Effectiveness of an Intelligent and Integrated Older Care Model on Quality of Life among Home-dwelling Older Adults: A Randomized Controlled Trial

Rongrong Guo, Jiwen Zhang, Fangyu Yang, Ying Wu

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Abstract

Background: Integrated care facilitated by Information and Communication Technology offers a promising approach to actively responding to the global older care burden. However, its effectiveness remains unclear.

Objective: This study aimed to evaluate the effectiveness of an intelligent and integrated older care model (SMART system) in improving the quality of life for older people living at home.

Methods: A randomized controlled trial was conducted. After assessing eligibility, participants were randomly allocated in a 1:1 ratio to receive the personalized integrated care delivered by the SMART system or usual care for 3 months from November 1, 2020, to December 31, 2020. The primary endpoint was the percent change in quality of life from baseline to the 3-month follow-up, while secondary endpoints included functional status and percent changes in health self-management ability, social support, and confidence in avoiding falling of older individuals from baseline to the 3-month follow-up. All data analysis followed the intention-to-treat principle. A covariance model or logistic regression model was performed to estimate the effectiveness as appropriate. Subgroup and sensitivity analyses were also conducted to verify the robustness of our findings.

Results: Of 94 participants included, 48 were assigned to the SMART Group. The SMART system demonstrated a statistically significant improvement in quality of life among home-dwelling older participants, with an estimated intervention difference of 11.97% (95% CI: 7.20%-16.74%, p<0.001). Similarly, it substantially enhanced health self-management ability and social support compared to the usual care (difference: 4.95%, p<0.05; difference: 6.75%, p<0.001). Furthermore, the SMART system significantly reduced instrumental activities of daily living (IADL) disability (OR: 0.34, 95%CI: 0.11-0.83, p=0.024), while no statistically significant reduction in activities of daily living (ADL) disability was observed. The subgroup and sensitivity analyses yielded identical results.

Conclusions: Personalized and integrated care provided via the SMART system significantly improved quality of life, health self-management ability, and social support among older individuals, while also reducing IADL disability. Clinical Trial: This study was prospectively registered in the Chinese Clinical Trial Registry (Registration number: ChiCTR-IOR-17010368) on 12/01/2017.

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Keywords: effectiveness, home care, integrated care, intelligent, older people, quality of life

Introduction

Recent advances in medicine, public health, and Information and Communication Technology (ICT) have contributed to increased life expectancy and a rapid global aging trend [1]. In 2021, approximately 963 million individuals aged 65 and above represented 12.2% of the population worldwide, with projections estimating this number will reach 1.65 billion by 2050, accounting for 16.4% of the total population [2]. Aging often accompanies physiological decline, a higher risk of chronic diseases, and decreased independence in daily activities, leading to rising demand for daily assistance and medical care to maintain an optimal quality of life (QOL) [3]. Despite a strong preference among older people to be cared for in their homes [4], the current older care model fails to address their home-based care needs that span medical and social care domains due to fragmented and inconsistent care services, highlighting the urgent need for a solution that allows older people to age in place while receiving timely and appropriate care for their daily life and diagnosed diseases [5, 6].

Integrated care has been proposed as a promising approach to address challenges in older care by linking all stakeholders involved and ensuring continuity in care delivery [7]. The World Health Organization (WHO) defined integrated care as a person-centered care model that provides comprehensive, coordinated, continuous, and proactive services across various levels and sites of care, encompassing daily life assistance, health promotion, disease prevention, diagnosis, disease management, and rehabilitation throughout the entire life cycle, all tailored to individual needs [8]. By harmonizing the efforts of healthcare providers, social workers, and family caregivers, integrated care can minimize redundancies, enhance health outcomes, prevent disabilities, and optimize resource allocation, ultimately enhancing the QOL for older individuals [9]. However, a universally accepted implementation framework for home-based integrated care for older adults remains absent.

ICT has emerged as a crucial enabler to successfully implement integrated care [10], with the potential to facilitate continuous monitoring, resource integration, seamless information sharing, and timely feedback [11]. For example, Kouroubali and colleagues developed an artificial intelligence (AI)-enabled system to support multidimensional, coordinated, and timely care for older adults with frailty, enabling early detection of frailty, preventing disability and adverse events, and reducing hospital admissions [12]. Another example is ProACT, a European digital health platform supporting integrated care for older adults with multi-morbidity through symptom monitoring, tailored intervention generation, and data sharing within a care network [13]. However, AI-based solutions often suffer from "black box" and hallucinations, making it difficult to trace or understand the reasoning processes. This lack of transparency can result in inaccurate or conflicting recommendations that may not align with established guidelines. Additionally, the lack of collaborative mechanisms among various care providers hinders the reconciliation of conflicting interests and clarification of responsibilities, limiting care integration.

To address these challenges, a knowledge-based clinical decision support system (CDSS) presents a viable solution [14][Error: Reference source not found]. It can customize interventions using transparent reasoning processes based on pre-embedded knowledge, guidelines, and rules, serving as a useful tool to promote consistent, accurate, and personalized integrated care. The principle of neural reflex, where receptors collect information and transmit it to the central nervous system for processing, and then send commands to effectors, can function as an effective collaborative mechanism to promote collaboration among various care providers [15]. This strategy can help streamline communication and clarify each care provider's responsibilities, ensuring more coordinated and consistent efforts in older care.

Therefore, we developed an intelligent and integrated older care model using a knowledge-based CDSS architecture inspired by the principle of neural reflex. Similar to how the neural reflex functions in biological systems, our system was designed to act as the “neural reflex” for older care, which consists of ***S***ensors and Scales (receptor), a ***M***obile Phone ***A***utonomous Response System (central nervous system in the spinal cord), a ***R***emote Cloud Management Center (central nervous system in the brain), and a ***T***otal Care System (effector, where care providers are incorporated to assume responsibility for specific types of care services for older people, thus promoting integrated and consistent care), in short, SMART system.

Although a previous study has confirmed acceptable usability of the SMART system among older people, its effectiveness in improving outcomes of home-dwelling older people remains unclear. This study aimed to evaluate whether the integrated care delivered by the SMART system can improve the QOL of older people living at home through a randomized clinical trial (RCT).

Methods

Study design

This study is a stratified RCT following the tenets of the Declaration of Helsinki. It was approved by the Institutional Review Committee of Capital Medical University (Approval No. 2015SY49U) and prospectively registered in the Chinese Clinical Trial Registry (Registration number: ChiCTR-IOR-17010368) on 12/01/2017. The current paper was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) [16].

Participants

We consecutively recruited older individuals hospitalized in the Neurology Department at a comprehensive hospital in Beijing, China, from November 1, 2020, and December 31, 2020.

Individuals were eligible for the study if they: (1) were aged 60 years or older; (2) were scheduled for discharge and returning home; (3) had one or more diagnosed chronic diseases and/or exhibited mild to moderate disability indicated by a Barthel Index (BI) between 60 and 100; (4) were able to communicate; (5) owned an Android-based smartphone for Internet access, as the SMART system is exclusively compatible with Android devices; (6) expressed a willingness to participate. Older adults were excluded if they: (1) were unable to use the SMART system despite repeated instructions; (2) were currently enrolled in any other clinical trials involving an investigational product or any other type of medical research judged scientifically or medically incompatible with the current study; (3) had participated in a clinical study and received treatment, whether active or placebo, within the last 30 days. All participants provided written informed consent on enrollment.

SMART system

The SMART system is an intelligent and integrated older care model designed to facilitate integrated home-based older care proactively. An article detailing the system development and usability testing will be published elsewhere.

In brief, similar to the principle of neural reflex, the SMART system collects data concerning the overall health status of older individuals through real-time monitoring and periodic assessments by the Sensors and Scales. This information is subsequently uploaded to the Remote Cloud and Management Center via Wifi or 5G networks for comprehensive analysis. We also developed a corresponding knowledge base supported by sufficient evidence, along with a set of trigger rules, which have been pre-integrated into the SMART system to enable accurate diagnoses of the care problems faced by older adults and the generation of customized interventions based on their heterogeneous characteristics. After review and adjustment by professional nurses, these identified care problems and tailored interventions are communicated to caregivers or professional care providers within the Total Care System, as appropriate. The Mobile Phone Autonomous Response System includes a set of simple algorithms to handle simple but urgent care problems.

The SMART system also features reminder functions to encourage older people to adhere to their medication schedules and complete the recommended interventions. Furthermore, the system can deliver health-related information tailored to individual interests by leveraging older people's login records. Additionally, a simple color-block game has been designed to provide entertainment, promote mental stimulation, and enhance cognitive function among older adults.

Interventions

Participants in the SMART Group received customized interventions from the SMART system for three months. Trained nurses provided instructions on how to download, install, and navigate the SMART system, ensuring that participants could independently access its various modules. Upon completing the login and registration process, participants were continuously monitored and regularly received customized and integrated care plans presented in texts, diagrams, pictures, and videos. These plans included specific care problems and personalized interventions across nine domains: decreased or lost self-care ability, falls, delirium, dysphagia, incontinence, constipation, urinary retention, cognitive decline, depression, impaired skin integrity, and common diseases. Throughout the intervention, personalized interventions were dynamically adjusted based on user completion status and feedback collected after each delivery. Compliance with the intervention was tracked via logs of participants' login activities, data uploads, and health information downloads recorded by the SMART system. Participants were considered to have good compliance if they used the system at least twice a week, moderate compliance if they accessed it once a week, and poor compliance if they did not engage with the SMART system for more than 2 weeks. Nurses then actively contacted participants with poor compliance to encourage greater engagement with the system. Additionally, older individuals in the SMART Group received routine discharge instructions that aligned with the established standard of care, covering crucial topics such as follow-up appointments, medication adherence, healthy eating, and rehabilitation exercises.

In addition to the similar routine discharge instructions, older participants in the Usual Care

Group were granted access to the SMART system, allowing them to only view health-related information without any personalized integrated care plans over the three months.

Endpoints

Primary endpoints

The primary endpoint was the percent change in QOL from baseline to 3-month follow-up, which was assessed using the World Health Organization Quality of Life Instrument - Older Adults Module (WHOQOL-OLD). The instrument comprises 24 items from 6 domains: Sensory Abilities (SAB), Autonomy (AUT), Death and Dying (DAD), Past, Present, and Future Activities (PPFA), Social Participation (SOP), and Intimacy (INT) [17]. Each item is rated on a 5-point Likert scale. The total score obtained by summing up the scores of each item is then converted to a percentage scale as the final score, with higher scores indicating better QOL [18]. The simplified Chinese version of the WHOQOL-OLD demonstrates satisfactory reliability, with Cronbach's α coefficients of 0.711-0.842 and intra-class correlation coefficients of 0.766-0.906, acceptable construct validity, and good discriminant validity [19].

Secondary endpoints

The secondary endpoints included the functional status, and percent changes in health self-management ability, social support, and confidence in avoiding falling of older individuals from baseline to the 3-month follow-up.

Functional status was assessed using the Katz Activities of Daily Living (ADL) scale and the Lawton-Brody Instrumental Activities of Daily Living (IADL) scale at baseline and 3-month follow-up. The Katz scale consists of six dichotomous questions on basic ADLs, including bathing, dressing, feeding, incontinence, toileting, and transfer [20]. The Lawton-Brody Scale evaluates participants' ability to perform instrumental ADLs across eight areas: shopping, food preparation, housekeeping, taking medications, laundering, using telephone, using transportation, and financial management, through a series of dichotomous questions [21]. Respondents score 0 for activities that could not be performed independently or could only be performed with assistance, and 1 point for activities that could be performed without any assistance. A summary score ranges from 0 (dependent) to 6 (independent) for ADL and from 0 (dependent) to 8 (independent) for IADL. ADL or IADL disability is determined by the presence of at least one difficulty in the relevant domains.

Participants' health self-management ability was assessed using the Rating Scale of Health Self-Management Skill for Adults (AHSMSRS). This scale comprises 38 items across three subscales: behavior, cognition, and environment. Each item is rated on a Likert scale ranging from 1 to 5, and the total score is subsequently converted to a standardized range of 0-100, where a higher score implies greater self-management ability. The scale was validated to have good reliability and validity in the Chinese context, with a Cronbach's α coefficient of 0.933, a split-half reliability index of 0.746, and a content validity index of 0.895, respectively [22].

The Social Support Rating Scale (SSRS) was utilized to assess the social support of the participants. This instrument, specifically designed for Chinese environment and culture, consists of 10 items spanning three dimensions: objective support, subjective support, and utilization of support. The total score is calculated by summing each item score and ranges from 12 to 66. The higher the total score, the better the social support status [23]. The scale has been widely used in Chinese populations with satisfactory reliability and validity [24], indicated by a Cronbach's α coefficient of 0.825-0.896 and content validity of 0.724-0.835 [23].

The simplified Chinese version of the Modified Fall Efficacy Scale (MFES) was employed to evaluate the confidence in avoiding falls. This self-assessment scale comprises 14 items to quantitatively examine the degree of perceived self-efficacy in avoiding falling during basic activities, ranging from 0 (no confidence) to 10 (absolute confidence) [25]. The average score of each item is regarded as the final MFES score. A lower total score indicates lower confidence and a higher fear of falling. The simplified Chinese version of the MFES has been proven to have good reliability, as evidenced by a Cronbach's α coefficient and a split-half reliability of 0.977 and 0.955. It also exhibits satisfactory discriminant and construct validity (all $p<0.05$) [26].

Safety assessments

Safety assessments encompassed intervention-emergent adverse events and early discontinuation of the SMART system due to adverse events during the intervention and follow-up periods. Cases of major adverse events and deaths were reviewed by an independent external adjudication committee.

Randomization and blinding

Participants were randomly allocated in a 1:1 ratio to either receive customized and integrated care delivered by the SMART system (SMART Group) or usual care (Usual Care Group), with stratification based on the BI (<100 or =100). A statistician, who was not involved in data collection or analysis, generated the allocation sequence using computer-generated random numbers. Trained nurses providing the intervention received sequentially numbered, opaque, and sealed envelopes, each containing a card labeled with either the number 1 (indicating integrated care delivered by the SMART system) or 2 (indicating usual care).

Due to the nature of the intervention, older participants and nurses providing the intervention cannot be blinded to group allocation, although they remained unaware of the detailed interventions provided to the other group until study completion. Only the trained investigators were blinded to intervention assignments.

Sample size calculation

The sample size was calculated using PASS software version 2021 (NCSS, LLC. Kaysville, Utah, USA). The primary purpose of this study was to demonstrate the superiority of the integrated care delivered by the SMART system over usual care in improving the QOL of older people. Based on previous studies, we anticipated a mean improvement of 8.00% [27]. To reach 90% power with a significance level (α) set at 0.05 (two-tailed), a minimum sample size of 31 participants per group was required following the One-Way Analysis of Variance F-tests, based on a 1:1 allocation ratio. After adjusting for an attrition rate of 20%, the minimum sample size for each group was increased to 39, resulting in a total minimum sample size of 78. The sample size of 78 also provided a power of 90% to demonstrate the superiority concerning other endpoints, at a 2-sided significance level of 0.05.

Statistical analysis

All data were analyzed based on the intention-to-treat (ITT) principle. To mitigate the loss of statistical efficiency and bias caused by excluding participants with incomplete data, missing values were imputed 100 times using the method of Multiple Imputation by Chained Equations (MICE) based on the same intervention group since Little's test suggested that data were missing at random (χ^2=13.78, p=0.54) [28]. Any missing categorical variables were dichotomized following the MICE imputation.

Continuous variables were presented as mean with standard deviation (SD) or median with interquartile ranges (25% percentile, 75% percentile), as appropriate. Between-group comparisons for continuous variables were performed using either the Student's *t*-test or the Mann-Whitney *U* test. Categorical variables were expressed as frequencies or proportions (%), with comparisons conducted using chi-square or Fisher's exact test. For the continuous endpoints, a covariance model including randomized group and stratification factor as fixed effects and baseline measure as a covariate was used [29]. Categorical endpoints were analyzed using a logistic regression model with the same fixed effects and covariate as continuous endpoints, where treatment difference was assessed by odds ratios (ORs).

To evaluate whether baseline characteristics could influence the superiority of the integrated care delivered by the SMART system over usual care in improving the QOL for older adults, subgroup analyses were performed by age group (60-69, 70-), gender (male and female), and body mass index (BMI) group (normal [18.5-23.9kg/m^2], abnormal [<18.5kg/m^2 or ≥24.0kg/m^2]) [30]. Additionally, we conducted several sensitivity analyses to assess the stability of our findings. First, we repeated the analyses on continuous endpoints by using the change values as a measurement approach. Second, we performed a per-protocol (PP) analysis by only including participants who adhered to the study protocol to avoid inaccurate estimation of the improvement of endpoints.

The statistical analyses were performed using R studio version 4.2.0 (Boston, MA, USA). Statistical significance was set at a two-sided *p*-value<0.05.

Results

Study participants and baseline characteristics

The inclusion process of the study participants was presented in Figure 1. Between November 1, 2020, and December 31, 2020, a total of 159 older individuals were screened for eligibility and 94 were randomly allocated to the Usual Care Group (n=46) or SMART Group (n=48). A total of 83 participants (88.30%) rigorously completed the predefined intervention.

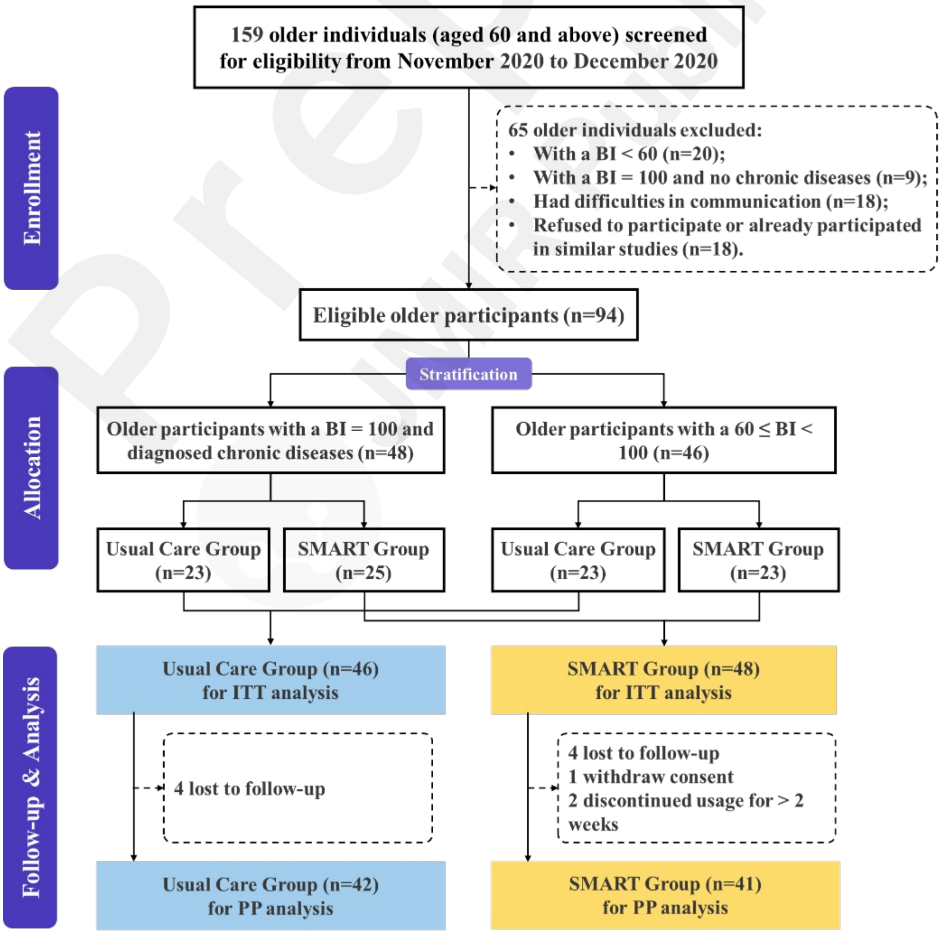

Figure. 1 The flowchart of older participants. BI, Barthel Index; ITT, intention to treat; PP, per

protocol.

Baseline characteristics of older participants were summarized in Table 1. The mean age of older participants in the SMART Group was 69.50±6.53 years old with 60.42% being male, while older individuals in the Usual Care Group were on average 70.83±7.11 years old with 60.87% being male. In both the SMART and Usual Care groups, the majority of older individuals were married and lived with others. Overall, baseline characteristics were similar across the two groups.

Table 1. Baseline characteristics of older participants in the intention-to-treat analysis

Variables	SMART Group (n=48)	Usual Care Group (n=46)	*t/Z/χ2*	*p*-value
Age	69.50 ± 6.53	70.83 ± 7.11	0.94[a]	0.349
Male	29 (60.42%)	28 (60.87%)	0.01[b]	0.964
Body mass index (kg/m^2)	24.34 ± 3.87	23.29 ± 2.48	-1.56[a]	0.122
Marital status			-[c]	0.196
Married	32 (66.67%)	37 (80.43%)		
Widowed	15 (31.25%)	9 (19.57%)		
Divorced	1 (2.08%)	0 (0.00%)		
Education			1.57[b]	0.666
Primary school and below	9 (18.75%)	5 (10.87%)		
Junior high school	13 (27.08%)	15 (32.61%)		
Senior high or vocational school	17 (35.42%)	15 (32.61%)		
College and above	9 (18.75%)	11 (23.91%)		
Dwelling status			-[c]	0.495
Living with others	46 (95.83%)	45 (97.83%)		
Living alone	2 (4.17%)	0 (0.00%)		
Nursing home	0 (0.00%)	1 (2.17%)		
Visual impairment	19 (39.58%)	17 (36.96%)	0.07[b]	0.793
Hearing impairment	17 (35.42%)	16 (34.78%)	0.004[b]	0.949
Smoking	14 (29.17%)	9 (19.57%)	1.17[b]	0.279
Alcohol drinking	10 (20.83%)	6 (13.04%)	1.01[b]	0.315

[a], Student-*t* test; [b], chi-square test; [c], Fisher's exact test.

