Machine translation of the Chinese original of the "Information and consent form" - prepared in accordance with the specifications and regulations of the China Medical University, School of Nursing

Informed consent

„SinoMAKS – a randomized controlled study to test the efficacy of the Chinese version of the nonpharmacological, multimodal MAKS® intervention for the treatment of degenerative dementia in mild and moderate stages"

Dear Sir, dear Madam,,

We kindly invite you to participate in the above-mentioned study. The study is a joint project between China Medical University, School of Nursing (Director: Prof. Yu Liu) and the Center for Medical Care Research (Director: Prof. Dr. Elmar Gräßel) of the University Hospital Erlangen. The SinoMAKS study will be conducted in approximately 17 nursing homes in Liaoning and Jiangsu provinces, and 200 people are expected to participate voluntarily. The study has been reviewed by the Medical Ethics Committee of China Medical University.

It is your voluntary decision whether or not to participate in this study. Before you decide, please read the following information carefully to better understand the background and intention of the project. If you have any questions, please do not hesitate to ask and the researcher will answer them. If you wish, you can also talk to your relatives and friends to help you make your decision. Below you will find an introduction to the background of this project:

1. Study background

With the ageing population in our country, more and more older people are suffering from cognitive disorders and are being cared for in nursing homes. Cognitive impairment affects the elderly's ability to perform activities of daily living, social interaction, and sometimes even abnormal and agitated behavior that is not understood by others, which is very distressing for both caregivers and the elderly. Unfortunately, there are no effective medications for cognitive disorders worldwide, and the role of non-pharmacological treatments in alleviating the symptoms of older people with cognitive disorders is increasingly emphasized. German experts and scientists have developed the non-pharmacological intervention program MAKS, which focuses on activities of daily living, physical training and cognitive training for older people in nursing homes. The program has achieved very good results in Germany and has been adopted by the German government as one of the official care measures for cognitively impaired elderly people in the country's elderly care facilities.

The Cognitive Nursing Research Group at the School of Nursing of China Medical University plans to introduce this MAKS program in China and adapt it accordingly to better fit the Chinese

situation and culture. In this process, we need to validate the effectiveness of this Chinese-adapted MAKS project. This project is the SinoMAKS project, which we will abbreviate later.

2. Aim of the study

The aim is to test whether the SinoMAKS program is effective for patients with mild and moderate cognitive impairment in Chinese elderly care facilities. The indicators for the effectiveness of this program are the improvement of their ability to take care of themselves in daily life, the severity of abnormal behavioral symptoms and their cognitive functions compared to the control group.

3. Content and study procedure

Over the next few months, the “SinoMAKS” program will be introduced in your care facility.

The study includes a 6-month continuous intervention, followed by a 6-month observation phase without intervention, so that participants are involved in the program for one year. Inclusion criteria for study participants are: mild to moderate dementia (MMSE < 24) that has been psychometrically assessed, basic language skills and literacy (Chinese) and consent to participate in this study. Exclusion criteria for the study participants were: Blindness, deafness; permanent bedriddenness/mobility; no basic literacy skills in Chinese (e.g., writing own name); inability to communicate (no response to simple closed-ended questions); vascular events (e.g., more than one stroke); Parkinson's disease; multiple sclerosis; severe brain disease (e.g., brain tumor, hydrocephalus). (e.g. brain tumor, hydrocephalus, result of brain injury/encephalitis); diagnosis of psychosis (schizophrenia, mania, bipolar disorder); diagnosis of depression; addiction (e.g. substance dependence or Korsakoff syndrome); recent intention to move out of a nursing home; severe dementia (MMSE 0-9).

