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Non-pharmacological, psychosocial MAKS® intervention for people with dementia in Chinese nursing homes

Submission date
24/07/2024

Recruitment status
No longer recruiting

Registration date
06/09/2024

Overall study status
Ongoing

Last Edited
03/10/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 MAKS® therapy. MAKS® 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, MAKS® 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 MAKS® 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 MAKS® 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 MAKS® - 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?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention, Treatment

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

Key secondary outcome(s))
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

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 < 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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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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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
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China
110122

Study participating centre
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Nanjing
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Study participating centre
Dalian Medical University
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Sponsor information

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

Funder(s)

Funder type
Research organisation

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

Results and Publications

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?
Protocol article		30/04/2025	01/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes