STUDY PROTOCOL

Effectiveness of a Smart Community- and Home-based Integrated Care Services System for Elderly People in Rural Chinese Communities: A Randomized Controlled Trial in Changsha County

Unique Protocol Number: 234083

Version: V1.0

Date: June 12, 2024

Sponsor: Liu Zhihan

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Protocol Summary

Study Title	Effectiveness of a Smart Community- and Home-based Integrated Care Services System for Elderly People in Rural Chinese Communities: A Randomized Controlled Trial in Changsha County
Version	V1.0
Date	June 12, 2024
Sponsor	Liu Zhihan
Objective	To assess the impact of the smart community home-based integrated care service system on the health of elderly individuals in rural communities.
Study Design	Randomized Controlled Trial
Total Participants	64
Number of Study Centers	1
Study Duration	3 years
Inclusion Criteria:	(1) Age ≥ 60 years (2) Normal verbal communication ability (3) No self-reported visual or auditory impairments (4) A long-term caregiver residing with the participant (5) Both the participant and their family members have given informed consent and voluntarily agreed to participate.
Intervention	Organize information sessions to introduce the “Hunan Province Medical and Elderly Care Smart Service Platform” and encourage elderly individuals in the experimental group to register and use the platform to receive integrated care services.
Statistical Analysis	t-test and ANOVA

1 Background

As the aging population grows, elderly health issues have become a key social concern. Effectively managing the health of elderly individuals and improving their quality of life are urgent needs in society.In recent years, the widespread application of emerging information technologies such as artificial intelligence, the Internet of Things, big data, cloud computing, and 5G has made "smart " a new breakthrough in the integrated healthcare and elderly care model. Smart Community- and Home-based Integrated Care Services , utilizing methods such as home hospital beds and mobile medical visits, ensure that key elderly groups with disabilities, dementia, chronic diseases, advanced age, and disabilities can receive the necessary medical services at home. This not only allows the elderly to live in familiar home environments, maintaining their independence and dignity, but also alleviates the pressure on medical resources, enabling more resources to be allocated to emergency care and highly specialized nursing. However, the smart healthcare and elderly care platform model is still in the pilot stage and requires more scientific evidence to verify its actual impact on the health of the elderly.Conducting a randomized controlled trial (RCT) will provide high-quality evidence to confirm whether the smart elderly care platform can improve elderly health and to identify potential issues in the implementation process, which could help refine the existing model.

2. Objective

To verify the potential health benefits of the smart elderly care platform. By collecting health data at multiple time points before and after the intervention, this study aims to compare the health indicators of elderly individuals who use the platform with those who do not, thereby providing scientific evidence for the promotion of the platform and its wider application among elderly populations.

3. Participant Selection and Withdrawal

3.1 Inclusion Criteria

(1) Age ≥ 60 years

(2) Normal verbal communication ability

(3) No self-reported visual or auditory impairments

(4) A long-term caregiver residing with the participant

(5) Both the participant and their family members have given informed consent and voluntarily agreed to participate

3.2 Exclusion Criteria

(1) Age < 60 years

(2) Severe physical or mental health conditions

(3) Participation in similar studies within the past year

(4) Elderly individuals residing in institutions

3.3 Withdrawal Criteria

Participants may voluntarily withdraw, or the investigator may terminate their participation in the following cases:

(1) If participants feel they are not benefiting from the study and request withdrawal.

(2) If participants are unable to continue due to circumstances beyond their control.

(3) If the investigator makes protocol adjustments requiring the participant to withdraw.

3.4 Risks and benefits

Elderly participants in this study will have the opportunity to utilize services provided by the "Hunan Province Intelligent Healthcare Integration Platform," such as in-home nursing, home care, and home-based medical and elderly care. These services are designed to help the elderly promptly identify health issues, manage chronic diseases, and prevent the onset of illnesses, thereby enhancing their overall health. The involvement of participants will aid researchers in obtaining more reliable data, which will be beneficial for the promotion and continuous improvement of future smart healthcare models for the elderly.

This study aims to improve the health levels of participants and poses no harm to the individuals involved.

4. Overall Study Design

4.1 Study Type/Design

This study is a randomized controlled trial (RCT), in which participants who have used the “Hunan Province Medical and Elderly Care Smart Service Platform” will be assigned to the experimental group, and those who have not used the platform will be assigned to the control group. The study will use a blind control method to compare the health indicators of the two groups to validate the potential improvement of the smart elderly care platform on elderly health.

(a) Enrollment Phase: The study will recruit participants from Guoyuan Town, Changsha County. Eligible participants will be selected based on inclusion and exclusion criteria and undergo a qualification assessment. Considering a 20% loss to follow-up, it is expected that 64 elderly individuals will be recruited from rural communities in Guoyuan Town.

(b) Intervention Assignment Phase: Participants will be randomly assigned to the experimental or control group using computer-generated randomization. Pre-intervention assessments will be conducted, including measurements of SF-36, Activities of Daily Living (ADL), Geriatric Depression Scale (GDS). In the intervention phase, elderly individuals in the experimental group will use the “Hunan Province Medical and Elderly Care Smart Service Platform” to receive integrated care services, while those in the control group will receive routine community-based care. Intervention measures will include organizing informational sessions to introduce the various services of the platform and encouraging the experimental group to register and use the platform.

(c) Follow-up Phase:Follow-up will occur three times: 3 months, 6 months, and 12 months after the intervention. During follow-up, the same measurements (SF-36, ADL, GDS) will be taken to assess the health status of participants. Some participants may drop out during the intervention phase, and the researchers will record the reasons and follow-up data. Data

will be collected using dual entry by two different data entry clerks, with regular checks to ensure accuracy. After the final follow-up, both data files will undergo double-checking for consistency.

(d) Analysis Phase:Statistical analyses will be conducted using t-tests and ANOVA to compare primary and secondary outcomes between the experimental and control groups, verifying the potential health benefits of the smart elderly care platform. Further analysis will examine influencing factors and underlying mechanisms.

4.2 Randomization and Blinding

4.2.1 Randomization Method

Randomization will be done using a fully computerized system.

A research assistant not involved in the study will use an online randomization program (http://www.randomization.com/) to generate random sequences. Participants who meet the inclusion and exclusion criteria will be assigned to either the experimental or control group.

4.2.2 Blinding

In this study, blinding will be used to reduce potential biases and enhance data reliability. Data collectors will be blinded to the group assignments, ensuring that they are unaware of whether a participant is in the experimental or control group. This design ensures the objectivity and independence of the data collection process. Additionally, outcome evaluators will also be blinded to prevent interference from the intervention during data analysis and outcome assessment.

4.3 Study Phases

4.3.1 Baseline Survey

A baseline survey will be conducted before the intervention to assess the health status of the elderly participants. The baseline survey will use standardized questionnaires, including

demographic information (e.g., gender, age, marital status, education level), medical history, SF-36, ADL, and GDS.

4.3.2 Follow-up

Follow-up surveys will be conducted at three-month intervals after the intervention. The same instruments used in the baseline survey will be applied to ensure consistency and comparability. The follow-up data will be recorded and analyzed. The final visit will take place at the end of the study to assess changes in health outcomes throughout the intervention period and evaluate the effects of the intervention.

5 Participant Treatment

5.1 Intervention

The experimental group will use the "Hunan Province Medical and Elderly Care Smart Service Platform" to receive integrated care services, while the control group will receive standard community-based care without using the platform. All intervention measures will be documented in detail to ensure consistency and control during the entire study period.

