

# Non-pharmacological, psychosocial MAK<sup>S</sup>® intervention for people with dementia in Chinese nursing homes

<b>Submission date</b> 24/07/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/09/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/05/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dementia is one of the most common causes of health impairments in older people. The prevalence of dementia has risen rapidly worldwide in recent years and it is expected that this increase will continue. About 10 to 15 million people with dementia live in China.

Psychosocial interventions have been shown to be highly effective for people with dementia. In particular, the combination of cognitive training, physical training and exercises for activities of daily living are seen to be beneficial. These recommended beneficial aspects are covered by MAK<sup>S</sup>® therapy. MAK<sup>S</sup>® therapy has already been proven to be effective in two large studies for people with mild to moderate dementia in German nursing homes and daycare centers. In both nursing homes and daycare, MAK<sup>S</sup>® therapy showed significant positive effects on the cognitive skills and skills of activities of daily living among people with dementia. Therefore, this multimodal psychosocial intervention has been adapted to the Chinese culture.

The study investigates the effectiveness of the culturally adapted Chinese version of MAK<sup>S</sup>® therapy (SinoMAKS) in people with mild to moderate dementia in Chinese nursing homes.

The primary aim is to prove that the culturally adapted Chinese version of the MAK<sup>S</sup>® therapy – SinoMAKS – will lead to better results in cognitive abilities than the care as usual in nursing homes in China.

The secondary aims are to prove that compared with the control group the SinoMAKS intervention will lead a) to fewer behavioural and psychological symptoms of aggression and agitation, b) fewer limitations in the activities of daily living, and c) a better clinical global impression.

### Who can participate?

People with mild to moderate dementia living in a nursing home in Shenyang, Nanjing or Dalian (China)

### What does the study involve?

This study will compare the culturally adapted psychosocial intervention of MAK<sup>S</sup>® - SinoMAKS - with the care as usual of people with dementia living in a nursing home. Participants are randomly allocated to one of these two groups in each nursing home.

What are the possible benefits and risks of participating?

People with dementia will benefit from participation in a free 6-month multimodal, structured and non-medical activation program (MAKS®). The effectiveness of this program has already been proven in inpatient and day-care settings in Germany. There are no risks to be expected during the study participation, based on the results of previous studies.

Where is the study run from?

1. Chinese Medical University (China)
2. University Hospital Erlangen (Germany)

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

July 2022 to August 2026

Who is funding the study?

Jiangsu Jicui Aging Technology Research Institute (JITRI Aging) (China)

Who is the main contact?

1. Prof. Dr. Elmar Graessel, [elmar.graessel@fau.de](mailto:elmar.graessel@fau.de)
2. Dr André Kratzer, [andre.kratzer@uk-erlangen.de](mailto:andre.kratzer@uk-erlangen.de)
3. Prof. Yu Liu, [liuyubmu@163.com](mailto:liuyubmu@163.com)

## Contact information

### Type(s)

Public, Principal Investigator

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**Type(s)**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

24-162-B

## Study information

**Scientific Title**

SinoMAKS - a randomised controlled study to test the efficacy of the Chinese version of the non-pharmacological, multimodal MAKS® intervention for the treatment of degenerative dementia in mild and moderate stages

## Acronym

SinoMAKS

## Study objectives

Primary hypothesis:

1. Compared to the control group (care as usual), people with mild to moderate dementia in the intervention group will have significantly better cognitive abilities at 6 months after baseline.

Secondary hypotheses:

2. Compared to the control group, people with mild to moderate dementia in the intervention group will have significantly fewer behavioural and psychological symptoms of aggression and agitation at 6 months after baseline.

3. Compared to the control group, people with mild to moderate dementia in the intervention group will have significantly fewer limitations in activities of daily living at 6 months after baseline.

4. Compared to the control group, people with mild to moderate dementia in the intervention group will have significantly better clinical global impression at 6 months after baseline.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

1. Approved 14/05/2024, Ethics Committee of the Medical Faculty, Friedrich-Alexander-Universität Erlangen-Nürnberg (Krankenhausstraße 12, Erlangen, 91054, Germany; +49 (0) 91318522270; ethikkommission@fau.de), ref: Ref. 24-162-B

2. Approved 06/09/2024, Ethics Committee of the China Medical University (No.77 Puhe Road, Shenyang North New Area, Shenyang, 110122, China; +86 (0)24 31939080; kyccgk@cmu.edu.cn), ref: 2024-181

## Study design

Prospective randomized controlled intervention study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Care home

## Study type(s)

Prevention, Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Dementia

## **Interventions**

The nursing home residents who are suitable for participation in the study according to the screening and who agree to participate in the study are randomly allocated to intervention and control group in a 1:1 ratio. This is stratified by the severity of dementia.

