

New activity choices for patients with dementia and their family member carers - establishment and evaluation of the Fit for 100 training as a new support program. [Neue Aktionsräume für menschen mit Demenz und ihre Angehörigen - NADiA]

Submission date 24/03/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 04/05/2011	Overall study status Completed	☐ Protocol
Last Edited 01/05/2013	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
24.17.01-62-V42A-3372

Study information

Scientific Title

Joint physical exercise with elderly patients with dementia and their family member carers in a two arm block randomized controlled trial: Does the "Fit for 100" training program support functional independence and help to decrease burden of care at the same time?

Acronym

NADiA

Study objectives

A new strength training programme has been developed in accordance to modern training principles and has been proved feasible for the elderly (ISRCTN55213782). The main question is now, whether the new programme can counteract or prevent the strength decline of patients with dementia and at the same time ease the physical capacity of their family member carers (FMC), who as a general rule belong to the elderly target group themselves.

Hypothesis: In comparison to the control group, the training programme increases

1. Physical capacity
2. Activities of daily living in the patients with dementia

The family member carers can achieve:

1. An increase in physical capacity
2. A decrease in the burden of home care

Please note that as of 01/05/2013, the anticipated end date of this trial was updated from 31/03/2013 to 31/12/2013

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the German Sport University Cologne, approved on 26/05/2009

Primary study design

Interventional

Study design

Two arms 3 phase multicentre block randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Dementia

Interventions

1. 12 week learning and 12 week strength exercise phase for intervention group
2. 12 week control phase + 12 week learning phase + 12 week strength exercise phase for control group

3. The exercise programme has been described in another trial (ISRCTN55213782)
4. It contains ten resistance exercises, covering muscle groups necessary for everyday movements, carried out in a slow, controlled manner
5. One or two series, ten repetitions per set, intensity about 80% of 1 repetition max
6. Exercise programme 2x60min/week over at least 24 weeks in a joint group for both the patient and family carer
7. General activation programme (social, cognitive) 2x60min/week from week 1 to week 12 in a joint group for both the patient and family carer
8. Afterwards the exercise programme 2x60min/week over 12 weeks will be offered compensatory

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Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Burden Scale for Family Carergivers (BSFC)
2. Functional independence measure plus functional assessment measure, UK FIM+FAM

Key secondary outcome(s)

1. Cognitive ability using the Mini Mental State Examination, MMSE, (German version - MMST)
2. Activities of daily living (ADL) - Barthel Index & Instrumental Activities of Daily Living (IADL)
 - 2.1. Timed "up and go"
 - 2.2. Physical ability - hand grip force
 - 2.3. Chair stand test - standing on a force plate in different foot positions (parallel, semi.tandem, tandem)
 - 2.4. Shoulder flexibility
 - 2.5. Hand-eye coordination test
 - 2.6. Actual quantity of motor activity in five categories, using a tridimensional accelerometer
 - 2.7. Daily movement questionnaire

Completion date

31/12/2013

Eligibility

Key inclusion criteria

Patients:

1. Diagnosed dementia
2. Ability to stand
3. Ability to work in groups
4. Written informed consent (acclamation by custodian)

Family member carers:

1. Willing to accompany the patient
2. Willing to participate in joint training

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients:

1. Mini mental state examination (MMSE) lower than 10
2. MMSE between 10 and 15 and Barthel-Index lower than 60.
3. For both groups: disapproval by the attending doctor

Date of first enrolment

01/04/2010

Date of final enrolment

31/12/2013

Locations**Countries of recruitment**

Germany

Study participating centre

Am Sportpark Müngersdorf 6

Cologne

Germany

50933

Sponsor information

Organisation

Institute of Sport Gerontology, German Sport University Cologne (Germany)

ROR

<https://ror.org/0189raq88>

Funder(s)**Funder type**

Government

Funder Name

Ministry of Work, Health and Social Affairs of the state North-Rhine Westphalia (Germany) (ref.: 24.17.01-62-V42A-3372)

Funder Name

Equalisation fund of the public long-term care insurance

Funder Name

German Sport University Cologne (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes