The Project About Loneliness and Social networks (PALS): a cluster-randomised trial comparing GENIE with usual care for socially-isolated people

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The authors declare there are no potential conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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Protocol Information This protocol describes the PALS trial and provides information about procedures for entering subjects. The protocol should not be used as a guide for the treatment of other subjects; every care was taken in its drafting, but corrections or amendments may be necessary. **Compliance**	

This study will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines. It will be conducted in compliance with the protocol, the Data Protection Act and all other regulatory requirements, as appropriate.

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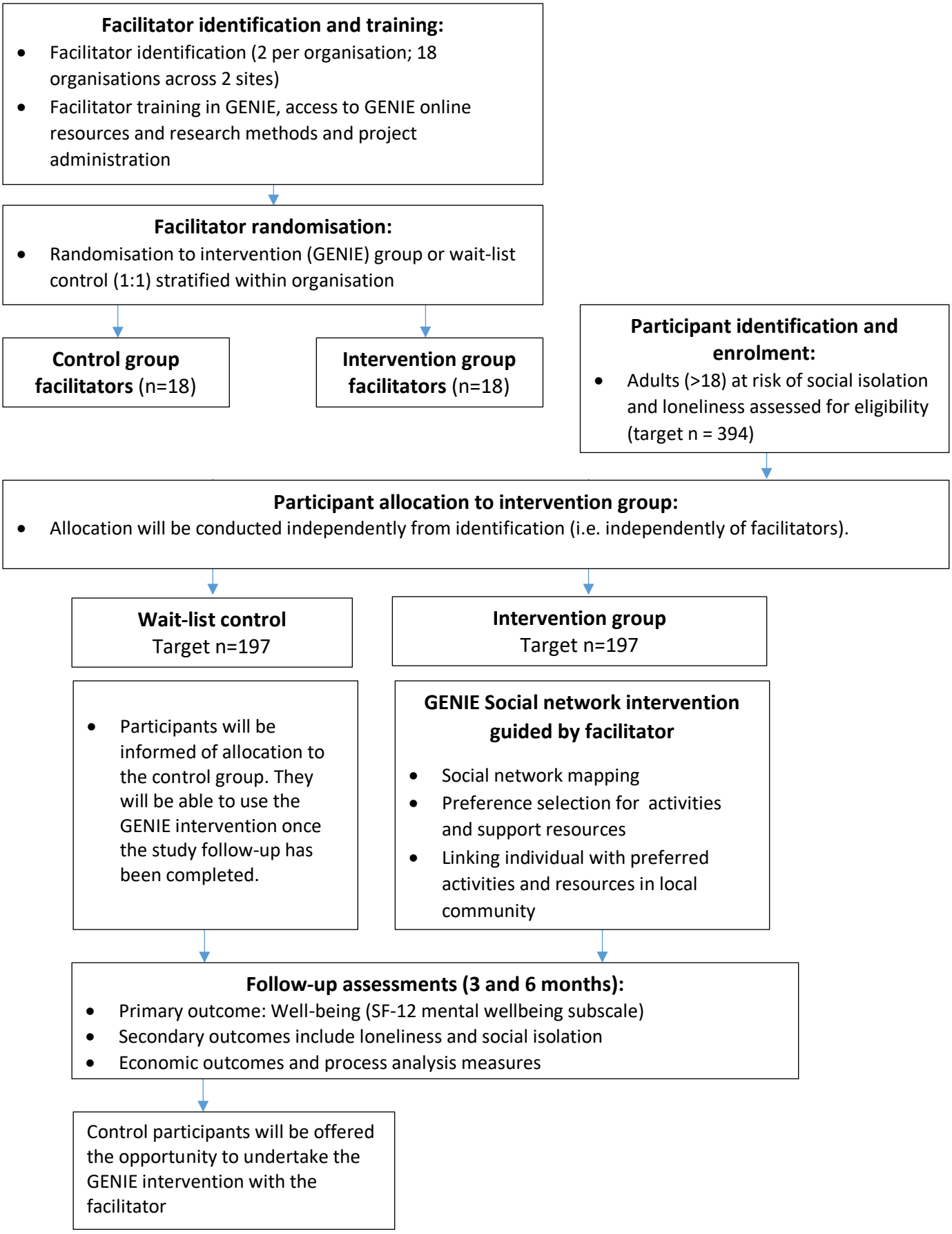
2. Trial Synopsis

Title:	The Project About Loneliness and Social networks (PALS): a cluster-randomised trial comparing GENIE with usual care for socially-isolated people
Sponsor:	Southampton University
Sponsor Ref Number:	TBC
Funder:	NIHR PHR
Trial design:	Pragmatic, multi-centre cluster-randomised controlled trial
Trial participants:	Adults at risk of social isolation and loneliness
Planned Sample size:	Centres: Southampton, Liverpool Facilitators: 36 (18 per arm) Participants: 394 (197 per arm; 12 per facilitator) assuming 15% drop-out
Primary Objective:	1. To determine the effect of GENIE compared to usual care on mental health at three and six months.
Secondary Objectives:	1. To assess the feasibility of running the study based on recruitment and retention during an internal pilot phase. 2. To determine the effect of GENIE compared to usual care on loneliness, social isolation, physical health, engagement, depression, anxiety, self-efficacy and quality of life. 3. To establish whether the use of GENIE within a community setting is cost-effective. 4. To explore the experiences of using GENIE, how the intervention impacts on loneliness and isolation, and the mechanisms by which participants enact change. 5. To explore environmental and organisational factors that impact the integration and scalability of GENIE in local and organisational settings.
Inclusion Criteria:	1. A socially isolated person as one for whom there is an “absence of social contacts or community involvement, or lack of access to services”.
Exclusion Criteria:	1. Currently hospitalised (i.e. not self-managing within a community setting) 2. Terminal disease or any acute exacerbation of the condition which impacts upon their ability to take part 3. Lacking sufficient capacity to consent or take part in the study 4. Having had previously used the GENIE intervention

Intervention	GENIE (Generating Engagement in Network Involvement) intervention
Control Group:	Wait-list
Primary Trial outcomes:	SF-12 Mental Health composite scale score
Secondary Trial outcomes:	Difference between intervention and control in: 1. SF-12 Physical Health composite scale score 2. De Jong Loneliness Scale 3. Social isolation (Duke Social Support index) 4. Warwick Edinburgh Mental Well-being scale (SWEMWBS) 5. Campaign to End Loneliness scale 6. Collective efficacy (CENS) 7. Social support (SPA) 8. Depression and anxiety (HADS) 9. Quality of life (ICECAP-A) 10. Perceptions of loneliness (modified B-IPQ) Intervention group only: 11. Healthcare utilisation (EUWISE questionnaire) 12. Participant engagement with new activities
Follow up duration	6 months

3. Study flow diagram



4. Schedule of observations and procedures

	Time point (month)		
Measure	Baseline	3 month follow-up	6 month follow-up
Socio-demographic measures	X		
Patient self-report measures (both groups)			
SF-12 Mental Health	X	X	X
SF-12 Physical Health	X	X	X
Loneliness (De Jong Scale)	X	X	X
Social isolation (Duke Social Support index)	X	X	X
Campaign to End Loneliness scale	X	X	X
Collective efficacy (CENS)	X	X	X
Social support (SPA)	X	X	X
Warwick Edinburgh Mental Well-being scale (SWEMWBS)	X	X	X
Perceptions of loneliness (modified B-IPQ)	X	X	X
Patient measures (network mapping, intervention group only)			
Participant engagement with new activities	X	X	X
Social network composition change at 3- and 6-month follow-up	X	X	X
a. Number of network members			
b. Types of network members			
c. New groups or activities			
d. Frequency of contact with network members			
Economic measures			
SF-6d	X	X	X
Quality of life (ICECAP-A)	X	X	X
Healthcare utilisation (EUWISE questionnaire)	X	X	X
Process evaluation			
Qualitative interviews with participants	X	X	X
Qualitative interviews with facilitators and stakeholders	X		X
Observations of facilitation	X		
Community staff observations of impact	X		X

