







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

<b>Submission date</b> 21/04/2016	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol not yet added
<b>Registration date</b> 03/05/2016	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 15/04/2020	<b>Condition category</b> Not Applicable	 Raw data not yet added
		 Study completed

## 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

**Contact details**  
Robert-Bosch-Krankenhaus  
Abteilung für Geriatrie und Klinik für Geriatriische Rehabilitation  
Auerbachstr. 110  
Stuttgart  
Germany  
70376

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**  
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  $\geq$ 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?
<a href="#">Results article</a>	results	03/07/2018		Yes	No
<a href="#">Results article</a>	results	01/07/2019	15/04/2020	Yes	No