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Putting Life in Years (PLINY): Telephone friendship groups research study

Evaluation of the effectiveness and cost effectiveness of an intervention to promote mental wellbeing in community living older people.

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Sponsor	University of Sheffield
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Putting Life in Years (PLINY): Evaluation of the comparative effectiveness and cost effectiveness of an intervention to promote mental wellbeing in community living older people

This document describes a clinical trial, and provides information about procedures for entering participants. The protocol is not intended for use as a guide to the treatment of those not recruited into the trial. Amendments may be necessary; these will be circulated to known participants in the trial.

Trial Summary

DESIGN: Pragmatic two arm parallel group randomised controlled trial with feasibility phase.
SETTING: Telephone friendship group intervention: the homes of participants.
TARGET POPULATION: People aged 75 years and over with reasonable cognitive function (Score of 7 or less on the Six Cognitive Impairment Test) living independently or in sheltered/ extra care housing and able to converse and respond in English.
RECRUITMENT: GP mail outs; NHS and Local Authority involvement; Identification by voluntary sector organisations and through pro-active community engagement.
INTERVENTION TO BE EVALUATED: Twelve-week, telephone-delivered, group intervention. The design of the intervention is underpinned by de Jong's loneliness model[28] and Bandura's (1997)[29] theory of self-efficacy, provided by local charities supported by Age UK and the Community Network compared with treatment as usual (control).
FEASIBILITY: An assessment of study feasibility will be made at 18 months, based on a pilot cohort which anticipates 90 people being recruited at 9 months. The feasibility phase will evaluate willingness to be randomised into the study (recruitment rate) as well as the capacity of those delivering the telephone friendship group service and whether they are able to meet demand. To enable those involved in service delivery to cope with the necessary throughput, we anticipate blocks of about 90 participants in total being approached and randomised at 9, 14 and 19 months.
MEASUREMENT OF OUTCOMES: Primary outcome: SF-36 Mental Health (MH) dimension; Secondary outcomes: (1) other dimensions of the SF-36 (and specifically physical health); (2) EQ-5D for health economic analysis (3) General Perceived Self Efficacy (GSE) Scale; (4) Patient Health Questionnaire (PHQ-9); (5) De Jong loneliness scale (6) health and social care resource use questionnaire (7) socio demographic questionnaire including a self-report of health status.
DURATION OF FOLLOW UP: The primary analysis will be undertaken at 6 months after randomisation. All outcomes will be assessed at randomisation, 6 and 12 months.
SAMPLE SIZE: A sample size of 99 participants for each trial arm achieves an 80% power to detect an eight-point difference in mean SF-36 MH scores at 6 months follow-up between the intervention and control groups. Taking into account participant drop out (20%), we will need to randomise 124 subjects to each arm (248 in total).
PLANNED ANALYSES: The aim of the analysis will be to establish firstly whether there are benefits from the intervention compared with the control group. Mean Quality of Life (QoL) scores at 6 months (primary outcome) and 12 months (secondary outcome) will be compared using a marginal general linear model which will include baseline covariates. Ninety-five percent confidence intervals will be reported for the mean difference in scores. We will use data collected at study visits plus standard costs and valuation sources to estimate costs and QALYs (via the EQ5D). We will produce cost-utility analyses from a NHS /social care perspective and a wider societal perspective. Cost-effectiveness will be described using cost-effectiveness acceptability curves.
PROJECT TIMETABLE: Months 1-7: study set up (obtain approvals, convene local implementation groups, agree service provision with charities, recruit and train research

assistants, launch recruitment, recruit Trial Steering Committee; Months 8-9: participant recruitment of first wave; Month 11: Intervention delivery starts; Months 13-14 participant recruitment of second wave; Month 18 interim assessment of feasibility; Months 19-20 complete recruitment; Months 17-36 follow up; Months 36-38 data cleaning, analysis, write up, dissemination.

1. Introduction

Introduction

Social isolation and loneliness have long been identified as being problems associated with older people. According to Age Concern England[15] many of Britain's older people are living in isolation, with those over the age of 65 twice as likely as other age groups to spend over 21 hours of the day alone. Mental illness, low morale, poor rehabilitation and admission to residential care have all been found to be correlated with either social isolation or loneliness or both[16]. Seemingly, older people are more at risk of developing mental illness, such as depression, as well as physical ill-health caused by social isolation and loneliness. In response to research gaps highlighted in NICE guidance on interventions to promote mental wellbeing in older people[18], this study proposal is concerned with providing evidence of population benefit of one intervention that aims to improve the mental wellbeing of vulnerable, community living older people.

Over the last decade there has been a continued focus upon the value of providing health promoting interventions to older people with the aim of compressing morbidity in the later stages of the life course and promoting quality of life[7;15,18-21] This is supported by robust evidence which has demonstrated the relationship between extent of social activity and morbidity and mortality[22]. The NICE guidance on interventions to promote mental wellbeing[18] was underpinned by a systematic review of the evidence of effectiveness and cost effectiveness of interventions[21]. However, the evidence to support the introduction of many interventions in practice, and particularly those that aim to promote socialisation and alleviate loneliness is lacking[21;23]. A systematic review[23] of research into interventions which aim to alleviate loneliness and promote socialisation identified 11 studies with sufficiently robust findings out of 30 that met the review inclusion criteria, with the majority of studies originating from North America. Despite the methodological challenges that this review posed, the results were able to identify that the most effective interventions were those conducted in a group with educational and/or supportive input. Only one study showed that benefit could be derived from one-to-one interventions. Further to this, Cattan et al (2010)[24] conducted an evaluation of eight schemes that participated in the “Call in Time” initiative, promoted through two national charities, the Community Network and Help the Aged. The results of the evaluation found that telephone befriending can provide a vital lifeline in helping older people who spend a lot of time in their home to regain confidence and promote levels of engagement and participation with a recommendation that one-to-one telephone calls with older people might be followed by encouragement to participate in telephone clubs. This recommendation echoes that identified out of earlier work conducted in North America[26]. The Foresight Project (2008) also notes that there is a strong case for giving priority to research that would assess the potential use of technologies through the life course, and its impact on individuals, An example cited is social networking for older adults (Foresight Final Report, 2008, p. 248)[27].

Rationale

The NIHR Public Health Research programme published a call for research into the population benefits and cost effectiveness of home based interventions (including telephone support) to promote the mental wellbeing of community living older people without cognitive impairment and aged 75 years and over. The design for this study was submitted and commissioned as a result.

Intervention

This study will evaluate the efficacy of a 12-week, telephone-delivered, group intervention based on de Jong's loneliness model[28] and Bandura's (1997)[29] theory of self-efficacy. The intervention will be delivered to older people living in the community by local Age Concern charities in the field work site. It involves older people receiving befriending from their peers or from volunteers (who may also be older people) through telephone calls which they take in their own homes. Other settings will be discounted. The intervention will mirror that recommended in the report by Cattan et al (2010)[24]. Participants randomised to receive the intervention will be offered up to six short introductory telephone calls with a volunteer who will introduce them to the concept of group telephone calls. These initial one-to-one calls may be more frequent than weekly, depending upon the preferences of the individual and will last no more than about 20 minutes. The person will then be invited to join a small group of others. The group will be hosted by the Community Network teleconference system and facilitated by a trained volunteer. In this model older people are networked together through a teleconferencing system with assistance from a volunteer facilitator. A total of 12 weeks per recruitment cycle will be provided by the host charities which will not exceed six months overall, for any particular participant. It is appreciated that the interventions need to be sufficiently flexible to match site-contextual needs and some people randomised to receive the intervention may not wish to go on to receive the group based intervention. In this situation, the host charity will be asked to consider if they are able to provide a one-to-one service to these individuals and they will be included in the trial and an intent-to-treat analysis will be performed. For the purposes of this trial we will endeavour to recruit new clients to receive telephone support, who have not previously experienced this intervention to minimise confounding.

The volunteers facilitating the telephone friendship groups will be trained by the Community Network and then supervised and mentored by [service provider]. Volunteers will have received standard volunteer training (including a CRB check) by [service provider] before receiving the specialist facilitator training. [Service provider] will identify volunteers using a number of general and targeted activities. From a pool of 50 volunteers over three recruitment cycles, we anticipate approximately 24 volunteers will be retained as volunteers for this study. For those volunteers who choose the telephone friendship group facilitation, [service provider] will then provide on-going support. This will ensure that volunteers feel sufficiently skilled and confident to cope with the extent and complexity of demand that can emerge when working with the target population. Additionally, a first contact point for troubleshooting any emergent problems with intervention delivery will be provided to participating charities.

