

# 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]

<b>Submission date</b> 24/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/05/2013	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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.nadia-projekt.de>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Study design**

Two arms 3 phase multicentre block randomised 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 a patient information sheet

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/04/2010

### **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

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

200 participants; 100 patients, each together with one family member carer.

### **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

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## **Sponsor information**

**Organisation**

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

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**Sponsor type**

University/education

**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**

**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