Primary endpoints

The analysis results of the primary endpoints were presented in Figure 2A and Table 2. The mean percent change in WHOQOL-OLD score from baseline to the 3-month follow-up was 29.56% (95% CI: 25.83%-33.26%) in the SMART Group and 17.59% (95% CI: 14.48%-20.69%) in the Usual Care Group, respectively. The covariance model demonstrates a statistically significant superiority of the integrated care delivered by the SMART system in improving the QOL, with an estimated intervention difference of 11.97% (95% CI: 7.20%-16.74%, $p<0.001$). Specifically, within the six dimensions of the WHOQOL-OLD scale, the interventions delivered through the SMART system resulted in significant improvements in the SAB, AUT, PPFA, and SP scores for older adults (all $p<0.001$). However, no significant enhancements were observed in the INT and DAD scores.

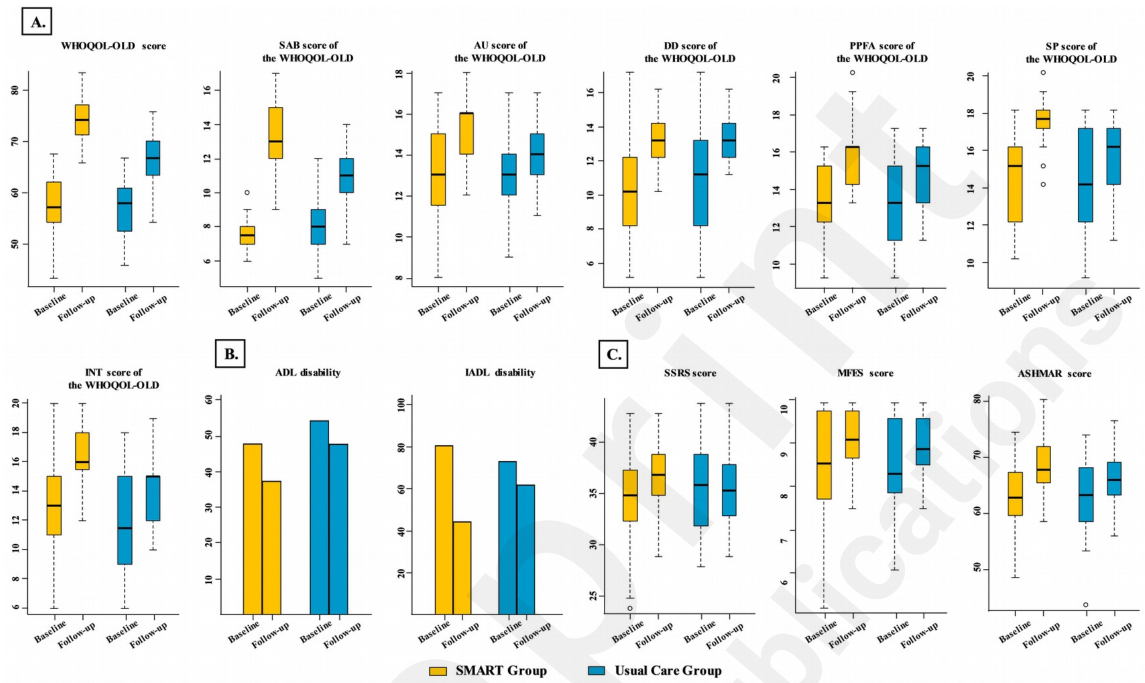

Figure. 2 Effect of the integrated care delivered by the SMART system vs usual care on primary and secondary outcomes in the intention-to-treat analysis. (A) Effect of the integrated care delivered by the SMART system vs usual care on quality of life in the intention-to-treat analysis. (B) Effect of the integrated care delivered by the SMART system vs usual care on functional status in the intention-to-treat analysis. (C) Effect of the integrated care delivered by the SMART system vs usual care on other secondary outcomes in the intention-to-treat analysis.

Secondary endpoints

Regarding the functional status of older participants (see Figure 2B and Table 2), the integrated care delivered by the SMART system significantly reduced IADL disability compared to usual care (OR: 0.34, 95%CI: 0.11-0.83, $p=0.024$), while no statistically significant reduction in ADL disability was observed ($p>0.05$).

As presented in Figure 2C and Table 2, improvements in the SSRS score were significantly greater in the SMART Group compared to the Usual Care Group ($p<0.001$), showing a change of 6.94% versus 0.19% from baseline to the 3-month follow-up. Similarly, the integrated care delivered by the SMART system resulted in a substantial improvement in the ASHMAR score of older participants compared to the usual care (10.60% versus 5.66%, *p*=0.003). Furthermore, although the SMART Group showed an 8.39% improvement in the MFES score from baseline to the 3-month follow-up, this was not significantly greater compared to the 5.51% improvement observed in the Usual Care group (*p*>0.05).

Table 2. Primary and secondary endpoints in the intention-to-treat analysis

Endpoints	SMART Group (n=48)	Usual Care Group (n=46)	Difference (95% CI)[a]	OR (95%CI)	*p*-value
Primary endpoints					
Percent change in WHOQOL-OLD score (%)	29.56 (25.85, 33.26)	17.59 (14.48, 20.69)	11.97 (7.20, 16.74)	-	*<0.001*
Percent change in SAB score of the WHOQOL-OLD scale (%)	78.11 (67.27, 88.96)	40.45 (31.57, 49.34)	37.66 (23.82, 51.49)	-	*<0.001*
Percent change in AU score of the WHOQOL-OLD scale (%)	20.48 (14.29, 26.68)	10.71 (6.09, 15.33)	9.77 (2.15, 17.40)	-	*<0.001*
Percent change in DD score of the WHOQOL-OLD scale (%)	40.51 (26.44, 54.58)	37.94 (20.31, 55.57)	2.57 (-19.69, 24.82)	-	0.584
Percent change in PPFA score of the WHOQOL-OLD scale (%)	20.05 (14.44, 25.66)	10.73 (6.58, 14.87)	9.33 (2.44, 16.21)	-	*<0.001*
Percent change in SP score of the WHOQOL-OLD scale (%)	26.93 (19.74, 34.11)	13.43 (8.99, 17.87)	13.50 (5.16, 21.83)	-	*<0.001*
Percent change in INT score of the WHOQOL-OLD scale (%)	34.73 (24.08, 45.38)	32.61 (19.95, 45.26)	2.12 (-14.20, 18.44)	-	0.628
Secondary endpoints					
Functional status					
Participants with ADL disability at 3-month follow-up, No. (%)	18 (37.50)	22 (47.83)	-10.33 (-30.49, 9.84)	0.54 (0.12, 2.16)	0.388
Participants with IADL disability at 3-month follow-up, No. (%)	21 (43.75)	28 (60.87)	-17.12 (-37.28, -3.04)	0.34 (0.11, 0.83)	*0.024*
Percent change in SSRS score (%)	6.94 (3.93, 9.95)	0.19 (-1.79, 2.18)	6.75 (3.19, 10.30)	-	*<0.001*
Percent change in MFES score (%)	8.39 (4.73, 12.06)	5.51 (3.07, 7.95)	2.88 (-1.47, 7.22)	-	0.169
Percent change in ASHMAR score (%)	10.60 (7.14, 14.07)	5.66 (1.88, 9.44)	4.95 (0.11, 10.00)	-	*0.003*

Italics indicate statistically significant variables (*p*<0.05); [a], data are absolute differences between mean changes and expressed in percentage points; OR, odds ratio; CI, confidence interval; WHOQOL-OLD, World Health Organization Quality of Life Instrument-Older Adults Module; SAB, Sensory Abilities; AUT, Autonomy; DAD, Death and Dying; PPFA, Past, Present, and Future Activities; SOP, Social Participation; INT, Intimacy; AHSMSRS, The Rating Scale of Health Self-Management Skill for Adults; SSRS, Social Support Rating Scale; ADL, Activities of Daily Living; MFES, Modified Fall Efficacy Scale.

Intervention compliance and adverse events

Among the older participants in the SMART Group, 12 (25.00%) demonstrated good compliance with the SMART interventions, 27 (56.25%) had moderate compliance, and 9 (18.75%) had poor adherence.

During the 3-month intervention period, no adverse events were reported in either the SMART Group or the Usual Care Group.

Subgroup and sensitivity analyses

As summarized in Supplementary Materials (P3-P21), consistent results were observed in both primary and secondary endpoints across the subgroup and sensitivity analysis, despite the integrated care delivered by the SMART system not demonstrating a significant reduction in IADL disability among older individuals aged 60-69 years and females, which verified the robustness of our findings to a certain extent.

Discussion

Principle Results

This study demonstrates a significant improvement in the QOL of home-dwelling older individuals who received personalized and integrated care provided by the SMART system, an intelligent and integrated older care model that facilitates integrated home-based older care, compared to those receiving usual care. In addition, substantial enhancements were also observed in health self-management ability and social support, along with a significant decrease in IADL disability. To the best of our knowledge, this represents the first RCT to evaluate the effectiveness of personalized and integrated care service delivered through a digitally structured system for home-dwelling older individuals.

