

# MAKS aktiv! Multi-modal activating therapy for dementia patients in nursing homes (activating therapy concerning everyday activities, exercise, cognitive and spiritual elements)

<b>Submission date</b> 27/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.maks-aktiv.de>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Elmar Gräßel

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

LT-DEMENZ-44-059

## **Study information**

### **Scientific Title**

Multi-modal activating therapy for dementia patients in nursing homes: a randomised controlled trial with an intervention group (standard care plus non-pharmacological activating therapy) and a control group (standard care)

### **Acronym**

MAKS aktiv!

### **Study objectives**

Principal aim of the study:

To prove the effectiveness of an intensive intervention consisting of everyday activities, cognitive, motor and exercise elements on dementia patients' cognitive and activities of daily living (ADL) capacities in five nursing homes.

Principal hypothesis:

In the 6 months observation period the multi-modal activating therapy results in significantly better cognitive and ADL capacities within the intervention group compared to the control group in the way that the capacities of the intervention group remain on average on their initial level, whereas the control groups' capacities decrease according to the disease's progression.

As of 30/07/09 this trial has been updated. Please note that recruitment for this trial has been completed. Patients wishing to learn more about the trial may use the contact details below to request more information or get informed at the trial's official website <http://www.maks-aktiv.de>

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics committee of the Faculty of Medicine of the University Erlangen Nuremberg gave approval on 10th July 2008 (ref: 3232)

### **Study design**

Multicentre randomised controlled single-blind intervention study

### **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**

Intervention:

Multi-modal activating therapy, consisting of everyday activities, exercise, cognitive and spiritual elements, in five groups of ten persons each, two hours per day, six days per week, for at least six months.

Control:

Standard care (no changes in the care situation).

Baseline data (t0) is collected directly before the 6 months intervention period. After the 6 months the first follow up outcome data (t1) is collected. Further follow ups are planned at 1.5 and 2.5 years after t1. This design is equivalent for all treatment arms (intervention and control group).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Competences in activities of daily living (ADL) operationalised with the Erlangen Test of Activities of Daily Living (E-ADL Test); score (0 = no ADL function, 30 = normal ADL function)
2. Cognitive abilities operationalised with the cognitive subtest of the Alzheimer's Disease Assessment Scale (ADAS-kog); score (0 = no cognitive impairment, 70 = severe impairment)

Primary and secondary outcome measures are collected for every participant individually in the week before (t0) and after (t1) the six months intervention period. For most of the participants the first measurements is from 20th to 31st October (t0) and again from 4th to 15th of May (t1). Participants who join the project at a later date to replace another participant who had to be excluded will have their t0 in the months of November 2008 until May 2009 and their t1 six months later, at the latest in November 2009.

**Secondary outcome measures**

1. Instrumental Activities of Daily Living (IADL) operationalised with the subscale IADL of the Nurses Observation Scale for Geriatric Patients (NOSGER); score (5 = full IADL function, 25 = no IADL function)
2. Global geriatric symptomatology operationalised with the NOSGER cumulative value; score (30 = no impairment, 150 = severe impairment)
3. Level of nursing care dependency operationalised with the level of care according to the criteria of the German Health Insurance companies (no level of care = no care necessary, level 3 =

highest level of care) and the Barthel-Index; score (0 = total care dependence, 100 = independent)

4. Care requirements and time cost operationalised with the Resource Utilisation in Dementia (RUD), items for ADL, IADL and supervision; score (time in minutes per day)

Primary and secondary outcome measures are collected for every participant individually in the week before (t0) and after (t1) the six months intervention period. For most of the participants the first measurements is from 20th to 31st October (t0) and again from 4th to 15th of May (t1). Participants who join the project at a later date to replace another participant who had to be excluded will have their t0 in the months of November 2008 until May 2009 and their t1 six months later, at the latest in November 2009.

#### **Overall study start date**

01/09/2008

#### **Completion date**

30/11/2009

## **Eligibility**

#### **Key inclusion criteria**

102 inhabitants of 5 nursing homes in Germany:

1. Existence of an degenerative dementia syndrome (diagnosed by a physician according to International Classification of Diseases, version 10 [ICD-10])
2. Mini-Mental State Examination (MMSE): value less than 24 points
3. Level of care of 0, 1 or 2 (not 3) according to the criteria of the German Health Insurance companies
4. Existence of an informed consent of the patient or his/her legal guardian

#### **Participant type(s)**

Patient

#### **Age group**

Senior

#### **Sex**

Both

#### **Target number of participants**

102 complete data sets, i.e. about 135 participants

#### **Key exclusion criteria**

1. Psychiatric-neurological disease other than dementia that explains the cognitive impairment (e.g. schizophrenia)
2. Purely vascular dementia (diagnosed by physician)
3. Level of care equals 3
4. Blindness
5. Deafness
6. Being bed-ridden
7. Other severe obstacle for participating in the intervention group

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

30/11/2009

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

University Hospital Erlangen

Erlangen

Germany

91054

## **Sponsor information**

**Organisation**

German Federal Ministry of Health (Bundesministerium für Gesundheit [BMG]) (Germany)

**Sponsor details**

c/o Dr. S. Gehring

Projekträger Gesundheitsforschung at the DLR

on behalf of the German Federal Ministry of Health

Heinrich-Konen-Str. 1

Bonn

Germany

53227

**Sponsor type**

Government

**Website**

[http://www.bmg.bund.de/cln\\_117/nn\\_1168252/SharedDocs/Standardartikel/DE/AZ/L/Glossarbegriff-Leuchtturmprojekt-Demenz.html](http://www.bmg.bund.de/cln_117/nn_1168252/SharedDocs/Standardartikel/DE/AZ/L/Glossarbegriff-Leuchtturmprojekt-Demenz.html)

**ROR**

<https://ror.org/05vp4ka74>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
German Federal Ministry of Health (Bundesministerium für Gesundheit [BMG]) (Germany) (ref: LT Demenz 44-059)

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2012		Yes	No
<a href="#">Results article</a>	follow-up results	05/12/2012		Yes	No