Putting Life In Years (PLINY): Telephone friendship groups

Submission date 11/04/2012	Recruitment status Stopped	[X] Prospectively registered	
		[] Protocol	
Registration date 11/04/2012	Overall study status Stopped	Statistical analysis plan	
		[X] Results	
Last Edited 29/08/2019	Condition category Other	Individual participant data	
		[] Record updated in last year	

Plain English summary of protocol

Background and study aims:

People are living longer and many experience a good old age. Unfortunately longer life is not always accompanied by health and wellbeing. Older people can become lonely, isolated and unhappy as a result of a whole number of factors such as diminished physical abilities and bereavement. Our research programme is examining how people aged 75 years and over can be helped to retain wellbeing and not feel unhappy due to feelings of loneliness and isolation. It is examining the possible benefits of group friendship over the telephone. Telephone befriending services are usually provided through the voluntary sector and are available in a number of locations. Befriending can take place on a one-to-one basis or through small groups of people linked together by telephone (teleconferencing). A small amount of research has already been conducted into telephone befriending. It appears to provide benefit but we need evidence from more people who have experienced befriending by telephone to be able to make clear statements about whether it should be recommended.

Who can participate?

To take part you need to be:

- 1. Aged 75 or over
- 2. Have reasonable memory
- 3. Live in your own home or with others such as with your family
- 4. Able to understand and converse in English

What does the study involve?

To ensure that the research is thorough we want to recruit and involve 248 older people aged 75 years and over who live in Sheffield. It will take us over a year to recruit the number of older people we need as the befriending services can only accommodate a certain number of people at any one time.

The main method of inviting people to participate in the research is through letters of invitation from primary care. However we are also using other ways to get the information to those who might be interested such as giving talks at community venues and asking health and social care professionals to identify people who they think might benefit. Everyone who has volunteered and is eligible to take part is randomly allocated to one of two groups. Not everyone will receive the research intervention (telephone friendship). Everyone is then asked questions about their

wellbeing and health when they first meet a researcher and once again six months later. We will compare the results from responses collected at the start of the study with the results collected six months later. We will look to see whether those involved in telephone friendship groups feel happier about their lives compared with the group who were allocated to help in the research by answering questions only. To find out whether there might be any lasting benefit we will then ask all participants the same questions for a final time about 12 months after the start. Those people allocated to receive telephone friendship will firstly receive up to six one-to-one calls from a trained and Criminal Records Bureau (CRB) checked Age UK Sheffield volunteer. The volunteer will talk to the participant for approximate 20 minutes and introduce them to the idea of group discussions over the telephone. They will then be invited to join a telephone friendship group with around six to seven other people. The friendship group then talk once a week for about one hour for 12 weeks with the group being assisted by an Age UK Sheffield volunteer. As telephone friendship/befriending services are relatively new, we will look to see how they are being delivered and how people experience the service by talking with a small number of people have participated in the telephone friendship group. We will also interview the Age UK Sheffield volunteers to find out if the telephone friendship service delivered to older people was as we intended. Older people are also helping us with the management of the study and continue to give their views on the progress of the project and any information that is being prepared. This is helping the researchers to ensure that what we ask people to do and any written material produced can be easily understood and meets the needs and expectations of those who are invited to take part.

What are the possible benefits and risks of participating?

We will keep in touch with everyone who has joined the study about every two months by sending information by post. We will explain how the study is progressing and when they can expect to hear from us again. Those allocated to telephone friendship will experience more frequent contact. The telephone friendship group may give these participants something to look forward to. They will provide an opportunity to talk with new people over the telephone and to share memories and interests with other people of a similar generation. Some people may not like some of the questionnaires that they are asked to complete. This will be noted as part of the research study. Those taking part in the telephone friendship groups may experience brief dissatisfaction with the group discussions. Conversations may stir painful memories. The volunteer facilitator will be trained to guide discussions if necessary. Those who are not allocated to receive the telephone befriending may consider that being part of the study is not worthwhile for them. We will try to ensure that everyone feels part of the study by keeping in regular contact.

Where is the study run from?

The study is being organised by the University of Sheffield in partnership with Age UK and Community Network.