Participants randomised to the control arm will not receive any study intervention. However, they will participate in baseline and outcome measurement and the extent of their health and social care service usage will be assessed (as for all participants) by application of a questionnaire to record use of their health, social care and community resources. This will also be used to compare interventions received across participants in the control arm of the study to check whether the groups are similar. It is proposed that all participants will receive communication from the research team **Contact card (17)** (submitted to REC) approximately every two months during the study. The communication will either be by telephone or via a letter/card which will thank the participant, provide an update on progress and help participants feel involved with the potential to help reduce the risk of attrition, especially in the control group (see Section 8).

Risks and Benefits

Individual participant recruitment: From our previous work we are aware of the challenges that exist when trying to involve older people who have become vulnerable and isolated, particularly in situations where they are not being directed to familiar services by professionals. Restricting the study to people aged 75 years and over increases the risk of attrition which means that enhanced recruitment strategies are necessary. Relevant professionals and others working in the research site will be fully briefed through group meetings and road shows to enable them to signpost people to the study. We will also stimulate recruitment through various sources. This will include mass invitations to participants living within discrete geographical (LA) wards in the study location, identified through the GP databases, (a strategy which has proven successful in other HTA-funded trials). Mail outs will be enhanced by other targeted strategies within each ward such as personal approaches to community staff to request identification of likely participants from their case loads, publicity material placed in local venues frequented by older people including libraries, supermarkets, Post Officers and GP surgeries and information about the project provided through local media using leaflets. Mail outs to different Local Authority wards in the study location will be staggered over the recruitment period thus enabling recruitment to be balanced with the capacity of the participating charities to deliver the intervention. Initial recruitment will focus upon [redacted] city, but if this does not yield adequate numbers of participants we will approach PCTs, the LA and charities in the neighbouring boroughs of [redacted], [redacted] and [redacted] for assistance with recruitment. Informed consent of participants is central to the ethos of the trial and any person who cannot provide full informed consent will not be recruited.

Testing: The extra burden imposed by baseline and post intervention testing are a further consideration as existing research has shown that excessive demands are unlikely to be tolerated, leading to non-participation or loss to follow up[120;121]. To mediate for this, a selection of instruments has been carefully chosen, each of which has modes of completion to match a range of abilities and preferences. The baseline assessment will be conducted via face to face researcher interview. The six month and twelve month follow-up will be completed either independently by the person or by face to face researcher interview. Where assistance is requested by the participant, a researcher will arrange to visit the participant in their home to help them complete the questionnaires. The Health and Social Care Resource Use and SF-36 questionnaires will be completed via telephone by the researcher unless a / follow up visit is already planned; in which case the researcher will complete the Health and Social Care Resource Use and SF-36 questionnaires at the same visit. During the feasibility phase (first recruitment wave) the burden on participants will be evaluated, following double data entry, by examining missing values in the completed questionnaires (likely to be set at more than 2%). The burden on participants will also be explored in the qualitative sub-study (Section 10.3). The benefits may include: sharing interests, good experiences and memories and more contact.

Site recruitment: There is reliance upon existing services and upon third sector partners to support the introduction of the majority of new initiatives to promote mental wellbeing of older people. Thus, the intervention that is the focus of this trial is embryonic across the UK. Where services do exist they tend to be very small scale so there will be challenges providing the necessary scale of interventions for a population based study. To mediate this risk partnerships have been established with Age UK nationally and at the study site.

[service provider] will provide resources for volunteer support. The study is also supported by the national charity "the Community Network" who will deliver the teleconferencing for the telephone friendship groups for a period of 12 weeks (per recruitment cycle). Community Network will provide training to volunteers to facilitate the telephone friendship groups. If an insufficient number of volunteers have been recruited by [service provider] by the end of April 2012, Age UK will approach other branches within [redacted] e.g. [redacted] or [redacted]. Similarly, if the demands of the telephone friendship groups (in the second and third wave) exceed what [service provider] can deliver, Age UK will approach other branches in [redacted]. Communication and engagement is on-going with the aim of establishing a strong collaboration between research staff and those who might assist with providing interventions for the purposes of this study and to ensure that the necessary infrastructure can be put in place to minimise the risk of insufficient numbers of volunteers to run the groups. Support has also been obtained from [redacted] PCT [redacted] Teaching Hospitals and the Local Authority with respect to participant recruitment. The approaches are varied to ensure the widest possible reach; District Nursing, Occupational Therapy and other community health and social care staff will be provided with social marketing materials to both inform them of the study and enable them to assist with the identification of appropriate and potentially interested older people (See section 8).

Intervention delivery: In accord with the existing evidence, individuals randomised to receive the intervention will be offered up to six one to one telephone conversations. These will take the format of brief friendly conversations with a trained volunteer (CRB checked) about regular every day events. The volunteer will introduce them to the concept of group telephone calls as a means of providing companionship. These initial calls may be more frequent than weekly, depending upon the preferences of the individual and will last for approximately 10 - 20 minutes. The person will then be invited to join a small telephone group of others, who may share similar interests, with an emphasis upon friendship and reciprocity. The group will be hosted by the Community Network and facilitated by an [service provider] volunteer who has been trained by them using their established programme.

Teleconferencing (group) calls will be weekly and be flexible in length; between approximately 30 minutes and 60 minutes. Each group will be supported for a period of three months. Members will be encouraged to make telephone calls to each other as well as receive them. There will be a range of needs and considerations that will have to be taken into account in the delivery of interventions, some of which will be site-contextual. For example we anticipate that some people randomised to receive the intervention may wish to continue with one-to-one calls despite being fully informed of the intervention remit. [Service provider] will have to decide whether they are willing and able to continue to deliver one-to-one calls. The individuals concerned will be included in the trial and an intention to treat analysis will be performed. One of the applicant team will advise on fidelity at the beginning of the study and at further points throughout the period of intervention delivery (MC). Challenges may include the consistency with which facilitators deliver the intervention and inconsistency in attendance levels among participants. Any issues which emerge through delivery of the intervention will be presented to the Trial Steering Committee for their independent view of what might be controlled and/or eliminated for the purposes of the trial. We will also convene a Local Implementation Group (LIG), to meet bi-monthly for the duration of the recruitment and implementation phase to ensure that methods of recruitment and delivery match the local context and that the intervention remains acceptable for longer

term roll-out in practice. The LIG will include a local older person as a lay representative and appropriate personnel from Age UK, NHS and LA.

The intervention does present some risks to the participant. The intervention may bring up painful memories. To mitigate this risk [service provider] volunteer facilitators will be trained, and give guidance, on choosing topics for discussion. One-to-one calls will explore topic choices with individual participants before group discussions commence. The volunteers will receive specialised training to monitor conversations and pick up on any distress. All participants will be contacted by the research team at baseline, six month and twelve month follow-up. In addition, we intend to contact all participants at regular intervals (see section 8) to maintain contact and help participants feel involved throughout. Participants in the intervention arm will experience more contact.

The participant may experience transient dissatisfaction. Group interventions have occasional found participants experience a level of transient dissatisfaction with the intervention. To mitigate this risk volunteer facilitators will receive training to enable them to deal with situations which may arise e.g. a participant experiencing some boredom due to the choice of topic chosen by the group. The benefits to the participant may include: tolerance of others and listening skills.

Participants in the telephone friendship groups may want to continue to have discussions over the telephone after the twelve week period has ended. In this situation, the [service provider] volunteer will discuss this with the group. It will be for the service providers to decide if they can support the groups to continue in the same way. Issues relating to sustainability of groups will also be explored in the ancillary sub-studies (see Section 10).

This trial will be conducted in compliance with the protocol, GCP and the NHS research governance framework.

2. Aims and objectives

Primary objective:

To determine whether mental wellbeing as measured by the SF-36 (mental health dimension) six months after randomisation is significantly increased in participants allocated to receive the telephone friendship group intervention compared to participants allocated to a control group (receiving only contact by card/letter or telephone at month 2, 4, 8 and 10 with no further contact other than follow up assessment). This will necessitate taking the following three factors into account: (1) participants are randomised between zero and two months before a telephone friendship group is ready for them to join; (2) the intervention may last between four and five months; (3) control arm participants get no protocol-specified intervention. The choice of six months follow-up for the primary outcome makes it likely that the intervention will have been completed, or at least will be well underway and have delivered a 'therapeutic dose'. The time point means that everyone (intervention arm, however close to start of intervention they were randomised; and, control arm) are assessed at the same point from randomisation.

Secondary objectives:

1. Identify the psychosocial and environmental factors, as well as implementation issues that may mediate or modify the effectiveness of the intervention using qualitative methods. This will include examining:
    a. voluntary sector readiness to take forward new forms of services;
    b. the best modes of delivery of telephone support/friendship;
    c. how volunteers (facilitators) can be supported and retained; and,
    d. the extent to which fidelity of the intervention is maintained within and across the participating organisations.
4. To determine if there is any lasting impact upon mental wellbeing by repeat measurement with all participants 12 months following baseline measurement
5. To examine whether there is any significant improvement on the physical dimension of the SF36 at 6 months and 12 months following baseline for the intervention arm compared with standard care.

6. To measure the extent of use of health and social care, and community facilities by participants over time to determine whether the intervention is cost effective compared with standard care.

3. Trial Design

Design

Pragmatic two arm parallel group randomised controlled trial with feasibility phase.

Endpoints

Primary outcome:

1. SF36 Mental Health (MH) dimension[32]

Secondary outcomes:

2. Other dimensions of the SF-36 to measure all aspects of health including physical health (Maruish 2011);
3. Reapplication of the PHQ9[33]
4. EQ-5D (for health economic analysis[34]
5. General Perceived Self Efficacy (GSE) Scale[35]
6. de Jong Gierveld loneliness scale[36]
7. A health and social care resource use questionnaire to collect participants' use of health, social care and community services for health economic analysis.

Design measures to avoid bias

The allocation schedule will be concealed through the use of a centralised web-based randomisation service. The trial steering committee (TSC) and trial management group (TMG), including their statisticians will be blind to treatment allocation whilst the trial is ongoing, but the trial manager and participants will not be blinded. Analysis will be by intention-to-treat. Where individuals are lost to follow-up or data is missing, imputation methods will be employed, which will be described in the statistical analysis plan.

Duration

The total duration of the trial, including three recruitment waves and 12 months post randomisation follow-up is three years and one month. The expected duration of involvement of each participant is 12 months.

Feasibility assessment

After the initial set up period of seven months we will run the first wave of recruitment as an internal pilot trial to assess the feasibility of both trial recruitment plans and the proposed intervention. It is assumed that one quarter of potential candidates will be eligible and willing to be randomised. Three phased mail shots will be sent from [redacted] GPs. Based on previous HTA-funded public health research we anticipate 250 respondents (a 5% response rate) out of this strategy. Other recruitment strategies will be instigated alongside the mail shots. We anticipate 90 respondents recruited in the feasibility phase, will be eligible and willing to be randomised. Assuming a 20% loss to follow-up this will allow outcome measurement in 72 individuals to estimate a standard deviation for the primary outcome, SF-36 mental health score, at six months after randomization, the correlation between baseline and six month score and the intra cluster correlation (ICC).

The main risks to trial success to be examined through the feasibility phase are:

1. Insufficient eligible individuals consenting to participate in the trial.

2. The study intervention (telephone friendship groups) will not be delivered effectively due to local implementation issues or inadequate acceptability by participants.

Stopping rules

The TSC will assess the feasibility of the trial seven months after recruitment has commenced, with both recruitment and retention being considered. We will need to recruit 248 people in total to account for an anticipated 20% loss to follow-up at six months (primary outcome assessment time point), giving us 80% power to detect a difference between befriending (n=100) and control (n=100). Because we believe we will be able to accommodate up to 45 befrienders in each cycle, we anticipate recruiting up to 90 participants in total during each cycle (45 in the intervention and 45 in the control).

If the first cycle does not recruit 68 participants, then there is no possibility of reaching our accrual target of 248 in three cycles. So, we propose a minimum of 68 participants with at least 55 people (80%) contributing outcome data at six months after randomisation for continuation. Similarly, if [service provider] cannot identify sufficient volunteers to facilitate telephone groups then there is no possibility of delivering the intervention.

On the basis of the pilot primary outcome data collected during the feasibility phase, the sample size for the main trial will be re-calculated, using the standard deviation, correlation and ICC from the pilot phase data and the minimum important difference of 8 points in mean SF-36 mental health scores used in the original sample size calculation. The sample size will either stay the same (if the SD of the primary outcome is less than 20 points; correlation more than 0.50 and ICC less than 0.04) or increase (if the SD is more than 20 points; correlation less than 0.50, ICC more than 0.04). This will be done seven months after randomisation of the first cohort. Assuming the protocol and intervention remain unchanged, the participants recruited during the feasibility phase will be included in the full trial

population. Processes will be included to try and identify the reasons for non-response and numbers that were excluded due to factors such as language challenges.

5. Selection and withdrawal of participants

Inclusion criteria

1. Aged 75 years or over;
2. Good cognitive function, defined as Six Cognitive Impairment Test[122] score of 7 or under;
3. Living independently (including those who are co-resident with others) or in sheltered/ extra care housing;
4. Able to understand and converse in English.

Exclusion criteria

1. Unable to use a telephone effectively with appropriate assistive technology;
2. In residential/ nursing care homes;
3. Already receiving telephone interventions.

Participants may withdraw from active participation in the study on request. Individuals removed from active participation in the intervention will not be replaced and will be followed up for all outcome information.

6. Randomisation and enrolment

Eligible participants will be randomised to one of the two arms by the trial manager or research assistant after receiving the consent form, via a centralised web based randomisation service provided through the Clinical Trials Research Unit (CTRU). The trial manager or research assistant will inform the individual and their general practitioner on the treatment allocation. The randomisation sequence will be generated in advance by the trial statistician. There will be no stratification factors in the randomisation sequence.

7. Trial treatment

The two arms of the trial are:-

(1) Telephone friendship groups provided through the voluntary (charitable) sector

(2) Usual health and social care.

Telephone friendship group intervention: This involves older people receiving befriending from their peers or from volunteers (who may also be older people) through phone calls which they receive in their own homes. Participants will be introduced to one-to-one telephone contact over a period of 6 short one-to-one calls with this being followed by facilitated telephone friendship groups. The support for telephone friendship groups is to be provided through study partners the Community Network. In this model older people are networked together through a teleconferencing system with assistance from an [service provider] volunteer facilitator. The Community Network has committed to providing training for facilitators and is able to host the teleconferences. The group of older people to be linked through teleconferencing may have a focus; for example a book club or knitting group but this will not be necessarily the case. During the one-to-one calls the volunteers will introduce the concept of group discussions and explore preferences for the type of topics they might want to discuss in the groups. The Community Network will provide access to their telephone lines for weekly calls which will extend over a maximum of three months per recruitment cycle. The host charities will determine whether groups can continue after completion of the trial treatment with feasibility issues explored in the qualitative sub-studies (Section 10). Available evidence suggests that almost all older people have a landline telephone. There are potential issues regarding loss of hearing and the subsequent capacity of individuals to be able to use telephone friendship services effectively. We will screen for deafness in the initial interviews by observation at the screening visit and asking candidates about any equipment need. We will liaise with Action on Hearing Loss (formerly, Royal National Institute for the Deaf) to ensure that potential participants obtain appropriate assistive technology if they get randomised to receive the telephone friendship groups intervention. We will also ensure that any participant randomised to receive the intervention with sight loss, obtains assistance from the Royal National Institute for the Blind to enable them to take part.

Treatment as usual: Participants randomised to the control arm will not be receiving any study intervention. However they will participate in baseline and outcome measurement and the extent of their health and social care service usage will be assessed (as for all participants) by a health and social care resource use questionnaire designed for the study by the health economist. The resource use questionnaire will serve to check the comparability of services received by the control group across different study sites.

