Full study protocol and statistical analysis plan

Official Title of the study:

A nurse-led family-oriented resilience program for caregivers of community-dwelling dependent older adults: a three-arm controlled trial

Date of the document: 24th July, 2024

NCT number: not yet assigned

Contents:

1. Participant Flow

Recruitment Details

We will choose 3 communities in Guiyang, a capital city of Guizhou Province in China, to recruit the participants. The recruitment will start at Dec 1st 2024. The recruitment announcement will be distributed to the participants via notice board in community health service center and the online chatting group of the caregivers of the dependent older adults in the community.

Pre-assignment Details [*]

We firstly will assess the recruited people to ensure meeting the inclusion and exclusion criteria. Than the final enrolled participants can be sure and randomized assignment will be conducted.

Enrollment (total, anticipatory)	**105**			Record the number of the eligible and the excluded
Allocation (randomized)	**Group A**	**Group B**	**Group C**	Record the number of the received and the unreceived
	35	**35**	**35**	
Follow-up (immediately after intervention)				Record the number of the received and the unreceived

Arm/Group Information *

There are three groups in the study.

Arm/Group Title *

Caregiving training intervention group= Group A

Caregiving training plus family resilience intervention group= Group B

Usual service controlled group= Group C

Arm/Group Description *§

Group A: The caregivers will receive caregiving training during home visit by nurse.

Group B: The caregivers will receive caregiving training and family resilience promotion during home visit by nurse.

Controlled routine activity group will have routine nursing care delivered by nurses in the community.

Period(s) *

There is only one stage in the study.

Period Title *

Overall Study.

Started *

There will be 105 participants initiating the intervention.

Those 105 participants will be randomly assigned to three groups with around 35 participants in each group.

Completed *

We will do follow-up, and the number in the follow-up will be recorded.

Milestone Title [*]

Before the intervention, we will measure the participants, and the stage is defined as T0.

We will do follow-up immediately after intervention (T1), 1-month (T2) and 3-month post intervention (T3).

Reason Not Completed Type [*]

We will record the exact reason (Adverse Event) why participants do not complete the study. The reason may be death, lack of efficacy, lost to follow-up, illness, withdrawal by subject or others.

2. Baseline Characteristics

Arm/Group Information *

Chi-square test will be applied to figure out the difference of enumeration data among three groups. ANOVA will be applied to test the difference of measurement data among three groups. F values and χ^2 values will be displayed to show the baseline data are no different in three groups.

Arm/Group Title *

Caregiving training intervention group= Group A
Caregiving training plus family resilience intervention group= Group B
Usual service controlled group= Group C

Arm/Group Description *§

All the recruited participants will be numbered and randomly allocated into three groups by random number table. The grouping results will be announced to the participants according to the random number table.

Overall Number of Baseline Participants *

There will be 105 participants initiating the intervention.

Baseline Measure Information *

A group of demographic characteristics will be measured in the study, including gender, age, marital status, income per month, etc.

Baseline Measure Title *

- Age * : Continuous(years)
- Gender * : Female, Male
- Years of caregiving: Continuous(years)
- Income per month: Categorical:
  - <=1000 RMB
  - >1000 and <2000 RMB
  - >=2000 RMB
- Educational level: Categorical:
  - Junior high school
  - Senior high school
  - College and above

Measure Type *

- Count of Participants: Gender of caregiver, gender of the dependent older adults receiving care
- Mean: Age of caregiver, age of the dependent older adults receiving care, Years of caregiving
- Number: Income per month, Educational level, disease of the dependent older adults receiving care

Measure of Dispersion *

- Standard Deviation
- Inter-Quartile Range
- Full Range

Baseline Measure Data *

The value(s) for each baseline measure, for each group and overall cannot obtain right now since the study has not been started.

3. Outcome Measures

Outcome Measure Information *

A questionnaire will be used during each measurement, including several scales in it.

Outcome Measure Type *

- Primary and secondary

Outcome Measure Title *

Primary

- Distress thermometer (DT): used to assess the level of psychological distress of primary caregivers. This scale was designed by Roth and translated into China by Tang Lili et al. in 2011. DT is a visual analog scale scale ranging from 0 to 10 points (0 indicates no psychological distress, 10 indicates extreme psychological distress). The reliability of the Chinese version DT retest is r=0.80, and the calibration validity is good. The reliability and validity of DT among the primary caregivers of disabled elderly have been tested in the

preliminary research of the research group, and it has been verified to have good test-retest reliability and criterion related validity, with a critical value of 5 points.

- The Walsh Family Resilience Questionnaire Chinese Version (WFRQ-C) is used to measure the level of family resilience of primary caregivers. This scale was developed by Walsh based on their concept model of family resilience in 2016, and the Chinese version of the questionnaire was localized and simplified by Wang Anni et al. in 2021. The questionnaire includes three dimensions and 26 items: family beliefs, communication and resolution, and external support. The questionnaire items are evaluated using a Likert 5-point rating system, with scores ranging from 1 to 5 from "never" to "always". The higher the score, the higher the level of family resilience. The Cronbach's alpha coefficient of the questionnaire is 0.93, with a test-retest reliability of 0.96, indicating good validity.
- Caregiver Task Inventory (FCTI): used to measure the caregiving ability of primary caregivers. This scale was developed by Clark and Rakowski in 1983, and later revised into the Chinese version of FCTI by Lee and Mok. This scale consists of 5 dimensions (adapting to caregiver roles, responding to needs and providing assistance, handling personal emotions, evaluating family and community resource professionals, and adjusting life to meet caregiving needs), with a total of 25 items. The Likert 3-level scoring method is used, with scores of 0, 1, and 2 indicating no difficulty, difficulty, and extreme difficulty, respectively. The total score is 50 points, with higher scores indicating more caregiving difficulties for caregivers. The Cronbach's alpha coefficient of the scale is 0.93, indicating good construct validity.

Secondary

- The Zarit Burden Inventory (ZBI) is used to measure the caregiving burden of primary caregivers. This scale was developed by Zarit et al. in the early 1980s, and the Chinese version of the scale was translated and revised by Wang Lie et al. [32] in 2006. This scale is a self-assessment scale consisting of two dimensions: personal burden and responsibility burden, with a total of 22 items. Using the Likert 5-point rating system, the scores range from 0 to 4 from "none" to "always", and the total score is calculated by adding the scores of each item. The higher the score, the heavier the caregiver's burden. Based on the score, the caregiving burden is classified into four levels: $\leqslant$ 19 points indicate no burden, 20-39 points indicate mild burden, 40-59 points indicate moderate burden, and $\geqslant$ 60 points indicate severe burden. The Cronbach's alpha coefficient of this scale is 0.87.
- The Connor Davidson Resilience Scale (CD-RISC) is used to assess the psychological resilience of primary caregivers. Developed by Connor and Davidson in 2003, and translated and introduced to China by Yu Xiaonan et al. in 2008. The Chinese version of CD-RISC includes 3 dimensions (resilience, strength, and optimism), 25 items, and is rated on a scale of 1-5, with higher scores indicating higher levels of psychological resilience. The Cronbach's alpha coefficient of the scale is 0.91, indicating good criterion related validity.
- Simplified Coping Style Questionnaire (SCSQ): used to assess the coping strategies of primary caregivers. This scale was developed by Jie Yaning in 1998. It includes two dimensions (positive coping and negative coping), with 20 items. The positive coping dimension includes items 1-12, and the negative coping dimension includes items 13-20. It is rated on a scale of 0-3 out of 4. The higher the total score of the positive dimension, the more likely the survey respondents are to adopt positive coping methods; The higher the total score of the negative coping dimension, the more inclined the survey respondents are to adopt negative coping strategies. The Cronbach's alpha coefficient of the positive coping style in this scale is 0.89, and the Cronbach's alpha coefficient of the negative coping style is 0.78.
- Perceived Social Support Scale (PSSS): used to measure the perceived level of social support among primary caregivers. This scale was developed by Zemit in 1987 and later translated into Chinese by Huang Li et al. and introduced into China. This scale

consists of 3 dimensions (family support, friend support, and other support), with a total of 12 items. It uses a 7-point scoring system ranging from 1 to 7, with higher total scores indicating higher levels of social support. The Cronbach's alpha coefficient of this scale is 0.92, indicating good test-retest reliability and construct validity.