5. List of Abbreviations and definitions

AE	Adverse event
B-IPQ	Brief Illness perception questionnaire
CENS	Collective efficacy in networks questionnaire
CI	Chief Investigator
CTRG	Clinical Trials and Research Governance
DSSI	Duke Social Support Index
GENIE	Generating Engagement in Network Involvement (GENIE) intervention
HRA	Health Research Authority
ICECAP-A	ICEpop CAPability measure for Adults
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trial Number
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
PALS	Project about loneliness and social networks (study name)
PC-CTU	Primary Care Clinical Trials Unit
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QALYs	Quality-adjusted life years gained
R&D	NHS Trust R&D Department
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SD	Standard Deviation
SOP	Standard Operating Procedure
TMF	Trial Master File
SPA	Social Provisions Scale
SWEMWBS	Warwick Edinburgh Mental Well-being scale (SWEMWBS)
TMG	Trial Management Group
TSC	Trial Steering Committee

6. Lay summary

Around 30% of the UK population experience loneliness. Older people, and those with long-term health problems are far more likely to be lonely and isolated than those in good health. Feeling lonely and isolated also has a negative impact on a person's emotional and physical health, and costs the NHS money due to more medical appointments and hospital visits. Evidence has shown that connecting with community resources can help protect against loneliness for those most at-risk.

This study will test if it is possible to reduce the negative impacts of loneliness and social isolation by focussing on the support networks that people have around them. GENIE is an online tool that allows people to map their social networks (which may include friends, family, groups, pets, daily activities). It also asks people about their interests and activities they might like to try to match them up with local activities. We will explore how GENIE can be used to improve social networks using existing local community groups and resources, to provide emotional and physical health benefits to participants.

We will work with many different types of local groups and organisations – including the NHS, housing associations, Fire service, Care and support organisations, health and community groups to help us to access those who are most isolated and lonely in two regions in the North and South of England (centred around Southampton and Liverpool). Any adult known to these groups will be eligible to take part. Half of the people in the study will be randomly selected to use GENIE. With the help of a facilitator, people using GENIE will be asked to think about the role of people around them, and how their networks might be improved, by including other people already around them who they did not initially think of, or from new connections to community activities. We have found that after using GENIE, people are able to build on existing relationships, as well as meet others with similar interests, which improves their sense of connection to the local community. The remaining people in the study will carry on as usual but will be able to use GENIE with a facilitator, if they want to, after 6-months once the study has finished. We will select a small number of people for interview to understand their experiences of loneliness and isolation, and how this might have changed because of the study.

The study will help us to understand how we can best use existing community groups, resources and organisations to access and help those most at risk. It will help us understand how reducing isolation and feelings of loneliness happens after using GENIE. The Campaign to end loneliness are also collaborating with the study team. By including a wide range of stakeholders we hope to share our findings more broadly and innovatively than within an academic context and if effective, we will be able to provide evidence for policy makers.

7. Study background

Loneliness and social isolation affect about 30% of the adult population in the UK (1) with greater incidence in early and late adulthood (1, 2). While the estimates regarding the levels of loneliness and isolation can vary (3), increased prevalence rates are identified in specific at-risk groups, such as the elderly, minority communities, and those with long-term mental or physical health conditions who are significantly more isolated than those in good health (2-4).

7.1 Defining loneliness and social isolation

Social isolation is considered to be an objective measure of 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 (5, 6).

7.2 The problem: health implications of loneliness and social isolation

The impact of loneliness and isolation on well-being and the associated health risks has been identified as significant public health concern (5, 6), with the complexity of loneliness, deprivation and marginalisation of key groups exacerbated by the prevalence of long-term conditions and advancing age (7). Both loneliness and social isolation are associated with poor physical and mental health outcomes (8, 9) and reduced quality of life (10, 11) across key points in the life course. Loneliness and isolation are linked to poorer physiological outcomes such as raised blood pressure and increased health-risk behaviours (e.g. sedentary behaviour) (12). Their impact on mortality is estimated to exceed that of traditional major risk factors such as obesity and cigarette smoking, with a 50% higher risk compared with socially-integrated participants (13-15). There are also significant costs associated with raised demand and use of health services, and loneliness is associated with increased GP appointments, emergency hospital admittance and premature social care use (16-18).

7.3 Factors influencing loneliness and social isolation

The ageing process, socio-economic deprivation (6), multi-morbidities and stigma associated with physical and mental limitations of some long-term conditions can contribute increased social isolation and feelings of loneliness (19, 20). Loss of employment through retirement or ill health can also have a detrimental impact on social status and connections with others (19). Reduced social contact and participation, social deprivation and widowhood are identified as additional risk factors (6, 21) which add barriers to sociability, creating a domino effect with a negative impact on quality of life (22, 23) and possible reinforcement of serious and sustained health related risk taking (24).

7.4 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 (25), with emerging evidence suggesting that improving the quality of interpersonal relationships and participation in social activities may be key to tackling the impact of loneliness (6). Evidence has indicated that increasing social interactions and the number of people who can be relied on is associated with reduced levels of distress (26), whilst connecting with community resources can help protect against loneliness for those who are most at risk (6, 27). Furthermore, there is evidence that social network interventions can significantly improve health outcomes, quality of life and increase the take-up of new activities (28, 29). A diverse and supportive network has been shown to reduce health service costs (30). A recent NICE quality standard recommends the navigation of older vulnerable people to community activities as a means of preventing loneliness in older people (27).

7.5 Rationale for the current study

In line with this evidence, there is a logical argument for introducing an effective social network intervention outside of the formal healthcare setting to connect people who are at risk of loneliness to others within their communities (27). The GENIE intervention involves mapping an individual's social network, identifying areas where the individual may benefit from new support or activities, and helping to identify how they can go about creating these links in their local area. Creative engagement with non-traditional informal providers of wellness management (such as through accessing locally available community groups) offers an alternative opportunity to address health and social needs in an increasingly resource-stretched NHS.

In our study we will assess the effectiveness of using GENIE in a community setting. We will map an individual's social network and link people with social activities and support as an intervention to address social isolation and loneliness, in comparison to a "usual care" wait-list control group. We will take into account health inequalities and address isolation through promotion of local resources There will be a series of qualitative process studies nestled within the trial to examine the processes (and issues) relating to implementing the intervention within the community context, and economic modelling to assess whether this is cost effective.

8. Study Aims and Objectives

The aim of the study is to assess the clinical and cost-effectiveness of the GENIE intervention compared to usual care within a community setting among at-risk populations, and to understand the implementation of GENIE in the context of different organisations who work in this environment.

8.1 Objectives:

Primary objectives

- To determine the effect of GENIE compared to usual care on mental health at three and six months.

Secondary objectives

- To assess the feasibility of running the study based on recruitment and retention during an internal pilot phase.
- To determine the effect of GENIE compared to usual care on loneliness, social isolation, physical health, engagement, depression, anxiety, self-efficacy and quality of life.
- To explore the experiences of using GENIE, 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 GENIE in local and organisational settings.
-

Economic objectives

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

9. Study design

The Generating Engagement in Network Involvement (GENIE) intervention is a facilitated web-based social networking tool designed to overcome the barriers to social participation, by identifying where social contact is lacking, focussing attention on valued activities and identifying potential access to social and health enhancing resources. In this study we will conduct a pragmatic, cluster-randomised controlled trial (PALS Trial) comparing participants receiving the GENIE intervention to a wait-list control group, with an internal pilot and embedded process evaluation.

The PALS trial will comprise:

1. Internal pilot trial: due to potential recruitment difficulties we will include an internal pilot to confirm the acceptability and feasibility of the full trial protocol and study procedures. Recruitment rates will be assessed against stop/go criteria at 12 months into the recruitment period.
2. Randomised controlled trial: A full randomised controlled trial will compare the GENIE intervention to a wait-list control group for individuals who are isolated or lonely. A total of 394 participants will be recruited, 197 per arm.
3. Health economic modelling and a qualitative process analysis study will also be embedded into the PALS trial.