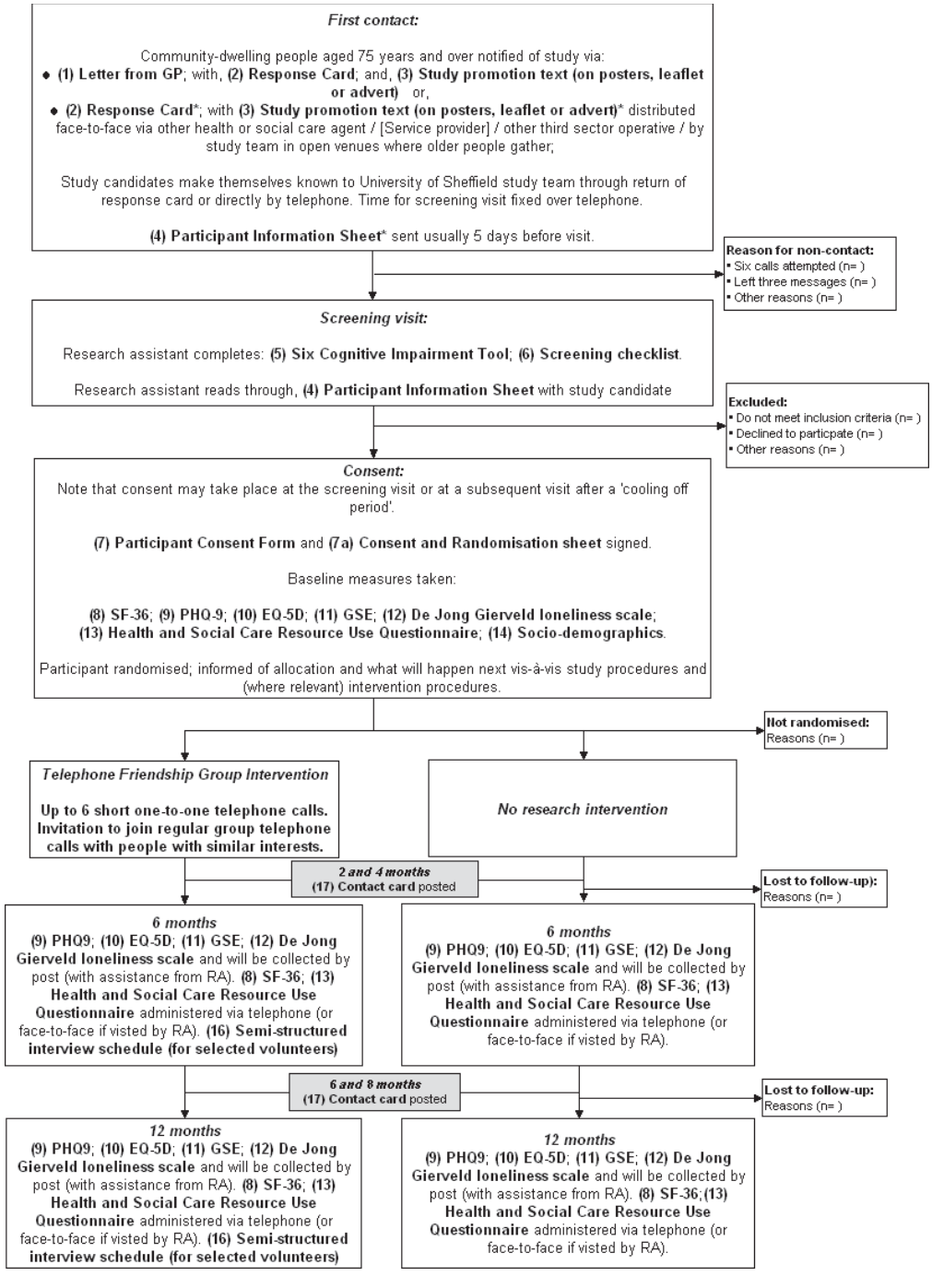
Management of co-morbidity: any unanticipated illness or risk situation that is observed in participant's and their homes at baseline or follow up will be managed in the following way:-
a. In situations where accident, injury or other unforeseen occurrence is encountered the RA will alert the emergency services.
b. In other non-emergency situations, the RA will report the observed problem to the Chief Investigator (GM) or their delegate (LG) who will take appropriate action (likely to involve encouraging the person to contact their GP).

Consent will be obtained from participants to share their information with The NHS Health and Social Care Information Centre and other central UK NHS bodies. This will alert the research team to a participant's health status and help to minimise the risk of telephoning or writing to participants who have died prior to follow-up.

Loss to follow up: A certain amount of attrition is inevitable during the period of intervention delivery which has been accounted for in the calculation of the target numbers for recruitment. Recruitment targets also anticipate a loss to follow up of 20%. Rigorous record keeping by the trials manager will ensure that loss to follow up will not occur due to administrative error.

8. Assessments and procedures

Figure 1 Participant flow



Procedures (and numbers provided in parenthesis) described below relate to the documentation outlined in Figure 1.

Procedures required at first contact

A letter from **GP (1)** will be sent to community dwelling older people aged 75 and over. A **Response card (2)** will be included inviting the person to complete their contact details and return to the research team.

The research team will receive the completed **Response card (2)** and make contact with the candidate by telephone. The team will arrange for a suitable time for a RA to conduct a screening visit. During the initial telephone call the RA will inform the candidate that a **Participant Information Sheet (4)** will be sent to their home address which provides information about the study and that they may want to read it in advance of the visit. On request, the RA will send the Participant Information Sheet via email.

The research team will make concerted efforts to make first contact with those who express an interest in participating from the information received on the **Response card (2)**. At least three telephone messages will be left and a minimum of six calls will be made to candidates where there is no facility to leave a message. If the candidate has provided an email address, the research team will also attempt to make contact via this method; including, where no telephone number has been provided on the response card. Reasons for non-contact will be recorded and may include:

- Still trying to contact
- No usable contact information
- Language requests other than English
- No facility to leave messages (min 6 calls attempted)
- Left 3 or more messages, no further follow-up.

Due to the nature of the study population, supplementary recruitment methods will also be employed to initiate first contact (see Figure 2). Third sector and other partner organisations will be given study information to enable them to discuss the study with candidates. Other 'referrers' may also be District Nurses, Occupational Therapists or other (allied) health or social care professionals. Additionally, **study promotion text (6)** displayed on posters, leaflets or adverts will be distributed by partner organisations to individuals who may be interested in finding out more about the study. Candidates

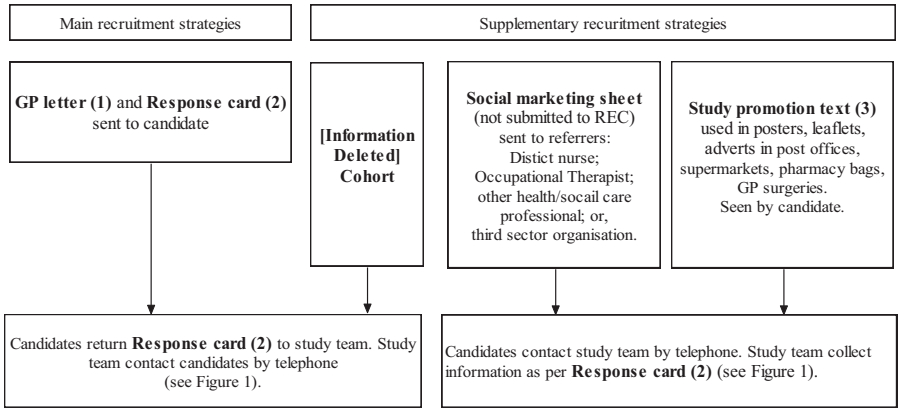
will be given contact details for the research team so they can make first contact. The research team will receive enquires and record the same information about the candidate on the **First Contact form (2a)** which records the same information as the **Response card (2)**. This will enable a screening visit to be arranged in the same way as with other recruitment strategies. The method of referral and attempts made to contact the candidate will be recorded in order to inform the feasibility assessment (see Section 3). The **First Contact form (2a)** will also record why eligible candidates chose not to take part (the option not to specify a reason will be offered).

Further to this, members of the [redacted] Cohort ([redacted]) may be used to identify candidates, subject to approval by [redacted] REC which oversees the [redacted].

Recruitment strategies

Figure 2 Describes recruitment strategies used in the study.

Figure 2. Methods of recruitment



The Participant Information Sheet will be sent to potential participants at their home (or via email, if requested), immediately after first telephone contact, which will usually be 5 days prior to the screening visit, to allow time for their consideration (see Figure 1 above).

Procedures required at screening visit

A RA will visit the potential participant at home and will read through the **Participant Information Sheet (4)**, answer questions and administer:

- **Six Cognitive Impairment Test (5)**
- **Screening Checklist (6)**

The research team will record reasons of ineligibility and for non-participation will be invited (with the option to not specify) using the **Screening Checklist (6)**. These documents (5 and 6) are combined within the **Eligibility form** (submitted to REC). Recording reasons of ineligibility will aid the recruitment strategy as the trial progresses. Basic details (age, sex, reason for exclusion/non-participation) will be collected to allow completion of the revised CONSORT diagram (Schultz et al, 2010)[123] – see appendix 1.

If a candidate is found not eligible, following a score of 8 or more on the **6CIT (5)** the following procedure will apply. The RA will thank the individual and inform them that a member of the research team will be in touch shortly. The Chief Investigator (GM) or their delegate (LG) will make direct contact with the candidate to discuss the 6CIT score and encourage the person to contact their GP.

If the candidate cannot be contacted within approximately one week of the original eligibility interview, a **6CIT non-eligible candidate letter** will be sent to the candidate. This will include an explanation of why it is not appropriate for them to participate in the study; and, advise that they should take the letter (which will include their score) to their GP. The letter will also include contact details should they wish to discuss the content of the letter further. The reason for non-eligibility will be recorded.

Procedures required before randomisation

A member of the research team will meet and consent the candidate at home **Participant Consent Form (7)**. Candidates will be offered as much time as they need to consider their decision however; consent will be permitted at the screening visit if requested by the candidate. Participants will be randomised by the research team. This will be recorded on the **Consent and Randomisation sheet (7a)** which will also capture reasons for non-consent. At this point the research team will capture information about any assistance required to participate in the study e.g. sight/ hearing loss or manual dexterity.

Baseline measurement will be administered face-to-face following consent and before randomisation by the research team and includes:

- **SF-36 plus ONS wellbeing and telephone service cost questions (8)**
- **Patient Health Questionnaire (PHQ-9) (9)**
- **EQ-5D (10)**
- **General Self Efficacy Scale– GSE (11)**
- **de Jong Loneliness Scale (12)**
- **Health and Social Care Resource Use Questionnaire(13)**
- **Socio-demographics (14)**

Procedures required after randomisation (Intervention arm only)

Participants randomised to receive the research intervention will be sent **Telephone Friendship Group Questions & Answers** by post; or, via email upon requested). The information will answer some of the practical questions participants may have about how they will receive calls and what to expect.

Study reminder (2 and 4 months)

All participants will receive a **Contact card (17)** by post from the research team, at 2 and 4 months. The brief card will thank the participant, provide an update on progress and a reminder that we will be in touch again in another 2 months.

Procedures required at six month follow-up

Six month follow-up data will be collected by the Research Assistant (RA) via telephone. Follow up data will involve completion of the following;

- **SF-36 plus ONS wellbeing and telephone service cost questions (8)**
- **PHQ-9 (9)**
- **EQ-5D (10)**
- **GSE (11)**
- **de Jong Loneliness Scale (12)**
- **Health and Social Care Resource Use Questionnaire (13)**
- **SAE Checklist (17)**

We anticipate that 20% of participants will require assistance face-to-face. In these cases the RA will seek permission to visit the participant at home to administer the questionnaire (**essential documents 8-13** and **17**) face-to-face. Approximately 4 (5%) telephone calls (in each recruitment wave) will be recorded, with consent, for researcher training and monitoring purposes.

Some participants in the intervention arm will be invited to participate in a **semi-structured interview (16)** as part of the qualitative sub-study (see Section 10 below). An RA will ask permission to either visit the participants' home, or to telephone them to conduct the interview.

Study reminder (8 and 10 months)

All participants will receive a **Contact card (17)** by post from the research team, at 8 and 10 months. The brief card will thank the participant, provide an update on progress and a reminder that we will be in touch again in another 2 months.

Procedures required at twelve month follow-up

Twelve month follow-up data will be collected by the Research Assistant (RA) via telephone. Follow up data will involve completion of the following;

- **SF-36 plus ONS wellbeing and telephone service cost questions (8)**
- **PHQ-9 (9)**
- **EQ-5D (10)**
- **GSE (11)**
- **de Jong Loneliness Scale (12)**
- **Health and Social Care Resource Use Questionnaire (13)**
- **SAE Checklist (17)**

We anticipate that 20% of participants will require assistance face-to-face. In these cases the RA will seek permission to visit the participant at home to administer the questionnaire (**essential documents 8-13** and **17**) face-to-face. Approximately 4 (5%) telephone calls (in each recruitment wave) will be recorded, with consent, for researcher training and monitoring purposes.

Procedures for withdrawal from the trial treatment or from the study

The participant will inform the research team (or the facilitator of the group) if they want to discontinue with the telephone friendship intervention. Follow-up will continue unless the participant explicitly withdraws their consent for follow-up. Data collected up to this point will be included and anonymised.

The research team will record reasons for withdrawal from the study where possible. The participant will be informed that they do not have to give a reason.

Procedures for attempted follow-up of participants "lost to follow-up"

Participants will be considered lost-to-follow-up if they fail to respond to three telephone messages and one reminder letter. A minimum of six calls will be made to candidates where there is no facility to leave a message. If the candidate has provided an email address, the research team will also attempt to make contact via this method. For those participants previously identified (at earlier points in the study) as requiring assistance, an additional telephone call will be made. There are no procedures for further follow-up.

Procedures required when closing a trial (premature or planned).

At the point at which all questionnaires have been collected (or participants have failed to respond despite reminders) and all data have been entered and cleaned, the management group will approve closure of the database. Further details will be presented in the **data management and monitoring plan** (not submitted to REC).

Procedures required to record (serious) adverse events

In line with previous studies which deliver interventions to promote self-efficacy, we do not anticipate adverse events associated with the research interventions. Four categories of serious adverse events (SAEs) will be recorded during follow-up: results in death; is life-threatening; requires hospitalisation (initial or prolonged); results in persistent or significant disability or incapacity. The collection and reporting of SAE data will be governed by [redacted] CTRU standard operating procedures.

At each follow-up (as described above), participants will be asked if they have experienced any event or illness in the last six months which:

- has required unscheduled hospitalisation; or,
- has resulted in persistent or significant disability / incapacity (see appendix 2).

Information obtained from the NHS Health and Social Care Information Centre will be used to inform the collection and reporting of SAEs, where appropriate.

It is the Chief Investigator's responsibility:

1. To follow the procedure outlined in the study protocol for the reporting of SAEs;
2. To assess each event for causality and AE category;
3. To provide the Dean of ScHARR and the University Research Office (in their capacity as representatives of the sponsor) with details of all SAEs identified within agreed timeframes;
4. To notify the Trial Steering Committee and Data Monitoring and Ethics Committee of any SAEs where appropriate; and,
5. To submit the annual safety report to the REC.

9. Statistics

Sample Size

For the purposes of sample size estimation the primary outcome will be the mean SF-36 mental health (MH) dimension score at six-months post randomisation. The SF-36 mental health dimension is scored on a 0 (poor) to 100 (good health) scale. A previous general population survey of [redacted] residents has demonstrated that the SF-36 can successfully be used as an outcome measure for community dwelling residents aged 75 or more where a response rate of 82% was achieved[39]. From this general population survey of 3,084 [redacted] community residents, the mean SF-36 mental health score was 68.3 with a standard deviation of 19.9[39].

The developers of the SF-36 have suggested that differences between groups of between 5 and 10 points on the 100-point scale can be regarded as "clinically and socially relevant"[40]. If we assume a standard deviation of 20 points for the SF-36 Mental health score at six months post randomisation and that a mean difference in MH scores between the intervention and control group of 8 or more points is the smallest difference that can be regarded as clinically and practically important. We are going to analyse the six-month outcome data with a multiple regression/analysis of covariance model (ANCOVA) model with baseline score as a covariate. We shall assume a correlation of 0.50 between the baseline and six-month mental health score. Then to have an 90% power of detecting this 8-point mean difference in MH scores at six months between the Intervention and controls as statistically significant at the 5% (two-sided) level will require 99 patients per group (2 x 99 = 198 in total).

However, the telephone befriending intervention is a group or facilitator-led intervention. Therefore the success of the intervention may depend on the facilitator delivering it so that the outcomes of the participants in the same group with the same facilitator may be clustered. If we assume an average cluster size of 6 subjects per telephone befriending group and an intra cluster correlation (ICC) of 0.04, then the design effect is 1.28. With these assumptions and 99 subjects per group the power of the analysis is reduced to 80% to detect a mean difference of eight points in six-month MH scores. If 20% of participants drop out and are lost to follow-up then we will need to recruit and randomise 124 per group (248 in total).

Statistical criteria to terminate the trial

There are no statistical criteria for stopping the trial early; as the intervention is considered low risk. Decisions to stop the trial early on grounds of safety or futility will be made by the Trial Steering Committee or funding body on the basis of advice from the DMEC.

Procedure for accounting for missing data

The primary analysis will be an intention-to-treat (ITT) analysis with participants with complete SF-36 data at six months post-randomisation. A sensitivity analysis will be undertaken to impute missing SF-36 and EQ-5D data using baseline and follow-up data from the group of patients with valid data from both measures at six-month post-randomisation. As this is an ITT analysis, withdrawals and protocol violations will be analysed in their groups as randomised.

Analysis of primary objective

As the trial is a pragmatic randomised, with a usual (control) treatment arm, data will be reported and presented according to the revised CONSORT 2010 statement[123]. The

statistical analysis will be performed on an intention-to-treat-basis. All statistical exploratory tests will be two-tailed with alpha = 0.05. Baseline demographic (age, gender) and person reported outcome measures (PROM) data (SF-36, PHQ-9, EQ-5D, GSE, de Jong Loneliness Scale, 6CIT) will be assessed for comparability between the groups.

The aim of the analysis will be to establish firstly whether there are benefits from a telephone friendship intervention compared with the control group. Since the intervention, the telephone friendship group, is a group or therapist based intervention, there may be clustering or correlation of the participants' outcomes within a telephone befriending group. Therefore to make allowance for this the primary analysis will compare mean SF-36 Mental Health dimension scores at six months between the intervention group and control group using a marginal general linear model (GLM), with robust standard errors, and an exchangeable correlation[46]. The marginal model will use Generalised Estimating equations (GEE) to estimate the regression coefficients. Participants in the control group will be treated as clusters of size one in the analysis. The exchangeable correlation assumes that participant outcomes within each cluster (telephone befriending group) have the same correlation. A 95% confidence interval (CI) for the treatment group coefficient, the difference in SF-36 mental health dimension scores between the intervention and control group, will also be calculated. An adjusted analysis will also be performed alongside this unadjusted analysis which will include baseline covariates, such as age, gender and baseline SF-36 mental health score in the marginal general linear model.

For the primary outcome, the SF-36 Mental Health dimension score at six months follow-up, missing data will be imputed through a variety of methods, including Last Observation Carried Forward (LOCF), regression and multiple imputations.

Analysis of secondary outcomes

Secondary outcomes such as the other dimensions of the SF-36, PHQ-9, de Jong Loneliness Scale, General Perceived Self Efficacy at six months follow-up will be compared between groups again using a marginal general linear model both with and without adjustment for covariates. A 95% confidence interval (CI) for the mean difference in this parameter between the treatment groups will also be calculated.

Participants are to be followed up for up to 12 months post randomisation. Mean SF-36, other dimensions of the SF36, PHQ-9, de Jong Loneliness Scale and General Perceived Self Efficacy dimension scores at 12 months follow-up will be compared between groups again using a marginal general linear model with and without adjustment for covariates. A 95% confidence interval (CI) for the mean difference in this parameter between the treatment groups will also be calculated.

The Sheffield CTRU will oversee randomisation, undertake data management and analysis and ensure the trial is undertaken according to Good Clinical Practice Guidelines and CTRU standard operating procedures.

Economic analysis

Following the feasibility phase, in which the data collection instruments will be tested for this population, in the main trial and from a societal perspective[52;124-127], the health economists will: cost the telephone friendship intervention; ask older adults through a (telephone) interviewer administered questionnaire about their primary and secondary care health service use, social care use, and voluntary and private sector service use. A primary cost-effectiveness analysis will be conducted using the SF-6D (derived from SF36) as our utility measure with EQ5D as a methodological comparator. We will undertake a secondary cost-

utility analysis using both utility scores as the measure of utility in the calculation of Quality Adjusted Life Years (QALYs)[34]. The two health related quality of life measures are used to explore their use in older populations and ensure methodological robustness QALY calculation. The cost-utility ratio i.e. cost per QALY will be compared with the NICE threshold of £30,000 per QALY, and cost effectiveness acceptability curves (CEACs) will be used using bootstrap resampling methods to convey to health and social care policy makers the probability that this intervention is cost-effective at a range of payer thresholds[128]. Sub-group analysis and sensitivity analysis will be carried out in order to inform policy makers of where the intervention might be best targeted.

10. Ancillary sub-studies

10.1 Introduction to the ancillary sub-studies

There are two ancillary sub-studies: (1) a fidelity assessment; and, (2) qualitative research. Each sub-study involves the collection and analysis of data from both participants who receive the research intervention and from those involved in delivering the intervention (facilitators). For clarity, it is important to state that some data collection tools, such as **semi-structured interview (16)** schedules, collect data for both sub-studies. The data collection tools which are only intended for those who receive the intervention have formed part of the submission to the NHS or Social Care Research Ethics Committees. The tools which are only intended for those who deliver the intervention (facilitators) have not been submitted and are clearly marked.

10.2 Fidelity assessment sub-study (facilitators)

The fidelity assessment will assess how well the telephone friendship intervention is delivered according to the intervention protocol (see Section 7). An intervention fidelity framework based on that identified by the Behaviour Change Consortium[54] has been developed (Table 1). The framework sets out the parameters by which quality and fidelity will be measured according to study design, training, delivery, receipt and enactment.

Facilitator attendance at facilitator training sessions will be monitored by a **training attendance register** (not submitted to REC) taken by a single trainer (Sarah Harwood, Community Network) who will train all facilitators to measure 'treatment dose'. The trial manager (RG-W) and content expert (MC) will observe a sample of training sessions (at least one per cycle) and use a **training content checklist** (not submitted to REC) to assure consistency of materials and practice by the trainer as well as to confirm facilitator skill acquisition.

Attendance at group befriending sessions will be monitored by the use of **participant attendance registers** (not submitted to REC) taken by the facilitators at every session during both the one-to-one and group phases.

A random sample of thirteen (5%) audio recordings of group sessions will be taken. Permission to audio record group sessions will be obtained via the **Participant Consent Form (7)** and again at the

start of a group session that has been selected. The trial manager (RG-W) and content expert (MC) will use a **facilitator checklist** (not submitted to REC) to assess:

- The match with the intervention protocol, in terms of the content and techniques delivered;
- The extent to which facilitators have enabled choice and decision-making;,
- “Drift" in facilitation skills and intervention delivery (for those facilitating groups across successive waves / cycles) with information on adherence being fed back to facilitators as necessary.

The group facilitation skills of individual volunteer facilitators will be self-assessed, with facilitators recording any difficulties with the delivery of the intervention protocol in a **facilitator diary** (not submitted to REC).

The **General Perceived Self Efficacy (GSE) Scale (11)** and **de Jong Gierveld Loneliness Scale (12)** will be used to test the extent to which baseline loneliness and self-efficacy affect all outcomes at follow-up.

The trial manager (RG-W) and content expert (MC) will use a **semi-structured interview schedule** (not submitted to REC) to explore the receipt, delivery and enactment of the intervention, the challenges of implementation and barriers to uptake with a convenience sample of facilitators. The trial manager (RG-W) and/or content expert (MC) will use a **semi-structured interview schedule (16)** to explore the receipt, delivery and enactment of the intervention with a sample of participants who received the research intervention (see Section 10.3 Qualitative research).

Table 1. Fidelity assessment strategies

Goal	Description	Strategies
Design		
Comparable treatment dose	Adequate description of the intervention dose to ensure that variation in dose is recorded.	• Set minimum/maximum number of one-to-one telephone contacts • Set minimum/maximum duration of one-to-one telephone contacts • Set frequency of one-to-one telephone contacts • Set minimum/maximum number of group telephone contacts • Set minimum/maximum duration of group telephone contacts • Set frequency of group telephone contacts • A feasibility phase within the design
Minimise the risk to implementation	Plan for foreseeable setbacks to successful implementation	• A number of recruitment strategies • Three recruitment cycles helping to match capacity with recruitment • Alternative provider of telephone conferencing technology • Alternative sources for the recruitment of volunteers (facilitators)
Training		
Standardised training	Attendance Use of standardised materials (and same trainer) Use of standardised practice	• Register by Trainer • Observed by Trial Manager Content checklist used by Trial Manager& Content Expert on an sample of sessions
Provider skill acquisition		• Observed by Trial manager • Content checklist used by Trial Manager& Content Expert on an sample of sessions
Minimise "drift" in skills/delivery (if facilitators are working across three cycles)	Adherence to training content/ delivery techniques	• Content checklist used by Trial Manager& Content Expert on an sample of sessions (during recruitment cycle 2 and 3 delivery)
Delivery		
Ensure delivery as intended	Attendance 6 one-to-one sessions Group sessions (12 weeks) Group facilitation skills Development of enabling choice and decision-making	• One-to-one register • Group register • Week 1-6 Content checklist used by Trial Manager & Content Expert on an sample of recorded sessions (audio recording) • Reflexive facilitator self-report • Checklist used by Trial Manager& Content expert Observed sample on an sample of recorded sessions (audio recording) • Semi-structured interview - Facilitators • Semi-structured interview - Participants
Receipt & Enactment		
	Impact on participant's: Wellbeing / self-efficacy / loneliness	• PROMS • Semi-structured interview – Facilitators • Semi-structured interview – Participants

Based on Bellg et al, 2004. Enhancing Treatment Fidelity in Health Behaviour Change Studies: Best Practices and Recommendations from the NIH Behaviour Change Consortium. Health Psychology, Vol 23, 5: p443-51

10.3 Qualitative research sub-study (participants only)

The purpose of the qualitative sub-study is to evaluate the impact of telephone friendship groups for older people as well as their perceived advantages and disadvantages. The objective is an assessment of the acceptability and appropriateness of the intervention in preventing loneliness and maintaining good mental health. Some aspects of the fidelity assessment (for instance views on the receipt and enactment of the intervention) will also be evaluated (see above, Section 10.2). The sub-study will also explore, as part of the feasibility assessment, the burden on participants from the completion of questionnaires.

Methods

To provide depth as well as breadth to the findings, an in-depth **semi-structured interview schedule (16)** will be used with older people to explore to what extent they considered telephone friendship groups to have made an impact on their wellbeing. Interview themes will include: the befriending process; the value of befriending for older people; the needs of older people in relation to the befriending service; the impact of the befriending service on the physical and emotional health of older people; the effect of the befriending service on social interaction amongst older people and older peoples' self-defined general well-being. Interviews will be conducted face-to-face with selected volunteers at the six month follow-up, with no fewer than 10% of trial participants allocated to the intervention (n=12). A purposive sample will be used to ensure a balanced representation of respondents in terms of both demographic characteristics. We anticipate undertaking approximately 15-20 interviews across the three recruitment waves however, interviews will continue until data saturation occurs. By convention, this is defined as being when no new themes occur in the data. We will seek to follow up a small number of participants who were randomised to receive the intervention but were non-adherent to explore the reasons why the intervention was unacceptable or inappropriate.

The interviews will be conducted either in people's homes or in a convenient place locally, if this is preferred and will last about 1 hour. A written and verbal explanation for the study will be given and confidentiality assured (**Participation Information Sheet (4)**; **Participant Consent Sheet (7)**). The interviews will be recorded with the participants' consent. Because of the sensitivity of the subject, a protocol has been devised on how to deal with issues of concern should they arise.

Analysis

The analysis of the data will commence during the data collection period with interviews, transcription and analysis forming a cyclical, continuous process where interviews inform analysis and analysis informs the interviews. Interviews will be digitally recorded and transcribed verbatim. Data analysis of transcripts will be conducted in NVivo using a constant comparative method to identify themes. Analysis and interpretation will follow 'Framework Analysis', a case-by-theme approach, a practical and effective way of managing, summarising and synthesising complex qualitative data[129]. Framework analysis will focus on the participants' views of the appropriateness and acceptability of the intervention.

First transcripts will be read to become familiarised with the data with notes made relating to initial themes based on the research question and information that emerges from the interviews. Second the transcripts and notes will be re-read independently by the Trial Manager (RG-W) and Content Expert (MC) for the participant and facilitator interviews. Using the Framework Analysis staged structure, transcripts will be systematically coded according to the themes that emerge and these will be grouped according to sub-headings within a framework structure. We will actively seek 'deviant' or 'negative' cases and modify

emerging themes accordingly[130]. Framework Analysis allows for the emergence of themes which have not been previously identified as important to the research question[48;49]. Sub-headings will be collapsed into key themes, which capture the essence of the interviews. Results will be used to explore potential explanations for the quantitative findings and identify if there are other emerging issues or factors influencing uptake and impact of the interventions that have not been previously documented[25;50]. The final outcome will be a synthesis of coded data, sub-themes and key themes.

11. Trial supervision

The University of Sheffield will act as sponsor for the trial. Three committees will be established to govern the conduct of this study: the Trial Steering Committee (TSC), the Data Monitoring and Ethics Committee (DMEC) and the Trial Management Group (TMG). These committees will function in accordance with Sheffield CTRU standard operating procedures.

The TSC will consist of an independent chair with clinical and research expertise in the topic area, and two other topic experts as the sponsor sees fit and as agreed by the grant awarding body. The TSC will meet every 6 months from the start of the trial. The DMEC will consist of a neutral chair with research expertise, an independent statistician and an independent content expert. The DMEC will meet once before recruitment commences and every 6 months from the start of the recruitment. The DMEC can recommend premature closure of the trial to the TSC in accordance with Standard Operating Procedure GOV003.

A full time Trial Manager will contact the Chief Investigator and meet with the Assistant Director of the CTRU at weekly intervals while co-ordinating the trial. The TMG will meet at least at three-month intervals and will consist of: the Chief Investigator, the trial manager, the study statistician and a lay representative (from [redacted] Expert Elders or a similar organisation).

A Local Implementation Group will meet every two months and involve all local stakeholders, including members of the academic study team as well as representatives from charities, the NHS and the lay community.

12. Data handling and record keeping

Data management will be provided by the University of Sheffield Clinical Trials Research Unit (CTRU) who adhere to their own Standard Operating Procedures (SOPs) relating to all aspects of data management including data protection and archiving. A separate data management and monitoring plan (DMMP) will detail data management activities for the study in accordance with SOP (Shef/CTRU/DM009).

For the duration of the study, all consent forms, data collection forms and interview transcripts will be kept in a locked filing cabinet in a secured area within the CTRU.

Archiving

Data from the study will be stored in accordance with the Directive 2005/28/EC Article 17 and the CTRU Archiving Standard Operating Procedure (Shef/CTRU/DM002) for at least 5 years following completion. It will be stored in on-site archive facilities; or in a commercial archive with overall responsibility being retained by the Sponsor. Access will be restricted to the sponsor and regulatory authorities. Archived documents will be logged on a register which will also record items retrieved, by named individuals, from the archive. Electronic data will be stored in an 'archive' area of the secure CTRU server for a minimum of five years to ensure that access is future-proofed against changes in technology. Electronic data may also be stored (e.g. on a compact disc) with the paper files.

Health economic analysis (Bangor University)

To facilitate health economic analysis, anonymised data will be downloaded from the secure CTRU web site hosted by a named researcher at the Centre for Health Economics and Medicines Evaluation (CHEME) at Bangor University. Alternatively, the data may be pre-processed and formatted in Sheffield, and then sent encrypted by email.

13. Data access and quality assurance

The study will use the CTRU's in-house data management system (Prospect) for the capture and storage of participant data. Prospect stores all data in a PostgreSQL database on virtual servers hosted by Corporate Information and Computing Services (CiCS) at the University of Sheffield. Prospect uses industry standard techniques to provide security, including password authentication and encryption using SSL/TLS. Access to Prospect is controlled by usernames and encrypted passwords, and a comprehensive privilege management feature can be used to ensure that users have access to only the minimum amount of data required to complete their tasks. This can be used to restrict access to personal identifiable data.

Participant confidentiality will be respected at all times. Candidate/participant names and contact details will be collected and entered on the database. Access to these personal details will be restricted to users with appropriate privileges. All other data will be anonymised and will only be identifiable by participant ID number, and no patient identifiable data will be transferred from the database to the statistician. The CRF/questionnaires will collect demographic details, some of which will be used to indicate the participant's socio-economic status.

Prospect provides validation and verification features which will be used to monitor study data quality, in line with CTRU SOPs and the DMMP. Error reports will be generated where data clarification is required.

Health economic analysis (Bangor University)

For all research projects, CHEME adheres to the Data Protection Act 1998. Files containing electronic data will be password protected, stored on a secure network where security of the data is centrally protected. All electronic data is centrally backed up on a secure server. All university laptops are encrypted. Workstations in CHEME are locked if the user leaves the computer unattended. Any electronic files which are saved in folders on a shared network, will be restricted to authorised CHEME health economists who have been allocated a password to allow access to the data. One copy of the electronic database will be write protected, to ensure a clean copy of the data. A further copy will not be write protected. This

will aid future research in this area by allowing additions and reanalysis of the data. Any unnecessary or duplicate information will be deleted on study completion.

When handling electronic files with any direct identifiers, specifically postcode only, the following will be observed:

Files containing direct identifiers will be available separately from other trial data and saved in a folder with access only to individuals who strictly need to see it for the purposes of one part of the economic evaluation

Files containing direct identifiers will remain in only one location in a secure area of the server and not be copied and saved elsewhere.