When is study starting and how long is it expected to run for? The study will be inviting people to join from approximately May 2012 until May 2013. It will run until December 2014 to enable us to follow-up participants, analyse the results and write a report of our findings.

Who is funding the study? National Institute for Health Research (NIHR), Public Health Research programme.

Who is the main contact? Rebecca Gossage-Worrall r.gossage-worrall@sheffield.ac.uk Study website http://www.sheffield.ac.uk/scharr/sections/hsr/ctru/pliny

Contact information

Type(s) Scientific

Contact name Ms Rebecca Gossage-Worrall

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT01754753

Secondary identifying numbers 11756

Study information

Scientific Title

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

Acronym

PLINY

Study objectives

The National Institute for Health Research commissioned this research with the following research question: "What is the relative effectiveness and cost effectiveness of home based support programmes in improving the mental wellbeing of older people living in their own homes?"

The project will evaluate whether telephone friendship groups, delivered by the voluntary sector over the telephone, can improve the mental wellbeing of older people aged 75 or over.

The research will also:

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:

1.1. Assess voluntary sector readiness to take forward new forms of services;

1.2. The best modes of delivery of telephone support/friendship;

1.3. Assess how volunteers (facilitators) can be supported and retained; and,

1.4. The extent to which fidelity of the intervention is maintained within and across the participating organisations.

2. Determine if there is any lasting impact upon mental wellbeing by repeat measurement with all participants 12 months following baseline measurement

3. Examine whether there is any significant improvement on the physical dimension of the SF-36 at 6 months and 12 months, following baseline measure, for the intervention arm compared with usual care.

4. 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 usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee Yorkshire and the Humber - South Yorkshire, 17/02/2012, ref: 12/YH0019

Study design

Pragmatic two-arm randomised controlled trial

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied Age and ageing

Interventions

248 participants will be randomly allocated to one of two groups.

1. Research Intervention: Telephone friendship groups

Participants allocated to telephone friendship groups will take part in 12 weekly group telephone discussions. The participant will be called, by a trained Age UK Sheffield volunteer, in their own home. The group discussions will take place for about an hour each week and involve between 6-8 participants. Participants will be introduced to weekly group calls by the volunteer who will call each participant individually for around 20 minutes each week for up to six weeks before the group is established.

The group may have a particular focus or talk about different topics each week. The individual participants are joined together through a teleconferencing system (provided by Community Network).

2. No research intervention (control): Health and social care as usual

Participants allocated to the control arm will not receive any research intervention. However, they will participate in the research by completing questionnaires about their health and wellbeing.

04/03/2013: Please note that as of 31/01/2013, this trial was stopped due to a lack of resources

Intervention Type

Behavioural

Primary outcome measure

SF-36 Mental health dimension measured at baseline, 6 and 12 months

Secondary outcome measures

- 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
- 7. Telephone friendship group call costs question; and, ONS Wellbeing question
- 8. Socio demographic questionnaire including a self report of health status

Overall study start date 01/05/2012

Completion date 01/12/2014

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

1. Aged 75 years or over

2. Good cognitive function, defined as Six Cognitive Impairment Test (Brooke P, Bullock R, 1999) 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

5. Target Gender: Male & Female

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants Planned Sample Size: 248; UK Sample Size: 248

Key exclusion criteria

1. Aged 74 years or younger

- 2. 6CIT score of 8 or more
- 3. In residential/ nursing care homes
- 4. Unable to understand and converse in English
- 5. Unable to converse on the telephone with assertive technology
- 6. Already receiving a telephone intervention

Date of first enrolment 01/05/2012

Date of final enrolment 31/05/2013

Locations

Countries of recruitment England

United Kingdom

Study participating centre

University of Sheffield Sheffield United Kingdom S1 4DA

Sponsor information

Organisation

University of Sheffield (UK)

Sponsor details

School of Health and Related Research Regents Court 30 Regent Street Sheffield England United Kingdom S1 4DA

Sponsor type University/education

Website http://www.shef.ac.uk/

ROR https://ror.org/05krs5044

Funder(s)

Funder type Government

Funder Name NIHR Public Health Research (UK) ref: 09/3004/01

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	24/04/2014		Yes	Νο
	results				

Results article

01/12/2014

Yes

No