9.1 Outcome measures

The intervention aims to improve social isolation and loneliness, which is linked to mental health. The primary outcome of the trial is mental wellness at 6-month follow-up as measured by the SF-12 Mental Health composite scale score (31). The Mental Health summary subscale has been used as a primary outcome in similar community based interventions with overlapping populations (32, 33). The SF-12 has been shown to have good psychometric properties (34), as has the mental health dimension (35).

Socio-demographic measures

We will measure indicators of socio-demographic position upon entry in to the study including gender, marital status, ethnicity, educational attainment, income, employment status, postcode, car ownership, housing and social status, household composition (38), dependents, and access to social capital resources (39). We will also collect additional information relating socio-demographic variables to long-term conditions (40).

Secondary outcomes:

1. SF-12 Physical Health composite scale score (31)
2. De Jong Loneliness Scale (36)
3. Social isolation (Duke Social Support index) (37)
4. Warwick Edinburgh Mental Well-being scale (SWEMWBS)(38)
5. Campaign against loneliness measure
6. Collective efficacy (CENS) (39)
7. Social support (SPA)
8. Perceptions of loneliness (modified B-IPQ) (40)

Economic outcomes:

1. SF-6d
2. Quality of life (ICECAP-A) (41)
3. Healthcare utilisation (EUWISE questionnaire) (42)
4. Participant engagement with new activities (43)

9.2 Assessing acceptability and feasibility in the internal pilot

Due to the potential difficulties in accessing the relevant population, we include an internal pilot with pre-specified stop/go criteria. The continuation (or otherwise) of the trial will be dictated by considerations of recruitment and retention; these will be assessed 12 months into the 21-month recruitment period. Based on a uniform rate of recruitment, we would anticipate approximately 225 participants to have been recruited by 12 months, with 170 having provided three month follow-up and 110 with six month follow-up. However, we acknowledge that: 1) recruitment patterns are rarely linear (we anticipate recruitment being lower in the early months) and 2) not all participants will have completed three- or six-month follow-up at exactly three and six months. Hence, we set the following criteria:

Criterion	**Cease if below (%)**	**Continue if above (%)**
Recruitment (relative to target)	30 (n=119)	50 (n=197)
Retention at 3m	60	85
Retention at 6m	50	85

9.3 Internal pilot contingency planning

We anticipate ceasing or continuing the trial should all the respective criteria be met; however, the Trial Steering Committee and funder (NIHR) will be responsible for taking the final decision on

whether the trial should progress or not. If any of the "continue" criteria are not met, we will investigate the best way to rectify the apparent issues in consultation with any collaborators deemed particularly relevant to the issue, including extending the recruitment area to Portsmouth. This will involve consideration of three-monthly recruitment figures and retention at three and six months within each organisation. The three month follow-up retention will also be used to judge progression should any issues with six-month follow-up be identified. We will extrapolate monthly recruitment figures to estimate final recruitment figures.

10. Participant Identification and Recruitment

10.1 Setting

The study will take place in communities within two cities in England: Southampton and Liverpool. We will work closely with partners in identifying participants and delivering the intervention, as well as informing our understanding of the challenges associated with implementation. Partners may include any group or organisation that has the potential to identify or access at-risk individuals. We anticipate we will need approx. 18 organisations across the two sites, each recruiting approx. 12 participants per facilitator (n=36 facilitators).

10.2 Partner set up

Additional partners will be recruited into the study as necessary and appropriate. Potential partner organisations who are interested in joining the study will be visited by the research team. This initiation visit will aim to develop an understanding of the ordinary working practices of the organisation (i.e. who are their usual client base, what is the level of ordinary contact between the organisation, its employees/ volunteers and potential participants, and the level of resource within the organisation, such as time, workforce, financial). During this visit the research team will establish who the potential facilitators are, and the specific way in which potential participants will be intensified in order to minimise risk of contamination and bias. The specific procedure will depend on if there is a) ongoing contact between facilitators and potential participants and b) any constraints on delivery, such as geographical or service boundaries which cannot be crossed (see recruitment and randomisation sections below).

Following this, a half-day training session will be arranged for the organisation; all facilitators and members of the organisation involved in the study will have access to the research training and

information to the study. Only intervention group facilitators will be trained in Genie at the outset of the study.

Finally, a post-training meeting will be arranged with the research team; where possible all stakeholders within the organisation should be present for this meeting (facilitators, line managers, research contacts, administrators etc.) to finalise the specific procedure within the organisation, clarify any outstanding queries and deliver the research packs to the organisation.

10.3 Study population

We will recruit any adult (aged 18 or over) who is identified as being isolated or at risk of loneliness. We will define as socially isolated person as one for whom there is an "absence of social contacts or community involvement, or lack of access to services" in line with the definition used by Hampshire County Council (taken from Social isolation and loneliness in Hampshire: A health needs assessment" http://documents.hants.gov.uk/public-health/js2013/LonelinessandisolationinolderpeopleJSNA2013.pdf).

Exclusions will include:

- Currently hospitalised (i.e. not self-managing within a community setting)
- Terminal disease or any acute exacerbation of the condition which impacts upon their ability to take part
- Lacking sufficient capacity to consent or take part in the study
- Having had previously used the GENIE intervention

10.4 Sampling and recruitment

We will use a multi-stranded recruitment strategy facilitated by our collaborating organisations in both regions: these have all been selected to ensure that we are able to identify and access those most at-risk, and importantly to increase the likelihood that our recruited sample will reflect the diversity of individuals who are living with loneliness or in isolation. We propose to undertake approximately two-thirds of recruitment in the Southampton site and the remainder in Liverpool, due to the distribution of resources and pre-existing relationships with local stakeholders. Appendix 1 provides additional details about our existing partners.

10.5 Participant identification and enrolment

Participants will be identified in a manner that best operates within existing working practices for each organisation, which will be different for each organisation/ collaborator. This is necessary as a key objective of the study is to explore the integration and scalability of GENIE in local and

organisational settings. Potential participants who meet inclusion criteria (i.e. are identified as being at risk of isolation or loneliness) may be invited by letter or be identified in routine visits/ appointments/ contact/ business (in line with the usual working practices of the partner organisation). In all cases, potential participants will be given a research pack including a PIS, a copy of the consent form, a reply slip and a freepost envelope. They will also be given the details of either the research team/ organisational contact with instructions on how to join the study or will be asked to give verbal permission for their details to be passed on to the study team/ facilitator.

10.5 Consent

Fully informed written consent will be obtained from participants. Participants will have the opportunity to ask questions prior to the researcher or facilitator taking fully informed consent and prior to the facilitation of the intervention. All participants will maintain the right to decline to participate in the study without giving reasons.

10.6 Randomisation

To overcome potential issues of contamination (where a facilitator could become familiar with how GENIE works and thus find out about local activities and advise control group participants), facilitators will be 1:1 randomised to either the intervention or control arm.

Randomisation will be stratified by organisation in blocks of two (i.e., one facilitator will be randomised to the intervention arm and one to the control arm) and carried out by the trial statistician (SE) using the statistical software R v3.5.1.

In some organisations, the risk of contamination does not exist (e.g. where the only contact between a facilitator and participants would be by delivering the intervention). In these cases, some efficiency is gained by randomising the participants individually (block randomised 1:1 to intervention and control, again stratifying by organisation).

The summary below details the different scenarios.

