The research plan

Identifiers: NCT06785857 **Unique Protocol ID:** K2021-05-024

Brief Title: A Study of Mobile Medical Supportive Care Program for Family Caregivers With Dementia Combined With Diabetes

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Ⅰ Research Background

Alzheimer's disease, a common degenerative disease of the central nervous system, refers to the overall impairment of intelligence, memory and personality that occurs in old age (age ≥60 years), manifested by memory, calculation, thinking, language, orientation and emotional disorders, as well as personality changes, and a decline in the ability to engage in social activities and the ability to live on one's own. The number of dementia patients in China accounts for about a quarter of the global population, making it the country with the largest number of dementia patients in the world. Studies have found that type 2 diabetes is highly susceptible to the development of dementia due to hyperglycemia and insulin resistance, and the risk of vascular dementia in diabetic patients is 2.27 times higher than that in non-diabetic patients. Alzheimer's patients with comorbid diabetes are at high risk for physical and mental health risks due to cognitive impairment and mental and behavioral abnormalities, and are almost incapable of self-care, and are heavily dependent on their caregivers. Caregivers are faced with complex clinical symptoms such as diabetic foot and neuropsychiatric manifestations of dementia, and may even develop a sense of despair

and fear. The provision of holistic, continuous, professional and personalized care services for caregivers is an urgent issue that needs to be addressed.

Ⅱ Purpose of Research

This project aims to build a mobile health supportive care program for family caregivers with dementia combined with diabetes, and to evaluate the clinical application effect of the mobile health supportive care program for family caregivers with dementia combined with diabetes. The research results will provide more economical and efficient care guidance for family caregivers, thus improving the overall quality of care and quality of life for patients with dementia and diabetes.

ⅢResearch Method

（1）Object of Study

1）Source of the study subjects and the sampling methods

The convenience sampling method started from May 2022 to the end of the sample number, and family caregivers with dementia and diabetes in 5 community neighborhood committees (cities) and 10 villages (rural areas) of a community health service center that met the inclusion criteria were selected.

2）Inclusion criteria for the study subjects

Caregivers:

- Carers have legal kinship with the patient (such as spouse, children, or siblings), nannies and hourly workers who do not charge care fees;
- work 8 hours / day and 5 days / week for 1 month;
- aware, reading and understanding adults;
- has at least one smart phone (access to Internet) and skilled use;

- informed consent and voluntary participation in investigation and research.

Care recipients:

- meets the diagnostic criteria for senile dementia;
- meets the diagnostic criteria for type 2 diabetes;
- patients are 60 years old and the resident population in the area.

3）Exclusion criteria for the study subjects

Caregivers:

- severe physical or mental illness;
- people with drug or alcohol dependence;
- caregivers are participating in similar intervention studies.

Care recipients:

- Serious physical illness, major disease or terminal disease;
- patients with drug or alcohol dependence.

4）Sample size estimation

The sample size is calculated according to the ratio of 1:1 between the test group and the control group, and the sample size calculation method of "difference test of two sample means comparison" is used. The calculation formula is:

$$n_1=n_2=2\left[\frac{(\mu_\alpha+\mu_\beta)}{\delta/\sigma}\right]^2+\frac{1}{4}\mu_\alpha^2$$

Based on the literature review, with the caregiver care burden as the main outcome measure of this study, n1 and n2 were the required sample size, respectively; α =0.05, β =0.1, two-sided test, μ0.05/2=1.96,μ0.1=0.282, mean difference δ = 33.91-27.04=6.87, and overall standard deviation of the intervention σ =6.85. After calculation, the sample size of both groups was 22 cases, considering 15% shedding

rate, at least 26 cases in each group, a total of 52 cases. Finally, 30 patients were included in each group, totaling 60 patients.

（2）Research Tool

① General Data questionnaire; ② Caregiver Burden Scale (Caregiver Burden Inventory, CBI); ③ Social Support Rating Scale (Social Support Rating Scale, SSRS); ④ Dementified Caregiver Knowledge Assessment Scale (Dementia Caring Knowledge Scale, DCKS).

（3）Data Processing and Statistical Analysis

Statistical data was analyzed using SPSS 25.0 software. Quantitative data were represented by normal distribution (± s), non-normal by M (QR); qualitative data by n (%). Quantitative data is designed to compare two independent samples. If sample data follows normality, independent sample t-test is used, otherwise Mann Whitney U test is used; for comparison before and after intervention; if the difference follows normal distribution, paired t-test is used, otherwise Wilcoxon rank sum test is used. To compare qualitative data between different groups, use χ 2 test or Fisher's exact test; compare rank data between different groups. Subject analysis (Per-protocol Subjects Analysis, PP).

四、The Project Involves the Implementation Plan of the Ethical Part

- Study subjects, number of cases, intervention methods, enrollment criteria, and exclusion criteria

There were 60 elderly family caregivers with dementia and diabetes, and the intervention method was mobile medical supportive care program. The enrollment criteria were: ① Care nannies and hourly workers with legal kinship (such as spouse, children or siblings), etc.; ② worked for 8 hours / day and 5 days / week for 1 month; ③ well-aware

and reading and understanding adults; ④ has at least a smart phone (Internet access) and skilled use; ⑤ informed consent and voluntary participation in research. Exclusion criteria: ① Severe physical or mental illness; ② patients with drug or alcohol dependence; ③ caregivers are participating in similar intervention studies.

- Specimens to be collected and the sources of the specimens

  No specimens were collected

- Recruitment and protection measures of the subjects

① Recruitment: Select family caregivers of elderly people with dementia and diabetes in 5 community neighborhood committees (cities) and 10 natural villages (rural areas) in the jurisdiction of a community health service center that meet the exclusion criteria.

② Protection: Carers have the right to refuse to answer any items that cause psychological discomfort and provide door-to-door assessment services whenever possible.

- Research risks and preventive measures

No medication or any radioactivity, invasive procedures, and in principle will not cause any risk or adverse effects on the physical health of the subject.

- The benefit of the study

Participation in this study may help subjects to better understand the health of their caregivers, and the intervention is expected to improve their social support function and reduce their care burden and poor mood. However, it is also possible that participation in this study did not directly benefit the subjects.

- Expsts and compensation for subjects' participation in the project

Throughout the study, the subjects were unpaid and no fees were charged to the subjects. When the subject is injured by his participation in this study, the necessary medical measures will be taken for treatment and compensation will be paid in accordance with the current national laws. If in this study, lost work or transportation expenses, reasonable expenses will be compensated.

- Information and confidentiality about the subjects

All information concerning the subject's personal privacy will be kept strictly confidential and only for academic purposes, and will not be disclosed by any public report of the results of this study. This information will not be available if necessary except for the ethics committee and relevant researchers.

- Process and procedure for the signing of the informed consent form

① Designated a member of the research group to explain the purpose, significance and research process of the study to the subjects and their caregivers (legal guardian or legal representative), do a good job in communication and coordination, gain their trust, establish a good cooperative relationship and sign the informed consent form.

② On the principle of the subject to sign together, the investigator and the subject to sign together. For adult subjects who are capable and able to identify themselves and are not illiterate, the legal representative or the legal representative may sign the informed consent, for subjects without capacity, incompetent, unconscious or illiterate to give informed consent, after the oral consent, the witness signed the informed consent on the informed consent form.

③ After recruitment, 20% of the subjects were selected from the population and asked whether they were informed of the study and the content of the informed consent.