Files containing direct identifiers will not be transferred via email or by other means unless encrypted. No data, including patients' identifiable data will be stored on home computers, personal laptops or unencrypted memory sticks.

14. Publication

Dissemination will be undertaken through peer reviewed scientific journals and clinical and academic conferences. We will also ensure regular dissemination to the third sector and older people's advocacy groups through regular project bulletins.

The study team are obliged, by the terms of its contract, to notify the PHR programme of any intention to publish the results of PHR-funded work at least 28 days in advance of publication in a journal. This also applies to public oral and poster presentations, for which the team will advise the PHR programme 28 days before submission of abstract to organisers of an "event". In this case, the notification form provided on the PHR website's 'Project outputs' page.

15. Finance

The trial has been financed by the NIHR PHR and details have been drawn up in a separate agreement.

16. Ethics and research governance approval

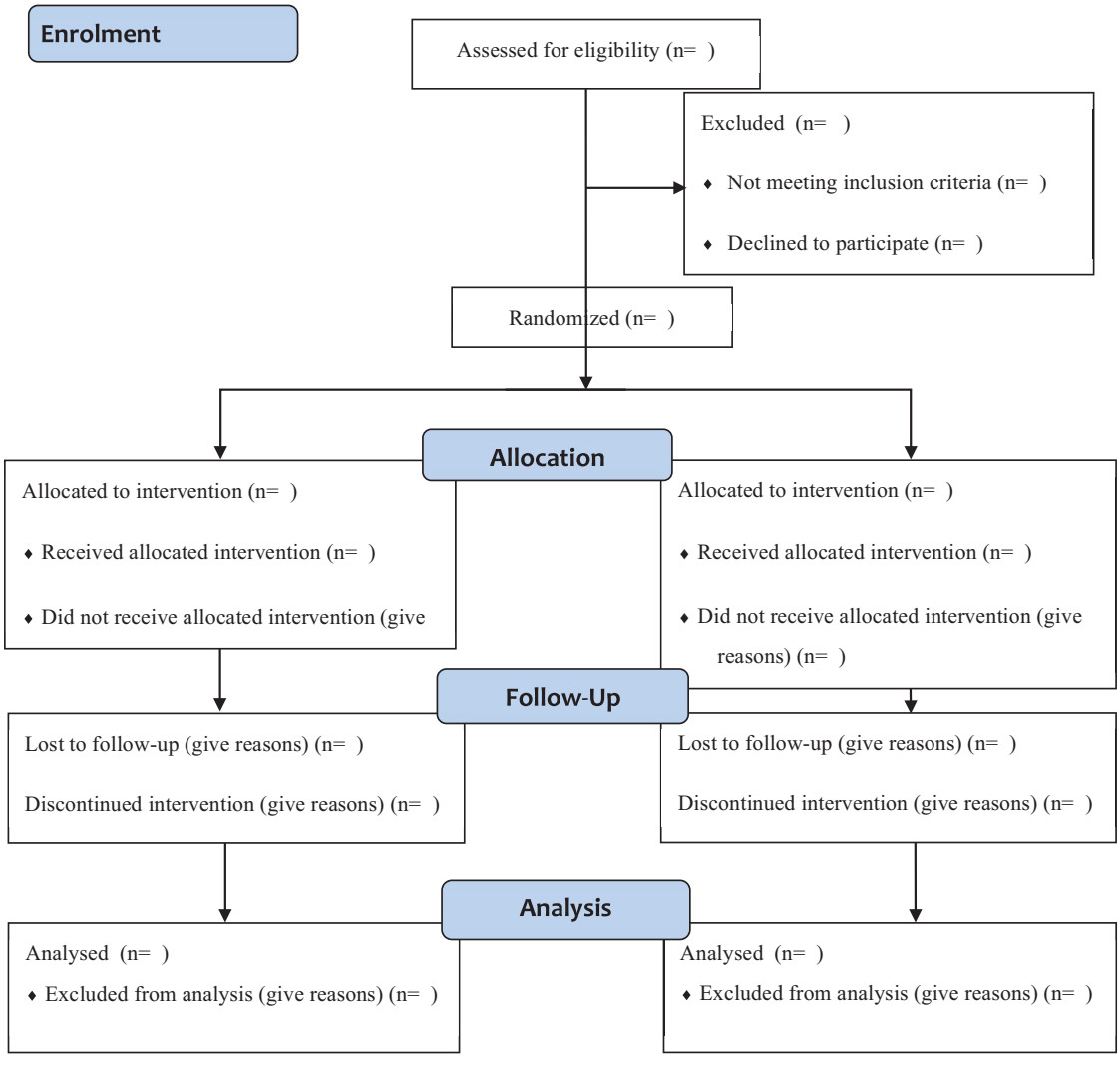
The trial will be submitted to a Research Ethics Committee (REC) through the IRAS central allocation system. The approval letter from the ethics committee and copy of approved patient information leaflet, consent forms, CRF's and questionnaires will be sent to the CTRU before initiation of the study and participant recruitment.

The trial will be submitted for NHS and Local Authority research governance approval.

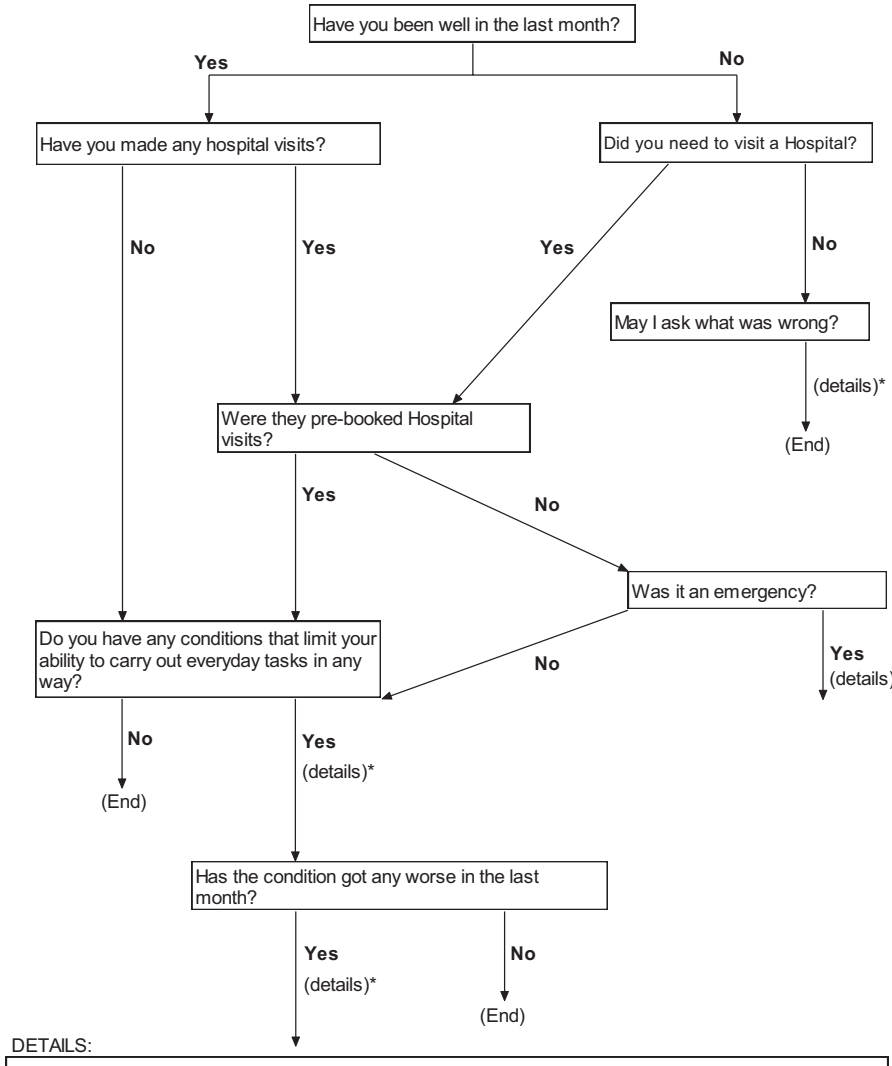
17. Indemnity / Compensation / Insurance

The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of this research project.

Appendix 1: Revised CONSORT 2010 Flow Diagram



Appendix 2: Serious Adverse Event Checklist (6 month and 12 month follow-up)



* If details are unclear was permission granted to contact GP for varification and/or confirmation?

Yes ☐ No ☐