5.2 Compliance

Compliance will be assessed based on the participant's registration and use of the "Hunan Province Medical and Elderly Care Smart Service Platform." Participants must use the platform at least once to be considered compliant. The study team will regularly monitor participant adherence and will take measures to encourage compliance for those with poor adherence, documenting reasons and corrective actions

6 Efficacy Evaluation

6.1 Primary Outcome

The primary outcome is the overall change in health status, assessed using SF-36. The comparison will be made between the baseline (T0) and the final visit scores to evaluate the effect of the intervention on elderly health.

6.2 Secondary Outcome

Secondary outcomes include changes in physical and mental health status. Physical health will be assessed using ADL, and mental health will be assessed using the Geriatric Depression Scale (GDS). These outcomes will help evaluate the comprehensive impact of the intervention.

7 Safety Assessment

7.1 Adverse Events

All adverse medical events, regardless of whether they are related to the research intervention, will be thoroughly documented. Adverse events include symptoms, signs, and abnormal findings reported by the participants during medical examinations. Safety monitoring will begin from the participant's enrollment and continue until the conclusion of the study, ensuring timely identification and management of any potential safety risks. All adverse events and serious adverse events will be recorded in the safety monitoring report and regularly submitted to the ethics committee.

8. Data Management

8.1 Source Data, Data Collection Form Filling, and Transfer

All source data will be accurately recorded in the data collection forms and regularly transferred to the data management center for compilation and analysis. The data collection forms will be filled out strictly according to the research protocol to ensure data accuracy and integrity.

8.2 Database Design

A database framework will be established using SPSS 26.0 software, with pre-entry debugging for the data.

8.3 Data Entry

The collected data will be entered by two independent data entry clerks, with each clerk

saving their data files separately. This dual data entry method ensures that the data is accurately recorded.

8.4 Data Verification

During data management, data will be verified through logical checks and manual reviews. Any discrepancies will be electronically recorded in the system, and the research center will be responsible for resolving the issues until all data is confirmed to be accurate. This process ensures the accuracy and completeness of the data.

9 Study Management

9.1 Declaration

A statement by the researchers will be issued for this study.

9.2 Ethical Considerations

This study will adhere to international ethical guidelines and comply with relevant regulations and the review opinions of the ethics committee to ensure the rights and safety of participants.

9.3 Original Records Verification

All original records and data will be carefully maintained and periodically verified to ensure the completeness and authenticity of the data.

9.4 Quality Assurance/Monitoring

A systematic quality assurance process will be established to ensure that the study implementation, data generation, recording, and reporting comply with the study protocol and relevant regulations. Regular monitoring will be conducted to ensure that all research activities and documentation are in compliance with the established guidelines.

9.5 Informed Consent

All participants in this study will sign an informed consent form.

9.6 Protocol Revision Rules

All revisions to the protocol will be documented as supplementary amendments. Any changes to the protocol will require approval by the ethics committee.

9.7 Monitoring

The study will be conducted according to the study protocol, standard operating procedures, and relevant legal requirements, with monitoring by the Ethics Committee of Central South University.

9.8 Confidentiality Agreement and Participant Privacy

The study will maintain the anonymity of participants. Data collection forms will use capital letters, numbers, and/or codes to identify participants. Documents that could reveal participants' identities will be strictly confidential.

10 Publication of Results

The study aims to publish 1-2 high-quality papers in journals such as SCI/SSCI/CSSCI/CSCD.

11 Archiving of Research Data

The research data will be electronically archived, ensuring security and compliance with privacy protocols.

12 APPENDICES

SF-36 QUESTIONNAIRE

Name:_____ **Date: _____**

Please answer the 36 questions of the **Health Survey** completely, honestly, and without interruptions.

GENERAL HEALTH:
In general, would you say your health is:

○ Excellent ○ Very Good ○ Good ○ Fair ○ Poor

Compared to one year ago, how would you rate your health in general now?

○ Much better now than one year ago
○ Somewhat better now than one year ago
○ About the same
○ Somewhat worse now than one year ago
○ Much worse than one year ago

LIMITATIONS OF ACTIVITIES:
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
○ Yes, Limited a lot ○ Yes, Limited a Little ○ No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Lifting or carrying groceries
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Climbing several flights of stairs
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Climbing one flight of stairs
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Bending, kneeling, or stooping
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking more than a mile
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking several blocks
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Walking one block
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

Bathing or dressing yourself

Yes, Limited a Lot | Yes, Limited a Little | No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities

Yes | No

Accomplished less than you would like

Yes | No

Were limited in the kind of work or other activities

Yes | No

Had difficulty performing the work or other activities (for example, it took extra effort)

Yes | No

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities

Yes | No

Accomplished less than you would like

Yes | No

Didn't do work or other activities as carefully as usual

Yes | No

SOCIAL ACTIVITIES:

Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all | Slightly | Moderately | Severe | Very Severe

PAIN:

How much bodily pain have you had during the past 4 weeks?

None | Very Mild | Mild | Moderate | Severe | Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all | A little bit | Moderately | Quite a bit | Extremely

ENERGY AND EMOTIONS:
These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pep?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a very nervous person?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt so down in the dumps that nothing could cheer you up?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt calm and peaceful?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you have a lot of energy?
- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you felt downhearted and blue?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel worn out?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Have you been a happy person?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

Did you feel tired?

- All of the time
- Most of the time
- A good Bit of the Time
- Some of the time
- A little bit of the time
- None of the Time

SOCIAL ACTIVITIES:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time
- Most of the time
- Some of the time
- A little bit of the time
- None of the Time

GENERAL HEALTH:
How true or false is each of the following statements for you?

I seem to get sick a little easier than other people

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

I am as healthy as anybody I know

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

I expect my health to get worse

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

My health is excellent

Definitely true | Mostly true | Don't know | Mostly false | Definitely false

Barthel Index of Activities of Daily Living

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation. Refer to the Guidelines section on the following page for detailed information on scoring and interpretation.

The Barthel Index

Bowels
0 = incontinent (or needs to be given enemata)
1 = occasional accident (once/week)
2 = continent
Patient's Score: _____

Bladder
0 = incontinent, or catheterized and unable to manage
1 = occasional accident (max. once per 24 hours)
2 = continent (for over 7 days)
Patient's Score: _____

Grooming
0 = needs help with personal care
1 = independent face/hair/teeth/shaving (implements provided)
Patient's Score: _____

Toilet use
0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)
Patient's Score: _____

Feeding
0 = unable
1 = needs help cutting, spreading butter, etc.
2 = independent (food provided within reach)
Patient's Score: _____

Transfer
0 = unable – no sitting balance
1 = major help (one or two people, physical), can sit
2 = minor help (verbal or physical)
3 = independent
Patient's Score: _____

Mobility
0 = immobile
1 = wheelchair independent, including corners, etc.
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid, e.g., stick)
Patient's Score: _____

Dressing
0 = dependent
1 = needs help, but can do about half unaided
2 = independent (including buttons, zips, laces, etc.)
Patient's Score: _____

Stairs
0 = unable
1 = needs help (verbal, physical, carrying aid)
2 = independent up and down
Patient's Score: _____

Bathing
0 = dependent
1 = independent (or in shower)
Patient's Score: _____

Total Score: _____

(Collin et al., 1988)

Scoring:

Sum the patient's scores for each item. Total possible scores range from 0 – 20, with lower scores indicating increased disability. If used to measure improvement after rehabilitation, changes of more than two points in the total score reflect a probable genuine change, and change on one item from fully dependent to independent is also likely to be reliable.

Sources:

- Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud*. 1988;10(2):61-63.
- Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J*. 1965;14:61-65.
- Wade DT, Collin C. The Barthel ADL Index: a standard measure of physical disability? *Int Disabil Stud*. 1988;10(2):64-67.

Guidelines for the Barthel Index of Activities of Daily Living

General

- The Index should be used as a record of what a patient ***does***, NOT as a record of what a patient ***could do***.
- The main aim is to establish degree of independence from any help, physical or verbal, however minor and for whatever reason.
- The need for supervision renders the patient not independent.
- A patient's performance should be established using the best available evidence. Asking the patient, friends/relatives, and nurses will be the usual source, but direct observation and common sense are also important. However, direct testing is not needed.
- Usually the performance over the preceding 24 – 48 hours is important, but occasionally longer periods will be relevant.
- Unconscious patients should score '0' throughout, even if not yet incontinent.
- Middle categories imply that the patient supplies over 50% of the effort.
- Use of aids to be independent is allowed.

Bowels (preceding week)

- If needs enema from nurse, then 'incontinent.'
- 'Occasional' = once a week.

Bladder (preceding week)

- 'Occasional' = less than once a day.
- A catheterized patient who can completely manage the catheter alone is registered as 'continent.'

Grooming (preceding 24 – 48 hours)

- Refers to personal hygiene: doing teeth, fitting false teeth, doing hair, shaving, washing face. Implements can be provided by helper.

Toilet use

- Should be able to reach toilet/commode, undress sufficiently, clean self, dress, and leave.
- 'With help' = can wipe self and do some other of above.

Feeding

- Able to eat any normal food (not only soft food). Food cooked and served by others, but not cut up.
- 'Help' = food cut up, patient feeds self.

Transfer

- From bed to chair and back.
- 'Dependent' = NO sitting balance (unable to sit); two people to lift.
- 'Major help' = one strong/skilled, or two normal people. Can sit up.
- 'Minor help' = one person easily, OR needs any supervision for safety.

Mobility

- Refers to mobility about house or ward, indoors. May use aid. If in wheelchair, must negotiate corners/doors unaided.
- 'Help' = by one untrained person, including supervision/moral support.

Dressing

- Should be able to select and put on all clothes, which may be adapted.
- 'Half' = help with buttons, zips, etc. (*check!*), but can put on some garments alone.

Stairs

- Must carry any walking aid used to be independent.

Bathing

- Usually the most difficult activity.
- Must get in and out unsupervised, and wash self.
- Independent in shower = 'independent' if unsupervised/unaided.

(Collin et al., 1988)

Geriatric Depression Scale (Short Form)

Name: _____ Date: _____

Instructions: Choose the best answer for how you felt over the past week. Note: when asking the patient to complete the form, provide the self-rated form (included on the following page).

No.	Question	Answer	Score
1.	Are you basically satisfied with your life?	YES / ***NO***	
2.	Have you dropped many of your activities and interests?	***YES*** / NO	
3.	Do you feel that your life is empty?	***YES*** / NO	
4.	Do you often get bored?	***YES*** / NO	
5.	Are you in good spirits most of the time?	YES / ***NO***	
6.	Are you afraid that something bad is going to happen to you?	***YES*** / NO	
7.	Do you feel happy most of the time?	YES / ***NO***	
8.	Do you often feel helpless?	***YES*** / NO	
9.	Do you prefer to stay at home, rather than going out and doing new things?	***YES*** / NO	
10.	Do you feel you have more problems with memory than most people?	***YES*** / NO	
11.	Do you think it is wonderful to be alive?	YES / ***NO***	
12.	Do you feel pretty worthless the way you are now?	***YES*** / NO	
13.	Do you feel full of energy?	YES / ***NO***	
14.	Do you feel that your situation is hopeless?	***YES*** / NO	
15.	Do you think that most people are better off than you are?	***YES*** / NO	
		TOTAL	

(Sheikh & Yesavage, 1986)

Scoring:

Answers indicating depression are in bold and italicized; score one point for each one selected. A score of 0 to 5 is normal. A score greater than 5 suggests depression.

Sources:

- Sheikh JI, Yesavage JA. Geriatric Depression Scale (GDS): recent evidence and development of a shorter version. *Clin Gerontol*. 1986 June;5(1/2):165-173.
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