Putting Life in Years (PLINY): a randomised controlled trial and mixed-methods process evaluation of a telephone friendship intervention to improve mental well-being in independently living older people

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Scientific summary

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Background

Social isolation in older adults is relatively common and is associated with increased morbidity. Systematic reviews of randomised controlled trials (RCTs) evaluating interventions to promote socialisation and alleviate loneliness reported shortcomings in the available evidence. In 2008, the UK National Institute for Health and Care Excellence (NICE) concluded that further research on home-based interventions that could improve or successfully maintain the mental well-being of vulnerable, older people living in the community was a priority.

Objectives

The primary objective was a RCT [the Putting Life in Years (PLINY) trial] to determine whether mental well-being, as measured by the Short Form questionnaire-36 items (SF-36) health instrument mental health dimension, 6 months after randomisation, is significantly improved in participants allocated to receive the telephone friendship (TF) group intervention compared with participants allocated to a control group. A necessary precondition for the RCT was pilot work to determine whether the main RCT was feasible, based on objective targets for recruitment and retention of research participants by the study team and the capacity of volunteers working with a voluntary sector service provider to deliver the intervention. Secondary objectives included a process evaluation using qualitative methods to identify the psychosocial and environmental factors as well as implementation issues that may mediate or modify the effectiveness of the intervention. This included examining voluntary sector readiness to take forward new forms of services and the extent to which the fidelity of the intervention was maintained.

Design

This was a two-arm, parallel-group, pragmatic, superiority RCT using web-based randomisation and with only the principal investigator and the analysts blind to allocation until after the final analysis. An internal pilot was carried out to assess study and intervention feasibility. Nested qualitative research and intervention fidelity substudies were also carried out.

Setting

The study setting was one urban centre in the UK.

Participants

Between June 2011 and December 2012, 528 participants from a longitudinal cohort study and 9051 people registered with general practices were invited to take part in the trial. Information packs were also distributed across services in the city. The eligibility criteria included being aged ≥ 75 years, living independently and having reasonable cognition [attaining a score of < 8 on the six-item Cognitive Impairment Test (6CIT)]. In total, 157 participants were recruited, consented and randomised to the intervention group ($n = 78$) or the control group ($n = 79$).

Interventions

1. Manualised TF with standardised training: (a) one-to-one befriending – 10- to 20-minute calls once per week for up to 6 weeks made by a volunteer befriender – followed by (b) TF groups of six participants – 1-hour teleconferences once per week for 12 weeks facilitated by the same volunteer.
2. Control: usual health and social care provision.

Volunteers, who had no previous experience of befriending or group facilitation, were recruited by a voluntary sector service provider. Friendship groups aimed to maintain or enhance social support and increase opportunities for social interaction to maintain well-being. All volunteers were trained in group facilitation using standardised manualised content delivered by the same trainer. Volunteers modelled facilitation scenarios to learn how to provide a suitable environment for TF, manage conflict and maintain ground rules and confidentiality.

Main outcome measures

Success criteria for progression to the main trial were the recruitment of 68 participants in the first 95 days, the retention of 80% of the participants at 6 months and the successful delivery of TF by a local franchise of a national charity (not defined).

The primary clinical outcome was the SF-36 mental health dimension score at 6 months. The developers of the SF-36 have suggested that differences between treatment groups of between 5 and 10 points on the 100-point scale can be regarded as 'clinically and socially relevant'. For the original sample size calculation we assumed that a mean difference in SF-36 mental health dimension score of ≥ 8 points at 6 months post randomisation between the intervention group and the control group is the smallest difference that can be regarded as clinically and practically important. Secondary clinical outcomes included other dimensions of the SF-36 for functional health and well-being; the European Quality of Life-5 Dimensions (EQ-5D) for health status; the Patient Health Questionnaire – nine questions (PHQ-9) for self-reported depression; the General Perceived Self-Efficacy Scale (GSE) for optimistic self-beliefs about ability to cope with difficult life events; the De Jong Gierveld Loneliness Scale for overall, emotional and social loneliness; and health and social care resource use.

Barriers to implementation of the intervention were assessed using e-mail communication, trial management group meeting minutes and field notes. Views on the acceptability, accessibility and effectiveness of the intervention were obtained through semistructured interviews with older people and volunteer facilitators. Interviews were audio recorded and transcribed verbatim, with transcripts coded using NVivo 9 (QSR International, Warrington, UK) (participants) and manually (volunteers) and analysed using framework analysis.

Researchers recorded volunteer training sessions and group TF sessions in which volunteers delivered the intervention to assess the fidelity of each. The fidelity of training delivered to the volunteer facilitators was assessed in three out of the four training groups using a specially designed checklist of prescribed content. Audio recordings of 11 separate facilitated telephone discussions were sampled from four groups at three time points: weeks 1, 6 and 12 (22% of all relevant sessions). Sessions were coded independently by two researchers using a specially designed checklist of prescribed and proscribed content, with median scores calculated afterwards. Participant fidelity was assessed using a checklist of four fidelity items that assessed group members' participation in calls in terms of observing ground rules, introducing topics, showing support and showing commitment. Samples were taken from all four groups at weeks 1, 6 and 12 (three groups only).