Preferred options (A&B) to be used whenever possible:

- Randomise facilitators and participants
- Intervention facilitators only to be trained

If there are organisational or setting constraints which prohibit facilitator or participant randomisation (e.g. the facilitator works within a specified geographic location) we will assess

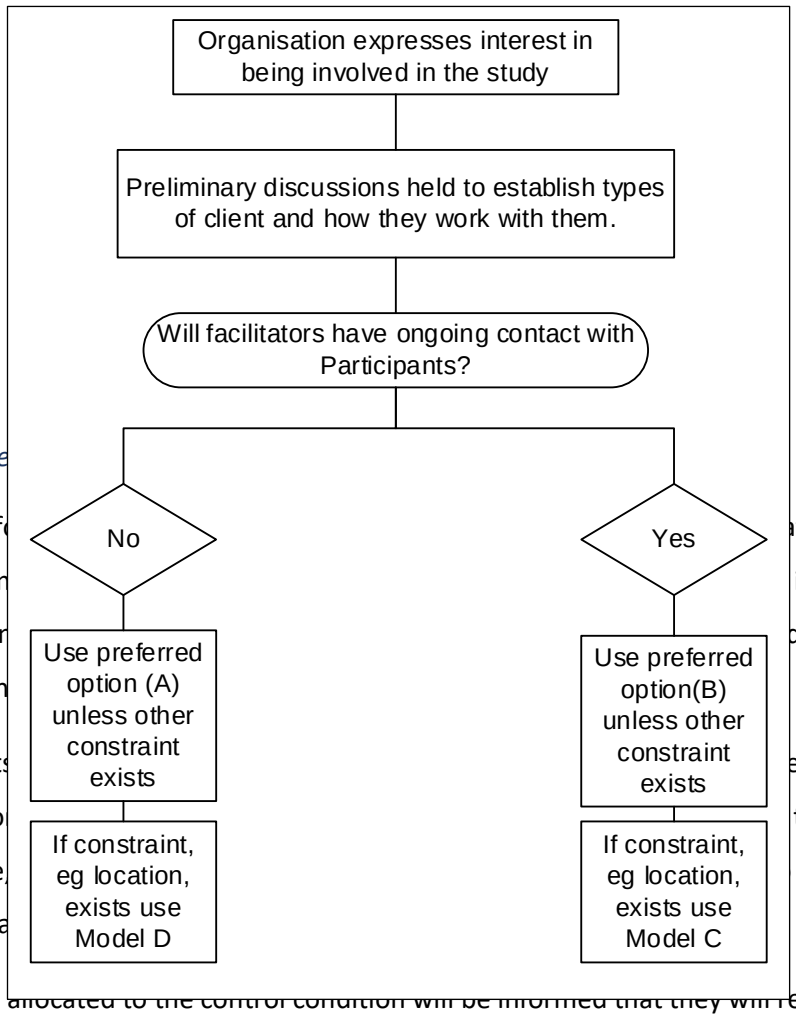
whether there is ongoing contact between the facilitator and potential participants. In these scenarios:

i) Where there is ongoing contact – (C)

- Train intervention facilitators only
- Randomise facilitators only
- Participants within each area allocated to facilitator (not randomised)

ii) Where there is no ongoing contact (D)

- Train all facilitators
- Randomise participants



10.7 Asse

Written inf ata collected (either on paper or on independently or with the assistar de online, by paper or over the ph

Participants ess to the GENIE interventio them, for example, in their home, recorded for the process eva

Individuals allocated to the control condition will be informed that they will receive follow-up questionnaires at 3- and 6-months, after which time they can have access to GENIE with the facilitator.

At 3 and 6 months after enrolment into the study, participants will be invited to complete follow-up assessments. All follow-up assessments will be recorded no earlier than two weeks before the follow-up date and no later than six weeks after the follow-up date. Each participant will be sent a £10 high street gift voucher with the initial reminder to complete the 6-month follow-up questionnaire.

10.8 Discontinuation/Withdrawal of Participants from Study

There will be clarification that each participant has the right to discontinue the intervention or to withdraw from the trial at any time without giving reasons. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Withdrawal of consent,
- Loss to follow up (i.e. no further contact when attempting to alert participant to follow-up measure timeframe).

If a participant withdraws having completed the baseline questionnaires, their data will be retained to evaluate potential differences and reasons for attrition.

11. Intervention and group details

11.1 Control arm

All participants allocated to the control group will be offered the opportunity to use the GENIE intervention with a facilitator once the 6-month follow-up has been completed. As we anticipate that a large proportion of the potential participants eligible for the study will be living in marginalized and deprived domestic situation, we have opted to make the intervention available for all control participants following the completion of the follow-up to avoid increasing inequalities as a result of the study.

11.2 GENIE delivery

The Generating Engagement in Network Involvement (GENIE) intervention is a facilitated web-based social networking tool designed to foster engagement and link people to opportunities for social involvement (www.genie.soton.ac.uk). It is based on evidence of social network properties and types, mechanisms and work relating to managing health and wellness (44-47). Previous testing of the principles has shown that it is both appropriate and acceptable to implement for individuals with a long-term condition (28-30), although by design it is generic to facilitate application to varied user groups (29). The process is initially introduced via a guided discussion with a trained peer (or another

individual – referred to as facilitators); this takes 30 to 40 minutes to deliver and has three stages: social network mapping, tailoring of preferences, linking users to valued resources and activities.

11.3 Genie facilitators

Guided facilitation is important for the process of reflection of social network composition and linking to engagement. Facilitators do not need a specific in-depth theoretical knowledge: instead, the local knowledge of facilitators is important and adds to the verity and value of the intervention. Recruiting facilitators who can relate easily to the person receiving the intervention is important for successful engagement, as this provides the opportunity for the participant and facilitator to work together to find a collaborative solution, which healthcare professionals might not achieve (29). This process increases participant focus, motivation and elicits a more honest response (29). GENIE facilitators receive a minimum of half day training from the research team, which may be refreshed over the course of the study and additional support provided by the research team if required. This will include a background to social networks, a demonstration of the intervention, pair-working exercises to practice using the tool and activities around building the database. Additional training materials including GENIE guides and videos are available online via the GENIE online platform, and face-to-face and over the phone follow-up support is also provided by the GENIE team to attempt to monitor fidelity to the intervention deployment and address issues arising regarding complex cases (or facilitator difficulties and distress).

11.4 Social network mapping

Facilitators guide participants to create a visual map of their current support network, using a concentric circles method (29). This involves thinking of, and visualising, the relationships relevant to health and wellness (family members, friends, acquaintances, healthcare professionals, local groups and pets). The concentric circles process provides insight into the user's current situation regarding social support; who they view as important in their daily lives; and then to reflect on renegotiating existing roles and responsibilities, and further map people and groups who could provide extended support (28-30). This process, when guided by the facilitator, helps the participant to realign thinking about their relationships (and conceptualise themselves within a network of support), explore family dynamics and recognise 'weak ties' (i.e. social acquaintances) that already exist in their network (29).

11.5 Linking individuals with valued and preferred local and online activities and resources

The next step involves tailoring access to local resources based on personal preferences, needs and acceptability to encourage engagement with sustainable choices (48). The participant is guided through a set of 13 questions, designed to help people focus on their interests, support, health and wellness needs and enjoyable activities (48). The questions elicit a set of local and online resources available, health-related information and activities such as exercise or weight loss groups, hobby groups, support for independent living, volunteering opportunities and educational courses tailored to people's individual needs (linked to a pre-created database of categorised local organisations and resources). The facilitated discussion of preferences is linked to the available and acceptable type and level of support from network members. Personalised results are presented in a user-friendly way aided by Google maps with clear details about access. Previous work has highlighted that this is often new and previously un-thought about information for participants (29).The network maps, description of individual networks, preferences, and the local and online resources identified as relevant by individuals can be printed to keep or re-accessed online later via a personalised GENIE page (48, 49). Two weeks after the intervention all Genie users receive a phone call by the facilitator and alternative or additional engagement activities are discussed. The follow up call takes up to 10-15 minutes.

11.6 Serious adverse events

11.6.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical trial subject which does not necessarily have a causal relationship with trial treatment or participation.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that at any dose:

- Results in death
- Is life-threatening*
- Requires hospitalisation**, or prolongation of existing inpatients' hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect
- Other important medical events***

*'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

**Hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.

***Other important medical events that may not result in death, be life threatening, or require hospitalisation may be considered a serious adverse event/experience when, based upon appropriate medical judgment, they may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

11.6.2 Causality

Assignment of causality to trial procedures of any serious event should be made by the investigator responsible for the care of the subject using the definitions in the table below. In this case it will usually be a responsible member of the partner organisation through which the participant was identified. If any doubt about the causality exists the local investigator should inform the PALS Trial manager who will notify the Chief Investigator. Other individuals may be asked for advice in these cases. In the case of discrepant views on causality between the investigator and others, all parties will discuss the case. In the event that no agreement is made, the Ethics Committee will be informed of both points of view.

Relationship	Description
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after following suggestions in the intervention). There is another reasonable explanation for the event (e.g. the subject's clinical condition, other concomitant treatment).
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after following suggestions in the intervention). However, the influence of other factors may have contributed to the event (e.g. the subject's clinical condition, other concomitant treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

Reporting procedures

The intervention is behavioural and therefore unlikely to impact their health directly, therefore only those deemed to be related to involvement in the study/interaction with the intervention will be reported as SAEs.

Non-serious Adverse Events

Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened or elective procedures for a pre-existing condition will not be classed as an SAE.

Serious Adverse Events (SAEs)

The assessment of whether or not an SAE is an expected consequence of receiving the intervention will be provided by the Chief Investigator (or Clinical Reviewer Delegate), it will not be provided by the Investigator responsible for the care of the participant. **All serious adverse events should be reported**. Depending on the nature of the event, the reporting procedures outlined in this protocol should be followed. Any queries concerning serious adverse event reporting should be directed to the trial coordination centre in the first instance. Reporting procedures are as follows:

- GPs or nurses will be asked to **notify us via an SAE form** if a participant experiences any SAEs.
- The Sponsor and main Research Ethics Committee (REC) will be informed of all related SAEs occurring during the trial according to the following timelines, where day zero is defined as the date the SAE form is initially received:
    - Events which are fatal or life-threatening will be reported no later than 15 calendar days after the sponsor is first aware of the reaction. Any additional relevant information must be reported within a further 8 calendar days.
    - Events that are non-fatal or non-life-threatening will be reported within 15 calendar days of the sponsor first becoming aware of the reaction.
- All Investigators will be informed of all related SAEs occurring throughout the trial. Local Investigators should report any SAEs as required by their Local Research Committee and/or Research and Development Office.

12. Statistics and Analysis

12.1 Description of Statistical Methods

Statistical analyses will be conducted in Stata. A formal statistical analysis plan will be finalised before the end of the follow-up period; the plan will be led by SE and DC and agreed with the research team and TSC.

12.2 Sample size

The sample size calculation is based on the primary analysis of the comparison of intervention and control arms on SF-12 mental health summary scale at six months (36). As the study is cluster-randomised, the sample size accounts for possible intra-cluster correlation (ICC; i.e., the potential similarity of outcomes in participants with 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. Although we accept the values derive from different populations and clustering structures (GP practices), previous studies have generally shown low ICCs for mental health scores from SF-12 and SF-36 (0.032 and below); (37, 38); we will use an ICC of 0.05 here. Previous studies (albeit in different populations) have suggested that differences of 3 and 4.7 points on the SF-12 would be clinically meaningful (39, 40). We have 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 (above Comment ref 2), 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). Having considered different combinations of the number facilitators and participants per facilitator, we decided on 12 participants per facilitator. This results in a design effect of 1.55 and an adjusted sample size of 335 people. Assuming 15% drop-out (35), we require 394 participants in total (197 per arm). This requires 33 facilitators; we will increase this to 36 facilitators to account for potential drop-out of facilitators.

12.3 Analysis of Outcome Measures/Endpoints

All analyses will emphasise estimation and confidence intervals over hypothesis testing, and will be conducted as intention-to-treat. Missing data will be assumed to be missing at random, unless accounting for more than 10% of the sample; if missingness is above this rate, approaches for dealing with missing data (e.g. multiple imputation) will be discussed within the research team. Missingness will be reported for each arm and summaries of baseline characteristics of those lost to follow-up and those not will be used to judge potential sources of bias.

Baseline socio-demographic data will be summarised within randomised arms using appropriate descriptive measures; likewise, all outcome measures will be summarised by arm at each time-point. We will produce a forest plot of estimated effects for each outcome within each organisation to explore any variability in the impact of the intervention.

The primary analysis will involve a mixed effects model (pending the model meeting the associated assumptions) comparing groups on SF-12 at six months. The model will include a random intercept for facilitator and organisation, with participants clustered within facilitators clustered within organisation (hence a three-level model), and control for baseline SF-12. This analysis will be complemented by an analysis using the same framework but with SF-12 as the outcome and a

random coefficient for time, where repeated measurements are clustered within participants (hence a four-level model).

12.4 Sources of bias

Non-response bias (i.e., where a particular group of participants are unavailable or refuse to participate) will be reduced by taking steps to increase the initial response rate and reduce drop-out over the course of the study. These include: presenting the study in a way that will maximise its face-validity and interest to the target population (through consulting with our collaborators and PPI panel), incentivising participation, keeping data collection sessions brief, using follow-up mailings and phone calls, as appropriate.

12.5 Economic evaluation

The primary economic outcome will be from a public services perspective, with a primary analysis of cost/QALY. Health related quality of life will be collected via SF-12 at baseline, 3 and 6 months, with utilities being derived by application of the SF-6D (50). In addition to SF-12, scored values from the ICECAP-A (41, 51) will enable a secondary cost-utility analysis (51). The use of ICECAP–A is planned to explore non-health attributes that might be important to this population, thus allowing for a broader measurement of wellbeing than might be captured by SF-6D. While the comparative data collected on both measures may inform future studies in similar populations, it will also provide decision makers with richer information than would be obtained by one or more generic HRQoL measures alone.

Intervention delivery resource will be recorded on proformas designed to capture cost categories (e.g. trainer time, pay scale, intervention setting, facilitator travel costs). Additionally, at baseline and 6 months will collect health related resource use following the intervention directly from participants using a modified version of a brief questionnaire (EUWISE questionnaire) (52). Additionally, an exploratory analysis will present cost-utility from a societal perspective. For this, health economists will collect patient level costs from research participants (i.e. patient/carer time and costs, out of pocket expenses) in addition to the costs falling on the public sector (broken down by sector). The analysis of costs will therefore provide detail on the cost-shifts within sectors (e.g. health compared to social care) as well as providing decision makers with guidance on what, in the broadest sense, is optimal for society (53). All analysis will follow practice guidelines (54-56), including those related to public health and/or complex interventions specifically (57-59). Cost utility analysis will also allow for the construction of cost-effectiveness acceptability curves to demonstrate that the intervention is cost-effective at a range of payer thresholds (60). Sub-group analysis will be carried out in order to inform policy makers' decision making with respect to the targeting of the

intervention. Such sub-group analyses (for instance looking at intervention effects in different groups) will be planned prospectively, and quantitative analysis - foreseeably including mixed effects modelling to account for the clustered nature of the data (61) - will be set out as part of the statistical and health economic analysis plan. The health economist will also work in conjunction with the process evaluation and qualitative leads to ensure that a joined up approach is taken with respect to resource and cost areas related to underlying mechanisms and contexts which might not come to light in more traditional 'black box' approaches to economic evaluation (62). Such an explanatory focus will be taken throughout with a view to interpreting study results and assessing study generalisability.

12.6 Mixed Methods Randomisation

Where geographical restrictions apply, only facilitators can be randomised; once a participant in a given area is recruited, their group is determined by the area they live in (rather, it is determined by the facilitator who oversees the area they live in). Where no restrictions apply, a participant will need to be assigned to a group, and the most desirable way to achieve this is through randomisation (so participants have an equal chance of being in either group, and differences in covariates between groups will be random). In all cases, there is clustering by facilitator. In the first case (geographical restrictions), the effect of the facilitator is indistinguishable from the effect of area (as area is constant for facilitator). Although distinguishing between facilitator and area is not relevant to the study (we are not specifically interested in the facilitator effect), it is possible that the data is generated by a different mechanism, where both facilitator and area influence the outcomes, and, for example, people are more highly correlated than where participants can be randomised. To explore if the two situations lead to differing results, we will run two models: 1) for organisations where restrictions apply; and 2) for organisations where no restriction apply. In each case, facilitator will be a random effect. The ICCs will be assessed in each model to judge how different the correlation may be within clusters (facilitators) and whether area may be playing an important role. The data will be analysed as one if no concerns are noted, and meta-analysed if there are noticeably different ICCs.

In the event that there is no contact between a facilitator and a participant and no restrictions, all facilitators can be trained and study efficiency will increase by having more facilitators with fewer participants each. Control participants would be considered as being their own cluster, and this situation would be analysed with the other organisations with no restrictions.

13. Process evaluation

The process evaluation will combine several complementary methods to understand the individual, environmental and organisational factors that inhibit or promote the engagement, workability, integration, sustainability and scalability of GENIE for addressing loneliness in open settings.

In order to explore the implementation, mechanisms of impact and context of the GENIE intervention in practice. We will explore the following research questions:

1. Was GENIE implemented as planned (i.e. implementation, embedding, integration)?
2. How did GENIE produce outcomes (i.e. mechanisms of impact)?
3. How do settings affect pre-implementation arrangements, intervention delivery, and outcomes and scalability (i.e. context)?

Secondary questions:

1. How is GENIE incorporated into the way in which organisations reach, negotiate, work and sustain options for linking people to resources and connections;
2. How is training delivered and GENIE adopted and integrated into participants everyday behaviour, cognitions, activities, relationships, connections, resources (social & economic opportunities);
3. How does GENIE impact on and becomes integrated into community organisational capacity, practice and policy to provide options for people who are lonely identifying potential for the scalability of GENIE.

13.1 Implementation theory

Concepts drawn from the Consolidated Framework for Implementation Research (CFIR) (67) will be used to guide the identification of factors promoting or inhibiting the routine incorporation and embeddedness of GENIE as a complex intervention. Concepts of outer setting, costs, adaptability, and cosmopolitanism will be used for verification of potential scalability to other contexts. The NASSS technology framework will be used to test the adoption abandonment scale up spread and sustainability of GENIE (63).

13.2 Methods

Project 1. Organisational and Outer setting study:

Project 1 will explore the fit of GENIE with public health, funding arrangements, local authority environment and forecasting; government and relevant agency policy; likely acceptability of the

intervention to different communities of interest; (e.g. peer support housing organisations; charities, probation; professional groups). Documentary analysis (literature review) of loneliness campaigns and stakeholder views supplemented by selected in-depth interviews will take place with purposefully selected key informants (representing public health stakeholders, public health and policy directors (national and local), academics, commissioners and those with experience of implementing large scale public health and social intervention programmes.

Project 2. Engagement, embedding, integration of GENIE for people who are lonely over time:

The processes of introduction, engagement, use of GENIE and impact on network and relationships will be captured across the follow-up time points. The network mapping will enable the exploration of the social relationships (including quantity, type, work, frequency and proximity of contacts) and outcomes are collected as part of the trial data (see above). This will be supplemented by purposeful sample for in-depth case studies of using qualitative analysis to follow approximately 20 patients over time.

Quasi-ethnographic methods will be used within participating organisations responsible for planning/ delivery monitoring of GENIE related activity with front line staff and people using GENIE. This will include semi-structured in-depth interviews with facilitators, stakeholders and participants, combined with observation (video recordings) of delivery and adoption at the time of intervention delivery and associated meetings.

Sample: 20 people selected based on the reporting of positive and negative outcomes to trial measures to undertake a personal community mapping exercise to explore the connections made and impact of GENIE as a result. The interviews will explore the perceived impact of the initial process of elicitation of preferences, social network mapping and introduction to new connections and resources on experience of isolation and everyday activities and management of risks to physical and mental health problems for participants. Analysis will focus on the meaning and attributions assigned to the initial network mapping exercise alongside describing and understanding the engagement and activities undertaken following the intervention. This will include exploration of how links with new networks and resources are identified and integrated and how new connections improve capacity to enact changes, improve wellbeing or reduce isolation (collective efficacy) (64).

Project 3. GENIE delivery (organisational, facilitator and stakeholder perspectives):

Mapping of Organisational Features and Local context: We will map the size, administrative organisation, work force structure, work roles, client group, function and institutional logics of each

of the partner organisations and relationship to other community organisations. We will use audit, meeting, promotional and other documentation to identify the nature and character of the organisation. A baseline picture of each organisation mapped will be used to modify how we introduce the intervention to maximize implementation. This will allow modifications to be made prior to the full scale introduction of GENIE. Development of relationships between organisations as an indicator of scalability).

Sampling and Semi-Structured In-Depth Interviews: We will sample between 20-25 facilitators and stakeholders of the partner organisations involved in delivering GENIE, selecting those with different institutional logics. We will explore the workability of GENIE in practice, exploring its content, training and introduction, focussing specifically on organisational barriers and facilitators and the fit and usability of GENIE with the locale.

Observations: We will observe the introduction of the intervention to participants. The inclusion of structured observational methods will be used to focus on interactions and engagement in GENIE introduction meetings with facilitators. Observation will include attention to how the system fits with the everyday routines of management and care practices for people who are lonely and facilitators, key community staff to observe the impact of the GENIE intervention on community organisations and encounters with other organisations and local connections.

Follow-up interviews: We will explore the ways that the new set of practices associated with GENIE has impacted on them and others around them within the context of working in the community.

13.3 Analysis of interview and observational data

All interviews conducted will be audio-recorded, fully transcribed and anonymized and typed observation notes will be imported into the software package Atlas.ti for data management. Analyses will be informed by the constant comparative method, narrative and thematic analysis. This will include initial coding of text segments from the interviews described above, followed by re-coding and memo writing to generate conceptual themes. Themes will be constantly compared within and across cases, paying attention to negative cases and possible reasons for differences. Analysis of visual data derived from the video recordings will be complementary to the above and where appropriate will be used to illuminate aspects of implementation.

13.4 The process evaluation outcomes and methods

Outcomes	Methods planned

Pre- and post-implementation assessment of the organisational context, capacity, and readiness to deliver GENIE, including: • Organisational composition, context, readiness. • Organisational resources, stability, staff. • Capacity to incorporate, deliver intervention and reach of GENIE candidates. The wider context the political economic and social context for GENIE adoption	• Observations and interviews with key informants about pre-implementation operations, resources and focus (identifying what will work well and what will challenge) • Mapping type of partner organisations (i.e. support, hobby, advice, health & wellbeing, community centre) as well as resource based organisations, key connections, and social networks of implementing agencies. • Audit and documentary analysis, including organisational staffing arrangements operations (through questionnaire/audit proforma, observations, documentary analysis) (63, 65, 66)
Fidelity of delivery (as designed) to people designated as lonely	• Observation & or ethnographic methods (audio/video) and interviews of facilitation. Analysis of delivery by facilitators.
Participant reasons for engaging, opting out, acceptability and continuing with GENIE burden of use fit with pre-existing identity personal resources, relationships, domestic settings Participants view of connecting to new resources and activities related to changes in social isolation	• Pre- and post- in-depth interviews with 20 people sampling based on of outcomes. Longitudinal telephone interviews at 9-12 months and perceptions of the locality and accessibility to resources in community settings. We will explore embedding and implementation over time and perceptions of the locality and accessibility to resources in community settings and impact on networks • Analysis of social network quantitative measures from trial • Post intervention in-depth interviews (3months) • Comparative interviews with control participants
Facilitator readiness, burden of delivery fit with role, identity, and personal resources & work settings	• Questionnaire of facilitators (re items) in-depth interviews with sub purposeful sample (survey of use of tools) (67)

14. Trial Management

Management Group and Steering Committee

The Trial Management Group (TMG) is responsible for overseeing progress of the trial. The day-to-day management of the trial will be co-ordinated through the trial coordinating centre and oversight will be maintained by the Trial Steering Committee, to provide strategic guidance and independent monitoring of progress and professional conduct. We shall encourage in person attendance at all these meetings where possible, but will also provide for attendance by teleconference when necessary, and will circulate papers and minutes before and after meetings for communication with those who cannot attend for any reason. We shall meet with the Steering Committee at least every six months. We shall establish if an independent data monitoring committee is required.

NHS collaboration

We will work in partnership with Solent NHS Trust – particularly around design, recruitment and dissemination. As an outward facing community Trust, their involvement will add weight to, and increase the likelihood of adoption in the community. We plan to include the Trust's PPI group in developing study materials and procedures and intend to recruit at-risk individuals during routine illness review and management consultations with community-based professionals by extending our current work with GENIE (in the COPD service) to other at-risk groups (i.e. pain management services). We are also currently working with Southampton City CCG to implement GENIE and will utilise existing connections with the Community Solutions group. We are developing links with West Hampshire CCG to link in to the WHOCS project, to provide a referral pathway for those identified as at-risk in routine care. Conversely, the use of GENIE for people who are lonely will increase long term health care management options in local NHS Trusts by building social capacity to support self-management. The GENIE tool will be introduced into services to improve options for relevant social groups.

Patient and public involvement

PPI is key to this programme of research, since our aim is to conduct the study in such a way that will be acceptable and feasible in the local environments.

Application development: Our established links with relevant partner organisations have contributed to work leading up to this proposal. We have presented the project at the Southampton Scrutiny panel for loneliness and consulted with the Campaign to end loneliness and our named partners; whom we have been working closely with to secure support (in relation to participant identification, recruitment and intervention deployment). We have also consulted with these organisations to ensure we can agree methods to identify participants, and put in place strategies to ensure that we address methodological issues while working in a pragmatic and flexible way to assess implementation issues.

Involvement in the study: Our PPI representatives will be invited to management group meetings will be held quarterly to provide strategic input to the study as a whole. In terms of more specific input, our PPI representatives will collaborate and comment on the design and content of the participant materials we develop and proposed processes. We will involve our PPI representatives in the interpretation of the findings from our studies, particularly those of user views. We will also disseminate our findings in collaboration with our PPI representatives and partner organisations in several ways (such as 'Tedex' style podcasts by facilitators or participants, targeted communications to relevant groups) and aim to produce a user guide for applying GENIE to loneliness and isolation.

15. Data Management

Access to Data

Access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Data Recording and Record Keeping

Manual data will be input into secure databases by members of the research team, such as research assistants or administrative staff, and filed in locked filing cabinet(s) in a locked room at 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).

16. Quality Assurance Procedures

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

17. Ethical and Regulatory Considerations

As with many intervention studies, there is the potential to cause distress simply by raising worrisome topics. In this particular intervention, we will focus on loneliness and social isolation, which may be sensitive for some people. However, our work to date suggests that distress is relatively uncommon in response to mapping social networks (even when these highlight a lack of social contact) (29). The facilitation process that accompanies the intervention is also an important process in mitigating this potential risk. Facilitators will be identified from our collaborators – all of which routinely work with the target population – and will receive training about what to do should participants become distressed. Previous qualitative work has highlighted that the facilitation process builds trust, and so enables the facilitator to move the participant forwards with respect to thinking about how to build on, or strengthen, their existing social network (29). In addition, our previous trial of a social network intervention demonstrated improved patient outcomes such as quality of life, engagement and health outcomes (28), in addition to health service use reduction and cost-savings (30). To address this, there is a statement in the participant information suggesting that if participants feel distressed, they can talk to a friend, family member, their GP or a charity such as

Age UK. We have addressed this on the PIS. Participation and engagement with the intervention are optional and participants can avoid it if they choose to.
We recognise the challenges of accessing and recruiting hard to reach individuals who are isolated, who may have concomitant mental health difficulties associated with loneliness. We have carefully considered our recruitment strategies to ensure they are appropriate and will maximise access to those who are likely to be isolated. We will use a wait-list control group as an incentive for participation in the study, meaning all participants will - at some time - have access to the intervention. We have included an internal pilot, allowing us to assess recruitment and retention during the study and consider how best to continue. We do not envisage major changes to the intervention (nor its delivery), and so view an internal pilot as a more efficient way of conducting this research than a standalone feasibility or pilot study followed by an effectiveness study.

The intervention may impose burden on the organisations who deliver it. We will provide training for facilitators from within these organisations to help integrate it into their practice. Despite this potential burden, we hope to provide a wider benefit to these organisations, firstly through staff development and training, and, secondly, by providing a resource and alternative referral pathway for individuals who they have identified at risk of isolation or loneliness (which could potentially extend beyond the life of the study). Lastly, a potential consequence of the intervention may be increased demand for local resources and services. However, as we are recruiting diverse groups and results generated individually tailored, linked to their immediate geographical location, it is unlikely that all participants will attempt to access the same resources at the same time. We also expect that participant involvement in local groups and organisations will also significantly contribute to the local community through increased social involvement in the groups.

Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to appropriate Research Ethics Committees (REC), Health Research Authority (HRA) and host institution(s) for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

Participant Confidentiality

Participant identifying information will not be passed to the study team without prior consent (which may be verbal). All participant details will remain confidential and participants' anonymity maintained in compliance with the Data Protection Act 1998 and the University of Southampton data management policy. The participants will be identified only by initials and a participants ID number. No observational recordings will be made without first obtaining written consent from the participant. All documents will be stored securely and only accessible by study staff and authorised personnel. There will be no storage of samples so The Human Tissue Act will not be applicable.

Expenses and Benefits

Facilitators and the community organisations will receive expenses for undertaking the GENIE training (1/2 day and a 1/2 day research training. All participants will receive a £10 high street voucher to thank them for their participation in the study upon completion of the 6-month follow-up. Participants who also take part in the qualitative interviews will each receive a £10 gift voucher for their time.

18. Finance and Insurance

Funding

Funding for this study is provided by the NIHR.

Insurance

The University has a specialist insurance policy in place which would operate in the event of any persons suffering harm as a result of their involvement in the research.

19. Publication Policy

All publications and presentations relating to the trial (including manuscripts, abstracts, and press releases) will be authorised by the Trial Management Group and will follow an agreed publication policy. Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

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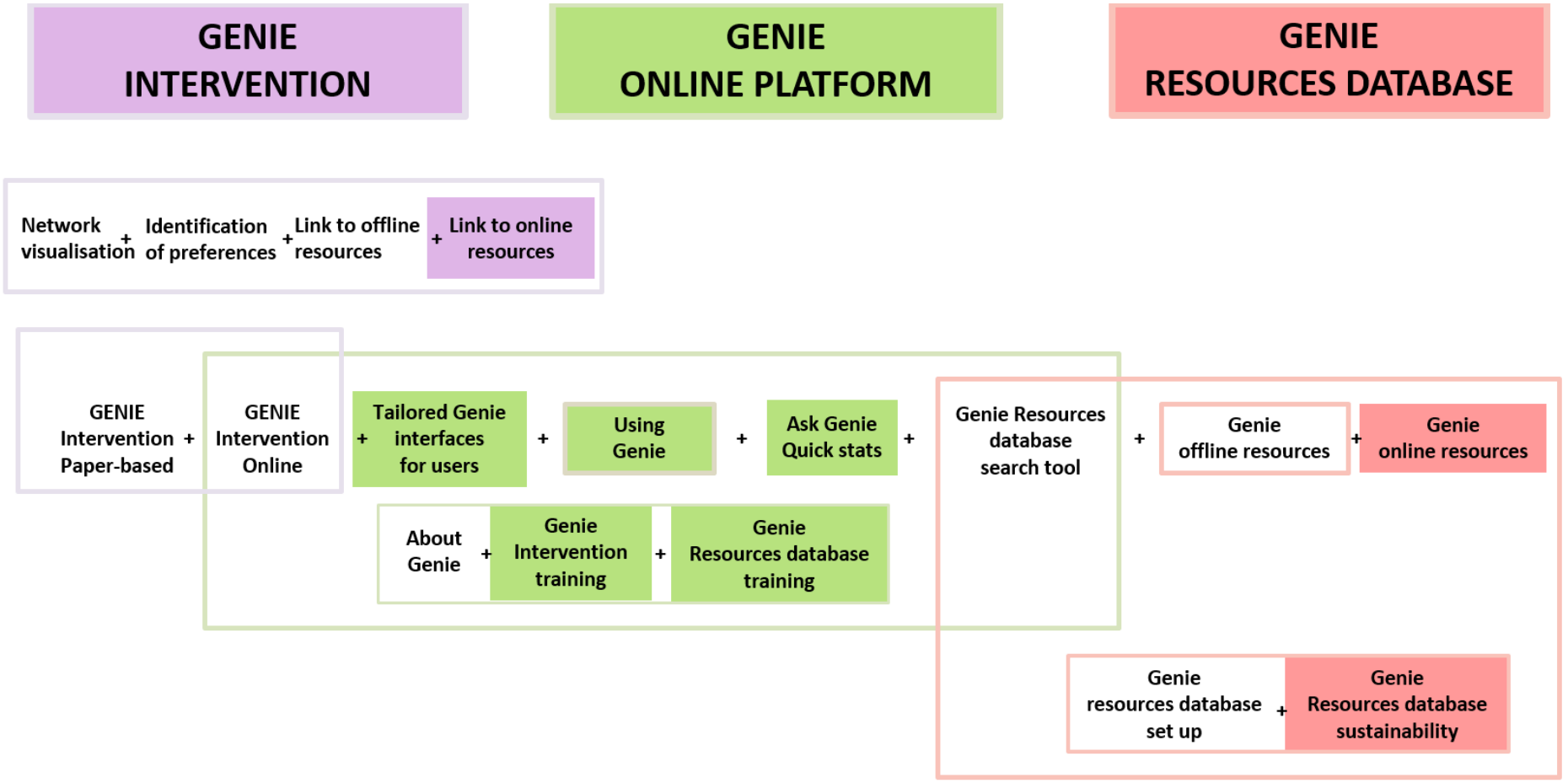
Appendix 1: Collaborating organisations for participant identification and facilitator recruitment