Participants are randomly allocated into one of the two groups:

Arm 1: SinoMAKS-therapy (intervention group)

Arm 2: care as usual (control group)

The intervention period is 6 months with a subsequent follow-up phase for both study arms of a further 6 months. Within these 6 months follow-up phase, the nursing homes are free to offer MAKS to the intervention group.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Cognition measured by the validated Chinese version of the Addenbrooke's Cognitive Examination-III (ACE-III) at baseline and after 6 and 12 months

## **Secondary outcome measures**

1. Behavioral and psychological symptoms agitation and aggression measured by the validated Chinese version of the Cohen-Mansfield Agitation Inventory – Short Form (CMAI-SF) at baseline and after 6 and 12 months

2. Activities of daily living measured by the Erlangen Test of Activities of Daily Living – Chinese version (E-ADL-CN) at baseline and after 6 and 12 months

(Note: the E-ADL-CN is a newly developed, cultural adapted form of the Erlangen Test of Activities of Daily Living, being validated before the start of the study in people with dementia in Chinese nursing homes)

3. Clinical global impression measured by the two scales Clinical Global impression-severity score (CGI-S) and the Clinical Global impression-improvement (CGI-I) score at baseline and after 6 and 12 months

## **Overall study start date**

01/07/2022

## **Completion date**

30/08/2026

## **Eligibility**

### **Key inclusion criteria**

1. Criteria of the dementia syndrome according to International Classification of Diseases (ICD) -10
2. Mild to moderate dementia:  $9 < \text{Mini Mental State Examination (MMSE) score} < 24$
3. Basic language skills as well as reading and spelling skills (Chinese)
4. Informed consent given

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

Patient, Resident

### **Age group**

Senior

**Sex**

Both

**Target number of participants**

200 people with dementia from about 17 nursing homes in Shenyang, Nanjing and Dalian, China

**Total final enrolment**

230

**Key exclusion criteria**

Current participant exclusion criteria as of 17/03/2025:

1. Completely blind or deaf
2. Permanently unable to get out of bed/immobile
3. Did not graduate from elementary school, i.e. less than 6 years in elementary school
4. Unable to communicate (does not respond to simple closed questions)
5. Diagnosis of another disease that causes cognitive impairment:
  - 5.1. Vascular events (e.g. multiple strokes)
  - 5.2. Parkinson's disease
  - 5.3. Multiple sclerosis
  - 5.4. Severe brain disease (e.g. tumor, injury, hydrocephalus)
  - 5.5. Psychosis (e.g. schizophrenia, mania, bipolar psychosis)
  - 5.6. Severe depression
  - 5.7. Alcohol abuse/drug consumption (addiction) or Korsakoff syndrome
6. Concrete plans/vision to move out of the nursing home

Previous participant exclusion criteria:

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2. Permanently unable to get out of bed/immobile
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  - 5.2. Parkinson's disease
  - 5.3. Multiple sclerosis
  - 5.4. Severe brain disease (e.g. tumor, injury, hydrocephalus)
  - 5.5. Psychosis (e.g. schizophrenia, mania, bipolar psychosis)
  - 5.6. Depression
  - 5.7. Alcohol abuse/drug consumption (addiction) or Korsakoff syndrome
6. Concrete plans/vision to move out of the nursing home

**Date of first enrolment**

14/10/2024

**Date of final enrolment**

31/12/2024

**Locations**

**Countries of recruitment**

China

**Study participating centre**

**China Medical University, School of Nursing**

No. 77 Puhe Rd

Shenyang North New Area

Shenyang

China

110122

**Study participating centre**

**Nanjing Medical University**

School of Nursing

101 Longmian Avenue

Jiangning District

Nanjing

China

211166

**Study participating centre**

**Dalian Medical University**

School of Nursing

No.9 West Section

Lvshun South Road

Dalian

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## **Sponsor information**

**Organisation**

Jiangsu Jicui Aging Research Institute of Technology Co., Ltd.

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**Sponsor type**

Research organisation

**Website**

<https://www.agingjitri.com>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Jiangsu Jicui Aging Research Institute of Technology Co., Ltd

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/02/2027

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analyzed during the current study are not expected to be made available because we assure in the participant information sheet that data will not be passed to any third party.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		30/04/2025	01/05/2025	Yes	No