ISRCTN19193075 https://doi.org/10.1186/ISRCTN19193075

The Project About Loneliness and Social networks (PALS)

Submission date
01/10/2018

Recruitment status
No longer recruiting

Registration date
02/10/2018

Overall study status
Completed

Last Edited
10/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Around 30% of the UK population experience loneliness. Older people and those with long-term health problems are far more likely to be lonely and isolated than those in good health. Feeling lonely and isolated also has a negative impact on a person's emotional and physical health, and costs the NHS money due to more medical appointments and hospital visits. Evidence has shown that connecting with community resources can help protect against loneliness for those most at risk. This study will test if it is possible to reduce the negative impacts of loneliness and social isolation by focussing on the support networks that people have around them. GENIE is an online tool that allows people to map their social networks (which may include friends, family, groups, pets, daily activities). It also asks about people's preferred interests and activities and provides links to local activities which match these. This study will explore how GENIE can be used to improve social networks using existing local community groups and resources, to provide emotional and physical health benefits to participants.

Who can participate?
Isolated and lonely adults in two regions in the North and South of England (centred around Southampton and Liverpool)

What does the study involve?
Participants are randomly allocated to two groups. One group uses GENIE. With the help of a facilitator, people using GENIE are asked to think about the role of people around them, and how their networks might be improved, by including other people already around them who they did not initially think of, or from new connections to community activities. By thinking about their whole network, people are able to build on existing connections and that linking to local activities and groups of interest gives people the opportunity to meet others with similar interests and improves the sense of connection to the local community. The other group carries on as usual but can use GENIE with a facilitator, if they want to, after 6 months once the study has finished. A small number of people are selected for interview to understand their experiences of loneliness and isolation, and how this might have changed because of the study.

What are the possible benefits and risks of participating?
The study will help us to understand how, where and why people are lonely within our local

communities particularly those living in disadvantaged situations (e.g. poor housing or with low incomes). It will show how best to use existing community groups, resources and organisations to access and help those most at risk. As GENIE is distinct from other approaches, such as befriending schemes, the study will help us understand how reducing isolation and feelings of loneliness happens after using GENIE. The researchers have been working with different groups across the two cities, including the NHS, housing associations, fire service, care and support organisations, health and community groups, to help target all relevant activities and services. GENIE will be delivered by people who work for these organisations. The Campaign to End Loneliness are also collaborating with the study team. By including a wide range of stakeholders the researchers hope to share their findings more broadly and innovatively than within an academic context and if effective, they will be able to provide evidence for policy makers.

Where is the study run from?
1. University of Southampton (UK)
2. Liverpool John Moores University (UK)

When is the study starting and how long is it expected to run for?
March 2018 to June 2022 (updated 09/02/2021, previously: February 2021)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Dr Rebecca Band
2. Kate Rodger

Contact information

Type(s)
Public

Contact name
Dr Rebecca Band

Contact details
PALS Trial Office
Faculty of Health Sciences
67/ E3011
Nightingale Building
University of Southampton
Highfield Campus
Southampton
United Kingdom
SO17 1BJ
-
r.j.band@swansea.ac.uk

Type(s)
Scientific

Contact name

Ms Kate Rodger

Contact details
PALS Trial Office
Faculty of Health Sciences
67/ E3011
Nightingale Building
University of Southampton
Highfield Campus
Southampton
United Kingdom
SO17 1BJ
-
k.rodger@soton.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
232890

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 38368

Study information

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

Acronym
PALS

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

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. South Central - Berkshire Research Ethics Committee, 27/06/2018, ref: 18/SC/0245
2. University of Southampton, Faculty of Health Sciences Ethics Committee, 06/03/2018, Ethics ID: 31638

Study design
Randomized; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Social exclusion

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

The PALS study will comprise:
1. Internal pilot trial: due to potential recruitment difficulties there will be an internal pilot to confirm the acceptability and feasibility of the full trial protocol and study procedures. Recruitment rates will be assessed against stop/go criteria at 12 months into the recruitment period
2. Randomised controlled trial: A full randomised controlled trial will compare the GENIE intervention to a wait-list control group for individuals who are isolated or lonely. A total of 394 participants will be recruited, 197 per arm. GENIE is initially introduced via a guided discussion with a trained peer (or another individual – referred to as facilitators); this takes 30 to 40 minutes to deliver and has three stages: social network mapping (creating a visual map of their current support network), tailoring of preferences (answering 13 questions designed to help people focus on their interest, support, health and wellness needs and enjoyable activities), linking users to valued resources and activities (receiving tailored access to local resources based on personal preferences)
3. Health economic modelling and a qualitative process analysis study will also be embedded into the PALS study

Intervention Type
Behavioural

Primary outcome measure
Mental health is measured using the SF-12 Mental Health composite scale score at baseline, 3 months and 6 months

Secondary outcome measures
1. Physical health is measured using the SF-12 Physical Health composite scale score at baseline, 3 months and 6 months
2. Loneliness is measured using the De Jong Scale and the Campaign to end loneliness scale at baseline, 3 months and 6 months
3. Beliefs about loneliness are measured using a modified version of the B-IPQ at baseline, 3 months and 6 months
4. Social isolation is measured using the Duke Social Support index and social support is measured using the SPA at baseline, 3 months and 6 months
5. Collective efficacy is measured using the CENS questionnaire at baseline, 3 months and 6 months
6. Wellbeing is measured using the Warwick Edinburgh Mental Well-being scale and quality of life measured using the ICECAP-A at baseline, 3 months and 6 months
7. Healthcare utilisation is measured using the EUWISE questionnaire and health utilities will be valued via application of the SF-6D algorithm to responses on the SF12 at baseline, 3 months and 6 months
8. Social network composition measured using GENIE at baseline and 3 months for intervention participants only

Overall study start date
01/03/2018

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. A socially isolated person as one for whom there is an absence of social contacts or community involvement, or lack of access to services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Participants: 394 (197 per arm; 12 per facilitator)

Total final enrolment
469

Key exclusion criteria
Current exclusion criteria as of 11/01/2022:
1. Currently hospitalised (i.e. not self-managing within a community setting)
2. Terminal disease or any acute exacerbation of the condition which impacts upon their ability to take part
3. Lacking sufficient capacity to consent or take part in the study
4. Having had previously used the GENIE intervention

Previous exclusion criteria:
1. Currently hospitalised (i.e. not self-managing within a community setting)
2. Terminal disease or any acute exacerbation of the condition which impacts upon their ability to take part
3. Lacking sufficient capacity to consent or take part in the study
4. Household member enrolled in the study (to avoid bias)
5. Having had previously used the GENIE intervention

Date of first enrolment
05/10/2018

Date of final enrolment
17/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO17 1BJ

Study participating centre
Liverpool John Moores University
Liverpool
United Kingdom
L3 5UA

Sponsor information

Organisation
University of Southampton

Sponsor details
Head of IP, Contracts & Policy
Southampton
England
United Kingdom
SO17 1BJ
+44 (0)2380595058
rgoinfo@soton.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/08/41

Results and Publications

Publication and dissemination plan
The study protocol is due to be submitted for publication asap. No other additional documentation is currently available. Planned publication of the study results in a high-impact peer reviewed journal ~2021.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4.0	11/06/2018	02/10/2018	No	Yes
Protocol article	protocol	18/08/2019	02/09/2020	Yes	No
Interim results article	data gathered before March 2020	26/04/2022	27/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study	19/05/2020	17/11/2023	Yes	No
Results article		01/03/2025	10/03/2025	Yes	No