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Feasibility of the adapted LiFE (aLiFE) intervention – a pilot study

Submission date 21/04/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/05/2016	**Overall study status** Completed	
Last Edited 15/04/2020	**Condition category** Other	

Plain English Summary
Background and study aims
A new behaviour change exercise programme named “adapted Lifestyle-integrated Exercise Program (aLiFE)” has been developed within the EU-funded project “PreventIT” (http://www.preventit.eu/). This study aims to evaluate the feasibility of the new aLiFE programme in young older adults aged 60-70.

Who can participate?
Community-dwelling men and women aged 60 to 70

What does the study involve?
The aLiFE programme is delivered by a specialist instructor during 4 home visits. The instructor teaches the participants balance and strength exercises which they can incorporate into their daily life. Participants are also taught to increase their physical activity level. Before and after the intervention participants undergo an assessment of their functional performance. After the intervention, participants are asked about their opinions regarding the aLiFE training.

What are the possible benefits and risks of participating?
Participants may benefit from the intervention in terms of improving their functional performance and increasing their physical activity, although this is not the aim of this study. The aim is to evaluate the participants’ opinions about the programme. The risk of adverse events during aLiFE training is estimated to be low.

Where is the study run from?
1. Robert-Bosch Hospital Stuttgart (Germany)
2. VU University Medical Center Amsterdam (Netherlands)
3. Norwegian University of Science and Technology (Norway)

When is the study starting and how long is it expected to run for?
January 2016 to December 2016

Who is funding the study?
European Commission Horizon 2020

Who is the main contact?
Dr Michael Schwenk

Contact information

Type(s)
Scientific

Contact name
Dr Michael Schwenk

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70376

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility of the adapted Lifestyle-integrated Exercise (aLiFE) Programme for improving functional performance and increasing physical activity in young older adults: a multicentre pilot study

Acronym
aLiFE pilot

Study hypothesis
Primary hypothesis: a newly developed adapted Lifestyle-integrated Exercise (aLiFE) Programme is feasible and well accepted in a sample of young older adults who are 60 to 70 years of age.

A secondary aim is to test the feasibility of different balance scales in young old adults regarding appropriateness, ceiling effects, and reliability in the target population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Stuttgart: Ethik-Kommission am Universitätsklinikum Tübingen, 07/04/2016, 033/2016BO2
2. Amsterdam: Medical Ethical Committee, VU University Medical Center, 13/04/2016, NL56456.029.16
3. Trondheim: REC central, anticipated date of approval 29/04/2016, central midt 2016/48

Study design
4-week one-group pre-post test intervention study

Primary study design
Interventional

Secondary study design
Pre-post test

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition
Preventing functional decline in older adults

Interventions
The adapted Lifestyle-integrated Exercise (aLiFE) programme is an adapted version of the LiFE programme developed by Clemson et al. (BMJ 2012;345:e4547). aLiFE includes strength, balance, and physical activities integrated in everyday life, so that the activities can be performed in natural settings multiple times throughout the day. The aLiFE programme has been specifically adapted to fit people between 60 to 70 year of age.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of aLiFE as defined by:
1. Willingness to participate
2. Adherence
3. Possible harms
4. Acceptability (rating of helpfulness, safety, level of difficulty, and adaptability)
5. Participants' views on:
5.1. Planning and engaging in aLiFE activities
5.2. The aLiFE manual
5.3. Support from the trainers
5.4. Their ideas for improving the programme (semi-structured interviews)

Secondary outcome measures

Appropriateness of balance scales in the population of young old adults (ceiling effects, reliability)

Overall study start date
01/01/2016

Overall study end date
21/12/2016

Eligibility

Participant inclusion criteria
Community dwelling men and women at age 60 to 70 years

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
30

Total final enrolment
51

Participant exclusion criteria
1. Inability to walk 500 meters without aid
2. Cognitive impairment (Montreal Cognitive Assessment, MOCA ≥24 points)
3. Existence of severe cardiovascular, pulmonary, neurological, or mental disease where exercise is contraindicated
4. Attending organised exercise classes more than twice a week and/or not exercising more than 2 hours on their own each week

Recruitment start date
01/05/2016

Recruitment end date
31/08/2016

Locations

Countries of recruitment
Germany

Netherlands

Norway

Study participating centre
Robert-Bosch Hospital Stuttgart
Germany
70376

Study participating centre
VU University Medical Center Amsterdam
Netherlands
1007

Study participating centre
Norwegian University of Science and Technology
Norway
7491

Sponsor information

Organisation
Robert-Bosch Hospital Stuttgart (Germany)

Sponsor details
Auerbachstr. 110
Stuttgart
Germany
70376

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/034nkkr84

Funder(s)

Funder type
Other

Funder Name
European Commission Horizon 2020

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
21/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/07/2018		Yes	No
Results article	results	01/07/2019	15/04/2020	Yes	No