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Public Health Research

Extended Research Article

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

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

Published March 2025
DOI: 10.3310/WTJH4379

Scientific summary

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Public Health Research 2025; Vol. 13: No. 1
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NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background and rationale

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

Aims and objectives

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

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

Methods

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

Inclusion criteria

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

Recruitment

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

Randomisation

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

Intervention

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

Outcomes

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

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

Data management and analysis

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

Results

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

Process evaluation

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

Qualitative study

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

Conclusions

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

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

Trial registration

This trial is registered as Current Controlled Trials ISRCTN19193075.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Public Health Research programme (NIHR award ref: 16/08/41) and is published in full in *Public Health Research*; Vol. 13, No. 1. See the NIHR Funding and Awards website for further award information.

Public Health Research

ISSN 2050-439X (Online)

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This article

The research reported in this issue of the journal was funded by the PHR programme as award number 16/08/41. The contractual start date was in March 2018. The draft manuscript began editorial review in February 2023 and was accepted for publication in January 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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