- The European Five Dimensional Five Level (EQ-5D-5L) health scale: used to measure the quality of life of disabled elderly and primary caregivers. This scale was developed by the European Society for Quality of Life and includes a brief descriptive system questionnaire and a visual analog scale. The system questionnaire evaluates health using five dimensions (mobility, self-care, daily activities, pain/discomfort, anxiety/depression), each dimension containing five levels (no difficulty, slightly difficult, moderate difficulty, severe difficulty, very severe difficulty/inability to proceed), forming a five dimensional and five level health status. This study will use the EQ-5D-5L utility value integration system established by Ronan et al.based on the Chinese population to convert the health status of the research subjects into health utility values, with a utility value range of [-0.391, 1.000]. The closer the utility value is to 1, the better the health status; The visual analog scale is a scale used by research subjects to measure their perceived health level, ranging from 0 (the worst imaginable health state) to 100 (the best imaginable health state). The higher the score, the better their perceived health. The Cronbach's alpha coefficient of this scale is 0.857, indicating good validity. This study adopts the method of peer evaluation for disabled elderly individuals.
- Qualitative Interview outline: What have you gained from participating in the family embedded intervention? What other suggestions do you have for implementing family embedded intervention? What other opinions do you have on carrying out family embedded intervention?

Outcome Measure unit *

The depression, anxiety, and sleeping quality are measured by scales with no unit.

Outcome Measure Time Frame *

We will do follow-up immediately after intervention (T1), 1-month (T2) and 3-month post intervention (T3).

Analysis Population Information

Overall Number of Participants Analyzed *

There will be 105 participants totally enrolled in the study.

Outcome Measure Data Table

Measure Type *

- Mean

Measure of Dispersion/Precision *

- Standard Deviation

Outcome Data *

The measurement value(s) for each outcome measure cannot obtain right now since the study has not been started.

Statistical Analysis Overview

Comparison Group Selection [*]

We will compare three groups' data.

Type of Statistical Test [*]

- Superiority
- Other (descriptive analysis)

P-Value [*]

P-Value will be set at 0.05.

Method [*]

- ANOVA
- Chi-Squared
- t-Test, 2-Sided

- Other: repeated measurement of variance analysis within different measurements among different groups

Estimation Parameter [*]

- Mean Difference (Final Values)

4. Adverse Event Information

Time Frame *§

The intervention lasts around 8 weeks, and we will record the adverse event at each home visit.

Adverse Event Reporting Description [*]

We will add relevant information about adverse event after finishing the study.

Collection Approach for Table Default *§

- Systematic Assessment: The psychotherapist in our research group will routinely determine whether or not certain adverse events have occurred through regular investigator assessment during intervention and in each follow-up.
- Non-Systematic Assessment: Self-reporting by participants or occasional assessment by the psychotherapist.

Adverse Event Term *

The most possible adverse event may be the psychological discomfort because the participants.

We will provide information for in three tables summarizing adverse events in each group, including all-cause mortality, serious adverse events, and other (not including serious) adverse events.

Organ System *

- Psychiatric Disorders

5. Limitations and Caveats

The measurements are mostly based on self-reported scales and may lead to unreliable data. We will invite nurse blind to the allocation to conduct the measurement and give instruction to the participants before fulfilling the questionnaire to ensure the participants understood.

6. Certain Agreements

Are all PIs Employees of Sponsor? *

- No: The principal investigator is not an employee of the sponsor

There is no agreement between the agent (university) and the principal investigators. The principal investigators are graduate students in the university. The principal investigators (PIs) can discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study.

7. Results Point of Contact

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