

Fit and Active in Age The Functional Movement Circle for Elderly (FuMoC-E): a new training program to affect fall-related risk factors [Fit und Aktiv im Alter Entwicklung und Evaluation eines gerätegestützten Sturzpräventionszirkels]

Submission date 02/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2014	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Falls are one of the main factors for older people to lose their independence and are often the reason for an older person to move into a nursing home. It is well known that physical activity training programs could prevent falls. These programs include strength and coordination /balance exercises. Our goal is to study the effects of a new training program (Functional Movement Circle for Elderly [FuMoC-E]) on fall-related risk factors.

Who can participate?

Men and women aged over 60 living in the city center of Cologne (Germany).

What does the study involve?

Participants will be randomly allocated to one of four different groups: three intervention groups and one control group. Participants in the three intervention groups will exercise two times per week over 6 months. Participants in intervention group 1 will take part in the FuMoC-E training program, with strength and balance exercises complemented by a track with different daily movements (stair climbing, road curbs) and different surfaces (carpet, stones). The participants of intervention group 2 receive the same training program as intervention group 1 with the exception of not having the track with the daily movements. In intervention group 3 the training is modelled like training in a usual sports club. Participants in the control group are encouraged to maintain their usual activities over 6 months. Afterwards they will get the opportunity to take part in the FuMoC-E program.

What are the possible benefits and risks of participating?

Those taking part will benefit immediately by improving their strength, power, balance and mobility. This will help to prevent falls.

Where is the study run from?

The measurements are set up in the Institute of Movement and Sport Gerontology of the German Sport University Cologne. The FuMoC-E training takes place in a gym in Cologne (Braunsfeld).

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

The study ran from March 2011 to April 2012.

Who is funding the study?

Funding has been provided by ERGO-FIT GmbH & Co. KG, TOYOTA Germany GmbH and the Institute of Movement and Sport Gerontology of the German Sport University, Cologne.

Who is the main contact?

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Study website

<http://www.sportgerontologie.de>

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The Functional Movement Circle for Elderly (FuMoC-E): a randomised controlled trial to determine the effects of a new training program for older people to affect fall-related risk factors [Der Sturzpräventionszirkel (FuMoC-E): Eine randomisierte, kontrollierte Interventionsstudie zur Ermittlung der Auswirkungen eines neuartigen Trainingsprogramms für Ältere auf sturzrelevante Risikofaktoren]

Acronym

FuMoC-E

Study objectives

The aims of the study are:

1. To improve fall-related risk factors in older people
2. To examine relationships between different risk factors
3. To provide a new training program for older people to promote their physical fitness and to prevent falls
4. To compare the effectiveness of different exercise programs (FuMoC-E vs strength and balance training and coordination training)
5. To evaluate the practicability and acceptance of the FuMoC-E training program

It is hypothesized that the implementation of the new training program 'FuMoC-E (Functional Movement Circle for Elderly)' positively affects fall-related risk factors.

Hypothesis 1: The hypothesis is that there will be significant ($p < 0.05$) positive improvements on the following risk factors: isometric and dynamic strength and power, functional mobility, gait parameters, fear of falling and fall frequency after 3, respectively 6 months of training in the FuMoC-E

Hypothesis 2: The hypothesis is that there will be significantly ($p < 0.05$) greater improvements in the intervention group which trained in the FuMoC-E vs the other two intervention groups and the control group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the German Sport University Cologne, 10/08/2010

Study design

Longitudinal interventional pre-post study randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Development and evaluation of a new training program

Interventions

1. Intervention group 1 (IG1):

Participants exercise two times per week over 6 months. Every session comprises 60 minutes (10 min warm-up on a cycling, cross or hand crank ergometer). The IG1 group performs training in the FuMoC-E with strength and balance exercises complemented by a track with different daily movements (stair climbing, road curbs) and different surfaces (carpet, stones). There are six strength exercises, two balance exercises (sensorimotoric exercises) and the track. In the first 8 weeks participants train with 60-75% of 1-repetition maximum (=1RM), 2 sets of 10-12 repetitions and 1 min rest (hypertrophy training), followed by 4 weeks of power training with 40-50% of 1RM, 2 sets and 6-8 repetitions and 2 min rest. The intensity of loading was gradually increased, adapted on subjectively perceived exertion (OMNI-RES scale). In the second 3 months only the intensity is increased on 70-85% of 1RM for the 8 weeks of hypertrophy training and on 60-70% for the following 4 weeks of power training, everything else was equivalent with the same details of the first 3 months (mentioned above). The participants of this group train in pairs, if one partner is training on one station the other partner passes the track with the daily movements, afterwards they change.

2. Intervention group 2 (IG2):

The participants of IG 2 receive the same training program like IG1 with the sole exception of not having the track with the daily movements included in the rests between the sets at each station. The participants train in pairs.

3. Intervention group 3 (IG3):

Participants exercise two times per week over 6 months. Each session includes 60 minutes of exercise. The training is modeled like training in a usual sports club. A 10 min warm-up is followed by the main part of each session which includes different exercises with tools and small equipment to strengthen muscles and improve coordination. At the end of each session a 5-10 min cool-down is realized.

4. Control group (CG):

Participants of the control group are encouraged to maintain their habitual activities over 6 months. Afterwards they will get the opportunity to train in the FuMoC-E.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Health-related fitness:

1. Strength (isometric and dynamic) and power in chest and leg press
2. Balance (modified Romberg Test)
3. Functional mobility (Timed Up & Go Test; Chair Rise Test; Maximum Step Length Test)

4. Gait velocity
5. Time on a track with different daily movements and surfaces

All outcomes are measured at baseline and after 3 and 6 months.

Secondary outcome measures

1. Leisure time and social activities
2. Fall diary
3. Fear of falling
4. Quality of life

All outcomes are measured at baseline and after 3 and 6 months. The fall diary is completed daily and delivered every 3 months.

Overall study start date

01/03/2011

Completion date

01/05/2012

Eligibility

Key inclusion criteria

1. Age \geq 60 years
2. Willing to be randomly assigned to any of the study intervention groups or the control group
3. Willing to participate over a maximum duration of 12 months in the study

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Older persons with one of the following diseases:
 - 1.1. Acute coronary heart diseases
 - 1.2. Thrombophlebitis
 - 1.3. Acute lung diseases
 - 1.4. Infections
 - 1.5. Osteoporosis
 - 1.6. Disc prolapse during the last 6 months
 - 1.7. Neuromuscular diseases
2. Older persons using a walking aid or having a diagnosed walking disorder
3. Older persons who are not able to sit or stand without aid

Date of first enrolment

01/03/2011

Date of final enrolment

01/05/2012

Locations

Countries of recruitment

Germany

Study participating centre

German Sport University Cologne

Cologne

Germany

50933

Sponsor information

Organisation

Ergo-Fit GmbH & Co. KG (Germany)

Sponsor details

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

Ergo-Fit & Co. KG (Germany)

Funder Name

Toyota Germany GmbH (Germany)

Funder Name

German Sport University, Cologne (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration