ISRCTN78426775 https://doi.org/10.1186/ISRCTN78426775

Promotion of mental well-being in older people

Submission date
23/02/2016

Recruitment status
No longer recruiting

Registration date
24/02/2016

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Health problems, losing touch with people and death of a spouse and/or friends can be difficult experiences for the aging population. For these reasons, older people are especially vulnerable to feelings of loneliness and melancholy (sadness). There is a lot of evidence to suggest that feeling lonely and depressed can have a negative effect on physical health and can even lead to premature (early) death. Previous studies have shown that social relationships and active participation in social activities can help to maintain and promote good health in ageing people. This study will provide a range of different programs designed to improve social interaction amongst older people, including exercise, group social activities (such as day trips) and personal counselling sessions helping people to become more resilient and independent. The aim of this study is to find out whether taking part in social activities such as these can help to lower feelings of melancholy and loneliness in people in their late seventies.

Who can participate?
Adults aged between 75 and 79 who live at home and are feeling lonely or melancholy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given the choice as to whether they would like to take part in an exercise, social activity or personal counselling program. For those who choose the exercise group, participants attend 20 hour-long sessions once a week for six weeks, in which they complete a variety of different exercises in groups led by a sports instructor. For those who choose the social activity groups, participants attend 20 two-hour-long sessions once a week for six weeks, in which they take part in activities such as arts and crafts or day trips. For those who choose the personal counselling group, they are able to meet with a counsellor on a one-to-one basis over the six week period as many times as suits their needs. In these sessions, participants are able to talk to a rehabilitation instructor who helps them to become more independent and take better care of their health and wellbeing. Those in the second group do not receive any additional counselling sessions of any kind during the six weeks of the study. At the start of the study, after the six week counselling period and then 3, 6 and 12 months later, participants in both groups are interviewed in order to find out if there has been any change to their mood and wellbeing.

What are the possible benefits and risks of participating?
Participants who take part in the counselling programs may feel less lonely and happier as they

are able to spend time with others in the groups. There are no notable risks of taking part in this study.

Where is the study run from?
The study is run from the GeroCenter Foundation for Aging Research and Development and takes place at Sport Services of Jyväskylä (exercise sessions), Jyväskylä City Library (social activity sessions) and Jyväskylä Central Area Health Centre (personal counselling sessions) in Finland.

When is the study starting and how long is it expected to run for?
June 2008 to June 2010

Who is funding the study?
1. Ministry of Social Affairs and Health (Finland)
2. Finland's Slot Machine Association (Finland)

Who is the main contact?
1. Professor Riku Nikander (scientific)
2. Mrs Katja Pynnönen (public)

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Effects of social and physical intervention on mental well-being in people aged between 75 and 79: A randomized controlled trial

Acronym
GoodMood-project

Study objectives
1. The six month social and physical intervention decreases depressive symptoms and feelings of loneliness, and increases perceived social togetherness compared to controls
2. The intervention increases quality of life and social and physical activity of participants

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Central Finland Health Care District, 16/09/2008, ref: 9E/2008

Primary study design
Interventional

Study design
Single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental and psychosocial well-being: depressive symptoms, perceived mood and loneliness

Interventions
At baseline, all participants have one counselling meeting before being randomly allocated to intervention and control groups.

Control group: Participants receive no additional counselling for the duration of the study.

Interventions group: Participants are allowed to choose participating either in exercise, social activity, or personal counseling program.
1. Exercise group: Participants attend 20 weekly hour-long sessions guided by municipal sports instructors. The program is planned together with the participants, and the meetings involved various types of exercise.
2. Social activity groups: Participants attend 20 weekly two-hour-long sessions and are

conducted by JAMK University of Applied Sciences. The sessions involve activities such as arts and creative methods, aesthetic experiences and day-trips.
3. Personal counseling group: Participants undergo personal counselling delivered by a rehabilitation instructor. The frequency and number of meetings are determined on a case-by-case basis (approximately 4-5 times per participant). The counselling sessions aim to promote subject's resources and self-efficacy with taking responsibility for one's health and well-being.

The total duration of the intervention is six months. Participants in both groups are interviewed at baseline and after six months during the 6-month trial. The follow-up measurements are conducted 3, 6, and 12 months after the intervention ended. In addition, the participants of intervention group have auditory interviews after the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Number of depressive symptoms are measured using the Geriatric Depression Scale at baseline and 6 months (after the intervention).

Key secondary outcome(s)
1. Perceived mood is measured using the question "How is your mood in general?", response options are: "Always or almost always melancholy", ""sometimes melancholy", or "almost always good", at baseline, 6, 9, 12 and 18 months
2. Feeling of loneliness are measured using the question "Do you feel yourself loneliness?", response options are: "Very rarely or not at all", ""sometimes", "often", or "always almost" at baseline, 6, 9, 12 and 18 months
3. Social togetherness is measured using the Social Provision Scale at baseline and 6 months
4. Subscales of Social Provision Scale: Attachment, Social integration, Guidance, Reliable alliance, Opportunity for nurturance, and Reassurance of worth are measured at baseline 6 months
5. Quality of life is measured using the The World Health Organization Quality of Life (WHOQOL) brief questionnaire at baseline and 6 months
6. Participation in activities outside home is measured at baseline 6 months using the questions “How often do you participate in exercise groups?” and “How often do you have self-directed exercise?”, response options are: “≥5 times per week”, “3-4 per week”, “1-2 times per week”, “less often than once a week”, and “no”. “How often do you participate in activities/hobbies outside home such as day care centers, organizations, clubs, activities in congregation, theatre, exhibitions, museums, library?”, response options are: “Daily or almost daily”, “at least once a week”, “2-3 times in month”, “once a month”, “few times in year”, “less often”, or “not at all”

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Aged between 75 and 79 years
2. Community-dwelling
3. Feeling loneliness and/or melancholy at least sometimes
4. Mini Mental State Examination (MMSE) score over 21
5. Willing to participate

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
223

Key exclusion criteria
1. Not feeling lonely and not feeling melancholy
2. Severe memory problems or MMSE < 20
3. Unwillingness to participate
4. Living in an institution
5. Severe health problems

Date of first enrolment
02/09/2008

Date of final enrolment
19/11/2008

Locations

Countries of recruitment
Finland

Study participating centre
GeroCenter Foundation for Aging Research and Development
Rautpohjankatu 8
Jyväskylä
Finland
40700

Study participating centre
Sport Services of Jyväskylä
Kuntoportti 3
Jyväskylä
Finland
40700

Study participating centre
City Library
Vapaudenkatu 39-41
Jyväskylä
Finland
40101

Study participating centre
Central Area Health Centre
Tapionkatu 7
Jyväskylä
Finland
40100

Sponsor information

Organisation
GeroCenter Foundation for Aging and Development

Funder(s)

Funder type
Government

Funder Name
Sosiaali- ja Terveysministeriö

Alternative Name(s)
Ministry of Social Affairs and Health, Social- och Hälsovårdsministeriet

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Finland

Funder Name
Finland’s Slot Machine Association

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No
Other publications		06/07/2017	15/03/2023	Yes	No