STATISTICAL ANALYSIS PLAN

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

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VERSION HISTORY

SAP Version	Version Date	Change(s)	Rationale
1.0	2024-06-12	First draft	

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1 LIST OF ABBREVIATIONS

Table 1: List of Abbreviations

Abbreviation	Term
AE	Adverse Event
ANOVA	Analysis of Variance
ADL	Activities of Daily Living
GDS	Geriatric Depression Scale
RCT	Andomized controlled trial
SAP	Statistical Analysis Plan
SAE	Serious Adverse Event
SD	Standard Deviation
SE	Standard Error
SF	Short Form Survey

2 PURPOSE OF THE ANALYSES

The purpose of this clinical trial is to understand and verify the potential health improvement effects of the smart healthcare and elderly care platform on the elderly. By collecting health indicator data at different time points before and after the intervention, the study will compare the differences in health indicators between community-dwelling elderly who have used the smart healthcare and elderly care platform and those who have not, providing scientific evidence for the promotion of the smart healthcare and elderly care platform model and further facilitating its application and popularization among the elderly in the community.

3 PROTOCOL SUMMARY

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.

The study will recruit participants from Guoyuan Town, Changsha County. Eligible elderly individuals from rural communities will undergo qualification assessment based on inclusion/exclusion criteria. Accounting for a 20% attrition rate, the study plans to enroll 64 elderly participants from rural communities in Guoyuan Town.

Participants will be randomly assigned to either the experimental or control group using computer-generated randomization. Baseline measurements will be collected using:SF-36 Health Survey,Activities of Daily Living (ADL) scale,Geriatric Depression Scale (GDS).

The experimental group will receive integrated care services through the "Hunan Province Integrated Smart Healthcare and Elderly Care Service Platform", while the control group will receive standard community care. Educational seminars introducing "Hunan Province Integrated Smart Healthcare and Elderly Care Service Platform" services.Assistance with platform registration for experimental group participants.Implementation of integrated care services via the platform

Follow-up assessments will repeat baseline measurements (SF-36, ADL, GDS) to evaluate health status changes. Participant attrition will be documented through follow-up tracking. All data will undergo double-entry verification using two independent data clerks maintaining separate files, with regular cross-verification and final reconciliation after the last follow-up.

4 GENERAL ANALYSIS AND REPORTING CONVENTIONS

This study aims to assess the impact of the "Hunan Province Elderly Care and Health Integration Intelligent Service Platform" on the health of community-dwelling elderly individuals, using a randomized controlled trial (RCT) design. Participants will be randomly assigned to either the experimental group or the control group. The analysis will focus on comparing the changes in health indicators between the two groups before and after the intervention. Descriptive statistics, group comparisons, and further analysis of influencing factors will be used.

Data will be carefully managed to ensure its accuracy and completeness. All source data will be recorded on data collection forms and periodically transferred to the data management center for aggregation. To ensure consistency, two independent data entry personnel will enter the data separately, and data will be verified through logical checks and manual reviews. For baseline analysis, descriptive statistics will be used to assess participants' gender, age, marital status, education level, medical history, and health conditions to ensure comparability between the experimental and control groups.

The primary endpoint is the overall change in health status, assessed using the SF-36 scale. Data will be analyzed using independent samples t-tests (for normally distributed data) or Mann-Whitney U tests (for non-normally distributed data) to compare the changes between the two groups. Paired t-tests or Wilcoxon signed-rank tests will be used for within-group comparisons over time. Secondary endpoints, including physical health (measured by ADL) and mental health (measured by GDS), will be analyzed similarly to evaluate the broader effects of the intervention.

Safety will be monitored through the recording of adverse events (AEs), and descriptive statistics will be used to report the type, frequency, and severity of any such events. Intent-to-treat (ITT) analysis will be applied to address any missing data or attrition, and the study will track participants' adherence to the intervention, with any deviations carefully documented.

All statistical analyses will be conducted using SPSS 26.0. Group comparisons will be performed with t-tests or ANOVA for normally distributed data, and non-parametric tests will be used for other data. The significance level for all tests will be set at $P<0.05$. The final report will include detailed descriptions of the statistical methods used, the results for primary and secondary endpoints, and any safety concerns.