Results

In total, 157 people were randomised to the TF group ($n = 78$) or the control group ($n = 79$). Two (out of three) success criteria for progression to the main trial were met: 70 participants were randomised in the first 95 days and 56 out of the 70 (80%) contributed valid primary outcome data 6 months later. The third criterion, successful delivery of TF, was deemed not to have been met as only 50 out of the 78 (64%) participants randomised to the intervention group received the intervention because the service provider could not recruit and retain a sufficient number of volunteer facilitators. Only 10 out of 42 (24%) potential volunteers completed training, of whom three out of 10 (30%) adhered long enough to deliver the group intervention. As a result, the trial closed early.

In the internal pilot trial, 35 people were randomised to the control group and 35 to the intervention group. Fourteen participants were excluded from the analysis because of incomplete primary outcome data, leaving 56 participants (control $n = 30$, intervention $n = 26$) in the intention-to-treat analysis.

At study closure, none of the remaining 101 participants had been followed up for long enough to contribute primary outcome data; the 56 participants from the internal pilot phase became the final intention-to-treat analysis set. The mean difference in SF-36 mental health score was 6.5 [95% confidence interval (CI) –3.0 to 16.0]; after adjusting for age, sex and baseline score the mean difference was 9.5 (95% CI 4.5 to 14.5).

During the interviews, participants mostly acknowledged that the groups were enjoyable but were beneficial for others rather than for themselves. Few technical issues with befriending were identified by participants; a minority experienced lines cutting out and confusion over who to contact when experiencing such incidents. Nine participants made positive comments about finding the groups acceptable and enjoyable, although three were frustrated that they could not see other members of the group face to face while they were speaking. Four expressed dissatisfaction with the input from other group members because of a lack of shared interests or attitudes. The remainder made fairly neutral comments, describing the intervention as useful, interesting or 'not too technical'. The groups varied in size, with members of larger groups reporting better group cohesion. Participants of groups whose numbers fell below five reported struggling to keep up a conversation for the 1-hour duration of a session. The three volunteer facilitators who completed the facilitation of the 12-week group intervention all expressed satisfaction with the role. In contrast, one volunteer who dropped out before commencing a befriending group was dissatisfied with the lack of face-to-face contact with participants. Volunteer facilitators who delivered the intervention expressed some lack of clarity about intervention procedures (e.g. procedures for closing groups) and occasional anxieties about managing group dynamics (especially conflict management), despite the training that they had received. They all reported experiencing few technical difficulties but found arranging times to make one-to-one and group calls challenging and frustrating at times. They thought that scheduling evening calls (prohibited by the teleconference provider, Community Network) would have been more successful. They reported that group calls were often interrupted by members receiving visitors while on the line. Two volunteers expressed a lack of confidence in the training and in the willingness or ability of the host charity to support them to deliver the intervention.

Training content was delivered faithfully, with > 95% of all fidelity checklist items present in two groups and > 91% present in the third group. The minimum duration of group telephone discussions sampled was 23 minutes and the maximum was 69 minutes, with a median of 55 minutes. The median intervention fidelity score of volunteer facilitators ranged from 30.2% to 52.1%, indicating that the volunteers did not facilitate the group discussions in line with the training content delivered. Two groups also showed a decline in fidelity score over the time points sampled. The most salient failings in intervention fidelity across volunteer facilitators relate to the setting of ground rules, the maintenance of participant confidentiality and the ending of each group programme, with regard to facilitating further contact between participants when desired. Three participants reported distress when the programme of

sessions was ended abruptly without proper arrangements for desired post-intervention contact between participants being properly facilitated:

> *I'm sad, I'm sad that it's stopped. Not . . . that the telephoning group stopped even, sad that that stopped I suppose but I'm sad that I'd, I'd been cut off.*
>
> *006, female*

> *Awful because I'd nothing to look forward to . . . And that was quite, quite . . . yeah I missed talking to them.*
>
> *008, female*

> *I would have liked to have stayed in touch with somebody just to ring up and say 'How are you today?'*
>
> *019, male*

> *Well, I enjoyed doing it but as I say, I was so upset when they came to a full stop.*
>
> *019, male*

Two volunteers admitted participating in, rather than facilitating, group calls and saw the training material as guidelines rather than protocol, reflecting that the technical content was more useful than that intended to help them manage group dynamics. Median fidelity scores for participants ranged from 49% to 71%.

Conclusions

The point estimates for the primary outcome and associated CIs suggest that the likely effect of the telephone befriending intervention is within a clinically relevant range and that it may be worth progressing to a full trial. However, there was no change in SF-36 mental health dimension score in the intervention group whereas the control group experienced a decline or deterioration in SF-36 mental health dimension score over the 6-month follow-up period.

The study design and protocol were found to be acceptable to participants and general practitioners; we observed no adverse events, although three participants voiced dissatisfaction with how the intervention was terminated, and the intervention seems to be safe. We were able to recruit our target sample and the attrition rate was within an acceptable range. However, we were not able to deliver the intervention as specified in the protocol, to the majority of the participants, which led to early termination of the study. Although the definitive RCT seems feasible in terms of acceptability to participants, safety and recruitment and retention, the delivery of the actual telephone befriending intervention was not feasible. Small voluntary sector organisations may not be in a position to recruit, train and retain adequate numbers of volunteers to implement new services at scale over a short time scale. A definitive trial may have to be run in more than one major population centre and include a number of voluntary sector providers and/or involve volunteer recruitment and management by specialists.

Trial registration

This trial is registered as ISRCTN28645428.

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