

Fit for 100: Physical activity offered for very aged persons (Fit für 100: Bewegungsangebote für Hochaltrige)

Submission date 23/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/03/2010	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.ff100.de>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G 24-64-V42A-2534 (01.06.05-31.05.07); G 24-64-V42A-2947 (01.06.07-29.02.08)

Study information

Scientific Title

Multi-level development and evaluation of a preventive strength training programme in residential care: an interventional single-arm multi-centre trial

Acronym

Ff100 (fit for 100 [fit für 100])

Study objectives

Introduction

There is scientific evidence that preventive physical exercise is effective even in high age. The present study focuses on the application and implementation of this knowledge for very aged people living in residential care.

Steps of realisation

1. To conceptualise a scholarly based strength and balance training programme targeting on very old persons endangered by, or actually in, need of care
2. To conduct this programme for the purpose of research and for developing sustainable good practice models.
3. To initiate broad diffusion and establishment of the program in institutions providing geriatric care.

Conceptual framework

1. Different levels of issues and interventions are playing roles, when preventive training in residential care is to be developed and implemented:
 - a. Individual-social level
 - b. Organisational-institutional level
 - c. Political-cultural level
2. Consequently, these levels are also considered in the evaluation of the programme. The evaluation is based on the RE-AIM framework (Glasgow, 2002), including the dimensions Reach, Efficacy/effectiveness, Adoption, Implementation and Maintenance (RE-AIM).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the German Sports University Cologne, approved on 12/01/2009.

Study design

Interventional single-arm multi-centre trial

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Residential geriatric care, frailty, dementia

Interventions

This is a multi-centre study with one year of interventions on multiple levels and four accompanying points of measurement, and a 12 month follow-up.

1. Individual level: Exercises 2 x 60 min training every week over one year, in group sessions (8-12 persons per group).

1.1. The principal part contains ten resistance exercises, covering the main muscle groups

1.2. One to two sets with 10 repetitions (weights can be increased now and then), one minute pauses between sets and exercises

1.3. Sensorimotor and communicative group exercises and games during the opening and closing phases of each group session

1.4. Alternative exercise for persons with no ability to stand

2. Institutional level: Sustainable implementation of training groups:

2.1. Demonstrative and motivating start by instructors belonging to the project

2.2. Training of institutional staff, who stepwise takes over the group

2.3. Supervision and coaching by project staff

2.4. Continuing information of the management and director of the institution, discussion on conditions and possibilities to resume training group after the end of the project

3. Political-cultural level:

3.1. Informing and convincing activities in professional, administrative and governmental contexts (institutionalised meetings and committees, specialised conferences, fairs)

3.2. Public relation activities (press, TV, internet)

3.3. Publication of a manual for implementing new training groups, organisation of a conference

3.4. Establishing an advisory council with renowned experts and public figures

Contact for Scientific Queries:

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Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Individual level:

1. Continuous documentation (every session) of individual participation and individual dumb bell and ankle weights

Institutional level:

2. Number of groups continued without external financial support:

2.1. After the end of the project

2.2. After one year (follow up)

Secondary outcome measures

1. Individual level: Data collection at four times (in the beginning and every 16 weeks):

1.1. Sensorimotor tests:

1.1.1. Timed soda pop test (turning beverage cans)

1.1.2. Five timed chair stands

1.1.3. Ten-second semi tandem balance stand

1.1.4. Rotational flexibility and shoulder flexibility

1.1.5. Grip strength

1.2. Care related assessment:

1.2.1. Subjective well-being

1.2.2. Mini mental state examination (MMSE)

1.2.3. Barthel index

1.2.4. Instrumental activities of daily living (IADL)

2. Institutional and political-cultural level: Qualitative outcome description after 12 months by quantitative and qualitative analysis of media response and structured interviews with stakeholders

Overall study start date

01/06/2005

Completion date

31/05/2008

Eligibility**Key inclusion criteria**

Political-cultural level:

1. Different administrative districts must be represented

2. Pre-selection of five regions by the Seniors' Agency of North-Rhine Westphalia

Institutional level:

1. Each geriatric residence found in the preselected regions was included in a 3-stage selection

and negotiation process

2. Selection criteria focused on general professional quality and readiness for a commitment to the project, in order to raise the probability of gaining sustainable models of good practice

Individual level:

1. Participants (men and women above 80 years of age) should be able to stand with assistance and to understand instructions.
2. Group integration of a small number of persons with no ability to stand (alternative exercises) or with orientation disorders (additional assistant) is possible
3. Participation of own volition
4. Doctor's approval

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

9 institutions (72-108 participants)

Key exclusion criteria

Institutional level:

1. Rate of educated nurses lower than 55%
2. Less than 60 ambulating residents
3. No staff to guide residents to/from the exercises
4. No staff to take part in the project training
5. Not enough room for regular group exercise

Individual level:

1. Residents not able to take part in a group activity
2. Refusal for medical condition

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2008

Locations

Countries of recruitment

Germany

Study participating centre

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Sponsor information

Organisation

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Sponsor type

University/education

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ROR

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Funder(s)

Funder type

Government

Funder Name

Ministry of Work, Health and Social Affairs of the state North-Rhine Westphalia (Germany) (ref: G 24-64-V42A-2534 [01/06/05-31/05/07]; G 24-64-V42A-2947 [01/06/07-29/02/08])

Funder Name

German Sport University Cologne (Germany)

Funder Name

University of Bonn (Germany)

Funder Name

Seniors' Agency of North-Rhine Westphalia (Germany)

Funder Name

State Sport Federation of North-Rhine Westphalia (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