The allocation of participants will be randomized. This means that neither the care facilities nor the researchers involved will have any influence on the distribution. The main procedure of the study is described below:

MAKS® therapy is a group therapy consisting of four components for up to 12 participants. It consists of motor exercises (M, e.g. bowling, balance exercises), practical activities (A, e.g. arts and crafts, preparing simple meals), cognitive exercises (K, e.g. memorization, picture puzzles) and social-communicative coordination (S). These four components form an intervention that lasts around two hours and is carried out by two trained MAKS® therapists who guide you. Each daily session begins with a ten-minute social-communicative coordination (e.g. welcome round). This is followed by approx. 30 minutes of motor training, in which general mobility, gross and fine motor skills, balance and sensory perception are trained through relaxation exercises, movement games and various types of games and sports. A break is followed by approximately 30 minutes of cognitive training with paper and pencil exercises as well as projector exercises to promote memory, recognition, association and specific cognitive skills such as language comprehension and logical thinking. A final 40-minute practical activity (which also includes housework or manual activities) promotes gross and fine motor skills, mobility and, above all, procedural memory (Eichenseer and Graessel, 2011). MAKS Therapy® is carried out three times a week on Mondays, Wednesdays and Fridays for six months. Other services provided by the nursing home

and the study participants' medication are not affected by the study.

4. What kind of cooperation is required for the study?
We hope that you will be able to participate in the entire study and try not to be absent. In addition, we would like to ask you to cooperate with us in some of the assessments, such as the assessment of your ability to care for yourself in everyday life, the assessment of your cognitive functions and the observation and assessment of your behavior. There will be three assessments, one before the start of the study, one in the 6th month after the start of the study and one in the 12th month after the start of the study. These assessments will consist of questions or observation sheets. We do not need to take any blood or body fluids from you, so you will not be in any pain. Please do not worry.

5. Possible risks, inconveniences and treatment when participating in the study
All information you receive will be treated confidentially. Your personal information and the data collected will be compiled in such a way that others will not be able to tell who you are. You will not have any adverse reactions during the assessment process.

6. Potential benefits and compensation for participating in the research
6.1 Benefits of the study for the subjects themselves
You can receive this series of non-pharmacological interventions for seniors with cognitive impairment that we offer free of charge. If you are in the intervention group, you will receive these methods earlier. If you are in the control group, we will offer you the corresponding non-pharmacological interventions one year later.

6.2 Benefits of the study for social groups
The results of the study may lead to more effective methods of non-pharmacological intervention being available to older people with cognitive impairment in the future. Only if as many people as possible are willing to participate in the study will it be possible to provide better care for cognitively impaired seniors in the future based on the results. That is why your participation is so important!

6.3 Compensation
No financial compensation will be granted for this study.

7. Voluntary participation/withdrawal from the study
Participation in this study is voluntary. You can refuse to participate in the study or withdraw from the study at any time without this affecting your medical treatment, nursing care or your rights.

8. Confidentiality of personal data
All information collected as part of the study will be treated confidentially and stored securely by the researchers. If necessary, the researchers, the members of the ethics committee and the responsible administrative authorities may inspect your pseudonymized documents within the framework of the legal provisions. No information about you personally will be disclosed when

the results of this study are published.

9. Contact information

You can ask questions about this study at any time. You can contact the researcher, contact person: Liu Yu, phone: 18640068209. If you have any questions about the rights and interest in participating in the study itself, you can contact the Medical Ethics Committee of China Medical University, Tel.: 024-31939080.

Informed consent

1 I have carefully read the above description of this study and have had the opportunity to discuss this study with the researcher and ask questions. All my questions have been answered to my satisfaction.

2 I understand that participation in the study is voluntary and I confirm that I have had sufficient time to think about it and that I understand that:

2.1 I am aware of the possible risks of participating in the study and know how to deal with them if they occur;

2.2 I can ask the principal investigator for further information at any time;

2.3 I can withdraw from the study at any time without suffering any disadvantages and that my medical treatment, care and rights will not be affected;

Finally, I have decided to participate in this study and I am willing to cooperate with the researcher in order to conduct the study as foreseen in the study protocol.

Signature of the person with dementia: Date: Phone:

Signature authorized representative: Date: Phone:

(In the case of minors or persons with limited legal capacity, a legal guardian must also sign)

Signature legal guardian: Date: Phone:

I have fully explained and justified to the volunteer the purpose of the study, the procedures and the potential risks and benefits of participating in the project and answered all the volunteer's questions satisfactorily.

Signature researcher: Date: Phone: