procedures, research practicalities, PALS intervention demonstration, recruitment and next steps) and lasted 1–2 hours.

The online training session was delivered to one or two facilitators from the same organisation. Researchers were able to share their screen with facilitators and demonstrate how to use PALS on the website, and facilitators were able to take part in an online demonstration with the researchers.

The main difference following the COVID-19 pandemic was that facilitators were delivering the intervention remotely rather than face to face with a participant. Therefore, it was important to ensure that facilitators were confident using PALS through an online platform such as Teams/Zoom, or over the telephone. This was achieved through practising during the training session and discussing challenges that could arise. Where necessary, facilitators were able to access a second practice session delivering the intervention via an online platform with the researcher at a later date. During the pandemic, for many of the partner organisations Zoom and Teams had become familiar platforms used within the workplace, therefore all facilitators felt comfortable using them during the training session.

Intervention delivery

Post restart, all participants within the study were offered the intervention via remote delivery (over the telephone or via the online platforms of Zoom and Teams). It was believed that the hypothesised mechanisms through which the intervention operates would remain unaltered despite the change in delivery method (see *Appendix 2* for the PALS intervention logic model). All participants opted to receive the intervention by telephone, and all intervention delivery was facilitated by the research team. Although six partner organisations undertook the intervention training post restart, all of the PALS intervention facilitation during this period was delivered by the research team. Feedback from organisations indicated that this was due to capacity issues with demand for their services rising during the pandemic.

Adaptations to each of the three stages of the PALS intervention to fit with remote delivery were as follows:

1. Personal community network mapping

To ensure the visual element was maintained, participants were asked to have a piece of paper and a pen to hand, so that they could create a picture of their networks of support. The facilitator worked on a laptop using the online version of PALS to create a visual image of a participant's existing support network. As the circle diagram was completed electronically by the facilitator, the participant was guided to create the same diagram on paper. Some participants chose not to do this and just engaged in the conversation with the facilitator, which explored the nature of participants' social connections.

2. The preference questionnaire

The discussion to find out what participants enjoy doing/used to enjoy doing in the past was easily adapted from a face-to-face approach to a conversation over the phone. The facilitator read out the questions as they appeared on the screen.

3. Linking individuals to prioritised and valued activities and resources

During the pandemic, some face-to-face activities in the PALS intervention database were paused or moved to an online presence. The database was updated to include new online services. The facilitated discussion then focused upon what participants intended to do in the future/as restrictions were eased. After completing the intervention, participants were posted a paper version of their digital social network map and a list of relevant local activities.

Chapter 3 The project about loneliness and social networks randomised controlled trial

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Methods

The protocol was developed by the research team, with input from our early community-based partner organisations and in collaboration with the Southampton Clinical Trials unit (University of Southampton, UK). Sections of this chapter are reproduced from the published PALS study protocol[54] and the published pre-implementation study.[55] Additional articles reporting on the main trial results are being written up for publication. This section will outline the methods and results assessing the effectiveness and the cost-effectiveness of the PALS intervention during a 12-month RCT.

Design

The study design was a pragmatic, community-based, cluster RCT with embedded health economic evaluation, process evaluation and qualitative study. Participants either received access to the PALS intervention immediately or were allocated to a wait-list control group. Both groups had access to 'usual care' for the organisation they were recruited from. An in-depth qualitative process evaluation was conducted to explore organisational settings and integration and potential scalability of the intervention in local settings. Qualitative interviews were conducted with participants to understand their experiences of living with isolation and loneliness.

Community-based partner recruitment and engagement with the study

Eligibility criteria

The study identified and recruited community-based partner organisations to collaborate with in two regions in England; these were located around Southampton (including Hampshire, the New Forest and Isle of Wight) and Liverpool (including Merseyside). No formal inclusion criteria were set out with reference to community-based partner organisations beyond having the 'potential to identify or access at-risk individuals'. This was deliberate to ensure we were able to sample the range and diversity of individuals living with loneliness or in isolation, respond flexibly to local conditions, and develop understanding of the community contexts best placed to both identify potential participants and deliver the intervention.

Community-based partner identification and flow through the study

Fourteen organisations provided support for the submission of the study funding application (although only eight of these went on to participate in the study). Subsequently, the study team purposively identified potential community-based partners as the study progressed; this was achieved primarily through snowballing existing partners' contacts and networks of organisations, as well as those linked to the study team.

Community-based partner set-up

Initial contact with potential partners eliciting interest in participation was made by e-mail or via a telephone call with one of the research team. This outlined the purpose of the study and the study aims and briefly explained study procedures. If the organisation was interested in taking part, an initial meeting would be set up.

Partner pre-implementation arrangements

Each partner organisation was presented with the same implementation plan, and then arrangements and alterations were made to accommodate the specific organisational needs. The plan presented to each organisation proposed a division of labour between the PALS study team and the partner organisation (as outlined in *Figure 1*). It was suggested partners would be responsible for identifying and allocating two members of their workforce: one who would recruit potential participants, and one to become a trained intervention facilitator. This was proposed in order to handle the issue of contamination, as trained facilitators would not have contact with control participants. It was also proposed that each organisation would identify and enrol people into the study (in line with the inclusion criteria). Ongoing support was available to community partners throughout the study via e-mail, telephone or face-to-face visits. Partner organisations remained in the study for as long as was feasible for them or until they had exhausted all potential participants (see *Results* for information regarding organisation engagement). All organisations who wished to participate in the study were asked to sign a collaboration agreement and receive a training session (for more information on the training please, see *Chapter 2* and *Appendix 2*).

Study participants

Eligibility criteria

To be eligible for enrolment in the study, participants had to be:

- aged ≥ 18 years
- at risk of loneliness or social isolation (this was defined as an 'absence of social contacts or community involvement, or lack of access to services' as outlined by Hampshire County Council).[56]

Participants were excluded if they:

- were hospitalised (i.e. not self-managing within a community setting)
- had a terminal disease or any acute exacerbation of a condition which impacted upon their ability to take part
- lacked sufficient capacity to complete the questionnaires (and/or intervention delivery)
- had previously used the GENIE intervention.

An exclusion criterion was removed from the protocol after consultation with the Trial Steering Committee (TSC); initially multiple household members could not be enrolled in the study (this amendment was approved in January 2019).

Recruitment

Participant recruitment into the trial began in November 2018 and finished in November 2021 (3 years total). This included a pause to the study from March to November 2020 due to the outbreak of the COVID-19 pandemic (approximately 8 months in total).

Identification

Potential participants were identified in several ways across the partner organisations. In each case, potential participant identification was set up so that it best aligned with the ordinary working practices of (or was minimally disruptive to) the organisation. For example, this ranged from volunteers being drafted in to call people waiting on a befriending list to adding presentations about loneliness and isolation during regular social activities. One partner organisation chose to identify potential participants from clients they were visiting on a regular basis. When a client met the inclusion criteria for the project, the facilitator incorporated an explanation about the research into the visit and gave out information packs.

Consent

Fully informed, written consent was obtained from all participants prior to entry into the study. All participants were provided with written information in addition to the opportunity to ask questions prior to participation and prior to the facilitation of the intervention. Additional consent was obtained from participants who participated in the qualitative interviews.

Randomisation

Randomisation was initially designed to be carried out at the level of facilitator, stratified by organisation (using blocks of two, ensuring organisations would deliver both the intervention and usual care). All participants would be recruited by a facilitator and allocated to the corresponding arm of this facilitator. This represented cluster randomisation by facilitator. One of the study's key objectives was to identify and recruit participants in a manner that best operated within the existing working practices of each organisation, to facilitate understanding of the integration and scalability of the intervention in local and organisational settings. It became clear that in order to achieve this objective, the process of randomisation would need to be flexible enough to work across different organisational contexts and scenarios while maintaining methodological rigour. It also became apparent that cluster randomisation was not necessary in most organisations, and individual randomisation was achievable; this allowed for efficiency in the study, by reducing the effects of clustering and removing a source of variation in outcomes. An amendment to the protocol was therefore submitted in January 2019. Randomisation was still stratified by organisation, with permuted blocks of sizes two and four.

It was set out that where possible, both facilitators and participants would be randomised within an organisation, and only facilitators randomised to the intervention group would be trained in how to deliver the intervention (to avoid contaminating the 'usual care' within that organisation). *Figure 1* outlines the potential randomisation scenarios. The key practical factors which determined the randomisation model used centred around whether it was possible in practice to randomise the individual participant, and to establish the nature of the relationship between facilitators and potential participants outside of the study. Therefore, where there were organisational or setting constraints that prohibited facilitator or participant randomisation (e.g. the facilitator working within a specific/contained geographic location), the relationship between the facilitator and potential participants was then assessed for ongoing contact.

In these scenarios, we decided:

- *Where there is ongoing contact between participant and facilitator* – in these cases, the facilitators would be randomised, and the participants within each area allocated to facilitator (not randomised). Only intervention facilitators would be trained.
- *Where there is no ongoing contact* – in these cases, there was no risk of potential contamination between control facilitators and potential participants, so it was decided that all facilitators would be trained and only participants would be randomised.

Participant allocation occurred at the end of the baseline data collection appointment.

Model A One-off contact between facilitator and participant at facilitation Area and location were not restricted Facilitators allocated to intervention or control delivery Participant recruitment by facilitators Participants were randomised to the intervention or control group	Model B Ongoing contact between facilitator and participant Area and location not restricted Facilitators randomised to intervention or control delivery Only the intervention facilitator received training Participant recruitment by facilitators where there was no prior connection to the participant If a prior connection existed, recruitment by non-facilitator Participants were randomised to the intervention or control group
Model D One-off contact between facilitator and participant Restricted within a geographical area Facilitators randomised to intervention or control The intervention and control facilitator received training Participant recruitment by non-facilitators Participants were not randomised but allocated to a facilitator within each area	Model C Ongoing contact between facilitator and participant Area and location not restricted Facilitators randomised to intervention or control delivery Only the intervention facilitator received training Participant recruitment by non-facilitators Participants were not randomised Participants within each area were allocated to a facilitator

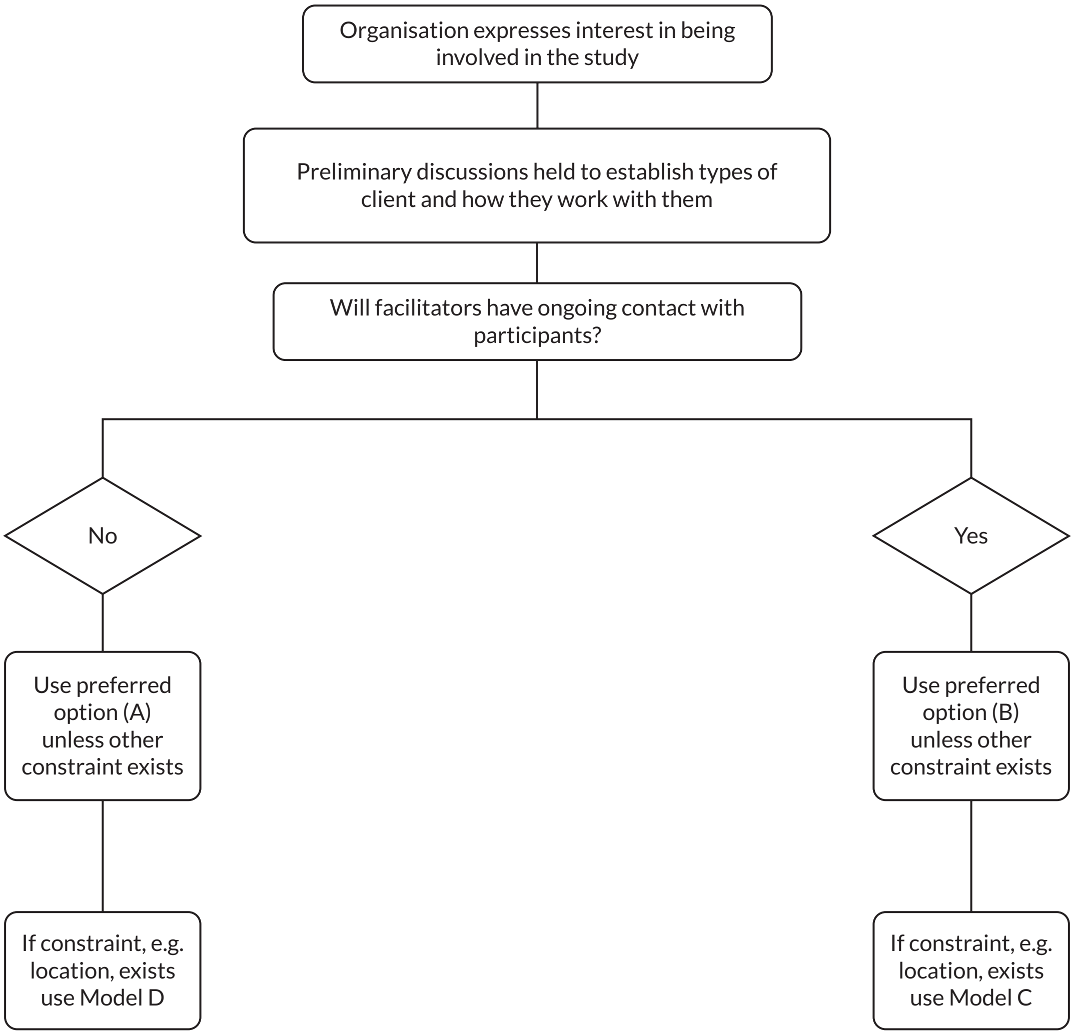


FIGURE 1 Randomisation model flow chart.

Intervention group

Participants who were allocated to the intervention group were contacted by the relevant facilitator (either from within their organisation or from the study team) in person (pre pause) or by telephone (post restart) to arrange a mutually convenient time and date to meet to go through the PALS intervention. The facilitator would meet/contact the participant at the prearranged time and place where the participant felt comfortable (e.g. at a community organisation, a library, café or participant's home). The facilitator would then go through stages of the intervention on their laptop or a PC, together if in person (pre pause) or over the phone (post restart).

Control group

Participants allocated to the control group continued to receive 'usual care' in terms of the provision they would have ordinarily received from the partner organisation from which they were recruited. As this varied significantly across organisations within the study, an in-depth description of the usual care within organisations is outlined in *Appendix 3*. All participants who were allocated to the control group were offered the opportunity to access the intervention after completion of their final data collection.

Outcomes and end points

This study aimed to improve social isolation and loneliness, which is linked to mental health. No previous research had examined these as primary outcomes at the time of study design; therefore, the primary outcome of the trial was mental wellness at 6-month follow-up as measured by the Short Form questionnaire-12 items mental health component score (SF-12 MCS).[57] The MCS had been used previously as a primary outcome in similar community-based interventions with overlapping populations,[58,59] and the SF-12 has been shown to have good psychometric properties,[60] as has the mental health dimension.[61]

Sociodemographic measures

Sociodemographic measures were collected upon entry into the study. These included age, gender, postcode, ethnicity, educational attainment, income, employment status, car ownership, housing status and household composition.[62]

Secondary outcomes

The following secondary outcome measures were collected:

- Physical health (SF-12 physical health composite scale score)[57]
- Loneliness (De Jong Loneliness Scale[63] and the Campaign Against Loneliness measure[64])
- Social isolation (Duke Social Support index)[65]
- Short Warwick–Edinburgh Mental Well-Being scale (WEMWBS)[66]
- Collective Efficacy Network Scale (CENS)[67]
- Social support (Social Provisions Scale)[68]
- Perceptions of loneliness (modified Brief Illness Perception Questionnaire).[69]

Economic outcomes

- Short Form questionnaire-6 Dimensions (SF-6D)[70]
- QoL [(ICEpop CAPability measure for Adults (ICECAP-A)][71]
- Healthcare utilisation (EUWISE questionnaire)[72]
- Participant engagement with new activities.[73]

Assessment and follow-up

All participants completed baseline data collection upon entry into the study. This was usually undertaken on paper (although electronic versions were available) and with the help of a research team member (either in person or over the phone). At 3 and 6 months after enrolment into the study, participants were sent follow-up assessments by post. Participants were able to complete these independently or with assistance from the research team (over the phone) if required. All follow-up assessments were recorded no earlier than 2 weeks before the follow-up date and no later than 6 weeks after the follow-up date. A £10 high street voucher was sent to each participant who completed the 6-month follow-up questionnaire.

Statistics and analysis

Sample size

The sample size calculation was based on the primary analysis of the comparison of intervention and usual care on SF-12 MCS at 6 months.[57] The SF-12 MCS is a score between 0 and 100, based on 12 items (a mix of two, three, five and six category responses) that are converted to a norm-based scale designed to have a mean of 50 and standard deviation of 10 for the US general population. Previous studies (albeit in different populations) have suggested that differences of between 3 and 4.7 points on the SF-12 would be clinically meaningful.[74,75] We based the current sample size on being able to detect a difference of 4 points. Based on a previous study in socially isolated older people,[58] we estimate the standard deviation of the outcome to be 10.4 (using a pooled estimate of baseline scores). Choosing

80% power and a type I error rate of 5%, an individually randomised study would require 216 people (108 per arm). As the study is cluster randomised, the sample size accounts for possible intracluster correlation (ICC; i.e. the potential similarity of outcomes in participants within the same facilitator), as well as the number of facilitators and number of participants per facilitator. In consultation with our collaborating organisations, it was determined that two facilitators per organisation would be feasible; it was also determined that up to 15 participants per facilitator would be acceptable. Different scenarios, based on varying the number of facilitators, participants per facilitator and overall sample size, were considered when deciding on the final sample size. No estimates for the ICC were found in the literature that were directly relevant to the current study design and population; however, previous studies have generally shown low ICCs for mental health scores from SF-12 and SF-36 (0.032 and below) across GP practices.[42,76] We used a value of 0.05 for the ICC with the view that this was likely to be more conservative, with the aim of avoiding underpowering the study. Having considered different combinations of the numbers of facilitators and participants per facilitator, we assumed 12 participants per facilitator. This results in a design effect of 1.55 and an adjusted sample size of 335 people. Assuming 15% dropout,[40] we required 394 participants in total (197 per arm). This worked on the assumption this would require 33 facilitators; this was increased to 36 facilitators to account for potential dropout of facilitators.

Following the recruitment pause, the overall target sample size was adjusted to reflect the loss to follow-up due to the pandemic. The complete cases target sample size was not changed (i.e. 335 people), but a total of 453 was the overall target (assuming that loss to follow-up post pandemic would be 15%).

Internal pilot study and progression criteria

An internal pilot was included within the study to mitigate against potential difficulties in accessing the relevant population (*Table 1*). This also allowed for assessment and confirmation of the acceptability and feasibility of the full trial protocol and study procedures. Recruitment and retention rates were assessed against stop/go criteria at 12 months into the recruitment period (of a total planned 21-month period).

The recruitment and retention data were discussed with the TSC in October 2019; the study had passed the automatic stop point. It was recommended that the study team requested a 3-month extension to complete the recruitment to target. This was due to be assessed in March 2020, at which point the study was progressing well but shortly after was paused due to the COVID-19 pandemic. The study restart extension was agreed in October 2020.

Statistical analysis

A statistical analysis plan was agreed prior to final analysis. Analyses were carried out in Stata v16.0 (StataCorp LP, College Station, TX, USA). The primary objective was to determine the effect of the PALS intervention compared to usual care on mental health at 6 months. According to the ICH-E9 (R1) addendum on the estimands framework, the primary estimand comprised the following:

- Population: anyone meeting the eligibility criteria.
- Treatment conditions:
  - *Control* – usual care as practised by the organisation and individual. This could include any interventions relating to improving mental health.
  - *Intervention* – PALS plus usual care.

TABLE 1 Progression criteria for PALS internal pilot study

Criterion	Cease if below (%)	Continue if above (%)	Actual recruitment at assessment point (November 2019)
Recruitment (relative to target)	30 (*n* = 119)	50 (*n* = 197)	*n* = 242
Retention at 3 months	60	85	97%
Retention at 6 months	50	85	95%

- End point: SF-12 mental composite score at 6 months.
- Population-level summary: mean difference.

The final aspect was to determine strategies for potential intercurrent events that may affect the collection or interpretation of the end-point data; the events and strategies are given in *Table 2*. The rationale for choosing the given strategies was largely driven by a preference for a pragmatic study that was felt to best reflect the reality of delivering the intervention in this setting.

The trial team agreed that although mental health may be impacted by the COVID-19 pandemic, the treatment effect would not necessarily be, as the proposed mechanism of treatment action should largely be unaffected by how the intervention is delivered and what resources are available to participants (in terms of social participation). The pandemic was therefore considered under the treatment policy strategy, where a single treatment effect covering the pre- and post-pandemic periods is thought to be meaningful. The choice of the treatment policy strategy is also a pragmatic decision; the pandemic occurred at a time that divided the participants into three approximately equal groups: (1) entirely (recruitment and follow-up) pre-COVID; (2) recruited pre-COVID but with follow-up during the first lockdown; (3) recruited post study pause (with varying restrictions in place). Cro *et al.*,[77] in considering estimands in the context of the pandemic, refer to two estimands: (1) the treatment effect in a hypothetical pandemic-free world and (2) the treatment effect in a world including a pandemic. In this case, the first estimand may be of more relevance, but considering a hypothetical strategy would mean imputing a very large proportion of the sample (as this would likely have to exclude at least the middle group identified above, and possibly the last group, where various restrictions were in place).

The primary estimand was therefore the treatment difference (PALS intervention vs. no PALS intervention) for all randomised participants who did not die, regardless of how the intervention was delivered and the participants' engagement with it, and regardless of the COVID-19 pandemic. All secondary outcomes were considered to have the same intercurrent events and would be dealt with using the same strategies.

Missing data were anticipated for all outcomes, particularly due to the impact of the COVID-19 pandemic. Recruitment was extended during the study to counteract the effect of missing data, to increase the chance of achieving sufficient complete data and ensure that a complete case analysis was adequately powered. It was believed a priori that only outcome data would be missing (models were planned to include terms for organisation, facilitator, baseline score of the outcome measure and time point, which are highly unlikely to be missing). Hence, following the guidance of Jakobsen *et al.*,[78] a complete case analysis was planned, even though this strategy did not necessarily align with the primary estimand (as only those who died would not be included in the analysis). However, as noted previously, sample size was adjusted to account for missing data, and so a complete case analysis should not be affected by reduced power relative to what was planned in the study design. A discussion of reasons for missing data will be presented to assess how the

TABLE 2 Intercurrent events and strategies for the primary estimand

Intercurrent event	Strategy	Rationale/justification
Intervention not delivered according to protocol (including not initiated; withdrawal from using PALS intervention)	Treatment policy	Likely to reflect reality of delivering and engagement with PALS intervention in practice.
Use of any other approaches to supporting mental health (competing or complementary interventions)	Treatment policy	Other approaches will be generally available outside of the trial, and aim is to assess PALS in this context.
Death	Principal stratum	As a terminal event, death cannot be considered under a treatment policy strategy. However, deaths are expected to be very low, and hence will be excluded from the analysis due to the assumed minimal impact on conclusions.
COVID-19 pandemic	Treatment policy	See discussion below.

results may have aligned (or not) with the proposed estimand; however, reasons for withdrawal were not collected systematically or consistently, making it difficult to fully explore reasons for missingness and the potential impact on study conclusions. Baseline data are presented by whether primary outcome data were collected. Any differences between those who did and did not provide primary outcome data were assessed informally.

Note that where individual items were missing within a questionnaire, the relevant guidance for that questionnaire was used to determine whether a participant's result should be considered missing or whether a value could be calculated; hence, missingness on an individual item was not necessarily a reason to exclude a participant if the questionnaire has a recommended method for dealing with missingness.

Primary end point

The primary end point of the trial was the difference in the SF-12v2® MCS score at 6-month follow-up between the intervention and control group using a linear mixed-effects model (accounting for clustering within organisation as random intercepts). The primary model was anticipated to include outcomes at 3 and 6 months, so participant was also included as a random effect. It was planned that if the mixed model did not converge, a model with only 6 months as the outcome would be the primary analysis. For the complete case analysis, it was planned that if missing data rates were higher for 3 months than for 6 months, a model with only 6 months as the outcome would be considered the primary analysis. This situation was thought possible due to the nature of the impact of the first UK COVID-19 pandemic lockdown on the study; in this instance, it was planned that participant and time would no longer be included in the model. Time (as a categorical variable) and baseline SF-12 MCS score were included as fixed effects. An unstructured covariance matrix for the random effects was used. It was planned that the model would be fitted using restricted maximum likelihood. The protocol stated that facilitator would be included as a random effect. However, it was felt that facilitator would not be an important factor due to the model of training provided and the fact that delivery was largely carried out by the trial team.

The above primary analysis was supplemented by implicit imputation using mixed models. Death (as a terminal event) precludes collection of outcomes, but, as noted in the intercurrent event strategy discussion above, this was handled under the principal stratum strategy, and hence outcome data for this group would not be considered missing as these people are excluded. However, other reasons that led to missing data did not lead to exclusion, and hence the estimand was then the hypothetical scenario where any reasons leading to missing data did not occur.

The Pro CoRE software provided by QualityMetric (Johnston, RI, USA) was used to derive the SF-12 MCS scores for each person at each time point. Scoring followed that described in the User's Manual for the SF-12v2 Health Survey, Third Edition.[79] Missing data were handled using the inbuilt Full Missing Score Estimation option; briefly, missing items on a single questionnaire may be imputed if they are in a domain with more than one question. Further details are provided in the User's Manual. This approach was also used for the secondary end point of SF-12 physical composite score (PCS).

Secondary end points

Appropriate models (linear mixed model or ordinal mixed model) were used for the secondary outcomes, following the same approach as that for the primary outcome.

Economic analysis

Overview and aims

The aim of the economic evaluation was to assess whether PALS, delivered in a community setting and compared to usual care, is a cost-effective intervention for individuals at risk of loneliness. A within-trial cost–utility analysis was conducted over a 6-month time horizon.

Questions addressed by the economic evaluation include:

- What is the estimated resource use and cost of delivering PALS in the community?
- What is the mean cost of delivering PALS per individual at risk of loneliness?
- What is the effect of PALS on preference-based health-related QoL (SF-6D)?
- What is the effect of PALS on capability well-being (ICECAP-A)?
- What is the cost–utility, in terms of net monetary benefit (NMB) of PALS?

Costing the PALS intervention

Training costs

Training sessions took place either at the organisation, at University premises, or virtually. Sessions included one or more organisations and were led by research staff involved in the PALS study. Training logs were completed after each training session. Trainers estimated the duration of intervention-specific and study-specific (i.e. research and RCT methods) training and reported the number of staff attending the sessions.

The intervention was costed as if it were delivered in the 'real world'. The following assumptions were made:

1. Training would take place at the organisation, therefore no venue hire costs were required.
2. Trainers would be employed in roles similar to a local authority health trainer. The salary of a local authority health trainer (plus salary on-costs) was used to estimate the cost of their time (*Table 3*).
3. It is possible that facilitators would be volunteers at the organisations. We assumed that facilitators would be paid for their time, as was the case in PALS. The salary of a well-being recovery worker (plus on-costs) was used to estimate the costs of their time (*Table 3*).
4. In the PALS study a large proportion of facilitation was conducted by study research team staff. We applied the same cost to all facilitators, regardless of job position.
5. Distance travelled was recorded inconsistently so was not included.

The majority of Southampton-recruited organisations received a follow-up training visit to clarify PALS and trial procedures in addition to the planned group training sessions (see *Chapter 2*, *Southampton site-specific arrangements*). For all Southampton sites, with the exception of the first two trained, where it was not offered, this additional session was costed. This was assumed to last 1 hour, be led by one trainer and be attended by three facilitators from the organisation.

Training costs were calculated for the Southampton and Liverpool sites. Participant training costs were calculated according to the recruiting site. Specifically, the total cost of training sessions for the site was divided by the number of individuals randomised to the intervention arm at that site (Southampton or Liverpool). Participants were allocated a training cost regardless of whether they received PALS intervention or not.

TABLE 3 Training and facilitation costs

Staff member	Description	Hourly cost, £	Source
Trainer	Local authority health trainer grade 7. £30,394.34. Gross employee costs including 3% pension and 13.8% National Insurance. 1599 hours per year.	19.01	Local authority advertised position
Facilitator	Well-being recovery worker. £26,812.08. Gross employee costs including 3% pension and 13.8% National Insurance. 1599 hours per year.	16.77	Advertised role at a recruiting organisation
Travel	HMRC car mileage rate.	0.45 per mile	HMRC

PALS intervention delivery costs

The intervention was delivered either at the recruiting organisation, at the participant's home or virtually. Facilitators recorded the time to deliver PALS and the distance travelled. Travel was costed using HM Revenue & Customs (HMRC) mileage rates (*Table 3*), with no travel costs associated with virtual delivery. Facilitator time was costed as per training costs (*Table 3*).

The initial protocol prescribed that participants in the intervention arm would receive PALS at baseline and 3-month visits. During the trial this changed, and the 3-month administration was modified, whereby some participants remapped their social networks while others just discussed their previous maps if this had not changed. The intervention was therefore administered either once or twice.

Health care and participant incurred costs

Healthcare resource use was collected at baseline, 3 and 6 months using a de novo participant-completed resource use questionnaire that included:

- health and social care service resource use [e.g. GP visits, accident and emergency (A&E) visits, mental health professional contacts]
- informal care received (e.g. unpaid assistance with everyday tasks from family and friends).

Additional questions were included to estimate personal expenditure on activities potentially facilitated by the intervention (e.g. attending activities suggested as a result of the intervention). A total activity cost was generated for each participant.

Resource use was valued using appropriate UK unit costs or participant valuations estimated at the time of the study delivery (2019–21). Unit costs and assumptions are provided in *Table 4*. NHS National Cost Collection data[80] were used to value hospital resource use (e.g. A&E visits and outpatient attendances). Primary care and social care costs (e.g. GP

TABLE 4 Description and sources of unit costs

Resource	Description	Unit cost	Source
GP appointment (face to face)	Per surgery consultation lasting 9.22 minutes. With qualification and including direct care staff costs	£39	Unit Costs of Health and Social Care 2020[81]
A&E visit	A&E, outpatient attendance	£133	2019/20 National Cost Collection (national schedule of NHS costs)[80]
Primary care nurse	Nurse (GP practice Band 5). Per surgery consultation lasting 9.22 minutes. £63 per hour of patient-related work	£9.68	Unit Costs of Health and Social Care 2020[81]
Mental health care professional (psychologist, counsellor, mental health nurse)	Clinical psychologist, counsellor specialist (Agenda for Change Band 7), hospital-based scientific and professional staff. £63 per hour. Assume one contact is 1 hour	£63	Unit Costs of Health and Social Care 2020[81]
Social worker	Social worker (adult services) unit cost per hour including qualifications. Assume one contact is 1 hour	£51	Unit Costs of Health and Social Care 2020[81]
Prescription	Prescription costs per consultation (actual cost)	£30.90	Unit Costs of Health and Social Care 2020[81]
Hours of formal care	Home care worker. Face to face: based on the price multipliers for independent sector home care provided for social service. £30 per hour	£30.00	Unit Costs of Health and Social Care 2020[81]
Hours of informal care	National living wage (age 25 years and over) per hour	£8.21	National Minimum Wage and National Living Wage rates April 2019–March 2020[83]
Out-of-pocket participant activity costs	Incurred cost	Variable	Self-report, based on individual participant data

visits) were valued using the Personal Social Services Research Unit's unit costs of health and social care.[81] Participants were also asked how many prescriptions they had received. A unit cost of one prescription (*Table 4*) was applied for each.

Unpaid care was collected using one question regarding hours of care received from friends and family. The value of this time was estimated using the opportunity cost approach,[82] using the National Living Wage 2019–20.[83]

Outcomes

The primary analysis uses the quality-adjusted life-year (QALY), derived from utility scores, obtained using the SF-6D algorithm,[84] which uses SF-12 data. Measurements were obtained at baseline, 3 and 6 months. A secondary economic outcome was the ICECAP-A measure of capability well-being.[71] UK tariff values[85] were used to generate utilities and years of sufficient capability (YSC) and years of full capability (YFC).

Quality-adjusted life-years were generated using the area under the curve approach.[86] YSC were generated using the method proposed by Mitchell, Roberts[87] and the threshold of sufficient capability defined by Kinghorn[88] (response profile of 33333).

Costs included in each perspective are reported in *Table 5*.

Analytic approach

A within-trial economic evaluation was conducted using the net-benefit approach. With the net-benefit approach, cost/QALY data are transformed into a continuous variable which allows both for correlation between end points and for easier manipulation of the data, including within a multilevel framework. Multilevel linear models (which adjusted for clustering by organisation) were used to analyse the incremental costs, outcomes and NMBs. Uncertainty around NMB was examined by using NMB plots and cost-effectiveness acceptability curves (CEACs). While our a priori planned primary analysis was complete case, which means that only individuals with complete data contributed values, we additionally carried out imputation to address the substantial amount of missing data. We used the framework of multiple imputation as it is viewed as preferable to some simpler forms of imputation which can underestimate uncertainty and do not consider all the observed data.[89] Missing data were assumed to be missing at random and were imputed at the component level. Costs and SF-12 scores were imputed jointly using chained equations and predictive mean matching; our imputation model matched our analysis model with the addition of age as an auxiliary variable. Analyses were conducted in Stata 16.1.

The trial management group did not recommend we carry out subgroup analysis. We adopted an explanatory focus in interpreting the economic results in the context of what we learned over the course of intervention delivery.[90,91]

Management of the study

The study was sponsored by the University of Southampton. The study team (comprising Senior Research Assistants, Research Fellow, Senior Research Fellow, Senior Trial Administrator and Trial Manager) were supervised by the

TABLE 5 Costs included in each perspective

	Perspective	
Costs	**Public sector**	**Societal**
Intervention delivery	Included	Included
Healthcare resource use	Included	Included
Formal care	Included	Included
Informal care	Excluded	Included
Participant activities	Excluded	Included

Principal Investigator, and met weekly throughout the project. The Study Management group, comprising the study team, co-applicants and a representative from the Clinical Trials Unit, met every 6 months. A TSC was appointed and approved by the funder. The TSC comprised of six independent members [with expertise in mental health, clinical psychology, medical statistics, research in the charity sector and patient and public involvement (PPI)] and two non-independent members (experts in social networks, trial methodology and clinical psychology). Meetings were scheduled approximately every 6 months and minutes uploaded to the funder.

Ethical arrangements

Revisions to the protocol

All substantial amendments to the study were approved by the sponsor and submitted for ethics approval. Four substantial amendments were made in total.

Data management

Access to data was available only to authorised representatives from the sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations. Manual data were immediately input into the secure database by members of the research team and then filed in locked filing cabinet(s) at the University of Southampton.

Anonymised data will be retained for a period of 10 years after publication and thereafter destroyed. Data with personal information will be deleted after the study period and write-up are complete (maximum 3 years after study end).

Serious adverse events

Serious adverse events (SAEs) were recorded, where possible, throughout the trial. In cases where participant death was reported to the trial management team, causality was assessed and assigned. As the intervention is behavioural and therefore unlikely to impact participant health directly, only incidents deemed to be related to involvement in the study/interaction with the intervention were eligible to be reported as SAEs. All of these SAEs were judged to be unrelated to study participation.

Patient and public involvement

Patient and public involvement was key to this programme of research, since our aim was to conduct the study in such a way that would be acceptable and feasible in the local environments.

Application development

We worked closely with relevant partner organisations with whom we had established links, who contributed to work leading up to the proposal. PPI representatives were involved in discussion with the Collaboration for Leadership in Applied Health Research and Care Wessex PPI group, and prior PALS engagement work. The project was presented at the Southampton Scrutiny Panel for Loneliness and consulted with the Campaign to End Loneliness.

Involvement in the study

We worked with our named partners and organisations to agree methods to identify participants, and to discuss recruitment strategies, intervention deployment and assessment of implementation issues. Our PPI representatives were invited to quarterly management group meetings to provide strategic input to the study as a whole. They were provided with the opportunity to comment on the design and content of the participant materials developed by the research team. An informal steering group involving PPI representatives provided informal advice and support on project management and delivery and interpretation of the study findings.

Dissemination

We will produce a creative and informative visual infographic with input from our PPI representative to be distributed to each community partner organisation that participated in the PALS study. The infographic will be designed in a format that is clear and easily accessible to a lay audience, displaying meaningful information, insights and imagery to reflect our key findings. We intend to organise an event which will bring together members of the research team and representatives of our community partner organisations.

Results

Community-based partners' engagement

In total, 44 community-based partner organisations recruited participants into the study. Of those, 25 recruited in the pre-pause stage only (i.e. up until March 2020), 14 recruited post restart (from November 2020) and 5 organisations recruited participants across both periods.

A further 22 organisations actively engaged with the study team regarding participation but did not go on to recruit participants. Reasons that organisations did not participate in the study included service users not being suitable for the study [i.e. people in crisis or experiencing more urgent or complex social care needs (*n* = 9, 40.9%)]; organisational capacity issues (*n* = 8, 36.6%); perceived they delivered a similar service to the intervention (*n* = 3, 13.6%); or misalignment with the work of the organisation – the remit of the intervention was not relevant to or did not complement the service provided by the organisation (*n* = 2, 9%). Additionally, 29 organisations were contacted but did not respond to the study team.

Organisational engagement with the study

Data were collated (where possible) regarding the length of time organisations were engaged with the study. Across all organisations, it took on average 139.5 days from the point of first contact with an organisation to the first participant recruited from that organisation (approximately 4.5 months). Partner organisations then spent an average of 283.33 days actively engaged in the study (approximately 9.5 months), as calculated by the time elapsed from them signing their collaboration agreement to the date of their last recruit. The average number of participants recruited by organisations was 10.52 [standard deviation (SD) = 13.40]. However, recruitment of participants varied greatly between organisations (median 7 participants, range 1–77 participants).

PALS facilitator training

Facilitator training sessions took place between July 2018 and August 2021. In total, 42 training sessions were conducted, across which 83 facilitators were trained. This comprised 51 intervention and 32 control facilitators, 25 of whom were based in Liverpool (17 intervention and 8 control) and 58 in Southampton (34 intervention and 24 control). On average, the median number of facilitators trained per organisation was 2 (although this ranged from 0 to 9 across organisations); almost one-third of organisations (29.5%) were not able to provide any facilitators to deliver the intervention. Consequently, the PALS study team facilitators (*n* = 5) delivered the intervention for participants from 24 organisations (54.5%) and shared the facilitation with a further nine organisations (20.5%).

Randomisation models used by organisations

The randomisation model used in each organisation was recorded; the majority of organisations were able to use the preferred recruitment models of A (*n* = 12, 27.3%) and B (*n* = 25, 56.8%), where randomisation occurred at both the facilitator and participant level. In total, two participating organisations conducted recruitment procedures in a way that did not align with any of the four prespecified recruitment models. In both cases, participants were randomised (see *Appendix 4* for randomisation information).

Participants

Recruitment and retention of participants

The CONSORT diagram (*Figure 2*) shows participant flow through the study. Over the course of the study, 656 potential participants were referred to the study team, and in total 469 participants (71.5%) were recruited into the study and completed baseline assessments. A total of 159 participants (33.9%) were recruited from the Liverpool site.

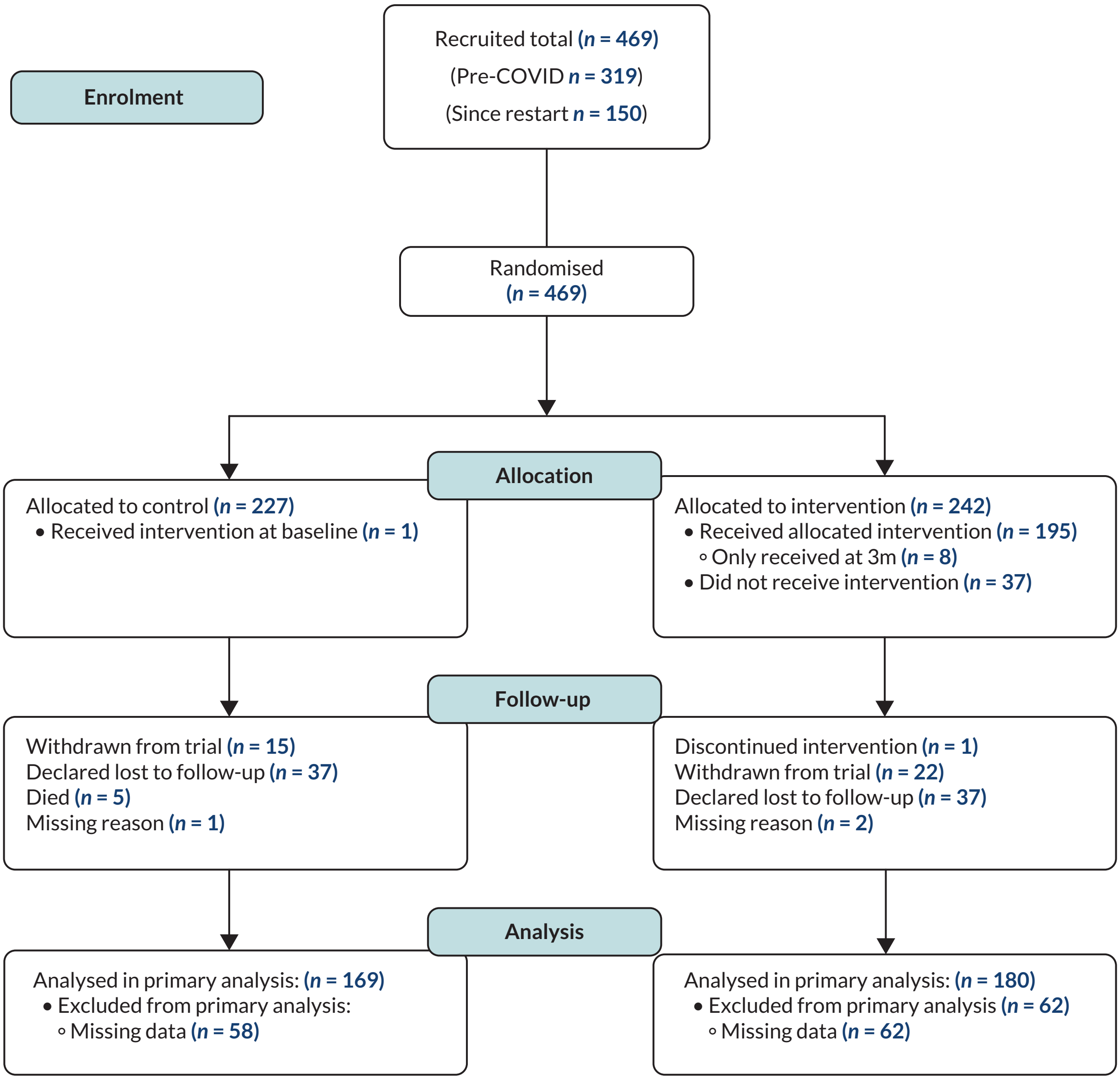


FIGURE 2 CONSORT diagram.

On average, approximately 15 people per month were recruited into the study (over 32 months); however, recruitment rates were almost halved following the COVID-19 pandemic (approximately 10 participants recruited per month compared with an average of 19 per month prior to the study pause).

Participant withdrawal

In total, 120 participants withdrew from the study (*Figure 2*). Over half of the withdrawals were classified as 'lost to follow-up' (*n* = 74, 61.7%) and a number as 'withdrawn from the trial' (*n* = 37, 44.4%). The distribution of withdrawals from the study was similar across groups (*n* = 62 intervention participants vs. *n* = 58 control participants). However, of the 120 total participants, 82 withdrew from the study between March and August 2020 (during the height of the COVID-19 pandemic restrictions), equivalent to approximately 68% of all study withdrawals.

Baseline characteristics of participants

The median age of participants who took part in the trial was 65 years, with participant ages ranging across the life course from 19 to 95 years. A total of 330 participants were female (70.4%), and 433 participants were of white ethnicity (92.3%). Approximately half of participants in the trial lived alone (*n* = 242; 51.6%), and of those living with at least one other person, 138 people reported the presence of a spouse (29.7%). The majority of study participants were not working at the time of entry into the study due to retirement (48%), being unable to work (22.4%) or being unemployed (9.6%). In addition, 76.5% of participants reported a household income of < £26k per annum, with 55.2% of respondents reporting < £15,600 income per annum. The mean indices of multiple deprivation decile score was 4.18 (SD = 2.76) across the sample, with Liverpool participant postcodes ranked as more deprived than Southampton postcodes (2.94 vs. 4.80). For detailed baseline participant characteristics, see *Appendix 5*.

A total of 227 participants were allocated to the control group and 242 to the intervention group. *Table 6* contains the baseline characteristics of all randomised participants. No major differences were seen between groups.

A total of five people died during the trial (all in the usual care). As prespecified in the statistical analysis plan, these participants are not included in the following primary or secondary analyses, leaving *n* = 464 (222 in the usual care, 242 in the intervention arm).

Intervention delivery

Of the 242 participants randomised to the intervention group, *n* = 19 (7.9%) received no intervention at either time point (i.e. at baseline or 3-month follow-up). The intervention was not delivered in these instances because the participant was uncontactable (*n* = 15, 78.9%), because they did not want the intervention (*n* = 1; 5.3%) or because of health issues (*n* = 3, 15.8%). In five cases, the participant did not receive the intervention at baseline but did receive it at 3-month follow-up and this was due largely to COVID-19 restrictions (*n* = 4, 80%) or health issues (*n* = 1, 20%). One participant in the control group received the intervention in error.

Main trial results

Primary end point: Short Form questionnaire-12 items mental composite score

Table 7 shows the number of questionnaires that were not analysable. These rates were similar for the two groups, with approximately one-quarter missing at the primary time point of 6 months.

Given the higher rates of missingness at 3 months, the primary analysis reverted to fitting a mixed-effects model on SF-12 MCS at 6 months only (as prespecified). Baseline and follow-up data, plus the comparison between groups at 6 months (primary analysis), are given in *Table 8*, alongside results of the secondary analysis for comparison of groups at 3 months. The mean differences, confidence intervals (CIs), and *p*-values are taken from linear mixed-effects models of the SF-12 MCS score at the given time point, controlling for baseline MCS score and organisation (as a random effect). The histogram of SF-12 MCS scores at 6 months is given in *Figure 3*.

The results for both 3- and 6-month analyses provide no indication to support a meaningful treatment effect (when considering the minimum clinically important difference of 4 points on the SF-12 MCS scale). The estimated mean differences between groups and corresponding CIs show the results are most compatible with there being no or little treatment effect (whether harmful or beneficial). Baseline SF-12 MCS was also fitted using restricted cubic splines (five knots, in the default positions using the Stata command mkspline) to allow for a nonlinear relationship with the outcome; this led to minimal change in the results (treatment effect: 0.21, 95% CI −1.74 to 2.17; *p* = 0.832). When using a linear mixed-effects model of 3- and 6-month SF-12 MCS data combined (using time as a fixed categorical effect and participant as a random effect nested in Organisation), the treatment effect was estimated to be −0.16 (95% CI −1.90 to 1.58; *p* = 0.858), leading to a similar conclusion of no or limited harmful or beneficial effect of treatment. Note that this analysis did not converge when excluding those with missing (3- and/or 6-month) data. Hence this represents the treatment effect based on the hypothetical scenario where intercurrent events leading to missing data did not occur; this also makes the assumption that those with missing data followed the patterns of those who did not have missing data.

The treatment effect at 6 months was further estimated in subgroups using interactions; these subgroups were based on Organisation and baseline demographics. These results are presented in *Figures 4* and *5*. While the smaller sample sizes mean no firm conclusions can be drawn, there was no strong evidence to suggest a variable effect across

TABLE 6 Baseline characteristics of participants in the control and intervention groups

Characteristic	Control (*N* = 227)	Intervention (*N* = 242)
Age (years), median (LQ, UQ)	65.0 (48.0, 76.0)	64.0 (47.5, 75.5)
Missing	8 (3.5%)	2 (0.8%)
Sex, n (%)		
Male	70 (30.8)	69 (28.5)
Female	157 (69.2)	173 (71.5)
Ethnicity, n (%)		
White	209 (92.1)	224 (92.6)
Other	18 (7.9)	18 (7.4)
Highest education level, n (%)		
Primary school	5 (2.2)	3 (1.2)
Secondary school	88 (38.8)	105 (43.4)
College	79 (34.8)	61 (25.2)
Higher education	51 (22.5)	71 (29.3)
Missing	4 (1.8)	2 (0.8)
Working status, n (%)		
Fulltime	18 (7.9)	18 (7.4)
Parttime	21 (9.3)	21 (8.7)
Retired	108 (47.6)	117 (48.4)
Unemployed	20 (8.8)	25 (10.3)
Unable to work	52 (22.9)	53 (21.9)
Education or training	3 (1.3)	5 (2.1)
Carer	0	1 (0.4)
Missing	5 (2.2)	2 (0.8)
Living status, n (%)		
Owner occupied	111 (48.9)	119 (49.2)
Rented from council or housing association	76 (33.5)	90 (37.2)
Rented from private landlord	30 (13.2)	26 (10.7)
Temporary accommodation	1 (0.4)	2 (0.8)
Other	5 (2.2)	3 (1.2)
Missing	4 (1.8)	2 (0.8)
Living alone, n (%)		
Yes	115 (50.7)	127 (52.5)
No	108 (47.6)	113 (46.7)
Missing	4 (1.8)	2 (0.8)
De Jong scale, mean (SD)	3.1 (2.0)	3.4 (2.1)

LQ, lower quartile; UQ, upper quartile.

TABLE 7 Missing data for SF-12 MCS

	Control (*n* = 222) (%)	Intervention (*n* = 242) (%)
Baseline	3 (1.4)	1 (0.4)
3 months	87 (39.2)	87 (36.0)
6 months	53 (23.9)	62 (25.6)
All time points	3 (1.4)	1 (0.4)

TABLE 8 Means and SDs of SF-12 MCS by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *N*	219	241
Mean (SD)	44.6 (11.5)	43.6 (12.4)
3 months, *N*	135	155
Mean (SD)	44.7 (11.5)	43.6 (12.0)
Mean difference (95% CI)[a]	–	−1.27 (−3.53 to 0.99)
p-value	–	0.271
6 months, *N*	169	180
Mean (SD)	41.9 (11.6)	42.7 (12.0)
Mean difference (95% CI)	–	0.21 (−1.74 to 2.16)
p-value	–	0.834

a Regression based on *n* = 289 due to missing organisation variable for 'usual care' group participant.

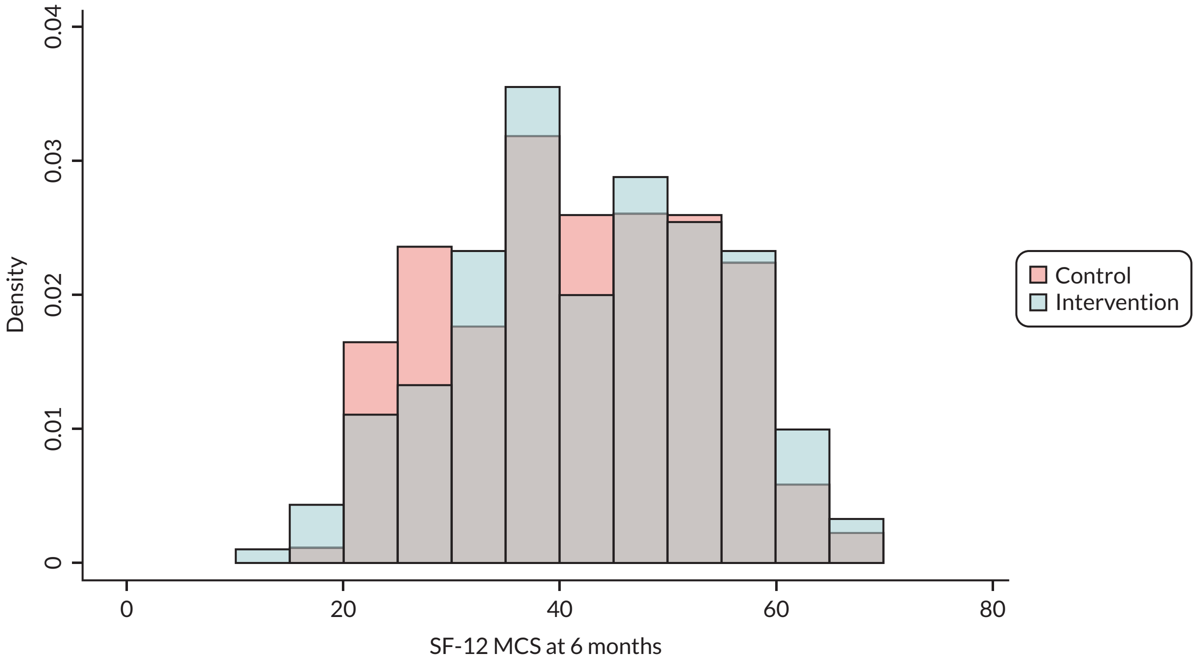
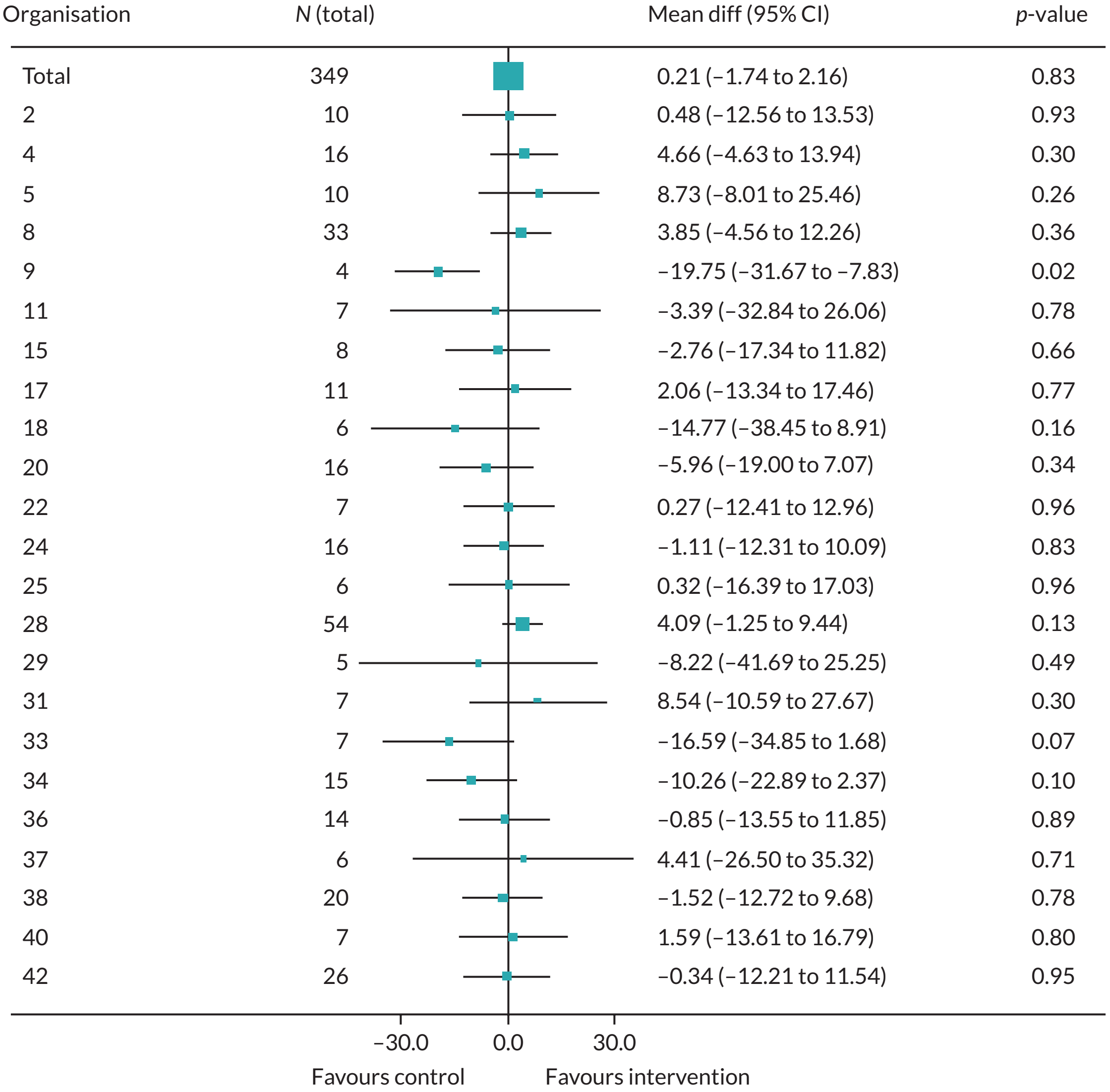


FIGURE 3 SF-12 MCS scores at 6 months by randomised group.



Organisation	*N* (total)	Mean diff (95% CI)	*p*-value
Total	349	0.21 (−1.74 to 2.16)	0.83
2	10	0.48 (−12.56 to 13.53)	0.93
4	16	4.66 (−4.63 to 13.94)	0.30
5	10	8.73 (−8.01 to 25.46)	0.26
8	33	3.85 (−4.56 to 12.26)	0.36
9	4	−19.75 (−31.67 to −7.83)	0.02
11	7	−3.39 (−32.84 to 26.06)	0.78
15	8	−2.76 (−17.34 to 11.82)	0.66
17	11	2.06 (−13.34 to 17.46)	0.77
18	6	−14.77 (−38.45 to 8.91)	0.16
20	16	−5.96 (−19.00 to 7.07)	0.34
22	7	0.27 (−12.41 to 12.96)	0.96
24	16	−1.11 (−12.31 to 10.09)	0.83
25	6	0.32 (−16.39 to 17.03)	0.96
28	54	4.09 (−1.25 to 9.44)	0.13
29	5	−8.22 (−41.69 to 25.25)	0.49
31	7	8.54 (−10.59 to 27.67)	0.30
33	7	−16.59 (−34.85 to 1.68)	0.07
34	15	−10.26 (−22.89 to 2.37)	0.10
36	14	−0.85 (−13.55 to 11.85)	0.89
37	6	4.41 (−26.50 to 35.32)	0.71
38	20	−1.52 (−12.72 to 9.68)	0.78
40	7	1.59 (−13.61 to 16.79)	0.80
42	26	−0.34 (−12.21 to 11.54)	0.95

FIGURE 4 Forest plot of treatment effect within each organisation. Note: organisations where an estimate or CI could not be derived or was excessively wide (due to small sample size) are excluded.

demographic categories. There was a wide range of effects by organisation (from approximately −20 to +8.5). However, this may be explained by some of the small sample sizes within some of the organisations.

To further investigate the impact of missingness, *Table 9* presents demographic information and baseline SF-12 MCS scores broken down by those who did and did not provide 6-month SF-12 MCS data. The demographics look largely similar between groups in terms of who provided data on SF-12 MCS at 6 months. The SF-12 MCS baseline scores for those in the intervention group and who did not provide SF-12 MCS data at 6 months are slightly lower (in terms of the median and quartiles) than other subgroups. It is plausible this would be most likely to lead to an overestimate of the treatment effect at 6 months if those with a lower score at baseline then have missing data at 6 months (given the level of correlation between scores over time; $\rho = 0.61$).

The intraclass correlation for Organisation (from the 6-month model) was 0.054 (95% CI 0.01 to 0.26; based on $n = 42$ organisations), which is slightly above the 0.05 assumed for the sample size calculation, meaning there may be some reduction in the preplanned power. However, given the width of the observed CIs, the apparent lack of effect (with respect to the *p*-value, at least) does not appear to be due to underpowering. For completeness, the ICC from the full model with repeated measures at 3 and 6 months was 0.04 (95% CI 0.01 to 0.24) for organisation and 0.54 (0.45 to 0.62) for participants.

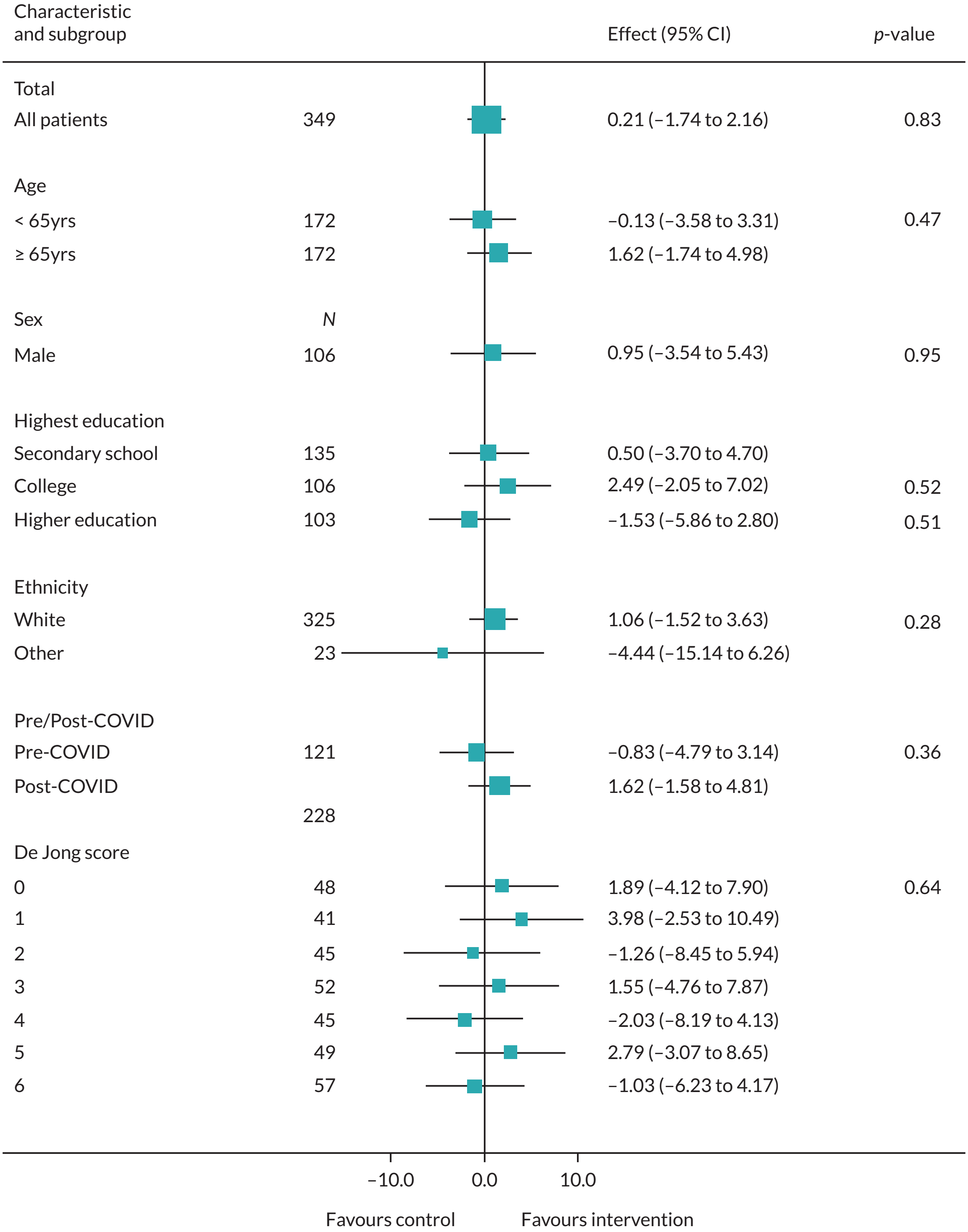


FIGURE 5 Forest plot of treatment effect by baseline characteristics.

Secondary end points

Short Form questionnaire-12 items physical composite score

Results for the SF-12 PCS are given in *Table 10*. Missing data rates were similar to the rates for MCS. The results of the linear mixed models for SF-12 PCS at 3 and 6 months again suggest data that are compatible with no or little meaningful treatment effect. The model using all 3- and 6-month data gave an estimated treatment effect of 0.12 (95% CI −1.44 to 1.68; $p = 0.880$; $n = 375$), leading to similar conclusions regarding the lack of meaningful effect.

TABLE 9 Demographics and SF-12 MCS at baseline by missingness of SF-12 MCS at 6 months

	Usual care		Intervention	
	Not missing outcome (*n* = 169)	Missing outcome (*n* = 53)	Not missing outcome (*n* = 180)	Missing outcome (*n* = 62)
Age (years)				
Median (LQ, UQ)	64.0 (49.5, 75.0)	72.0 (39.0, 79.0)	65.0 (51.0, 75.5)	62.0 (44.0, 75.0)
Gender				
Female	114 (72.6%)	43 (27.4%)	129 (74.6%)	44 (25.4%)
Male	55 (78.6%)	15 (21.4%)	51 (73.9%)	18 (26.1%)
Ethnicity				
White	157 (75.1%)	52 (24.9%)	168 (75.0%)	56 (25.0%)
Other	11 (78.6%)	3 (21.4%)	12 (75.0%)	4 (25.0%)
Education level				
Primary school	2 (40.0%)	3 (60.0%)	2 (66.7%)	1 (33.3%)
Secondary school	63 (71.6%)	25 (28.4%)	72 (68.6%)	33 (31.4%)
College	61 (77.2%)	18 (22.8%)	45 (73.8%)	16 (26.2%)
Higher education	42 (82.4%)	9 (17.7%)	61 (85.9%)	10 (14.1%)
SF-12 MCS	45.3 (35.7, 54.1)	47.4 (41.2, 55.9)	46.0 (35.9, 53.5)	41.0 (31.8, 50.5)

TABLE 10 Means and SDs of SF-12 PCS by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	219	239
Mean (SD)	42.6 (13.4)	43.9 (13.6)
3 months, *n*	133	155
Mean (SD)	39.5 (12.7)	42.2 (12.4)
Mean difference (95% CI)[a]	–	1.47 (−0.37 to 3.31)
p-value	–	0.118
6 months, *n*	169	180
Mean (SD)	40.9 (13.5)	41.5 (13.3)
Mean difference (95% CI)[b]	–	−0.69 (−2.48 to 1.10)
p-value	–	0.451

[a] Regression based on *n* = 285 due to missing data.
[b] Regression based on *n* = 348 due to missing data.

Warwick–Edinburgh Mental Well-Being Scale (short version)

The WEMWBS scores range from 7 to 35 (based on seven items scored from 1 to 5). The results at 3 and 6 months, as well as combined full model, suggest a small decrease in well-being for the intervention group, but the data are compatible with no or small (harmful or beneficial) treatment effects (*Table 11*).

TABLE 11 Means and SDs of the WEMWBS by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	217	239
Mean (SD)	21.1 (4.0)	21.4 (4.5)
3 months, *n*	129	148
Mean (SD)	21.4 (4.9)	21.8 (5.0)
Mean difference (95% CI)[a]	–	−0.18 (−1.07 to 0.70)
p-value	–	0.688
6 months, *n*	158	175
Mean (SD)	21.0 (4.9)	21.4 (4.4)
Mean difference (95% CI)[b]	–	−0.39 (−1.14 to 0.36)
p-value	–	0.310
Mixed model ($n = 370$)		
Mean difference (95% CI)	–	−0.21 (−0.88 to 0.47)
p-value	–	0.546

a Regression based on $n = 275$ due to missing data.
b Regression based on $n = 331$ due to missing data.

De Jong Loneliness Scale (short version)

The De Jong Loneliness Scale comprises six items, with possible scores between 0 (least lonely) and 6 (most lonely). Differences of a magnitude around 0.5 may be meaningful, representing a notable shift on a 6-point scale. The results at 6 months suggest data compatible with such a change in favour of the intervention, although the results are also consistent with no effect (or small harmful effect) (*Table 12*).

Campaign to End Loneliness measure

The Campaign to End Loneliness scale is based on three questions scored from 0 to 4, with an overall score ranging from 0 (least lonely) to 12 (most lonely). Differences in the order of one may be meaningful on a scale of this size, and the results at 3 months suggest such a difference is plausible in favour of the usual care group; however, the results are also compatible with no effect or a small beneficial effect (*Table 13*).

Duke Social Support Scale

The Duke Social Support Scale comprises 10 items scored from 1 to 3 and an overall score representing the sum of all items. Higher scores indicate better social support. The results from each analysis suggest data compatible with no or small effects of treatment (*Table 14*).

Collective Efficacy Network Scale

The CENS comprises 12 items scored from 1 (strongly disagree) to 5 (strongly agree), with two subscales, one representing network responsiveness and a second measuring access to collective efficacy. A higher score represents better collective efficacy. The results in each case suggest data compatible with no to small treatment effects (*Table 15*).

Social Provisions Scale

The Social Provisions Scale comprises 24 items scored from 1 (strongly disagree) to 4 (strongly agree), with an overall score based on the sum of the items. A higher score represents better perceived social provision (i.e. support from social relationships). The results from all models suggest data compatible with no or small effects of treatment (*Table 16*).

TABLE 12 Means and SDs of the De Jong Loneliness Scale by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	211	231
Mean (SD)	3.1 (2.0)	3.4 (2.1)
3 months, *n*	120	143
Mean (SD)	3.0 (2.1)	3.1 (2.0)
Mean difference (95% CI)	–	0.05 (−0.29 to 0.40)
p-value	–	0.765
6 months, *n*	153	164
Mean (SD)	3.4 (2.1)	3.2 (2.2)
Mean difference (95% CI)	–	−0.21 (−0.55 to 0.13)
p-value	–	0.232
Mixed model (*n* = 442)		
Mean difference (95% CI)	–	−0.04 (−0.2 to 0.12)
p-value	–	0.620

TABLE 13 Means and SDs of the Campaign to End Loneliness scores by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	216	241
Mean (SD)	9.7 (3.1)	9.8 (3.1)
3 months, *n*	136	154
Mean (SD)	8.7 (3.9)	9.1 (3.8)
Mean difference (95% CI)	–	0.34 (−0.51 to 1.19)
p-value	–	0.435
6 months, *n*	167	180
Mean (SD)	9.1 (3.8)	9.0 (3.8)
Mean difference (95% CI)	–	−0.00 (−0.76 to 0.76)
p-value	–	0.999
Mixed model (*n* = 456)		
Mean difference (95% CI)	–	0.08 (−0.29 to 0.46)
p-value	–	0.655

Health economic data results

Facilitator training costs

A total of 42 facilitator training sessions were conducted: 12 in Liverpool and 30 in Southampton. Intervention-specific training took an average of 1.22 hours per session (range 30 minutes to 4.5 hours, accounted for by the shorter post-restart training sessions being online – see *Chapter 2*). PALS-specific training at Southampton sites was longer and attended by more training staff. A mean of 2.5 organisation staff (range 1–9) and 1.76 (range 1–5) training staff

TABLE 14 Means and SDs of the Duke Social Support Scale by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	214	234
Mean (SD)	22.1 (4.4)	22.2 (4.4)
3 months, *n*	117	131
Mean (SD)	21.8 (4.6)	22.1 (4.6)
Mean difference (95% CI)	–	−0.21 (−0.97 to 0.55)
p-value	–	0.582
6 months, *n*	144	152
Mean (SD)	21.6 (4.6)	22.4 (4.5)
Mean difference (95% CI)	–	0.35 (−0.40 to 1.11)
p-value	–	0.363
Mixed model (*n* = 344)		
Mean difference (95% CI)	–	0.25 (−0.40 to 0.89)
p-value	–	0.454

TABLE 15 Means and SDs of the CENS subscales by group and time point, and group differences over time

	Usual care	Intervention
Network responsiveness (CENS subscale)		
Baseline, *n*	213	233
Mean (SD)	3.47 (0.70)	3.43 (0.75)
3 months, *n*	131	147
Mean (SD)	3.46 (0.83)	3.35 (0.94)
Mean difference (95% CI)	–	0.01 (−0.15 to 0.16)
p-value	–	0.941
6 months, *n*	165	177
Mean (SD)	3.33 (0.86)	3.36 (0.89)
Mean difference (95% CI)	–	0.02 (−0.13 to 0.16)
p-value	–	0.833
Mixed model (*n* = 365)		
Mean difference (95% CI)	–	0.01 (−0.11 to 0.14)
p-value	–	0.838
Access to collective efficacy (CENS subscale)		
Baseline, *n*	217	236
Mean (SD)	3.41 (0.80)	3.30 (0.81)
3 months, *n*	136	150
Mean (SD)	3.35 (0.85)	3.29 (0.91)

continued

TABLE 15 Means and SDs of the CENS subscales by group and time point, and group differences over time (*continued*)

	Usual care	Intervention
Mean difference (95% CI)	–	−0.03 (−0.21 to 0.15)
p-value	–	0.761
6 months, *n*	169	178
Mean (SD)	3.44 (0.87)	3.32 (0.87)
Mean difference (95% CI)	–	−0.03 (−0.19 to 0.13)
p-value	–	0.705
Mixed model (*n* = 367)		
Mean difference (95% CI)	–	−0.04 (−0.18 to 0.11)
p-value	–	0.621

TABLE 16 Means and SDs of the Social Provisions Scale by group and time point, and group differences over time

	Usual care	Intervention
Baseline, *n*	183	195
Mean (SD)	72.9 (6.8)	73.3 (7.8)
3 months, *n*	110	129
Mean (SD)	75.5 (8.7)	74.7 (8.8)
Mean difference (95% CI)	–	−0.45 (−2.35 to 1.45)
p-value	–	0.644
6 months, *n*	128	149
Mean (SD)	74.4 (8.6)	74.5 (9.2)
Mean difference (95% CI)	–	0.12 (−1.65 to 1.89)
p-value	–	0.894
Mixed model (*n* = 377)		
Mean difference (95% CI)	–	−0.05 (−0.86 to 0.76)
p-value	–	0.906

attended across both sites. Extra training sessions were estimated for 34 Southampton organisations, with a total cost of £2762.86. The total training cost was £7472.23 (*Table 17*). The mean cost of a training session was £121.79. The per-participant training costs were calculated for individuals randomised to the intervention arm by recruiting site. This resulted in costs of £17.90 and £37.89 for Liverpool and Southampton participants, respectively.

Facilitation delivery costs

The cost of facilitator visits is presented in *Table 18*. One participant in the usual care group received PALS at baseline, resulting in a small intervention cost in this group. The duration data did not distinguish between PALS and PALS study delivery, so it potentially overestimates the cost of the intervention. During the study, it was not always feasible to deliver the intervention at 3 months; therefore, only some participants had the opportunity to complete PALS twice. Mean cost of PALS delivery was £15.27 at baseline and £6.22 at month 3. Visit duration and distance travelled were lower in month 3, resulting in a lower cost. Lower travel costs were due to PALS being delivered virtually in later stages of the study.

TABLE 17 Facilitator training costs

	Liverpool	Southampton	Total
Training sessions conducted (*n*)	12	30	42
Training staff total hours	27	96.75	123.75
Organisation staff total hours	58	106.75	164.75
Training staff cost (£)	£513.27	£1839.22	£2352.49
Organisation staff cost (£)	£972.66	£1790.20	£2762.86
Extra training session cost (£)	0	£2356.88	£2356.88
Total training cost (£)	£1485.93	£5986.30	£7472.23
Mean training cost per session (£)	£123.83	£120.98	£121.79
Mean training cost per participant (£)	£17.90 (£1485.93/83)	£37.89 (£5986.30/158)	£31.01 (£7472.23/241)

TABLE 18 Facilitation costs

		Baseline		Month 3
		Intervention	Control	Intervention
Duration of visit (minutes)	Mean (SD)	51.8 (20.6)	90	30.1 (15.8)
	n	203	1	149
Distance from facilitator’s base (miles)	Mean (SD)	8.1 (12.3)	30	3.6 (8.3)
	n	203	1	149
Facilitator time cost (£)	Mean (SD)	14.49 (5.76)	25.20	8.43 (4.42)
Facilitator travel cost (£)	Mean (SD)	3.63 (5.54)	13.5	1.64 (3.76)
Combined facilitation visit cost (£) Mean across all participants in group	Mean (SD)	15.27 (10.49)	0.12 (2.59)	6.22 (7.09)
	n	221	224	241

Total intervention costs

Table 19 presents the estimated total costs of PALS, to include both training of facilitators and PALS delivery. The total cost was £12,688.65. The mean intervention cost per participant was £52.65.

Resource use

Resource use questionnaire missing data was high (however, the questionnaire was unavailable for the first 20 or so participants). Missing data was highest at month 3 (control: 38%; intervention: 35%) and lowest at baseline (control: 6%; intervention: 5%). No differences were observed between groups. *Table 20* presents NHS, personal and social services

TABLE 19 Intervention costs

	Intervention	Control[a]	Total
Total training cost (£)	£7472.23	–	£7472.23
Total facilitation cost (£)	£5117.73	£38.70	£5216.43
Total intervention cost (£)	£12,649.95	£38.70	£12,688.65

a Due to a protocol violation, one participant in the usual care received PALS at baseline. Consequently, a small intervention cost was applied to the usual care.

TABLE 20 Descriptive statistics of NHS, PSS and informal care costs

		Baseline			Month 3			Month 6		
		Control	**Intervention**	**Total**	**Control**	**Intervention**	**Total**	**Control**	**Intervention**	**Total**
GP visits	Total visits	304	345	649	193	225	418	228	254	482
	Mean visits	1.44	1.51	1.48	1.41	1.45	1.43	1.42	1.42	1.42
	Total cost (£)	11,856	13,455	25,311	7527	8775	16,302	8892	9906	18,798
	Mean cost (£)	56.19	59.01	57.66	54.94	56.61	55.83	55.23	55.34	55.29
	SD (£)	71.91	89.26	81.3	103.46	83.53	93.25	88.46	96.22	92.49
A&E visits	Total visits	51	71	122	31	54	85	47	77	124
	Mean visits	0.24	0.31	0.28	0.22	0.35	0.29	0.28	0.43	0.36
	Total cost (£)	6783	9443	16,226	4123	7182	11,305	6251	10,241	16,492
	Mean cost (£)	32.15	41.24	36.88	29.66	46.64	38.58	37.43	56.58	47.39
	SD (£)	91.17	112.45	102.78	81.71	127.71	108.5	127.17	153.65	141.69
Nurse visits	Total visits	166	231	397	178	170	348	369	168	537
	Mean visits	0.8	1.01	0.91	1.29	1.1	1.19	2.25	0.95	1.58
	Total cost (£)	1606.88	2236.08	3842.96	1723.04	1645.60	3368.64	3571.92	1626.24	5198.16
	Mean cost (£)	7.73	9.81	8.81	12.49	10.62	11.5	21.78	9.24	15.29
	SD (£)	12.83	22.8	18.72	39.23	26.29	32.98	99.56	26.76	71.94
Mental health visits	Total visits	168	98	266	138	143	281	75	92	167
	Mean visits	0.8	0.43	0.61	0.99	0.92	0.95	0.45	0.51	0.48
	Total cost (£)	10,584	6174	16,758	8694	9009	17,703	4725	5796	10,521
	Mean cost (£)	50.4	26.96	38.17	62.1	58.12	60.01	28.29	32.02	30.23
	SD (£)	198.25	92.55	152.81	486.35	458.34	471.04	100.37	186.96	151.51

TABLE 20 Descriptive statistics of NHS, PSS and informal care costs (*continued*)

		Baseline			Month 3			Month 6		
		Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total
Prescriptions	Total prescriptions	1007	1076	2083	621	656	1277	867	849	1716
	Mean prescriptions	4.77	4.72	4.74	4.57	4.32	4.43	5.35	4.99	5.17
	Total cost (£)	31,116.30	33,248.40	64,364.70	19,188.90	20,270.40	39,459.30	26,790.30	26,234.10	53,024.40
	Mean cost (£)	147.47	145.83	146.62	141.09	133.36	137.01	165.37	154.32	159.71
	SD (£)	128.31	145.25	137.22	134.49	139.8	137.13	182.25	186.21	184.09
Social worker visits	Total visits	30	22	52	42	42	84	38	18	56
	Mean visits	0.14	0.1	0.12	0.3	0.27	0.28	0.23	0.1	0.16
	Total cost (£)	1530	1122	2652	2142	2142	4284	1938	918	2856
	Mean cost (£)	7.25	4.92	6.04	15.41	13.73	14.52	11.6	5.13	8.25
	SD (£)	32.96	23.91	28.61	55.48	104.33	84.76	70.96	30.15	53.87
Professional care hours	Total hours	82	221	303	292	218	510	217	179	396
	Mean hours	0.39	0.97	0.69	2.09	1.41	1.73	1.31	1.02	1.16
	Total cost (£)	2460	6630	9090	8760	6540	15,300	6510	5370	11,880
	Mean cost (£)	11.66	28.95	20.66	62.57	42.19	51.86	39.22	30.51	34.74
	SD (£)	85.56	190.34	149.64	437.75	182.12	328.75	175.17	121.21	149.69
Informal care hours	Total hours	582	837	1419	542	565	1107	536	927	1463
	Mean hours	2.77	3.69	3.25	3.93	3.69	3.80	3.33	5.24	4.33
	Total cost (£)	4778.22	6871.77	11,650	4449.82	4638.65	9088.47	4400.56	7610.67	12,011.20
	Mean cost (£)	22.75	30.27	26.66	32.25	30.32	31.23	27.33	43	35.54
	SD (£)	107.12	134.3	121.91	88.74	122.01	107.35	60.65	161.11	123.95

(PSS) and informal care resource use and costs. There was little difference in GP visits between time points and groups. At each time point, participants in the intervention group had on average more A&E visits, with this difference increasing at month 6. At months 3 and 6, participants in the control group had on average more nurse visits, with the difference again increasing at month 6. There were only small differences in mental health professional contacts and prescriptions between groups at months 3 and 6. Social worker contacts were higher in the control group at month 6, but differences were minimal at other time points. Finally, paid-for and informal care showed inconsistent differences between groups and time points. Informal care was similar between arms, but participants in the intervention group received more professional care at month 6. For participants with complete activity questionnaires, the mean number of activities at each time point was similar (baseline mean = 2.28 and 2.34 for usual care and intervention participants, respectively), and increased by a small amount at 3 months in both groups (*Table 21*). At 6 months, there was no evidence of an uptick in the number of activities in either group; however, the usual care group reported activities below baseline levels. Longitudinal and comparative assessment is not possible due to the high proportion of missing data.

Table 22 summarises the public sector costs, which comprise the NHS and PSS costs (excluding baseline), combined with the intervention costs. In total, 265 (57.1%) of participants completed the NHS and PSS resource use questions at both time points. Across both groups, the total cost was £190,834 from a public sector perspective, with mean costs higher in the intervention arm compared to the control (intervention: £744.26; control: £691.84). When informal care and out-of-pocket activity costs are included (societal costs), mean costs remain higher in the intervention arm compared to the control (intervention: £652.89; control: £566.48), but this relates to substantially missing data (26.9% completeness of participants overall). Comparative analysis of public sector and societal costs is provided in *Table 27*.

Preference-based outcomes

We present data on: (1) completeness of preference-based outcomes (missing data summaries) in terms of frequency and percentages and (2) utility (SF-6D; *Tables 23* and *24*) and capability measure score (ICECAP-A) and standard deviation (*Tables 25* and *26*). The ICECAP-A was slightly more complete at each time point than the SF-12. Scores for both measures were similar between groups. Both scores showed a slight decrease in the mean score at each subsequent time point.

TABLE 21 Mean and SD of participant activities by group and time point[a]

	Usual care	Intervention
Mean (SD) number of activities at baseline	2.28 (1.61), *n* = 137	2.34 (1.55), *n* = 149
Mean (SD) number of activities at 3 months	2.38 (1.41), *n* = 88	2.57 (1.71), *n* = 100
Mean (SD) number of activities at 6 months	1.97 (1.25), *n* = 91	2.37 (1.66), *n* = 107

a Table reports all available cases.

TABLE 22 Descriptive statistics of costs by sector by group

		Arm		
		Control	Intervention	Total
Public sector costs[a] (£) (3 million and 6 million)	Total	84,404.70	106,429	190,834
	Mean	691.84	744.26	720.13
	SD	1009.81	912.55	957.07
	n	122	143	265
Societal costs (complete case)[b] (£) (3 million and 6 million)	Total	32,289.40	44,396.50	76,686
	Mean	566.48	652.89	613.49
	SD	470.44	601.32	545.15
	n	57	68	125

a Includes NHS and PSS costs at 3 and 6 months (complete case) and intervention costs.
b Includes NHS and PSS costs, informal care and activity data at 3 and 6 months (all complete case).

Short Form questionnaire-6 Dimensions

TABLE 23 Short Form questionnaire-6 Dimensions missing data summary: number and percentage of participants with available data

	Control (*n* = 222)	Intervention (*n* = 242)
Baseline	221 (99.5)	236 (97.5)
3 months	124 (55.9)	143 (59.1)
6 months	151 (68.0)	170 (70.2)

Note
Percentages were calculated out of those randomised to each group.

TABLE 24 Short Form questionnaire-6 Dimensions mean and SD of outcome measure by time point and group

	Control	Intervention
Baseline	0.648 (0.141)	0.650 (0.155)
3 months	0.622 (0.144)	0.636 (0.144)
6 months	0.611 (0.152)	0.623 (0.153)
QALYs	0.315 (0.069)	0.319 (0.071)

Note
Where appropriate, median and quartiles will be used instead of mean and standard deviation.

ICEpop CAPability measure for Adults and years of full and sufficient capability

TABLE 25 ICEpop CAPability measure for Adults missing data summary: number and percentage of participants with available data

	Control (*n* = 222)	Intervention (*n* = 242)
Baseline	219 (98.6)	239 (98.8)
3 months	135 (60.8)	150 (62.0)
6 months	165 (74.3)	177 (73.1)
All time points	115 (51.8)	135 (55.8)

Note
Percentages were calculated out of those randomised to each group.

TABLE 26 ICEpop CAPability measure for Adults: mean and SD of outcome measure by time point and group

	Control	Intervention
Baseline	0.714 (0.194)	0.709 (0.216)
3 months	0.678 (0.219)	0.712 (0.230)
6 months	0.672 (0.216)	0.686 (0.244)
YFC	0.348 (0.097)	0.360 (0.109)

Comparative analysis of economic outcomes and costs

We report incremental and mean differences in QALYs, YFC and YSC to three decimal places or the first significant figures because of small numbers. *Table 27* presents the total and incremental QALYs, YSC and YFC, costs and NMB associated with the intervention associated with the public sector services perspective.

Analysis of quality-adjusted life-years

After adjustment for clustering by organisation, there was a negligible 0.002 (95% CI −0.012 to 0.007) difference in QALYs. This was not significant.

Analysis of years of sufficient capability and years of full capability

Similar to the result for QALYs, there were negligible and non-significant differences in both YSC and YFC. Outcomes were even closer to zero after adjustment.

Analysis of costs

After adjustment for clustering by organisation the incremental cost was £88.96, which favours usual care but is a non-significant result (95% CI −£132.52 to £310.45).

Primary economic analysis: complete case

Analysis of NMB was undertaken for 214 participants (46.1%) who contributed both QALY and cost data for the primary analysis of public sector costs.

After adjustment for clustering by organisation, the incremental net monetary benefit (iNMB) (intervention vs. usual care) was −£443.72 (95% CI −£1060.38 to 172.93). This negative sign on iNMB for the intervention favours usual care, but the CI overlaps zero, showing that this is non-significant. To consider decision uncertainty as the threshold value of the willingness-to-pay (WTP) threshold varies, we additionally present iNMB plots (*Figure 6*). As seen in *Figure 6*, iNMB was just below zero at lower threshold WTP values, and positive thereafter. The fact that the iNMB tracks zero but is below the line suggests that the results for PALS are fairly equivocal to usual care, albeit slightly less preferred. As can be seen by the upper and lower bounds for the iNMB 95% CIs, there is a high degree of uncertainty surrounding the

TABLE 27 Quality-of-life and well-being capability tariff scores, QALYs, YSC and YFC and costs

Measure (control, *n*; intervention, *n*)	Mean (SD) score		Mean difference (95% CI)	Adjusted for baseline level (QALYs only) and organisation random effects[a]	Multiple imputation and adjusted for baseline and organisation random effects[b]
	Usual care	Intervention arm	Unadjusted		
QALYs (95,119)	0.315 (0.069)	0.319 (0.071)	0.004 (−0.015 to 0.022)	0.002 (−0.012 to 0.007)	−0.028 (−0.054 to −0.001)
YSC (115,135)	0.389 (0.010)	0.399 (0.009)	0.010 (−0.017 to 0.036)	−0.00007 (−0.013 to 0.0135)	NR
YFC (115,135)	0.348 (0.097)	0.360 (0.109)	0.012 (−0.014 to 0.038)	0.002 (−0.011 to 0.015)	NR
Public sector cost (£185,195)	691.84 (1009.81)	744.26 (912.55)	52.42 (−178 to 283.08)	£88.96 (95% −£132.52 to £310.45)	382.07 (−72.33 to 836.48)
NMB (£95,119)	8961.87 (2326.10)	8815.95 (2711.37)	−145.92 (−845.11 to 553.26)	−£443.72 (95% CI −£1060.38 to 172.93)	−5515 (−9980.40 to −1051.26)

a Output reports CI (parametric) from a mixed model which is adjusted for baseline level and with a random-effects term for organisation.
b Multiply imputed results are based on 50 imputed data sets, using predictive mean matching (knn = 5) and for an imputation model congenial to the analysis model, but with the addition of age as an auxiliary variable.

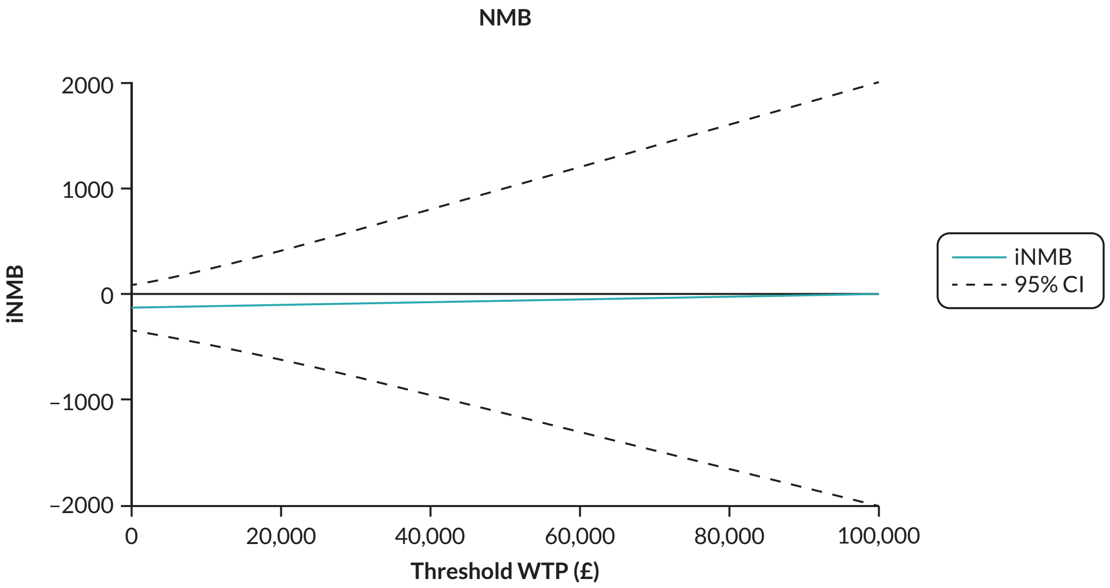


FIGURE 6 Primary analysis: net benefit by WTP.

results, and this uncertainty increases at higher threshold values of the WTP threshold. This is anticipated as a higher WTP threshold will weight changes in QALYs more, magnifying the uncertainty.

To examine the uncertainty in the results, a CEAC (*Figure 7*) was created. The CEAC is upward sloping but levels off at higher WTP thresholds. At thresholds of £20,000 and £30,000 per QALY, the probabilities that PALS is cost-effective are 34.5% and 39.85%, respectively.

Secondary economic analysis: considering the effect on capability well-being

Negligible (very close to zero) and non-significant differences in incremental YFC and YSC coupled with very small differences in costs mean that the calculation of a cost per extra year of full/satisfactory capability would be uninformative.

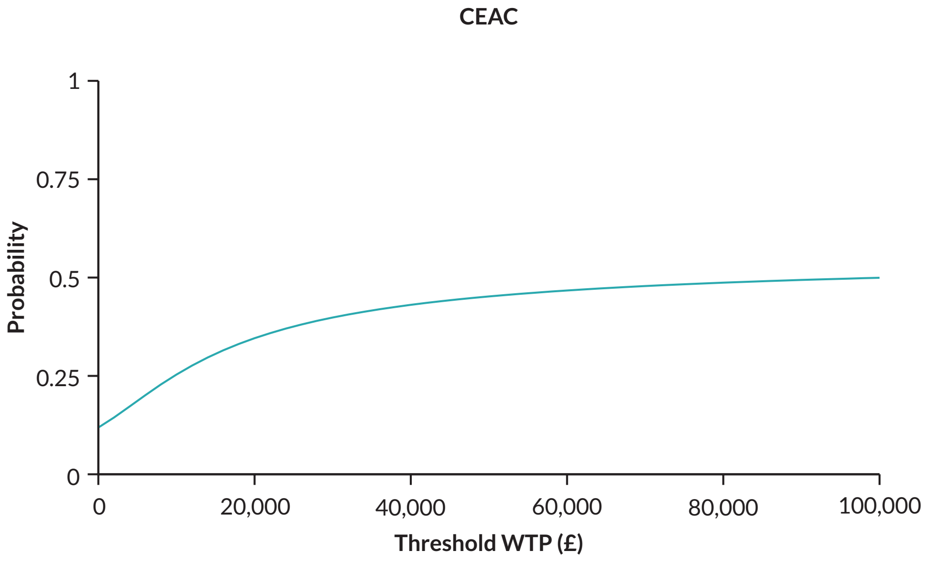


FIGURE 7 Primary analysis: CEAC.

Secondary analysis: using multiply imputed data

With multiply imputed data, we found the uncertainty in iNMB remains wide, allowing for both positive and negative values, and is increasing as the WTP threshold increases (*Figure 8*). In contrast to the complete case analysis, *Figure 9* shows the probability that PALS is cost-effective is now 58.4% and 60.2% at the respective £20k and £30k thresholds.

Findings

To our knowledge, this is the first economic evaluation of a social network mapping intervention in the community setting alongside a full trial (although previous economic evaluations of similar trials have been undertaken[34]). We found no compelling evidence to suggest that PALS is more cost-effective when compared to usual care. A limitation

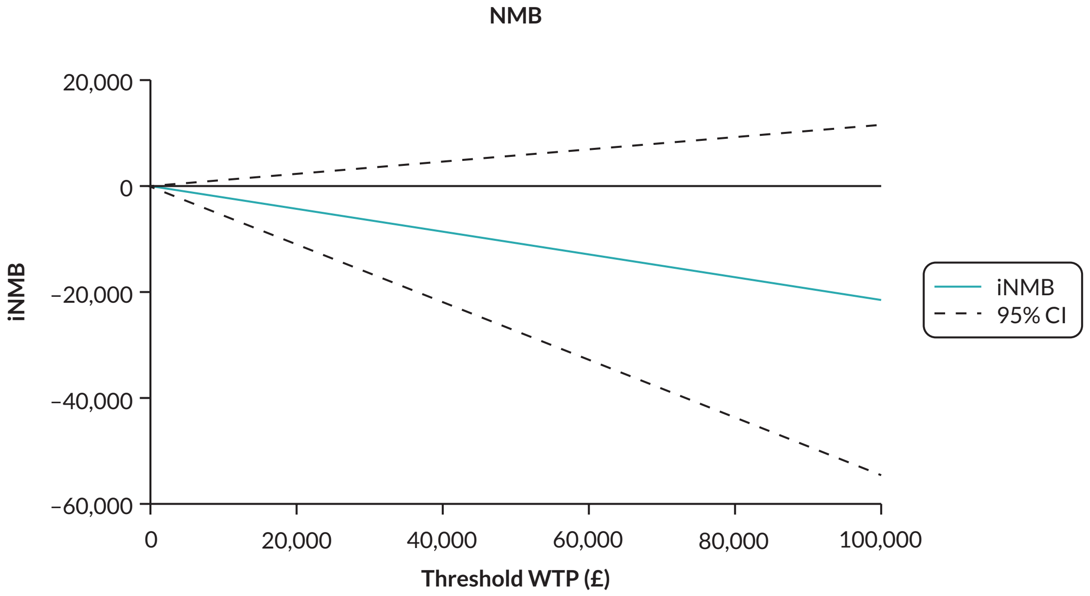


FIGURE 8 Secondary analysis: net benefit by WTP (imputed data).

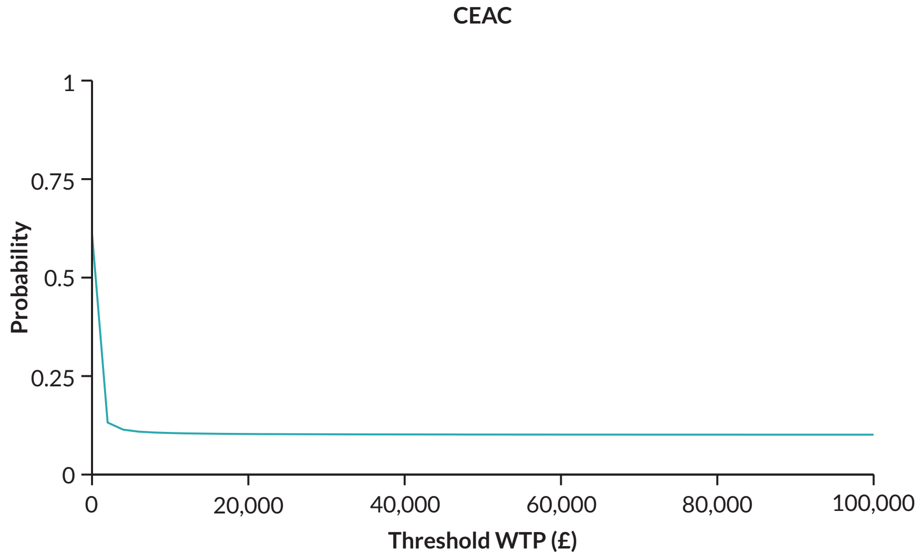


FIGURE 9 Secondary analysis: CEAC (imputed data).

of our study was missing data: NMB was between 41.1% and 49.0% complete in the usual care and intervention arm, respectively. Examination of patterns and mechanisms of missingness did not identify sources of systematic bias, which lends support to the complete case analysis but does not preclude the possibility that there might be unmeasured predictor variables introducing bias, especially as within-trial processes for establishing reasons for missingness were inconsistent. Both the complete case and multiply imputed analyses reveal a high degree of imprecision, indicated by the wide CIs on NMBs. Owing to even more extensive missing data in societal cost categories, we did not explore an incremental analysis of societal costs. The intervention was relatively inexpensive to deliver at £52.65 per participant. As there was no evidence of a difference in costs or QoL or capability well-being scores, extrapolation of these results to a longer-term horizon is not indicated.

Chapter 4 Profiling the optimal factors that prepare a community context for implementation, and sustainability, of a network intervention for loneliness

Aims and objectives

A process evaluation was conducted concurrently to understand the individual, organisational and environmental factors that inhibit or promote the engagement, workability, integration and sustainability of the PALS intervention for addressing loneliness in open (i.e. community) settings.

The process evaluation examined:

- whether settings affect pre-implementation arrangements, intervention delivery, outcomes and scalability
- whether the PALS intervention was implemented as planned; how it was incorporated into the everyday practices of the organisation; and how it impacted on, and was integrated into, the organisation's capacity, practice and policies and to provide options for people who are lonely/socially isolated
- how the PALS intervention produced outcomes.

Methods

A mixed-methods approach combined observations, interviews and documentary analysis of relevant documents to capture the process of introducing, engaging and delivering the PALS intervention. Initially, data collection focused on the pre-implementation arrangements relevant to the introduction of the intervention. This included the process of planning how the intervention was best able to fit the everyday routines of the organisation, engagement with the study and developing a picture of the organisation's context, capacity and readiness to deliver PALS. Subsequently, the implementation of the intervention was explored, focusing particularly on how it was integrated into, and subsequently impacted on, everyday practices of each organisation.

Theoretical approach

Concepts from the Consolidated Framework for Implementation Research (CFIR) were used to guide the identification of factors promoting or inhibiting pre-implementation arrangements,[92] incorporation and integration of the intervention in the participating organisational settings (see *Appendix 6* for more details on the CFIR). A typology of third sector organisations[93] was used in conjunction with the CFIR to illuminate the nature of partners' contexts. The pre-implementation work resulted in adaptations to the typology of third sector organisations that was used to inform the examination of contextual sensitivities in the implementation process. Details of the adapted typology of community contexts can be found in the results section (*Table 28*).

Data collection

Observations were made of collaborating organisations between October 2018 and February 2022. This included the introductory meetings with representatives of the organisations, the facilitator training sessions, follow-up meetings and site visits between the partner organisation and the PALS team. Field notes were recorded in situ and a reflective journal maintained after each event. All in-person observations took place during the pre-pause phase of the study.

Interviews (1 : 1 interview and focus groups) were conducted with key organisation stakeholders (managers and facilitators) in both the pre-implementation and implementation stages. All partner organisations were invited to a 1 : 1 interview; these were conducted either in person or via the telephone/video call (determined by the interviewee's preference and the restrictions in place due to COVID-19). Three facilitators were asked to participate in an online focus group at the end of the study. All interviews loosely followed an interview guide that was developed with

TABLE 28 Organisation typologies and characteristics

Typology	N	Characteristics	Pre-implementation arrangements	Example organisations
Type 1: fully professionalised organisations	14	The leading characteristics of these organisations are the formal hierarchical structure and large, paid workforce. Of all the community partners, these organisations were competitive and entrepreneurial in nature. The organisations' security comes from holding long-term and repeated contracts with government departments and local health and well-being authorities. Fully professionalised partners often provide a service for a specific identified need, following a service user being referred into the organisation	The key pre-implementation arrangements involved understanding the intervention's 'unique selling point' (i.e. relative advantage) and the service user needs, and securing leadership engagement and multilevel support across the organisation	NHS Trusts, fire and police services, primary care providers and housing associations
Type 2: aspirational community, voluntary and social enterprise	26	These partners were characterised by a small-to-medium paid workforce that had an element of formal structure. The aspirational community partners held contracts for services with local health and well-being authorities, and/or their services were funded by grants. Crucially, these partners were also reliant (to different degrees) on voluntary income as well as volunteer involvement. The organisations, as indicated in the name, were aspirational in their growth, and as such were entrepreneurial in nature as they sought to expand and grow their service deliveries	These organisations had grown beyond their founding need or purpose but continue to operate in accordance to, or at least be mindful of, their founding values and ethos. Understanding these values and how to work within them is an important pre-implementation activity	Franchises of national charities, regionally based social enterprises and community interest companies
Type 3: non-professionalised community-based groups	4	These informal groups are embedded within the local community in which they are based. They offer activities which are not eligible for funding and rely heavily on voluntary donations and volunteers. These groups emphasise acceptance, promote community cohesion and are a site of sociability and often solidarity	The networking and outreach work performed led to a referral, often to a well-connected, locally situated individual who would become the implementation champion in these groups and negotiate entry with leaders (often religious leaders)	Faith or community-based groups

consideration of the theoretical approach taken, and were audio-recorded and fully transcribed. In addition, reflexive notes were taken directly after each interview by the researcher leading the interview. In total, 14 1 : 1 interviews were conducted in the pre-implementation stage with representatives from 11 organisations, and 19 1 : 1 interviews were conducted in the implementation stage with representatives from 12 organisations. One focus group was conducted with three facilitators who were also members of the research team.

To help facilitate and plan implementation, documents such as the study protocol and training material were collected. Local health and well-being reports and strategies were collected to understand the broader political landscape, and leaflets and materials produced by the partnering organisations were also collected to help understanding of the organisational context.

Data analysis

Data management was undertaken using the qualitative data analysis software NVivo (QSR International, Warrington, UK). Layder's adaptive theory[94] informed the approach to data analysis through a process of constant comparison, starting with familiarisation, then coding (inductively and deductively) and interpretation. Deductive coding drew upon the CFIR. Themes were compared within and across cases (organisations), with attention being paid to difference and the reasons for this. Analysis was led by one researcher who collaborated with the team to sense-check and interpret the data.

Process evaluation results

The following section outlines the process of implementation across the different settings (typologies). The focus is on understanding the unique aspects of each setting in order to explore how to prepare the context for implementation (the pre-implementation phase) and how implementation differed across the three typologies. Data are drawn from the interviews, observations and documents collected. The letters I, O and D are used to label the data excerpts from interviews, observations and documents, respectively, and the partner (P) numbered in correspondence to *Appendix 7* (organisation typologies). Parts of this section are reproduced from Ellis *et al.* (2020) and Ellis *et al.* (2022).[55,95]

The development of an organisational typology

The organisational contexts in which the study was implemented differed across community partners in terms of their size, structure and workforce. These variations influenced both the pre-implementation work required and the implementation process. Understanding the range of organisations was relevant to constructing the necessary conditions for implementation and future sustainability potential. To better portray the nuances between partner contexts and the complexities experienced when implementing in open systems like community contexts, a typology of community organisations was developed (*Table 28*). The typology is best seen as a continuum in which organisations had more or fewer features relevant to three factors influencing implementation: 'service user needs', 'workforce' and 'organisational structure'. The term 'service user' refers to the individuals who were accessing support from the community partner. To address factors relevant to implementation, we explored the needs of people, specifically in order to understand the nature and experience of loneliness and social isolation. The 'workforce' refers to the paid and unpaid personnel who support the service users and 'organisational structure' to the culture and capacity of the partners. All three factors were relevant to implementation in each of the organisations, but in different ways.

Fully professionalised organisations

Pre-implementation arrangements

Fourteen partner organisations were defined as fully professionalised organisations (hereon in referred to as 'fully professionalised'). On average, the time taken from first contact with the organisation to first participant recruited into the study was 7.45 months (SD 4.5 months). During this time, the organisation was undertaking preparations for the implementation of the intervention.

For fully professionalised partners, a hierarchical structure meant first approaching management to facilitate initial buy-in, which for the study team meant developing an initial understanding of the division of labour of the workforce and what influences were relevant to be able to engage with uptake and implementation of the initiative. As these partners were reliant upon government contracts, they appeared to be influenced by the political landscape. This meant that where there was alignment between the 'unique selling point' (i.e. the relative advantage) of the intervention and the existing political agenda, buy-in from management was easier to secure. This was particularly the case when leaders saw the intervention as an advantage because it fulfilled a strategic objective:

> *I think also we have the added complication that we are very politically swayed depending on what government is in at that particular time and what initiatives they're going to be setting up and how that impacts on us as a housing association, and I think as such we've had a very changing corporate strategy.*
>
> *I: P8*

Subsequent to leadership buy-in, pre-implementation engagement activities needed to extend to individuals who would be directly overseeing the implementation. In fully professionalised organisations, these individuals were often excluded from the early engagement conversations. This potentially had a negative effect on the pre-implementation context as these individuals held valuable insights into how work is done in these contexts, and where need should be prioritised.

> *This is benefiting the service, but they [the potential facilitators] see people with real difficult psychological problems who are in immediate threat, there's safeguarding and real difficult stuff. Loneliness is important, and I'm not saying it isn't, but is it of the same standard. Can I justify their time?*
>
> *I: P5*

Thus, engaging all levels of the workforce was key in creating the optimal pre-implementation context in fully professionalised organisations. Nonetheless, this required pliability on behalf of the context and research team in order to be optimised across organisations. Through a process of monitoring and reflection on behalf of the PALS team, the need to secure multilevel buy-in became an early priority for the team (i.e. rather than assume it would be secured internally). This was solved by the introduction of the pre-training and post-training meetings, as outlined in *Chapter 3*, which helped engage the whole workforce as quickly as possible to arrange the division of labour. These meetings were introduced for all typologies but were especially useful for the fully professionalised partners where the workforce was larger, and there was more of a risk of disconnect between leaders and those overseeing/working on the project.

Third and finally, understanding how the organisations operated was important in order to act on the pre-implementation work. Fully professionalised organisations were most 'business-like' in their operation, with clear timely objectives driving the workforce; this often meant the pace of the work was the fastest of all the community typologies. Thus, when the optimal pre-implementation context was created, the study team had to be ready to act.

> *. . . it is a changing picture, when we say 'go' you go or you've missed it.*
>
> *I: P8*

Therefore, any delay on behalf of the study team could risk the window of implementation readiness closing. This was experienced when ethical administration approval was delayed, causing some moments of readiness to be missed, and as a result some of the pre-implementation work had to be repeated (i.e. the training of facilitators).

Implementation arrangements

Given the pre-implementation contexts outlined above, the fully professionalised partners often considered that the implementation of the PALS intervention offered an additional service to their service users. Service users were often in contact with the partners for a discrete period, for a specific issue.

> *I guess the feeling of being in those services actually I guess there was a need, it felt like people wanted more support than just the service, they wanted to connect and perhaps were feeling isolated.*
>
> *I: P1*

However, the nature of the business carried out by the fully professionalised partners meant there was typically less alignment or fit between the intervention and the everyday work of these organisations. As such, only five (35.7%) were able to facilitate the intervention themselves, requiring the study team to take on the whole intervention facilitation for five organisations and jointly facilitate with the four (28.5%) remaining organisations.

In order to support the fully professionalised partners with implementation, a process of (re)socialisation was required. (Re)socialisation included, but was not limited to, intervention-specific training but also changes to work practice, in the case of the bureaucratic organisation, into more dynamic work practices that would facilitate implementation. Finding flexibility in the context and ways of working, coupled with flexibility from the study team, helped embed the intervention work.

> *It felt like we probably put in quite a lot of my time but actually not many people were recruited, so I think that was when we had that meeting review, put our heads together and came up with a different plan [. . .] three or four of us went to the group and we just used to sit there and chat to people about the research which turned into a real success and then I guess we changed the plan really which was to look at areas where there's big groups of people so it was more time effective.*
>
> *I: P1*

However, of all the types of organisations, these partners were the most resource-rich, and this supported implementation. Most notably, the dedicated human resource that was available for the study.

> *[Female] going on mat [maternity] leave in June, but as we were leaving the office we were introduced to [Male] who will replace [Female] as the facilitator. PALS had already been written into his objectives for the next quarter.*
>
> *I: P8*

Given the extensive reach of fully professionalised partners, and the characteristic that their service users were typically more able to engage with the intervention, fully professionalised organisations were generally able to access larger quantities of potential participants than other organisations (with an average of 14 participants per organisation compared to a study average of 10 per organisation). However, the cultural misalignment (in the work required for implementation and the work of these organisations) brings into question the sustainability potential of these partners. This was further exacerbated following the outbreak of the COVID-19 pandemic, when of the 14 fully professionalised organisations only two were able to continue with the study due to the increased service demand and client need. Many organisations used capacity and resources to change the delivery of their service to meet the service user need.

> *Lots of new volunteers were recruited and their roles were mainly to do food shops and make calls to lonely and isolated people. Clients without a befriender (mainly people on the waiting list) were connected with a volunteer who made weekly check-in calls. However, when COVID restrictions were lifted lots of the volunteers went back to work and stopped making their weekly phone calls.*
>
> *I: P12*

> *The social isolation has been immense during COVID. Many of our clients haven't left the house for over 2 years and they are still worried about the virus. Getting them to start thinking about leaving the house and going out into the world again is really hard. We've seen depression and anxiety really rise.*
>
> *I: P12*

Aspirational community, voluntary and social enterprises

Pre-implementation arrangements

Twenty-six community partners were categorised as aspirational community, voluntary and social enterprises (hereon in referred to as 'aspirational community partners'). The time taken to recruit an aspirational community partner into the study was on average 3.74 months (SD 5.69).

Aspirational community partners were often founded in response to an identified need or to fulfil a specific purpose, and had gone on to grow beyond their original purpose but were able to continue to operate in accordance with their founding values and ethos. Understanding these values, and how to work within them, was an important pre-implementation activity for the study team, especially in securing leadership buy-in.

An additional part of securing leadership buy-in was to understand the advantage the intervention offered the organisation. The existence of many of these partners was precarious; aspirational community partners held shorter-term contracts and, as such, they often reported being in a constant cycle of applying for funding to ensure their survival. Therefore, participating in the study (and specifically the RCT element of the study) was appealing to these organisations, especially where they felt there was alignment between the intervention and the everyday work of the organisation. The evaluation was viewed as something that could provide evidence of their everyday work and potentially contribute towards the funding applications and ultimately the organisation's survival.

> *[PALS is] a formalised version of what we do with people who use our service . . . I want to be able to measure the impact of the work, the service, I want evidence about what we do.*
>
> *O: P20*

Upskilling the workforce was of particular interest to aspirational community partners as their everyday work more closely aligned to that of the intervention, and they were more financially insecure. These organisations also had low resource and relied on volunteers; thus the opportunity for the workforce to receive training was seen as an advantage of participation. This low resource availability was the most important pre-implementation arrangement barrier to overcome (once buy-in had been secured and benefits of participation identified).

> *At the moment we're very short-staffed, I don't think we have the capacity in our paid staff to do it [PALS] through them.*
>
> *I: P29*

The limited financial, physical and human resource meant there was less flexibility, as the personnel of the small workforce were required to do several jobs. In response, to create the necessary pre-implementation conditions, flexibility on behalf of the study team was required, particularly around undertaking the intervention facilitation for those who were unable to do so themselves. This was especially necessary during the post-restart phase of the study as the organisations were dealing with the consequences of the COVID-19 pandemic. Therefore, in summary, finding the most suitable division for each context was a key pre-implementation activity for these kinds of organisations.

> *When you've been to see people face to face, you've built up a bit of a more trusting relationship, whereas when you're just the voice on the end of a phone sometimes it's harder to do. So missing that social contact for me made recruitment more difficult, plus I was limited to working from home myself so I wasn't getting out much either.*
>
> *I: P23*

> *Where our roles changed, the focus was on delivery of the groups. We were still able to do the initial recruitment but not the PALS facilitation. We just didn't have the capacity within the team.*
>
> *D: P26*

Implementation arrangements

Implementation across the aspirational community partners was aided by the close alignment between the intervention work and the everyday work of the partners. The process of facilitating the intervention required good interpersonal skills and relational working on behalf of the facilitators. Implementation was more successful where this aligned with the nature of the organisation's everyday work. This was especially so during the first stage of the intervention where the facilitators guided the users to map and reflect on their personal social networks, as this stage lends itself more favourably to the roles and individuals with experience of relational working.

> *My role as a link worker made the project a very natural fit into my existing role.*
>
> *D: P20*

> *We did it because it is what we do anyway, but we have the ability to go with people.*
>
> *O: P21*

Having this natural alignment between the intervention work and the everyday work supported successful implementation as it allowed the workforce, where capacity allowed, to apply their pre-existing skills to deliver the intervention within their 'everyday' workload. This also speaks to the sustainability potential of an intervention like this in these settings.

Despite this alignment, some of the aspirational community partners raised concerns regarding the suitability of the intervention for some of the service users. While aspirational community partners, like all partners, were in contact with people experiencing loneliness and social isolation, some service users being supported by the aspirational community partners had more additional needs that needed to be addressed more urgently; these included issues with housing, financial and health needs that meant the individual was in a state of crisis. In these instances, organisations felt these needs precluded them from being able to participate in the intervention designed to tackle loneliness and social isolation.

> *. . . when people are firefighting, when they are sorting out housing, food, money, it's hard to think about the bigger stuff like isolation. It [intervention] is better when people are more stable.*
>
> *O: P15*

> *People may not be engaging because they are coping with housing issues, debt, drugs and alcohol, children not attending school.*
>
> *I: P15*

The service users' needs that prevented them from engaging might also be considered contributing factors towards loneliness and social isolation; however, when people have multiple needs, 'loneliness was a tiny part of the bigger picture' (I: P20), and thus an intervention designed to help with loneliness and social isolation was not a priority. Where service users from aspirational community partners did want to engage with the intervention, which was designed to connect people to local resources, the success of this was affected by the users' socioeconomic circumstances that could prevent them from fully benefiting from the offering.

> *Some of the young people find it hard to communicate and socialise with others, money is a really big barrier so people don't necessarily have the money to go and do what they want to do.*
>
> *I: P15*

Thus, the complex needs of service users meant the reach of aspirational community partners was, in reality, restricted for an intervention of this kind. The sustainability of the intervention was also brought into question as the partners were experiencing a rise in demand for their services coupled with an increase in service user needs, especially following the COVID-19 pandemic. With rising demand and increasingly complex needs, the partner organisations themselves could be said to be in a state of crisis where they had to raise the threshold to access support and prioritise their scarce resources to those deemed most in need. This perfect storm of demands placed additional strain on the partners' capacity to deliver the intervention.

> *People used to call up because they were a little lonely and they used to send a befriender [but] now they can't do that, people have to be really lonely.*
>
> *I: P32*

> *Especially [difficult] since the council and social care is changing and there is no preventative work going on.*
>
> *I: P20*

> *[Name] said that she feels like 'they collude with statutory services because they know they will do it anyway . . . Because the voluntary sector have a different value base . . . because we see the face standing in front of us and we won't turn them away.*
>
> *I: P20*

With little additional funds to support the rising demand for support and increasing complexity in service user needs, this, a factor of the sociopolitical context, affected implementation especially with the aspirational community partners, as it stretched the capacity of already overburdened organisations further.

Implementation was further affected by the precarious nature of the workforce. Volunteer involvement was an important and supplementary part of the workforce in aspirational community settings, and was integral to the running of the services aspirational community partners offered. However, this reliance made for precarious capacity as volunteers withdrew their labour with immediate effect, which did at times bring the implementation of PALS completely to a halt. The withdrawal of volunteer involvement in aspirational community partner settings was especially an issue following the pandemic and is reflected in the increase in facilitations the study team took on following the pandemic.

> *As [P20] develops, it is difficult for me to stay whether the organisation would or wouldn't have capacity as this would depend on the various other projects that the team are working on.*
>
> *D: P20*

> *Our volunteers will worry about whether or not they could actually (a) do it and then (b) carry the commitment through.*
>
> *I: P32*

> *I don't think it's peculiar to [charity], it's happened everywhere. We've had people retire and we haven't been able to replace them, maybe it's made people have different values as well. Some people have got older and thought 'I've volunteered for so long, maybe it is time and I've got used to not volunteering'. This is what happens, you're doing it every week and then you stop doing it and you think 'do I really want to be doing that every week', and as a volunteer they get that decision and they can choose.*
>
> *I: P34*

Therefore the aspirational community partners' capacity fluctuated due to a combination of increase in service user need and workforce turnover but also factors relating to funding whereby, as outlined above, the partners were in a continuous state of reapplying for funding to secure their survival. This cycle really brings into question the sustainability potential in these settings within the current system of commissioning and service provision, despite these organisations comprising the majority of the community partners working with the PALS study team.

> *The current funding from the housing association and Children in Need is running out. There are different funding pots with different timescales but no core funding to maintain sustainability.*
>
> *O: P27*

Non-professionalised community-based groups

Pre-implementation arrangements

Only four of the partners were categorised as a non-professionalised community-based group (hereon in referred to as 'community-based groups'). These partners were often faith-based organisations and/or informal activity groups that were embedded within the community they serve, and included church, mosque and mental health activity groups. The term 'community' here is used to refer to geographical and congregational community. Unlike other partner types, these partners were wholly dependent on volunteers and voluntary donations, including a nominal fee from service users to access the group. These partners also stayed exceptionally close to their founding values and promoted acceptance and inclusion among the members for whom they provided a site of sociality and solidarity.

Recruiting a community-based group required the most relational work of all the partner types, which on average took 5.5 months, and access was often through a network referral. While the 'way in' to these settings appears fortuitous, access often arose as a result of considerable networking and relational work. Often inroads into these most informal settings were made indirectly through a process of engagement with members of structured organisations (i.e. local authorities, county councillors) and also with other partners who had a high degree of cosmopolitanism. The networking and outreach work performed led to a referral, often to a well-connected, locally situated individual who would become the implementation champion in these groups and negotiate entry with leaders (i.e. religious leaders).

> *I've now had the chance to talk with my colleagues at the church and they're all very interested.*
>
> *O: P44*

The pre-implementation work for these settings was in some ways, once entry had been secured, easiest of all partner types. The key pre-implementation task was understanding the culture and the values of the groups, and where the intervention was perceived to align with these values – that is, it was deemed to be beneficial to the community – this led to a commitment from the leadership and strengthened the champion's resolve to implement PALS.

> *[PALS is] an excellent project that could be very beneficial to our community therefore we're at your disposal.*
>
> *O: P44*

The integral role of the champion in these settings cannot be overstated. However, the reliance on one individual did contribute towards a slow achievement of implementation readiness. Despite low resource availability and thus low absorptive capacity within groups, the commitment to support the community was the primary motivator, and even though the readiness for implementation was slower to achieve, the motivation remained.

> *I am like a tortoise . . . but hopefully we'll get there in the end.*
>
> *I: P42*

Limited resources negatively affected community-based groups, yet these groups were most influenced by the commitment to serve and support their local community (both the immediate congregation and the geographical community). Without such devotion of a champion, however, it is reasonable to question whether readiness for implementation would be achievable, and this reliance went on to affect implementation sustainability.

Implementation arrangements

Implementation in these partners' settings was highly affected by the limited resource availability. The role of the champion continued to be a pivotal one; although the role was more about raising awareness than it was around intervention delivery, the champion kept momentum in these settings. Of the four partners, the PALS study team facilitated for three. Due to the extremely low human resource, the research-related task of recruitment, as well as the intervention task of facilitation, was performed by the study team. This brings into question the issue of sustainability. A further factor affecting the issue of sustainability is the reliance of these partners on few individuals (volunteers). In the event that the individual withdraws their support (labour) from the setting, the implementation efforts stop, and there is an absence of capacity to absorb this.

> *I was the main point of contact at the church really, for the project – there wasn't anybody else that could do the recruitment and tell people about the research. So when I left there was nobody else to carry on that role unfortunately.*
>
> *O: P42*

Finally, due to the nature of these groups, it was found that once the intervention had been offered to the group on several occasions (over a short period of a couple of weeks), those who wished to access the intervention had an opportunity to do so; with few new members joining over time, the reach of these groups was therefore limited.

Delivering the intervention: reflections from PALS facilitators

To better understand how the intervention was delivered in practice and uncover the lessons learned from this, a focus group with three facilitators was conducted. In total, these facilitators (*n* = 3), who were part of the study team, were responsible for over 55% of all intervention deliveries and contributed to 20% of the joint deliveries with organisations (see *Chapter 3*, *PALS facilitator training*). These individuals are therefore very experienced in interpersonal working and the delivery of the intervention, and with their participation in up to 75% of intervention deliveries, the fidelity of the delivery can be assured.

How the intervention was intended to be delivered is covered in *Chapter 2*; what is discussed here are the reflections on the delivery, in order to explore how the intervention may have produced the intended outcomes. In what follows are two points which are considered important considerations and contributors during the intervention delivery. The first ('creating a personal experience') and the second ('guiding steps to change') are discussed ahead of offering recommendations for the intervention delivery.

Creating a personalised experience

Loneliness concerns the quality of one's relationships (see *Chapter 1*). The quality of the relationships between facilitator and participant was an integral component in the intervention delivery. The facilitators agreed that personal qualities and experience of interpersonal working assisted this.

> *So then again, it's very much down to the facilitator, you know, if there's good rapport been developed with the facilitator, they're can sort of start to eke out.*
>
> *I: F1*

The facilitators felt that a quality, personalised intervention experience was more likely to be created when delivering the intervention face to face and allowing the participant time and space to discuss their stories during the intervention delivery. Both in-person and remote (over the phone) delivery took place during the study (the latter due to the COVID-19 pandemic restrictions). Although the facilitation was possible through both modes, it was felt that the telephone (remote) delivery hampered the quality of interaction and that face to face was a 'lot richer experience'. The interaction, and thus intervention experience, was sufficient but the experience was boosted by in-person delivery. This was often because it was felt easier to build a rapport with the participant as facial expressions and body language were of assistance. Alongside this, skilled facilitators would also draw upon the physical surroundings (often the participants' homes) to support the discussions and personalise the prompts, which helped to create a personal experience.

> *As a, as a sort of a stand-alone intervention, I agree it's far more effective to be present, to be with the person and you pick up on all sorts of other cues as well. Yeah. You see where they're living. You see everything from, you know, body language to . . .*
>
> *I: F3*

Taking time to go through the intervention and allow the participant space to reflect upon the questions and prompts was considered helpful in the creation of a personalised experience. This helped to move the experience from being a more transactional conversation towards a more personal, and therapeutic, interaction. Participants experiencing loneliness often had complex and multiple needs, and building a rapport and creating a personal experience meant that the intervention delivery could be flexed to suit participants' needs. Through a flexible, personal experience, participants were then better placed to be guided to change.

Feedback from participants also indicated that they benefited from the facilitated conversations as it provided an opportunity to think about life after restrictions were lifted and (re-)engaging with community activities.

Guiding steps to change

Following stage 1 of network mapping and reflection on relationships, stage 2 (preference questionnaire) was designed to encourage participants to reflect on points of interest and identify areas of support. What was found is that this was often too prescriptive and diluted the personal experience when participants followed the questions as they appeared in the online version of the intervention.

In moving the conversation from transactional to more personal, asking more guided questions, and questions informed by reading body language and taking clues from the physical surroundings, was found to help participants by triggering the imagination. Guided questions helped participants to imagine the past. When a participant became reminiscent, this was often a positive sign of imagining activities of enjoyment, and in many instances imagining the past helped to return the participant to a self – a self not experiencing loneliness.

> *There were certain times when there were sort of elements of reminiscence that when people started to say, you know, they'd start to remember what they were like before, the things that they used, you know, I used to love dancing. I used to love cycling, those conversations then sort of often led to really sort of excited or new sort of ideas really, because they remembered who they'd been before and what, really.*
>
> *I: F2*

Through guided questions, imagining the past helped participants to imagine a different future, and it was felt that through the rich conversation, participants were able to give themselves permission to do something new and different that might lift them from the loneliness being experienced. Once this stage was reached, participants required more support than the intervention in its current guise offers.

It was felt that participants would benefit at this juncture from more tailored, guided questions that would go beyond the prescriptive questions of the intervention. Stage 3, identification of community resources, merely illustrated resources in the local vicinity and asked a few questions regarding how the participant might be able to connect to these. What was found was that participants required more support than the intervention offer in taking the first step towards connecting to local resources. Often participants had complex needs and/or experienced low self-confidence and efficacy to be able to make the first step. From this, it was suggested that going forward with the addition of guided questions that would be task-oriented and directed by the participant would be beneficial in helping to create smaller, more manageable steps that could be put in place to work towards the end goal of connecting to a local resource.

> *In cases where, you know, people really want to do something and they're finding it very, very difficult to see somebody in their network. Helping them or facilitating them to do that, there might be a time that the facilitator buddies them to do it and then. And then that is passed over to maybe a network member, helping them just for a bit more involvement.*
>
> *I: F1*

However, even when participants were able to identify activities or connections they would like to pursue, often more practical support was required to facilitate this next step. The intervention in its current form does not offer any onward support beyond signposting and discussing who in the existing network may be able to assist with building connections (which of course may be difficult to achieve for people with small networks and those with a number of relational difficulties). The facilitators felt that to help momentum and boost the intervention experience, participants would benefit from having a follow-up call shortly after the intervention (i.e. a few days, not 3 months) and also the addition of a buddy, who might help support them with the first step.

Furthermore, it was found that on a number of occasions the intervention database did not identify any local resources for the participant to be able to connect to. This could have been due to lack of information contained within the database, but in many cases, it was due to a lack of assets and resources in the locality of the participant. This was a challenging scenario for facilitators to manage, and threatened to add to the experiences of loneliness and social isolation, and often local knowledge on behalf of the facilitator was able to compensate for the gaps in the database.

Recommendations for intervention delivery

In order to maximise the benefits the participants receive from the intervention, additional support and tailored questioning, as discussed above, are required. The following section outlines the recommendations for future intervention delivery based on these reflections of the experienced facilitators.

Firstly, in considering who is best to deliver the intervention and what training is required, it has been found that those skilled at interpersonal working, and specifically being able to build or capitalise on a good rapport, are better placed to facilitate this type of intervention. The latter lends itself to organisations that have close, enduring relationships with their clients, those whose ethos might include being a ‘good neighbour’ or a ‘buddy’. These organisations are likely to foster getting to know the individual well and gaining the trust and confidence of the person that will enable a richness in conversation that would not otherwise be achieved. Alongside this consideration, the training of facilitators needs to be adapted in order to upskill potential facilitators in this way of working. Training would be enhanced with more of a focus on creating richness in the interaction (delivery in person, allowing time and using visual clues to tailor prompts), and the means to recognise when it is going well and when it might become more transactional. An effective means of training might be through allocating more time to observing and role play in the training programme. Furthermore, potential facilitators are likely to benefit from knowledge of how to assist behaviour change, which is especially pertinent to the second part of the intervention and guiding steps to change. Training might also benefit from being adapted to focus on upskilling facilitators in supporting slow, steady behaviour change. Participants might also benefit from additional support in taking initial steps to engaging with new connections and activities, which lends itself to facilitators coming from organisations that can afford the time to provide this early support.

Secondly, the intervention itself requires a greater degree of flexibility than it currently offers. Conversations, questions and prompts could be more tailored to meet the participants’ needs, and a skilled facilitator can lead this. This does bring into question the formulaic, rigid nature of the questions currently embedded within the intervention. In its current form, it was found to be repetitive in form and to depersonalise the experience. Greater focus on the individual’s needs is likely to better support change. The addition of a nudge, a follow-up a few days after completion of the intervention, is likely to be of benefit as it lends itself to continuing to build on the rapport between facilitator and participant and supporting momentum.

The benefits to the participants largely came through rich interaction with the facilitators that enabled the participant to be heard and explore past, present and future experiences. With some alterations to training and intervention delivery, participants could benefit further from the intervention experience.

Concluding remarks

The process evaluation set out to examine both the pre-implementation arrangements and the delivery of the PALS intervention and to explore the integration of the intervention into the everyday practices of the organisation. Our work highlights how this is a complex picture, where the open system of the community has settings with differing demands. Understanding and tailoring arrangements to create an optimal pre-implementation context has been illustrated across the typologies where leadership engagement and division of labour are driven by the contextual needs. Once the optimal context was taken into account, implementation was affected by the service user needs and the structure and composition of the organisational workforce.

No single context was found to possess all the facets necessary for implementation and sustainability. Fully professionalised organisations had the resources, stable workforce and reach required to access suitable participants but lacked the necessary skilled workforce required to deliver the intervention. By comparison, the aspirational community organisations had the skills and alignment to deliver the intervention, but – similar to the community-based groups, and despite enthusiasm to support service users in any way they could – suffered with chronic capacity issues and fought continually for their own survival. A more networked approach to implementation that connects the facets of reach and delivery is likely to help facilitate intervention delivery in each setting and thus support sustainability.

Finally, an overarching point that affected implementation and its possible sustainability was the sociopolitical context of austerity. Austerity has led to an increase in demand for support from community organisations as service users' needs grow in complexity. In the context of loneliness and social isolation, the environment of austerity negatively affects organisational capacity in numerous and interacting ways. Of particular note was the precarious nature of many community organisations which, alongside providing support to individuals, are continuously seeking financial investment to secure their own survival. It is recognised that the lack of sustainable funding to community and voluntary settings contributes to widening of health inequalities.[96] Similarly, in this environment our organisations faced increasing pressures on their ability to respond, and as such this is the key determinant as to whether an intervention like this could be implemented and sustained in the future.

Chapter 5 Qualitative study with participants (experiences of loneliness)

Aims and objectives

In this qualitative study, we were interested in learning about the meanings attached to social loneliness to assess the likelihood of whether a social network intervention could bridge this gap. We asked questions about social relationships (including what kind of support they provided, neighbours and community, meeting new people) and spending time alone, and about their loneliness and whether this had changed over time. The data presented here are being submitted for publication.

Methods

This was a qualitative study nested within the PALS trial. Participants were selected based either on the field notes of the researchers who conducted baseline quantitative data collection, or on the size of their personal community captured in the network maps coproduced during the intervention, and also as a result of responses to the baseline question ‘How much does loneliness affect your life?’. We aimed to speak to participants at a range of time points during their 6-month participation within the trial, and to sample broadly to reflect the diverse demographic characteristics of participants included within the wider study.

Semistructured interview schedules were developed within the team and included experts in sociology and health psychology. Open, inductive questions were used to explore experiences of loneliness especially through life transitions, the meaning and value of connections and relationships, and participants’ experiences since receiving the intervention. Initially, interviews were conducted face to face from November 2019 until March 2020, after which 11 subsequent interviews were conducted over the telephone due to the outbreak of the COVID-19 pandemic. Informed consent was taken in person or collected by post (during telephone interviews).

Interviews were conducted by three researchers involved in data collection for the study (KK, LJ and TCB). All interviews were audio-recorded and transcribed verbatim. Field notes were completed after each interview and discussed with the study team. Recruitment was stopped once the researchers agreed that data saturation had been reached.

Data analysis

Data collection and analysis were undertaken in parallel to allow for purposive sampling based on researcher insights, team discussions and analytical insights, which facilitated an iterative process of analysis. Inductive thematic analysis methods were used, and included line-by-line coding and constant comparison.[97,98] A coding manual was developed and refined, with codes checked against the interview data and discussed within the team to ensure trustworthiness and authenticity of participant experiences. All data broadly relating to experiences of loneliness, relationships with others and their local environment were analysed.

Qualitative study results

Participants

In total, 20 participants were interviewed, ranging from 21 to 86 years old, with a mean age of 59.7 years (SD 17.74) and 9 of the participants were male (45%). In response to the question, ‘How much does loneliness affect your life?’ interviewed participants scored an average of 7.4 (SD 1.93), with scores ranging from 2 to 10 (of a potential range of 1–10). In addition, participants listed an average of 5.2 network members (SD 3.12).

The interviews illuminated a number of themes, which included networks and relationships with others; the experiences of, and the strategies employed to live with, the experience of loneliness; readiness to participate and structural barriers which link with meaningful activities.

Feeling alone in the face of others: an absence of intimacy

Several aspects of loneliness linked appraisal of, and feelings about, individuals they had contact with on a daily basis. Contrary to popular narratives regarding the nature of loneliness, many respondents did not complain about a lack of people around them. They therefore felt lonely even when (or despite being) surrounded by others, highlighting the distinction between feelings of loneliness and isolation. Many participants described the 'lifeline' that key network members represented in their lives, although this was largely in relation to others being available to provide practical help and support:

> *Literally she does a hell of a lot for me; she does the laundry, she does my shopping, sometimes she's cooked me dinner. I'm very grateful. Very grateful. Because I can't do a lot, you know?*
>
> *PT18*

> *Ah, well she's very good, she comes, she phones me twice a week and she ferries me to hospital appointments and dentists and things like that.*
>
> *PT16*

However, the lack of emotional connectedness meant opportunities for meaningful social interaction with others became limited despite physical connection, proximity to others and the availability of instrumental support. This emotional distance, the inability to connect, and an absence of communication presented as a source of hidden distress:

> *You can be in a room with a thousand people and feel lonely, I know that for a fact, you know . . . it's about your mental state and how you handle all the different interactions and things, you know, and how much you worry about how you're perceived and all that sort of thing, you know.*
>
> *PT8*

> *And sometimes I can be in a crowded room and feel lonely and it's a strange one that it's almost like you feel you can't connect, particularly if you're in a room with people that you don't know.*
>
> *PT19*

> *. . . having no-one to talk to sometimes within the house, within the household, it means even when everybody's around me I can still be lonely. It means boredom, it means anxiety, it means depression, it means wanting to hide away and become more and more isolated, not wanting to go out because I don't want to interact so it's everything.*
>
> *PT9*

The unavailability of emotional support or companionship from one's immediate network required participants to look for connectivity further afield. The use of the internet and social media opened up opportunities to connect with people and groups around shared interests, as well as providing a means for communicating with others outside of the immediate physical environment:

> *Yeah, I've recently joined . . . my favourite band of all time was Madness. And I've recently joined the Madness fan group thing online. And then this guy asked me to be his friend and then he asked me to join all his other groups that he runs. So, in that sense, that's quite good to sort of join in that. What else? Cats. I've got a cat lovers' group. And black cats are the best sort of thing, because mine's a black cat. So, yeah, that's quite nice.*
>
> *PT19*

> *I mean, it's what I call cyber social life, yes. Yes, I get enough emotional strength, I get enough emotional nourishment, if you know what I mean.*
>
> *PT1*

> *I interact with a lot of people online.*
>
> *PT11*

This was especially useful for individuals who were limited physically, for example by illness or having small children, which made the possibility of finding new, meaningful connections in person challenging. However, for others, using digital spaces to interact was something that they weren't interested in engaging with: 'I don't understand this going online thing' (PT6).

Loneliness as entrapment and boredom

People described loneliness as being a private sadness that happened 'behind a closed door'. This experience was commonly expressed as an acute sense of dislocation from the outside world, coupled with a sense of complete and enduring boredom:

> *It's your day-to-day not being filled the way it should be.*
>
> *PT7*

> *Bored. Bored and isolated.*
>
> *PT1*

> *I wake up and I think, it's what I call a 'nothing' day, in inverted commas.*
>
> *PT16*

The marginalised, mundane and repetitive nature of being confined to the home was often described:

> *At the moment I've got four walls. I think I could count all the squares on every wall.*
>
> *PT18*

> *Just seeing something different. I'm not seeing the same walls or the same people all the time.*
>
> *PT13*

In response to feelings of boredom and alienation from others, participants reported trying to keep busy. This involved filling time to avoid prolonged periods at home ruminating, and attempting to find a balance between doing what one is able to do in such circumstances and not succumbing to it. This included for example, working within the parameters of the present situation – even if sometimes that meant only watching the TV or looking out of the window:

> *No, I need to be busy, honestly if I was sitting in my house, I'd just think in my own thoughts and it's not healthy to do that.*
>
> *PT12*

> *Well, if you're feeling very down then all the things that you're sad about it all comes back doesn't it so then you have to put your mind somewhere else . . . read or watch something.*
>
> *PT11*

> *And I feel very isolated. I did it this morning, I raised the door, I always do it when I come down, I raise the door and see how the world's doing, what the weather's doing.*
>
> *PT16*

In addition, some participants disclosed a preference for face-to-face interactions when possible:

> *There are, there are a number of people now that I've got to know over the past year, you know, just acquaintances, but they're always asking after me.*
>
> *PT8*

> *She's someone that I met through [a friend] actually. She lives up the road from me. She's the one that waved at me (laughs). And you know, because I like photography and she's really into photography, we tend to go out on little trips to . . . like the other month we went and found kingfishers, so we were, you know, photographing kingfishers.*
>
> *PT19*

> *You can get off your arse and go and sit on a stool outside your front door. Somebody, even if it's only the post-girl, is bound to say hello to you, you know what I mean . . .*
>
> *PT8*

The benefits of organising face-to-face interactions likely extend beyond the interaction itself and alleviate some of the boredom associated with loneliness. Specifically, the organisational aspects involved in arranging and undertaking in-person interactions provide additional structure and purpose to the day (i.e. getting ready, travel to and from destination), which break up the day in ways which digital interactions may not. Beyond these attempts to add routine where there was none, many described a sense that this was just how things were, and that in order to cope, they must just accept the situation and keep going:

> *Well I am, because I have to, I don't have any choice. What can I do? Sit there and cry? I can't do – well, I could but that's not going to do me any good. I just have to keep pushing on.*
>
> *PT17*

> *No, I just think must do better. Get up and do something . . . Yeah, try and be positive, I always think. Because it's, you know, a terrible world in some ways isn't it so . . .*
>
> *PT15*

Engaging with meaningful social activity as a way out of the imprisonment of loneliness

Feelings of being socially isolated have been linked not only to an absence of meaningful relationships but also to activity,[63] and the results here also highlighted that in line with the boredom experienced, largely, valued activities were also missing. In this respect, opportunities for accessing meaningful social activities were viewed as a potential, if challenging, route to participation as a way of ameliorating social isolation by respondents:

> *And so actually doing new groups, which is something that I think I ought to do and that I should do and it would be interesting, actually doing it for the first time I would really struggle with, even though I want to do it.*
>
> *PT19*

> *Just to get us open and give the men who are struggling a little bit of light, somewhere they can go where they can have a coffee, something to eat, have a game of snooker . . .*
>
> *PT4*

Readiness in terms of levels of felt stigma, personal self-worth and potential social rejection inhibit the ability to think about linking to new activities. In turn, this is linked to a sense of legitimacy of whether one is being judged as being of the appropriate social status or at the right point in the life course to be morally worthy of being lonely and engaging with community activities in particular social situations and settings:

> *I think maybe there's a stigma attached to loneliness when you're not elderly. I think people think, 'Well why is she lonely?' and the example of a mother with a new baby that I used earlier, people probably think, 'Well why are they lonely?' I think it's acceptable to be old and lonely but not quite so acceptable to be younger and lonely.*
>
> *PT17*

> *You can't go to anything that's mainly families and children. You can't go there (parent and child groups) on your own because you're going to be judged. So I think for the man, it's a big hurdle to cross, obviously if you've got a girlfriend or a wife that you're going with, you both blend together, but you just sort of stick out like a sore finger, you know.*
>
> *PT3*

This fed into a sense of apprehensiveness and wariness about engagement or participation with groups and activities, and the nagging awareness of this impacting on potential for relating to others in everyday encounters. Others lacked the necessary skills and confidence to attempt ameliorative steps:

> *So yeah, it's a bit, like, embarrassing, humiliating, just, like, you feel a bit like a lost puppy.*
>
> *PT4*

> *Yes, to walk in somewhere on your own is really hard.*
>
> *PT15*

> *I won't show up sort of unannounced on my own because I'm just a little bit shy even though I'm probably, you know, I will talk to anyone and people think that I'm extrovert, I'm really not so it would have been nice to have like a buddy that could come along, introduce themselves, spend several sessions with you, you get used to them and then go along to something that might have been designated suitable for you.*
>
> *PT9*

In addition, a number of structural barriers were identified as important for preventing engagement. Being able to physically travel to a community location was often seen as an insurmountable obstacle for some, for reasons such as ill health or poor mobility, lack of access to transport or simply a lack of appropriate activities or services:

> *Transport and lack of energy and lack of funds and, yeah, because funding for me would be a big thing.*
>
> *PT9*

> *Well, I can't afford it [to go to groups], I'm on Universal Credit. I don't even have my heating on, I can't afford my heating so to fork out for taxis when I can't put my heating on seems a little bit over the top.*
>
> *PT17*

> *It is frustrating because physically I would like to be able to do more but physically I can't! It is so restrictive and it can get depressing at times, but I have managed that pretty well, to be fair.*
>
> *PT11*

> *Yeah, I would like to get out, yeah, but I can't go out alone any more, I have to accept that.*
>
> *PT18*

These structural factors were often seen as things beyond their control that they had little power to overcome and change. Given the potential benefit from engaging with valued activities, there are potential missed opportunities for addressing loneliness which are likely to disproportionally affect those who are already most marginalised through lack of accessibility.

Chapter 6 Discussion

Summary of key findings

In this study, we set out to assess the clinical and cost-effectiveness of a social network intervention implemented in a community context for people who were socially isolated and lonely. Acceptability to both community organisations and individuals was high. However, the findings from this study illustrate the barriers to, and difficulties of, delivering interventions in this setting. Furthermore, there was no evidence of a significant impact on participant mental health, physical health or other outcomes (including loneliness and isolation).

Strengths of the study

Overall, the PALS study achieved a number of objectives, and the strengths of the study will be discussed below.

Reach and recruitment through community groups of people experiencing loneliness

At the outset of the study it was, given the varied contexts and range of people experiencing loneliness, not entirely clear who the target population was for this type of intervention, and whether it would be possible to access and engage people who were isolated and lonely. We were able to deliver the recruitment to the required sample size, with over 650 individuals referred to the study and a total of 489 consented. We were also able to continue to successfully recruit appropriate participants during a global pandemic where much of the community-based work and resources ceased to exist (or rapidly shifted to an online context).

Our work in developing positive collaborations with so many community partners in both localities was an essential component in achieving the recruitment goals and illuminated the willingness, openness and positivity of community groups to participate in research where there is relevance to the people they are in contact with on a daily basis. Our initial focus in developing a process by which to engage and train organisations proved to be a valuable investment of time early in the project. This is relevant since we had to collaborate with many more organisations than we had anticipated at the outset (actively engaging with 66 organisations to collaborate with 44, compared with our initial assumptions that we would be able to recruit to target with approximately eight organisations). In having developed processes that worked at each site, we were able to quickly establish whether an organisation was appropriate and likely to be able to participate in the study. However, it is worth noting that our experiences of building and sustaining relationships with community partners required a lot of both time and investment on behalf of the study team (taking on average 4–5 months to set up each organisation, although this did vary considerably between organisations and across the study). The established links supported by institutional infrastructure and a history of collaboration between formal organisations such as the NHS and researchers were absent, and so costly in a wide sense when dealing with community groups from scratch and operating in open systems. As outlined in the process evaluation section, buy-in to the study was required at all levels within community organisations – from the senior management and aligning with the strategic vision and goals of the organisation, down to engaging the people who would be actively supporting recruitment or intervention facilitation ‘on the ground’ – and establishing this early on was crucial in developing a successful collaboration. Such arrangements are much more transient and variable than dealing with formal institutional structures of health and social care.

Part of the reason we did ultimately have to collaborate with many more organisations than we expected was due to some extent to the ability and resilience to withstand increasing pressure on the community organisations and the diminishing resources and capacity within the sector. A number of key organisations disappeared from view due to crises of funding, the rising costs of accommodation, and the ability to retain volunteers and continue with core tasks. Prior to the COVID-19 pandemic, the pre-implementation work for all community organisations involved enormous efforts at troubleshooting limited resource availability and funding sources despite the value of provision and increasing reliance of statutory bodies on such organisations as sources of support to vulnerable people in the community. Of the organisation types, fully professionalised organisations had more depth of resources than aspirational community and non-professionalised community-based organisations. Following the COVID-19 pandemic, the drop in resources for all organisation types was catastrophic. While fully professionalised organisations remained the most resource-rich of all community types, their apparent 'richness' was only marked in relation to other organisations. In contrast, aspirational community organisations saw the most dramatic drop in resources and capacity, as funding declined, service user need increased in demand and in complexity, and the voluntary workforce they so heavily relied upon diminished. Thus, the implications for the project were that it meant collaborating with more organisations to ensure the necessary reach of the intervention and to help overcome the resource constraints through a networked approach.

Our procedures were purposely pragmatic and designed to fit within existing practices within organisations, rather than imposing multiple research procedures on organisations (which would have very likely made participation difficult to implement in practice). Our aim was to ensure we were able to retain methodological rigour while being flexible and responsive to the local contexts (e.g. by modifying the randomisation procedures to align with what was practically feasible), which in turn would inform the process evaluation about the potential scalability of an intervention such as this.

Understanding living with loneliness

Turning our attention to the study participants, the findings presented here highlight that adults of all ages are at risk of experiencing loneliness and social isolation. Although we did not observe any statistical differences between participant outcomes as a result of the intervention, we did identify that individuals within our study reported both very poor mental and physical health outcomes (as indicated by the SF12 composite scores) and poor health-related QoL (as indicated by the SF-6D score). Around 40% of participants in the current study reported MCS and PCS scores 'well below' population benchmarks, with mean scores notably lower than 'healthy' population scores (0.832) and comparable to those of cancer patients (mean 0.632).[99]

Participants provided detailed descriptions of their daily lived experience, yet often feeling lonely was not simply a result of being alone. Our data highlighted that for these individuals, the meaning of loneliness consists of an absence of intimacy while being surrounded by others, feeling out of place, a lack of belonging and sense of relatedness to others, a daily sense of entrapment and boredom and having limited access to meaningful activities. Below we discuss issues around access to meaningful activities before discussing the psychological and relational aspects of loneliness.

The demographic information highlighted that a large proportion of participants were living in marginalised circumstances. For example, some were living in deprived areas, were not working or were on low incomes. Structural barriers, such as lack of local services, no access to transport and costs required to increase social contact, were outlined as barriers to social participation in the interviews undertaken with participants, and echoed as concerns by our study partners. The economic data suggested that participant activities were reasonably low across both groups and all time points (although there was a high level of missingness of this data). There is a strong connection between poverty and the risk of social isolation,[100] and evidence suggests that locality-based connections and activities have to be very local and proximate for those who are marginalised and lack resources to be able to link to them.[43] Thus, the likely traction, uptake and sustainability of interventions that seek to harness the power of social capital and community resources need to be seen in the context of the availability and sustainability of very localised community assets. This suggests that investment in community assets and resources (including things such as the availability of affordable and reliable transport) is essential in providing opportunities for those who are isolated or lonely. However, while the focus of this study, and the intervention, was to connect people to community-based meaningful activities, we acknowledge, based on our findings (the trial results, the qualitative analysis and our own reflections of the intervention delivery) that by itself, signposting people who are isolated and lonely to activities in their community is simply insufficient. The process of mapping one's personal community is beneficial for positively disrupting an individual's status quo by providing a visual representation of support and allowing for exploration of the self, important others and wider activities, especially when guided by a skilled facilitator.[101] However, we suggest this social network mapping is not appropriate for everyone at every time point. There is a degree of psychological and physical readiness required before it is appropriate to engage with this process (i.e. both feeling ready to make a change and being in a position to actually do so). Previous work has highlighted a lack of focus on psychological factors and their role in loneliness.[102,103] However, our qualitative work suggests that for those with personal apprehension about accessing external activities and others, addressing psychological aspects of loneliness (such as cognitions about the social self and others, and building confidence and efficacy in social situations) may need to be offered prior to attempting to increase engagement. Additional physical support to overcome the perceived barriers (i.e. getting to activities or having a buddy to accompany them for the first few times) would also likely be beneficial to many individuals who have been lonely and isolated for some time.

Previous research exploring network processes in long-term condition management has highlighted the role of harnessing personal community support, which involves a process of first being able to identity who is the most appropriate person within their network before they are able to ask for help or support,[67,104] which is most often practical in nature.[105] The presence of efficacy within the network alone is insufficient if individuals are unaware of it or unable to access it to meet their need. In this case, the individuals interviewed here expressed lacking the emotional connections and support from those around them. Having people in close proximity was not enough to alleviate feelings of loneliness, and in fact may increase feelings of alienation when there is an absence of belonging with one's personal community. Relational difficulties were a central theme interwoven through all the interviews and included both historical and current problems in both forming and maintaining emotionally satisfying relationships. We believe this would be an area that could benefit from further exploration and theoretical development.

The intervention used here in PALS had previously been successfully applied to long-term condition management, and comparison with this work highlights the differences when applying this to loneliness in open settings.[106,107] Those with chronic illness expressed the need to reconnect with lost (through loss of employment as a result of ill health and peers) previously valued activities, social contacts and status as a result of developing a long-term condition.[108] While some of the barriers to participation and cognitive rehearsal of linking to new activities were the same (e.g. lack of transport or material resources), there were stark differences. The most obvious one is about people experiencing loneliness having a sufficient sense of ontological security and emotional connectedness to muster the confidence to contemplate engaging with community activities. Our qualitative interviews highlighted that participants wanted to engage with meaningful social activities but barriers to doing so were psychological (i.e. confidence and competence) and practical (i.e. transport or cost). It may have been that one of the reasons for the lack of effect was that the social network model (GENIE) lacked sufficient workability in some respects and required simplification in others.

The social network mapping was the most successful aspect of the intervention, firstly by allowing people to readily engage in a process of reflection on existing networks and connections. Secondly, it allowed participants to formulate needs, and in this respect discussing preferences was also a valued part of the discussion. However, the database was found to be difficult to maintain and lacked sufficient options to be considered as a workable resource for those administering the network tool. It detracted from the positives of the network mapping process. The intervention in its current form does not offer any onward support beyond signposting and discussing who in the existing network may be able to assist with building connections (which as we suggest above is hampered for those with restricted connections and insecurities and barriers to engaging relationally and with activities). Thus, both more psychological support and more pragmatic support are implicated in engaging with community activities, while the usefulness of the database stage is questionable.

Limitations

Equality, diversity and inclusion

In working with a broad array of community partners, it was hoped that we would be able to access the spectrum of individuals within the population who were at risk of loneliness and isolation. However, despite our attempts to engage with minority groups, our final sample consisted mostly of white British and female participants. While this lack of ethnic diversity may reflect, to some extent, the underlying demography of the regions in which the study was situated, the results presented here must be interpreted accordingly. Some groups were cautious about mapping their personal network, and particularly in relation to who would have access to this information, which may have acted as a barrier to participation in some cases.

The timing of COVID-19 and associated restrictions (approximately splitting trial follow-up into thirds of pre-COVID, during the first lockdown and following the trial reopening) meant its impact on the trial is difficult to assess. There were high levels of missing data (20–30% for most outcomes at 6 months), though methods to handle missing data did not change the conclusions of the trial. The impact of running and participating in a study of this nature during the pandemic must, however, be acknowledged. The pandemic also impacted on the study delivery; due to COVID-19, all contact with community organisations and participants was carried out remotely following the pandemic, including the delivery of the intervention. We believe the mechanisms of change for the intervention should remain the same even when facilitated remotely, and the delivery of this study in this way highlights that online or remote delivery of interventions is feasible to achieve in this group. However, facilitators felt that the participant experience of the intervention was perhaps not quite the same. In addition, the intervention was delivered by the research team following the study pause, rather than the partner organisations, due to the extraordinary demand placed upon the community organisations at this time. Although this was not how the study was originally intended to be delivered, and so the external validity of the findings around implementation may be called into question, we suggest this supports our overall reflections that a networked approach (i.e. bringing together different organisations and organisational capacity) would be the optimal approach in future initiatives. Our monitoring of participant demographics did not indicate that participants recruited into the study following the pandemic were particularly different from those we had recruited prior to the pandemic; however, it is possible that increased rates of loneliness and poor mental health experienced at the population level and the suspension of in-person community activities and resources may have also impacted the results presented here.

Finally, we would like to address the issue of the outcome measures used within the current study as a potential reason for the lack of evidence highlighted here. During the development of the study, we could find no evidence of loneliness being used as a primary outcome, and so, as a result, we opted for the widely used and well-validated SF-12 Mental Health subscale as a proxy measure. It is of course possible that a longer follow-up of participants may have highlighted additional information not observed in the 6-month follow-up. However, in hindsight, and given the external circumstances, it is perhaps not surprising that no significant evidence of change in loneliness was observed here. Future studies would benefit from research exploring what constitutes a meaningful change in loneliness on existing scales (and perhaps the timescales over which meaningful changes occur) or indeed, developing additional measures of loneliness.

Future directions for research

A wide range of interventions have been shown to be potentially effective in improving the status of loneliness. This includes interventions oriented to improving social skills, enhancing social support, increasing opportunities for social contact and addressing maladaptive social cognitions. Previous work involving social skills training and provision of opportunities for social support and contact has demonstrated limited to mixed evidence of such interventions effectively combatting loneliness and social isolation,[29,109] while those addressing cognitions have previously been found to be most effective.[29]

While the PALS intervention encompassed aspects of the second and third of these approaches (improving social skills and opportunities for social contact), we propose that a tailored package of interventions addressing the psychological, interpersonal and social needs of the individual would likely be most effective. This might involve, for example, a ‘multistepped approach’ where some individuals require more intensive addressing of psychological needs initially in order to prepare for interventions of social support and those designed to connect them to community activities and resources. Given the susceptibility of organisational capacity to deliver interventions of this type, it seems clear that future interventions may require a dual focus on the individual coupled with a focus on the development of community assets and generating broader community capacity. Social prescribing may provide some capacity to establish links on an ongoing basis with a broad range of social interventions in local communities.[110]

However, the extent to which a RCT is the best methodology for this type of study must be considered. Although it is considered the ‘gold standard’ for obtaining evidence, we suggest that interventions addressing psychosocial issues such as loneliness and social isolation may be evaluated in other ways to generate evidence for acceptability, feasibility and effectiveness. Although we were able to work pragmatically in this study (as we had set up the study to manage a degree of flexibility) and consequently were able to manage the demands of undertaking such a study during the pandemic, the rapidly changing and unpredictable nature of research in community contexts is not best suited to the RCT methodology. In addition to this, although we purposely kept the inclusion criteria for the study broad – first, to explore the characteristics of participants and second, to avoid the possibility of treating loneliness as akin to a diagnostic criterion – it is an area of potential criticism for the study in terms of validity. While we retain the conviction that it was necessary to be inclusive in this instance, further work in potentially clarifying this would be beneficial.

Conclusions

Our findings do not provide strong evidence of the efficacy of the PALS intervention to address the complexities of loneliness and social isolation. Although the intervention was acceptable to participants and community organisations who hold the potential to deliver such an intervention, sustainability would require a networked approach between organisations to mitigate against the challenges found in each organisation. Future interventions for loneliness would likely benefit from utilising a multistep approach providing tailored psychological, relational and social components.

Additional information

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Rebecca Band (https://orcid.org/0000-0001-5403-1708) (Senior Research Fellow, Health Psychology) was the Chief Investigator and initiated, led and had overall responsibility for the programme.

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All authors made substantial contributions to design, or acquisition of data, analysis and interpretation of data, all were involved in the drafting of the manuscript or revising it critically for important intellectual content, and all authors approved the final version to be published.

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Patient data statement

The data collected here were not collected by the NHS as a part of patients' care or treatment.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review. Qualitative data generated are not suitable for sharing beyond that contained within the report.

Ethics statement

The study received ethical approval from the South Central – Berkshire Research Ethics Committee (reference 18/SC/0245) and from the Health Research Authority (HRA) on 27 June 2018.

Information governance statement

The University of Southampton is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, The University of Southampton is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.southampton.ac.uk/isolutions/staff/data-protection-and-gdpr.page.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/WTJH4379.

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Appendix 1 Background to the GENIE intervention development

GENIE emerged against a background of equivocal evidence about policy interventions designed to improve the self-management of chronic disease, which proliferated during the 1990s. While these had aspired to offer a patient-centred, non-clinical approach, they lacked a focus on processes (networks) and were not sensitive to the range of socioeconomic conditions and their implications for unequally distributed community resources.

Previous research had shown that, despite being a policy priority, these interventions were not always routinely adopted because of their perceived lack of relevance and a lack of effective connection with recognisable sources of local support. Additionally, health professionals, and in particular those in primary care, were challenged to facilitate resources and approaches for self-management support, which lay outside of traditional clinical settings, and their traditional control over symptom management and monitoring of chronic illness. At the centre of this change of direction, about researching the implementation of self-management policies, was the recognition that lay knowledge in its social context was a core consideration. The social dimension of the biopsychosocial model needed more attention than had accrued to date in self-management programmes. What was becoming clear in the reflections of those developing GENIE was that:

1. Lay knowledge was as important as professional knowledge and it needed to be understood and utilised in its everyday settings of the home and neighbourhood.
2. Existing self-management programmes, such as expert patient programmes, suggested a tendency for ‘the rich getting richer’, leaving the challenge of those who were not prone to engage. People’s lack of motivation (the psychological emphasis in self-management to date) was a reductive account. Another possibility was that people did not engage because what was on offer did not make sense to them or chime with what they valued.
3. Generic protocols for self-management, which privileged professional knowledge, were insensitive to the particular daily circumstances of patients. They needed to be recast to make them biographically appropriate. This meant a dual focus within GENIE on *both* individual agency *and* its unique relational setting.