The conclusions drawn from this analysis will provide valuable insights into the potential benefits of the intelligent service platform in improving the health of elderly individuals, offering a scientific basis for its broader application and further development.

4.1. Assessment Time Windows

Assessments should be performed within the windows stated in the protocol and will be analyzed by the visit/time point that they are entered into the case report form (CRF) under.

5 SAMPLE SIZE

Based on studies by scholars such as Luo Jing, He Jie, and Chen Jianfeng on elderly health under the medical and elderly care integration model [1-3], the estimated difference in overall health score after three months of intervention is approximately 10 points. Using the formula for sample size calculation with a 1:1 comparison between the intervention and control groups, the study assumes a significance level of $\alpha = 0.05$ (two-sided), thus $Z_{1-\alpha/2} = 1.96$; with 80% power ($\beta = 0.2$), $Z_{1-\beta} = 0.84$; a population standard deviation (σ) of 10; a permissible error (Δ) of 2, based on empirical values; and an expected increase of more than 10 points in the intervention group's mean score. After applying these parameters to the formula (1), the required sample size per group (intervention and control) is 32, with a total minimum sample size of 64 participants, considering a 20% dropout rate.

$$n_T = n_C = \frac{2\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \sigma^2}{\left(|D| - \Delta\right)^2} \quad (1)$$

6 STUDY SUBJECTS

6.1. Disposition of Subjects

The study will recruit elderly individuals from the Guoyuan Township of Changsha County, with participants randomly assigned to either the experimental or control group. Randomization will ensure that there is no bias in the allocation of participants to the respective groups, with the experimental group receiving care via the "Hunan Province Elderly Care and Health Integration Intelligent Service Platform" and the control group receiving standard community care. All participant dispositions,

including enrollment, randomization, completion of the study, and any withdrawals or dropouts, will be carefully tracked and documented.

6.2. Demographic and Other Baseline Characteristics

Demographic characteristics such as age, gender, marital status, and educational level, as well as baseline health status indicators, will be collected at the time of participant enrollment. These baseline characteristics will help ensure that the two groups are comparable at the outset of the study. Additionally, information on prior health conditions, medical history, and any medications taken by the participants will be recorded. This will allow for a more detailed understanding of the study population and facilitate statistical adjustments in case any baseline differences are identified between the groups

6.3. Medical History

A comprehensive medical history will be obtained for each participant prior to enrollment in the study. This history will include the presence of any chronic conditions (e.g., cardiovascular diseases, diabetes, arthritis), previous surgeries, or other significant health events. Understanding the medical history of participants is crucial as it can influence the outcomes of the study. Any pre-existing conditions may also affect how participants respond to the intervention, and adjustments to the analysis will be made to account for these factors, if necessary.

7 STATISTICAL ANALYSIS

Statistical analyses will be conducted using SPSS 26.0. For continuous variables that are normally distributed and have equal variances (e.g., age, SF-36, ADL, GDS), data will be presented as mean($\bar{x} \pm s$)standard deviation (SD). Between-group comparisons will be conducted using independent sample t-tests (Student's t-test). If data are not normally distributed, non-parametric tests (Mann-Whitney U test) will be used, and data will be presented as median values. Within-group pre-post comparisons,

if normally distributed, will be analyzed using paired t-tests (Dependent t-test). For non-normally distributed data, the Wilcoxon signed-rank test will be used. A two-sided significance level of $P < 0.05$ will be considered statistically significant.

8 STUDY OPERATIONS

8.1 Protocol Deviations

In the event of a protocol deviation, the investigator will immediately notify the sponsor or data management team. The deviation will be assessed to determine whether it is a significant deviation that could impact the integrity of the study results. If the deviation is minor and does not affect participant safety or data quality, it will be documented and managed accordingly. However, if a deviation is significant, it may lead to exclusion from the study or result in further corrective actions, including additional monitoring or retraining of staff.

8.2 Andomization

Randomization in this study will be performed using a computer-generated randomization sequence. A randomization program will be utilized to ensure an unbiased distribution of participants between the experimental group (receiving the "Hunan Province Elderly Care and Health Integration Intelligent Service Platform" intervention) and the control group (receiving standard community care services). The randomization process will be overseen by an independent research assistant who is not involved in the recruitment or intervention process to prevent any potential bias.

8.3 Measures of Treatment Compliance

Compliance with the treatment protocol is critical to the success of the study. In this trial, treatment compliance will be monitored regularly throughout the study duration. For the experimental group, compliance will be measured by the registration and active use of the "Hunan Province Elderly Care and Health Integration Intelligent

Service Platform" to access integrated care services. Participants will be considered compliant if they use the platform at least once during the intervention period.

Regular check-ins will be conducted via phone or in-person visits to assess whether participants are adhering to the platform's usage guidelines. Non-compliant participants will be identified, and the study team will work with them to understand the reasons for non-compliance, providing additional support or reminders if necessary.

For the control group, compliance will be evaluated based on their engagement with the standard community care services. Adherence to scheduled visits or interventions will be tracked. Non-compliance in either group will be addressed by providing additional instructions or follow-up interventions to help participants maintain their involvement in the study.

The treatment compliance data will be reviewed regularly, and adherence rates will be reported. In cases where compliance significantly deviates from the expected levels, sensitivity analyses will be performed to evaluate the impact of non-compliance on the study results.

9 ENDPOINT EVALUATION

9.1 Overview of Efficacy Analysis Methods

The efficacy of the intervention will be evaluated through a series of well-defined analyses. These analyses aim to assess the potential benefits of the "Hunan Province Elderly Care and Health Integration Intelligent Service Platform" in improving the health of elderly individuals. The primary efficacy outcomes will focus on overall health status, while secondary outcomes will explore specific domains like physical and psychological health.

9.2 Timing of Analyses

The efficacy analyses will be conducted at three key time points: baseline (pre-intervention), 3 months post-intervention, 6 months post-intervention, and 12 months post-intervention. The timing of the analysis is structured to capture the short-term and long-term impacts of the intervention on the health outcomes of the elderly participants.

9.3 Primary Endpoint Analysis

The primary Endpoint analysis will compare changes in SF-36 scores from baseline to final visit between the experimental and control groups using t-tests or ANOVA, to assess the intervention effect of the smart elderly care platform.

9.3.1 Computation of the Primary Endpoint

The primary endpoint will be calculated as the difference in SF-36 scores between baseline and post-intervention follow-up visits. The final scores will be derived as the average of the scores across the relevant domains, and changes from baseline will be evaluated for both the experimental and control groups.

9.3.2 Primary Analysis of the Primary Endpoint

The primary analysis will use an intention-to-treat (ITT) approach, which includes all participants who were randomized to the study, regardless of whether they completed the intervention or adhered to the treatment protocol. The analysis will compare the mean change in SF-36 scores from baseline to the final follow-up (12 months) between the experimental and control groups using appropriate statistical tests, such as t-tests or ANCOVA.

9.3.3 Sensitivity Analyses of the Primary Analysis

Sensitivity analyses will be conducted to assess the robustness of the primary analysis. These will include examining the impact of missing data and participant non-compliance. For example, a per-protocol analysis may be performed to determine the effect of the intervention in participants who fully adhered to the study protocol.

9.4 Secondary Endpoint Analysis

The secondary Endpoint analysis will compare changes in ADL and GDS from baseline to final visit between the experimental and control groups, to evaluate the impact on physical and mental health, providing further evidence of the comprehensive effects of the intervention.

10 SAFETY EVALUATION

10.1 Overview of Safety Analysis Methods

Safety will be evaluated through the monitoring and documentation of adverse events (AEs) and serious adverse events (SAEs) throughout the study. This evaluation will assess whether the use of the "Hunan Province Elderly Care and Health Integration Intelligent Service Platform" causes any negative effects on participants' health, including physical, psychological, or other side effects.

10.2 Adverse Events

All AEs, regardless of whether they are related to the intervention, will be recorded and analyzed. AEs will be classified by severity (mild, moderate, severe) and by relationship to the intervention (related, unrelated). The frequency and types of AEs will be compared between the experimental and control groups. Special attention will be paid to any potential safety concerns arising specifically from the use of the intelligent service platform or the intervention methods used within the experimental group.

11 REFERENCES

[1] Luo Jing, Liu Yao, Luo Yuru, et al. Meta-analysis on the impact of the integrated healthcare and elderly care model on the health-related quality of life of elderly individuals. Chinese General Practice, 2019, 22(17): 2075-2083.

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