Please note that this list of collaborating partner organisations is not exhaustive and may change throughout the project due to the pragmatic community-based nature of the project.

Organisation name *(Site)*	**Description of the organisation, target population(s), service(s) that the project will link into**	**Potential reach**
Hampshire Fire and Rescue Service *(Soton)*	*Safe and well assessments* – offered to vulnerable individuals at fire risk i.e. over 60s; living alone; with a physical or learning disability; sensory impairment; substance dependence.	7000 visits p/a
SCA group (Social care in Action) *(Soton)*	Local social enterprises focussed around health and wellbeing. Specific projects and services include: *Dial-a-ride* – a transport service for community members unable to access mainstream public transport; *Domiciliary and day care services* - providing support in the community; Links with *sheltered housing*; *Advocacy and counselling services* – including individuals in contact with magistrate courts and with gambling addictions.	423 people accessing dom. care and day services currently
NHS Solent Trust *(Soton)*	Community Trust providing mental health and community services to Southampton and some parts of Hampshire. Relevant services to include the musculoskeletal (MSK) service, access to Health trainers.	
Communicare *(Soton)*	Accessible, local charity with a main focus on the quality of life of lonely and isolated people in Southampton. Volunteers act as good neighbours, offering users free practical help and emotional support through creative strategies. Offer services for ex- offenders and those with mental health problems.	200 volunteers currently
Action on Hearing Loss *(Soton)*	Experts in providing support for people with hearing loss and tinnitus. Day-to-day care for people who are deaf and have additional needs; Communication services and training; Practical advice to help people protect their hearing; Awareness campaigns to change public policy around hearing loss issues; Research support.	20,000 members but we will focus on Southampton
Radian Housing *(Soton)*	An affordable housing association providing 3500 homes in Southampton, a significant portion including sheltered and supported housing, together with key worker accommodation. Support provision provided to 450 individuals through Radian care.	3500 homes in Southampton, 7000 in Hampshire
West Hampshire CCG *(Soton)*	*WHOCS* – project enabling GPs to refer individuals presenting with risk factors for social isolation, including school refusers; young parents/ single parents; over 65s with 2 or more long-term conditions; widow(ers).	
Southampton City CCG *(Soton)*	Scrutiny panel established around loneliness programme in the city following a city survey last year. Local neighbourhood, illness, charity and third sector groups are represented and linked in to the CSG.	

Irish Community Care *(Lpool)*	Provides information and advice on a range of services including welfare, homelessness, health, and cultural isolation through information, advice and support services, health and wellbeing activities and community engagement events. ICCM works with significant BAME communities who experience serious inequalities in health and socio-economic disadvantage.	2509 Service Users engaged (2015)
Voluntary and Community Action Wirral *(Lpool)*	Voluntary and Community Action Wirral is local infrastructure organisation that works with local community groups and voluntary organisations which Includes a befriending service, volunteering service and a specific care for older people, families and carers (amongst others).	Works with approximately 1200 groups per year.
Crosby Housing Association *(Lpool)*	A community-based housing association operating in South Sefton who own just over 400 properties, mostly located in Seaforth and Waterloo. The Association provides good quality housing at rents that are affordable to those on low incomes.	400 properties
Sefton Council for Voluntary Services (CVS) *(Lpool)*	Sefton CVS supports local charities and organisations to deliver services to support sustainable communities and independent resilience in the borough of Sefton.	
Sahir House *(Lpool)*	Sahir House is a charity supporting a range of people living with HIV, including asylum seekers, refugees, and LGBT people.	230 people living with HIV in 2015-16.
Whitechapel *(Lpool)*	Provides support for rough sleepers, people living in temporary accommodation and those at risk of becoming homeless	2,605 accessed in 2015.


GENIE INTERVENTION
GENIE ONLINE PLATFORM
GENIE RESOURCES DATABASE
Network visualisation
Identification of preferences
Link to offline resources
Link to online resources
GENIE Intervention Paper-based
GENIE Intervention Online
Tailored Genie interfaces for users
Using Genie
Ask Genie Quick stats
About Genie
Genie Intervention training
Genie Resources database training
Genie Resources database search tool
Genie offline resources
Genie online resources
Genie resources database set up
Genie Resources database sustainability

Appendix 3: Timeline for the PALS trial

	Jan 2018	**Feb 2018**	**March 2018**	**April 2018**	**May 2018**	**June 2018**	**July 2018**	**August 2018**	**Sept 2018**	**Oct 2018**	**Nov 2018**	**Dec 2018**
			Month 1	*Month 2*	*Month 3*	*Month 4*	*Month 5*	*Month 6*	*Month 7*	*Month 8*	*Month 9*	*Month 10*
Obtain ethical approval												
Prepare GENIE databases												
Draft and create questionnaire portals, basic testing												
Plan randomisation												
Identify and train facilitators												
Participant recruitment Southampton												
Participant recruitment Liverpool												
Interviews with facilitators and stakeholders												
Observational recordings of facilitators												
Nested participant interviews												
6-month follow-up												

	Jan 2019	**Feb 2019**	**March 2019**	**April 2019**	**May 2019**	**June 2019**	**July 2019**	**August 2019**	**Sept 2019**	**Oct 2019**	**Nov 2019**	**Dec 2019**
	Month 11	*Month 12*	*Month 13*	*Month 14*	*Month 15*	*Month 16*	*Month 17*	*Month 18*	*Month 19*	*Month 20*	*Month 21*	*Month 22*
Identify and train facilitators												
Participant recruitment Southampton												
Participant recruitment Liverpool												
Observational recordings of facilitators												
Nested participant interviews												
6 month follow up												

	Jan 2020	**Feb 2020**	**March 2020**	**April 2020**	**May 2020**	**June 2020**	**July 2020**	**August 2020**	**Sept 2020**	**Oct 2020**	**Nov 2020**	**Dec 2020**
	Month 23	Month 24	Month 25	*Month 26*	*Month 27*	*Month 28*	*Month 29*	*Month 30*	*Month 31*	*Month 32*	*Month 33*	*Month 34*
Participant recruitment Southampton												
Participant recruitment Liverpool												
Interviews with facilitators and stakeholders												
Nested participant interviews												
6 month follow up												
Analysis and write up												

	Jan 2021	**Feb 2021**
	Month 35	Month 36
Analysis and write up		