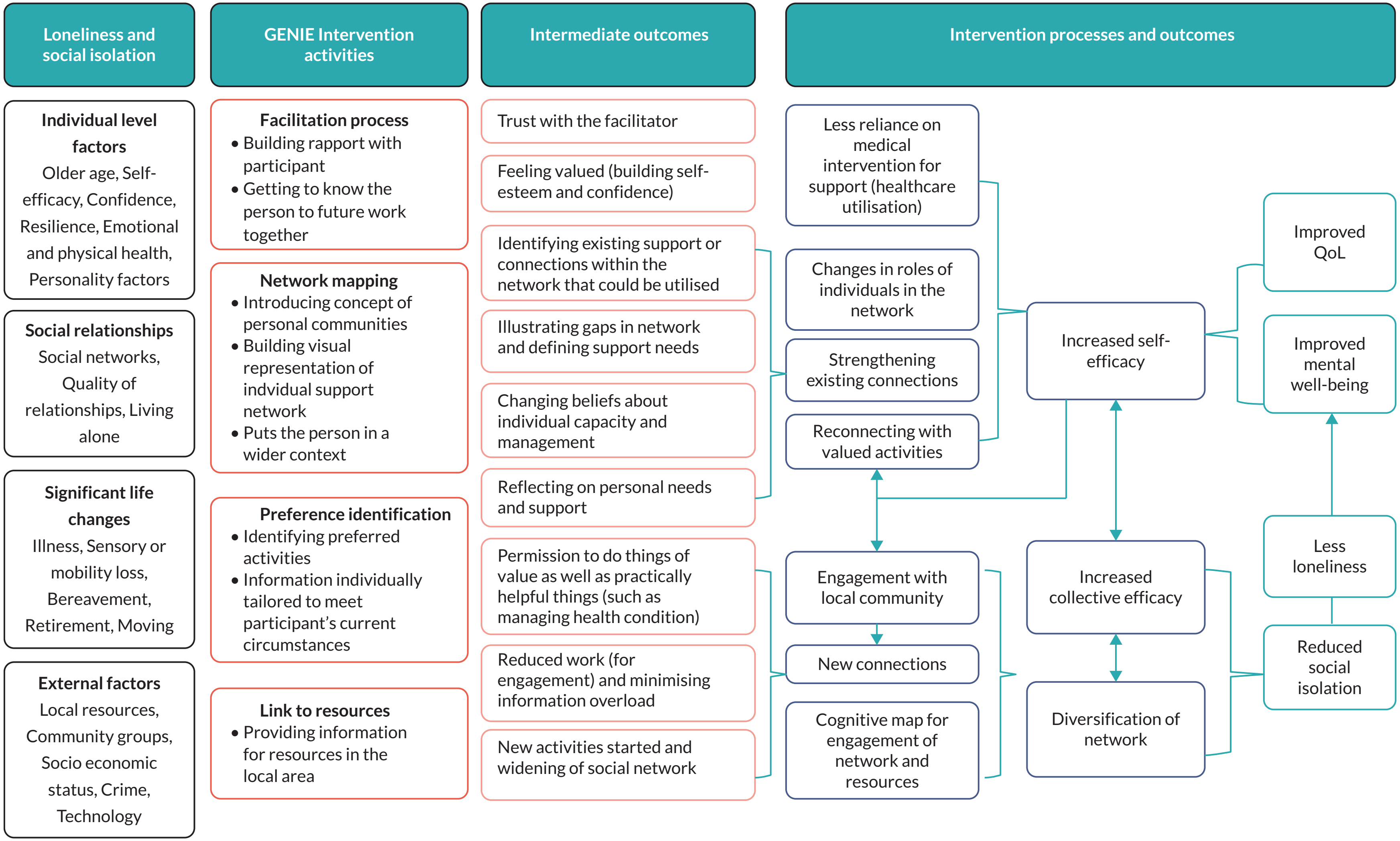
That recasting of a social intervention, in the light of lessons learned from research on traditional self-management, required a fuller theoretical understanding of situated social networks. The theoretical links for the GENIE researchers are summarised below:

- The support role of networks tends to expand in line with increasing needs from the person with the long-term condition and can substitute for health service utilisation.[36]
- Participation in community organisations is associated with better physical and mental health in patients with low incomes and prompts physical activity.[45]
- Contact with diverse groups and individuals renders more support than restricted networks.[111]
- Strong-tie relationships (e.g. partners) provide most support.
- Weak ties are more distributed, sporadic, and fleeting (e.g. neighbours, taxi drivers) and provide less overall support but are less liable to loss over time than stronger ties because they respond to limited demands and offer reciprocity with, rather than dependency upon, others.[47]
- Meaningful ties are not only people. They include pets, music, newspapers and access to technology (such as the TV and the internet).[48]

There was a clear line of public health research pointing to the power of social networks and relationality as a means of developing a more community-focused and alternative approach to well-being that transcended what type of long-term condition a person had. Thus, GENIE incorporated the importance of social influence, social capital and cultural capital and the role of others. As a socially oriented approach to self-management interventions, GENIE incorporated assumptions from work on relationality, namely that relationships offer the possibility of support and access to resources, and engaging in social interaction (connectivity) is in and of itself health-enhancing or -denying. Moreover, relational interdependence creates the foundations of a personal system of management in a shared context, and new forms of connection may be made as a means of staving off social isolation. An individualistic focus on personal activation or motivation alone ignores the prospects of mutual dependence and reciprocity.

The GENIE tool has been implemented in parts of the UK and in other countries. Its impact on NHS costs and patient outcomes had been evaluated to a limited extent prior to its use in the context of the PALS study. For example, there is evidence of its cost-effectiveness in terms of improvements in health and reports of QoL. Details of its evaluation can be found at www.nihr.ac.uk/documents/clahrcs-celebrating-10-years-of-nihr-report/12158.

Appendix 2 PALS intervention logic model



Appendix 3 PALS usual care (control) group

The usual care that organisations provided was categorised into four categories:

1. *No contact* – the standard provision of care could be accessed/delivered without the need for contact. For example, the use of a green space (*n* = 3).
2. *Ad hoc contact* – accessed through irregular points of contact. A frequent need exists on an ad hoc rather than ongoing basis; for example, attending a social supermarket to buy food. A person does not have to attend on a regular basis but they can access the service whenever they require it (*n* = 10).
3. *Frequent contact for a set amount of time* – accessed through scheduled points of contact. The need exists and can be met over a predetermined time, over a set period; for example, a 12-week healthy eating course. A person commits to attending a course or group for a limited duration (*n* = 10).
4. *Frequent contact for an unlimited amount of time* – undefined points of contact. A regular and ongoing need that is not restricted to a specific time frame. For example, attending a weekly art and crafts group. A person can attend the class regularly for as long as the activity is run (*n* = 10).

The majority (*n* = 21) of the community organisations offered support for an unlimited amount of time; 10 organisations provided support for a set amount of time, and 10 provided support on an ad hoc basis. The type of care offered differed within each organisation but could be categorised into four broad areas:

1. *Emotional or social* – expressions of caring, empathy, trust, connection and belonging. For example, a befriending service or social group (*n* = 15).
2. *Informational* – advice, information, suggestions and referrals. For example, a drop-in information centre (*n* = 0).
3. *Practical* – tangible aid and service. For example, a transport service or social supermarket (*n* = 8).
4. *A combination of any of the three types of support (emotional/social, informational and practical)* – for example, a community centre that runs a social supermarket and offers debt advice and a weekly coffee morning or craft group (*n* = 21).

The majority (*n* = 21) of the community organisations offered a combination of emotional/social, informational and practical support; 15 organisations provided emotional or social support, and 8 provided practical support.

Community organisations who recruited (organisation number linked to organisation typologies)	Usual care description	Usual care category	Type of care provided
1	Community and mental health services for Southampton	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
2	Research centre for clinical trials into dementia and mild cognitive impairment and memory problems	Frequent contact for a set amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
3	A-level and vocational full-time courses for all abilities	Frequent contact for a set amount of time	Practical
4	Health and well-being programmes	Frequent contact for a set amount of time	Emotional or social
5	One-off home safety visit	No contact	A combination of any of the three types of support (emotional/social, informational and practical)
6	The organisation offers support to people in the UK and around the world	Frequent contact for a set amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
7	The organisation cares for over 700 children and young people each year. They deliver a comprehensive range of services including residential social care, health care, fostering, outreach support, training and education services	Frequent contact for a set amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
8	Affordable housing and community development support	Ad hoc contact	A combination of any of the three types of support (emotional/social, informational and practical)
9	Housing provision	No contact	Practical
10	A dedicated transport service for people unable to use mainstream public transport. It is for people of all ages, living in Southampton, with specially adapted vehicles that can carry wheelchairs and seated passengers for journeys anywhere within the Southampton City boundaries Offers support to vulnerable people in the community, many of whom are at risk or isolated in their homes, from personal care to shopping, picking up prescriptions; no task is too big or too small	Ad hoc contact	Practical
11	Educational courses	Frequent contact for a set amount of time	Practical
12	The organisation helps people to stay independent by working with them to identify ways to do this. They offer a range of social group activities that encourage people to have stronger networks of friendship and support	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
13	A variety of support and groups to reduce loneliness and social isolation	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)

Community organisations who recruited (organisation number linked to organisation typologies)	Usual care description	Usual care category	Type of care provided
14	A weekly lunch club led by one member of staff and other volunteers. Various outings throughout the year	Frequent contact for an unlimited amount of time	Emotional or social
15	Courses to support people to get into work	Frequent contact for a set amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
16	Online and face-to-face health and exercise classes	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
17	Health trainers offer a 12-week programme of support around health and well-being; for example weight loss, anxiety and depression	Frequent contact for a set amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
18	A variety of paid courses; some are free for people on benefits	Frequent contact for a set amount of time	Practical
19	IT weekly group, exercise class, swimming club	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
20	The organisation offers an extensive range of health and well-being activities, access to support around finances, education, housing, health and well-being, social isolation. During COVID- they proactively engaged Irish community groups and organisations as partners. The project recruited over 70 volunteers delivering: • practical help with shopping and prescriptions • befriending: connecting beneficiaries with volunteers with similar interests • connecting people digitally • programme of activities to engage Irish and Irish Traveller people in prison in north west, doubly isolated in lockdown	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
21	The organisation provides personalised one-to-one support and/or group interventions to improve well-being	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
22	Information and support, health and well-being activities	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
23	The organisation aims to engage isolated people back into the community Assists GPs by making sure people attend appointments Self-sustaining groups run through the project, knit and natter group, mental health drop-in, breathe easy group for people with chronic obstructive pulmonary disease. There are various activities at the shop, which is a place of welcome where lonely people can attend. Volunteers will talk to people and signpost them to activities	Frequent contact for an unlimited amount of time	Emotional or social

continued

Community organisations who recruited (organisation number linked to organisation typologies)	Usual care description	Usual care category	Type of care provided
24	Art therapy/group sessions	Frequent contact for an unlimited amount of time	Emotional or social
25	Physical and emotional support for people with disabilities on Isle of Wight	Ad hoc contact	A combination of any of the three types of support (emotional/social, informational and practical)
26	Art programmes	Frequent contact for an unlimited amount of time	Emotional or social
27	Social supermarket, Weight Watchers group, social breakfast, lunch club, stay and play, IT courses	Ad hoc contact	A combination of any of the three types of support (emotional/social, informational and practical)
28	Access to the food hub once a week for £12 per month	Ad hoc contact	Practical
29	Council-run bus service with a charge attached	Ad hoc contact	Practical
30	Services to enable older people to stay living independently in their own homes for as long as possible, with the best possible QoL Through befriending, activity and friendship sessions, outings, escorts to appointments and much more. Activities: • Befriending, outings • Holidays, penfriend scheme, walking and coffee group, litter-picking group, singing for well-being group • Lunch and learn group • Fish and chip Friday group • One-to-one walking service • Digital communities service	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
31	Exercise classes	Frequent contact for a set amount of time	Emotional or social
32	Befriending project, family support, practical and emotional support	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
33	The organisation runs supervised family contact sessions and courses including Early Years, a local baby group, social groups and a men's club	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
34	'Forever Young' group every Friday and a coffee morning	Frequent contact for an unlimited amount of time	Emotional or social
35	Well-being support group on a Wednesday can hold 30 people	Frequent contact for an unlimited amount of time	Emotional or social

Community organisations who recruited (organisation number linked to organisation typologies)	Usual care description	Usual care category	Type of care provided
36	The organisation offers a range of services to residents in Liverpool. Uniform shop offers full school uniform for parents living in deprivation. Food bank, wash house with washing machines and dryers. Pregnant/new mums living in deprivation can be supported with all needs associated with becoming a new mum. Activities offered: lunch and bingo every Thursday from 12 p.m. to 2 p.m.	Frequent contact for an unlimited amount of time	A combination of any of the three types of support (emotional/social, informational and practical)
37	Health and well-being activities: ladies' keep fit, Slimming World group, bingo group, line-dancing, chair-based exercise, tai chi, Asperger's/autism group. Light Bites which is a sandwich or a light meal and tea and coffee and raffle and bingo, luncheon club, after school club for children under 10	Ad hoc contact	Emotional or social
38	During lockdown, provision included delivery of regular meals, packs of essential supplies, fresh fruit and vegetables, milk and bread along with packs of games and puzzles to keep people entertained during lockdown. Provided to residents for free During school half-term, local children were provided with a free packed lunch delivered to their home	Ad hoc contact	Practical
39	Art or gardening projects	Ad hoc contact	Emotional or social
40	Centre activities such as soft play and bingo	Ad hoc contact	Emotional or social
41	Park events	No contact	Emotional or social
42	Activity group every Thursday 10.30 a.m.–2.30 p.m.	Frequent contact for an unlimited amount of time	Emotional or social
43	The Friendlies, Lunch Club and Coffee and Cake	Frequent contact for an unlimited amount of time	Emotional or social
44	Attending mosque for prayer	Frequent contact for an unlimited amount of time	Emotional or social

Appendix 4 Organisational randomisation information

Randomisation and facilitation delivery within different organisational settings

Model	Number of organisations	Facilitation delivery
A	12	Organisations: 2 PALS team: 10 Joint (organisation and PALS team): 0
B	25	Organisations: 7 PALS team: 11 Joint (organisation and PALS team): 7
C	5	Organisations: 0 PALS team: 3 Joint (organisation and PALS team): 2
D	0	Organisations: 0 PALS team: 0 Joint (organisation and PALS team): 0
E	2	Organisations: 2 PALS team: 0 Joint (organisation and PALS team): 0
Total	44	Organisations: 11 PALS team: 24 Joint (organisation and PALS team): 9

Information about two miscellaneous randomisations

Both organisations had one-off or ongoing contact with participants and delivered facilitation through the organisation (therefore not fitting with any of the models outlined above).

Appendix 5 Baseline characteristics of participants

Characteristic	Full sample (*n* = 469)	Southampton (*n* = 310)	Liverpool (*n* = 159)	Pre-COVID (*n* = 319)	Post-pause (*n* = 150)
Age (years) – median (LQ, UQ)	65 (48, 76)	67 (49, 77)	61 (48, 73)	63 (43.5, 75.5)	68 (56, 76)
Missing – n (%)	10 (5.1)	4 (1.3)	6 (3.8)	7 (2.2)	3 (2.0)
Sex – n (%)					
Male	139 (29.6)	91 (29.4)	48 (30.2)	91 (28.5)	48 (32.0)
Female	330 (70.4)	219 (70.7)	111 (69.8)	228 (71.5)	102 (68.0)
Ethnicity – n (%)					
White	433 (92.3)	285 (91.9)	148 (93.1)	291 (91.2)	142 (94.7)
Other	30 (6.4)	18 (7.4)	7 (4.4)	19 (7.9)	8 (5.3)
Missing	6 (1.3)	2 (0.7)	4 (2.5)	6 (1.9)	0
Highest education level – n (%)					
Primary school	8 (1.7)	1 (0.3)	7 (4.4)	7 (2.2)	1 (0.7)
Secondary school	193 (41.2)	124 (40.0)	69 (43.4)	130 (40.8)	63 (42.0)
College	140 (29.9)	98 (31.6)	42 (26.4)	93 (29.2)	47 (31.3)
Higher education	122 (26.0)	85 (27.4)	37 (23.3)	83 (26.0)	39 (26.0)
Missing	6 (1.3)	2 (0.7)	4 (2.5)	6 (1.9)	0
Working status – n (%)					
Fulltime	36 (7.7)	27 (8.7)	9 (5.7)	29 (9.1)	7 (4.7)
Parttime	42 (9.0)	25 (8.1)	17 (10.7)	27 (8.5)	15 (10.0)
Retired	225 (48.0)	157 (50.7)	68 (42.8)	144 (45.1)	81 (54.0)
Unemployed	45 (9.6)	28 (9.0)	17 (10.7)	34 (10.7)	11 (7.3)
Unable to work	105 (22.4)	63 (20.3)	42 (26.4)	70 (21.9)	35 (23.3)
Education or training	8 (1.7)	6 (1.9)	2 (1.3)	7 (2.2)	1 (0.7)
Carer	1 (0.2)	1 (0.3)	0	1 (0.3)	0
Missing	7 (1.5)	3 (1.0)	4 (2.5)	7 (2.2)	0
Living status – n (%)					
Owner occupied	230 (49.0)	170 (54.8)	60 (37.7)	142 (44.5)	88 (58.7)
Rented from council or housing association	166 (35.4)	97 (31.3)	69 (43.4)	123 (38.6)	43 (28.7)
Rented from private landlord	56 (11.9)	33 (10.7)	23 (14.5)	39 (12.2)	17 (11.3)
Temporary accommodation	3 (0.6)	2 (0.7)	1 (0.6)	3 (0.9)	0
Other	8 (1.7)	6 (1.9)	2 (1.3)	6 (1.9)	2 (1.3)
Missing	6 (1.3)	2 (0.7)	4 (2.5)	6 (1.9)	0

continued

Characteristic	Full sample (*n* = 469)	Southampton (*n* = 310)	Liverpool (*n* = 159)	Pre-COVID (*n* = 319)	Post-pause (*n* = 150)
Living alone – n (%)					
Yes	242 (51.6)	154 (49.7)	88 (55.4)	152 (47.7)	90 (60.0)
No	221 (47.1)	154 (49.7)	67 (42.1)	161 (50.5)	60 (40.0)
Missing	6 (1.3)	2 (0.7)	4 (2.5)	6 (1.9)	0

Appendix 6 Consolidated framework for implementation research

The CFIR is a framework for implementation that combines a range of constructs the implementation science literature observes are influential in the process of implementation. It has been described as a 'pragmatic structure'[92] for approaching the complex task that is implementation. The framework has five domains, each with associated constructs. The table below is taken from the CFIR website (cfirguide.org) and presents the domains, constructs and short descriptions.

Construct		Short description
1. Intervention characteristics		
A	Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed
B	Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes
C	Relative advantage	Stakeholders' perception of the advantage of implementing the intervention vs. an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs
E	Trialability	The ability to test the intervention on a small scale in the organisation, and to be able to reverse course (undo implementation) if warranted
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement
G	Design quality and packaging	Perceived excellence in how the intervention is bundled, presented and assembled
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply and opportunity costs
2. Outer setting		
A	Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritised by the organisation
B	Cosmopolitanism	The degree to which an organisation is networked with other external organisations
C	Peer pressure	Mimetic or competitive pressure to implement an intervention; typically, because most or other key peer or competing organisations have already implemented or are in a bid for a competitive edge
D	External policy and incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives and public or benchmark reporting
3. Inner setting		
A	Structural characteristics	The social architecture, age, maturity and size of an organisation
B	Networks and communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organisation
C	Culture	Norms, values and basic assumptions of a given organisation
D	Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported and expected within their organisation
1	Tension for change	The degree to which stakeholders perceive the current situation as intolerable or needing change

continued

Construct		Short description
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems
3	Relative priority	Individuals' shared perception of the importance of the implementation within the organisation
4	Organisational incentives and rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions and raises in salary, and less tangible incentives such as increased stature or respect
5	Goals and feedback	The degree to which goals are clearly communicated, acted upon and fed back to staff, and alignment of that feedback with goals
6	Learning climate	A climate in which: (a) leaders express their own fallibility and need for team members' assistance and input; (b) team members feel that they are essential, valued and knowledgeable partners in the change process; (c) individuals feel psychologically safe to try new methods and (d) there is sufficient time and space for reflective thinking and evaluation
E	Readiness for implementation	Tangible and immediate indicators of organisational commitment to its decision to implement an intervention
1	Leadership engagement	Commitment, involvement and accountability of leaders and managers with the implementation
2	Available resources	The level of resources dedicated for implementation and ongoing operations, including money, training, education, physical space and time
3	Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks
4. Characteristics of individuals		
A	Knowledge and beliefs about the intervention	Individuals' attitudes towards and value placed on the intervention as well as familiarity with facts, truths and principles related to the intervention
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals
C	Individual stage of change	Characterisation of the phase an individual is in, as he or she progresses towards skilled, enthusiastic and sustained use of the intervention
D	Individual identification with organisation	A broad construct related to how individuals perceive the organisation, and their relationship and degree of commitment with that organisation
E	Other personal attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity and learning style
5. Process		
A	Planning	The degree to which a scheme or method of behaviour and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training and other similar activities
1	Opinion leaders	Individuals in an organisation who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention
2	Formally appointed internal implementation leaders	Individuals from within the organisation who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader or another similar role
3	Champions	'Individuals who dedicate themselves to supporting, marketing, and "driving through" an [implementation]'[100] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organisation
4	External change agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction
C	Executing	Carrying out or accomplishing the implementation according to plan
D	Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience

Appendix 7 Organisation typologies

Typology	Partner number	Partner description	Who facilitated
Fully professionalised organisations (14)	1	Statutory service provider	PALS
	2	Statutory service provider	Organisation
	3	Education provider	Organisation
	4	Collection of GP practices	Joint
	5	Statutory service provider	PALS
	6	International charity – local branch	PALS
	7	Private education provider	Organisation
	8	Housing association	Joint
	9	Housing association	Organisation
	10	Group of charitable social enterprise	Joint
	11	Private education provider	Organisation
	12	National charity – local branch	Joint
	13	National charity – local branch	PALS
Aspirational community partners (24)	14	National charity – local branch	PALS
	15	Combined authority programme provider	Organisation
	16	Charity – city based	PALS
	17	Healthy living centre	PALS
Non-professionalised community based (4)	18	Charity – city based	PALS
	19	Charity – city based	Organisation
	20	Charity – city based	Joint
	21	Community interest company	Organisation
	22	Charity – city based	PALS
	23	Council for voluntary services	Joint
	24	Community recovery project	PALS
	25	Charity – city based	PALS
	26	Charity – city based	PALS
	27	Community centre	PALS
	28	Charity food bank	PALS
	29	Charity – city based	Joint
	30	National charity – local branch	PALS
	31	Charity – city based	PALS
	32	Charity – city based	Joint

continued

Typology	Partner number	Partner description	Who facilitated
	33	Community interest company	Organisation
	34	Charity – city based	Organisation
	35	Charity – city based	PALS
	36	Community centre	Joint
	37	Community centre	
	38	Community association	PALS
	39	Community association	PALS
	40	Community association	PALS
	41	Charity – city based	PALS
	42	Church	Organisation
	43	Church-based community group	PALS
	44	Mosque	PALS
			Organisations: 11 PALS team: 24 Joint (organisation and PALS team): 9

EME
HSDR
HTA
PGfAR
PHR

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