Promoting wellbeing through active ageing

Submission date 30/08/2017	Recruitment status No longer recruiting	[X] Prospe [X] Protoc
Registration date 30/08/2017	Overall study status Completed	[_] Statisti [X] Results
Last Edited 19/10/2021	Condition category Other	[_] Individu

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Plain English summary of protocol

Background and study aims

All too often, policy makers consider active ageing as disability prevention and a way to save on health and social care budgets. Such an approach represents older people as a burden for society thus raising the risk of discrimination and so-called "ageism". In this study active ageing is defined as an interplay between ability, activity, ambition and autonomy. Based on this approach a counselling intervention will be developed to promote active ageing with the older people's own activity goals as the starting point. The aim of this study is to assess the effect of individualized counselling on promoting active ageing and wellbeing.

Who can participate?

Older people aged 75 or 80 who live independently in the community in the City of Jyväskylä with moderate levels of physical activity

What does the study involve?

Participants are randomly allocated to either the intervention group or the control group. The control group receive written general health information. Over 12 months participants in the intervention group receive individually tailored counselling in a face-to-face session and phone calls. During the face-to-face counselling session, participants are encouraged to set goals according to their interests regarding activities and behaviours that they would like to introduce to or increase in their everyday life. During the follow up phone calls they discuss their progress on achieving their goals, share their successes, failures, and are encouraged to continue their efforts towards active ageing. During the first face-to-face counselling session, an information booklet regarding active ageing activities and behaviours and a Newsletter is given to them. The information booklet includes tips and self-help exercises to be used as an additional support.

What are the possible benefits and risks of participating?

Participants may benefit from receiving practical information on ways to promote their wellbeing through active agency based on their goals. By participating in this study, participants help researchers to better understand active aging and well-being and to find ways to promote active aging and well-being. Eventually, this and other studies in this area may provide opportunities to change the recommendations for health promotion of older people and impact policies. The interviews, tests and intervention do not exceed the strain of daily life and no other side effects are expected.

Where is the study run from? University of Jyväskylä (Finland)

When is the study starting and how long is it expected to run for? January 2017 to December 2019

Who is funding the study? European Research Council

Who is the main contact? Prof. Taina Rantanen taina.rantanen@jyu.fi

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers The European Research Council Grant Agreement 693045 AGNES

Study information

Scientific Title The effect of individualized counselling on promoting active ageing and wellbeing

Acronym

AGNES-PROMO

Study objectives

To develop and test feasibility and effectiveness of a multicomponent sustainable individually tailored counselling intervention aiming to promote active ageing in community-dwelling older people. The overall goal of the counseling intervention is to promote active ageing, that is, any participation in valued life activities. Current evidence suggests that physical, social, cultural and generative activities predict more favorable health trajectories among older people. Individualized counselling supporting the autonomy and agency of the participants in striving for their individualized goals will increase active ageing and wellbeing.

Ethics approval required

Old ethics approval format

Ethics approval(s) Central Finland Health Care District Ethical Committee, 23/08/2017, Protocol No 7/2017

Study design Single-centre single-blind randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Home

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Active ageing and wellbeing

Interventions

The overall goal of the 12-month counseling intervention is to promote active aging, that is, any participation in valued life activities. The intervention development is based on the COM-B model and the Behavior Change Wheel framework. The Self-determination theory and the Theory of Planned behavior are the two theoretical frameworks that their constructs are used as hypothesized mechanisms that will be activated to produce the expected changes. A health information group will function as control group.

Participants will be randomized to intervention or control group following the baseline assessments using a computer generated randomization scheme, which is stratified by age and sex.

The counseling intervention condition includes a face-to-face counselling session and 4 followup counselling phone calls in month 2, 4, 6, and 9. During the face-to-face counselling session, participants will be encouraged to set goals according to their interests regarding activities and behaviors that they would like to introduce to or increase in their everyday life. During the follow up phone calls there will be a discussion regarding their progress on achieving their goals, share their successes, failures, and they will be encouraged to continue their efforts towards active ageing. During the first face-to-face counseling session, an Information Booklet regarding active ageing activities and behaviors and a Newsletter will be delivered to them. The information Booklet will include tips and self-help exercises to be used during the one year of the intervention program as an additional support. Additional newsletters will be sent by post in month 1, 3, 6, and 9 in order to increase their knowledge about available opportunities in the area of Jyvaskyla.

The health information control group will receive by post printed general health information material during months: 1, 3, 6, and 9, which is used in the usual health care services for older people. After completion of all study assessments, participants of the health information control group will receive the Information Booklet regarding active ageing activities and behaviors that counseling intervention participants received during their initial counseling session.

Intervention Type

Behavioural

Primary outcome measure

Active ageing, measured using the University of Jyväskylä Active Aging scale (UJACAS) pre-trial, at 6 months and at 12 months (post-trial)

Secondary outcome measures

Current secondary outcome measures as of 30/05/2018:

1. Wellbeing, assessed with the Ryff scale pre- and post-trial

2. Depressive symptoms, assessed with the Center for Epidemiologic Studies Depression Scale (CES-D) pre- and post-trial

3. Quality of life, assessed using the Older People's Quality of Life questionnaire (OPQOL-brief) pre- and post-trial

4. Autonomy in outdoor mobility, assessed using a subscale of the Impact of Participation and Autonomy scale (IPA) pre- and post-trial

5. Mobility, assessed with the University of Alabama at Birmingham Life-space mobility assessment (LSA) pre- and post-trial

6. Physical activity, assessed objectively with trial axial accelerometers and using self-reports (the Yale Physical Activity Survey for Older Adults [YAPS]) pre- and post-trial

7. Personal goals studied with an open-ended question modified from the Personal Project Analysis

8. Autonomy in outdoor mobility assessed with the 'autonomy outdoors' subscale of the Impact on Participation and Autonomy questionnaire

Previous secondary outcome measures:

1. Wellbeing, assessed with the Ryff scale pre- and post-trial

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3. Quality of life, assessed using the Older People's Quality of Life questionnaire (OPQOL-brief) pre- and post-trial

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Autonomy scale (IPA) pre- and post-trial 5. Mobility, assessed with the University of Alabama at Birmingham Life-space mobility assessment (LSA) pre- and post-trial 6. Physical activity, assessed objectively with trial axial accelerometers and using self-reports (the Yale Physical Activity Survey for Older Adults [YAPS]) pre- and post-trial

Overall study start date

01/01/2017

Completion date

30/09/2019

Eligibility

Key inclusion criteria

Current inclusion criteria as of 30/05/2018:

- 1. Living independently in the community
- 2. Aged 75 or 80 years
- 3. University of Alabama at Birmingham Life-Apace mobility Assessment (LSA) score between

52.3 - 90.0

- 4. No evident cognitive decline
- 5. Participants will be recruited from a cohort study

Previous inclusion criteria:

- 1. Living independently in the community
- 2. Age 75, 80 or 85

3. University of Alabama at Birmingham Life-Apace mobility Assessment (LSA) score between 52.3 - 90.0

- 4. No evident cognitive decline
- 5. Participants will be recruited from a cohort study

Participant type(s)

Healthy volunteer

Age group

Senior

Sex

Both

Target number of participants

200, half in the intervention and half in the control condition

Total final enrolment 204

Key exclusion criteria

1. Mini-Mental State Examination score (MMSE) of 24 or lower

2. Unwillingness to participate

Date of first enrolment 20/09/2017

Date of final enrolment 19/06/2018

Locations

Countries of recruitment Finland

Study participating centre Gerontology Research Center, Faculty of Sport and Health Sciences, University of Jyväskylä PO Box 35 (viv) Jyväskylä Finland Fi-40014

Sponsor information

Organisation University of Jyvaskylä

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Sponsor type University/education

Website www.jyu.fi

ROR https://ror.org/05n3dz165

Funder(s)

Funder type Research council Funder Name European Research Council

Alternative Name(s) ERC

Funding Body Type Government organisation

Funding Body Subtype National government

Location

Results and Publications

Publication and dissemination plan

Study protocol will be published in 2018. The knowledge produced by this project is communicated to the scientific community through articles published in international scientific journals and presentations in scientific and professional congresses. The trialists prioritize open access publishing and comply with the JyU recommendation for parallel publishing in the open access digital JYX repository. They will inform the general public about the research results through traditional and social media. After the end of the intervention, the effects on the main outcome will be reported in an international peer-reviewed journal during the year 2020. Publications on secondary outcomes will follow in 2020-2022.

Intention to publish date

30/09/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	07/01/2019		Yes	No
Results article		01/04/2020	19/10/2021	Yes	No
<u>Results article</u>		07/01/2019	19/10/2021	Yes	No
<u>Results article</u>	Secondary analyses	10/06/2020	19/10/2021	Yes	Νο