Our findings exhibit both face and internal validity for the following reasons. First, in line with previous studies [31, 32], the current study confirms the positive effect of personalized, intelligent, and integrated care interventions on improving outcomes of older people, particularly the QOL. Moreover, our research design employs a RCT, recognized as the gold standard for establishing causality [Error: Reference source not found]. The random assignment of participants minimizes selection bias and controls for confounding variables, ensuring that any observed outcome differences can be attributed directly to the SMART system interventions. Furthermore, the use of standardized interventions and measures throughout the study enhances the reliability and validity of our findings. Finally, the sensitivity analyses yield consistent results, further supporting the reliability and generalizability of the research findings.

Through a three-month intervention, our study demonstrated that personalized and integrated care significantly enhanced the QOL, health self-management ability, and social support, while also reducing IADL disability among older adults living at home. Several reasons may account for these outcomes. Firstly, as a knowledge-based CDSS, the SMART system can deliver integrated care interventions tailored to the specific needs and preferences of older adults in easily understandable formats, such as text, images, and videos. This customization and ease of use fosters trust and engagement with the recommended interventions, promoting a sense of ownership and empowerment that leads to improved health outcomes in the QOL and IADL functioning [Error: Reference source not found, Error: Reference source not found]. Secondly, the SMART system creates a supportive feedback environment that transcends time and space limitations [36]. It continuously adjusts interventions based on real-time monitoring and provides timely encouragement and reminders, which allows older adults to focus on the recommended interventions, thus greatly promoting proactive health behaviors and helping manage their conditions more effectively. Thirdly, the personalized interventions and health-related information provided by the SMART system likely contribute to the significant improvements observed in participants' health self-management ability. Fourthly, the SMART system can facilitate social connections through virtual platforms, reducing feelings of isolation and enhancing social support networks, which in turn contributes to the improved QOL [37]. However, the SMART system did not significantly improve fall efficacy or effectively reduce ADL disability among older adults, which can be attributed to the fact that the short intervention period was insufficient to produce noticeable effects.

Regarding the subgroup analyses, no significant reduction in IADL disability was observed among older women and individuals aged 60-69 after receiving the personalized and integrated care delivered by the SMART system. One possible explanation is that women were found to exhibit lower digital literacy, making it more difficult for them to adapt to the new strategies introduced by the SMART system, thereby affecting their responses to these interventions [38]. Additionally, given that individuals aged 60-69 typically maintain relatively good functional capacity, the potential for improvement may be limited, which could restrict the effectiveness of any intervention [39]. Lastly, the short intervention period may not allow sufficient time for participants to fully integrate the interventions into their daily routines or to experience noticeable improvements.

This study is the first RCT exploring the effectiveness of personalized and integrated care on older adults living at home. The positive findings provide valuable evidence to support the potential use of similar systems in clinical practice and offer insights for the future development of such systems. By demonstrating the effectiveness of integrated care facilitated by our SMART system, the study also emphasizes the importance of tailoring interventions to meet older people’s specific needs, which can in turn lead to better health outcomes and enhanced functional status, ultimately improving the QOL.

Limitations

There are several limitations in this study. Firstly, although a sample size of 78 provided sufficient statistical power, our study included relatively small sample sizes. Secondly, our study was inherently limited to finite representativeness by a short intervention period. A larger sample size with a long intervention period is therefore required to further validate our findings for wider generalization. Thirdly, due to the challenges posed by the Coronavirus Disease 2019 pandemic in accessing older adults’ homes, we only included older individuals who were about to return home after discharge and owned Android-based smartphones for internet access. While this approach may introduce a potential selection bias, it can also provide valuable insights and yield reliable results. Fourthly, the nature of the intervention made it impossible to blind the older participants and nurses providing the intervention. To reduce the risk of bias, other procedures such as proper allocation concealment were implemented to ensure rigor and reproducibility [40]. Finally, although we primarily relied on self-reported ratings for effectiveness evaluation, using percent changes as a metric for measuring outcomes provided a more objective assessment and mitigated potential biases effectively [41].

Conclusions

The current study demonstrated a significant improvement in the QOL of older individuals living at home after receiving personalized and integrated care provided by the SMART system. Future RCTs with large sample sizes and long intervention periods are needed to validate their effectiveness in Chinese older population.

Authors' Contributions

Rongrong Guo contributed to the methodology, investigation, data curation, and writing of original draft. Jiwen Zhang contributed to the methodology, investigation, data curation, and writing of original draft. Fangyu Yang contributed to conceptualization, methodology, and supervision. Ying Wu contributed to the conceptualization, methodology, funding acquisition, review and editing of the manuscript, and supervision.

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Conflict of Interest

None declared.

Abbreviations

ADL: activities of daily living

AHSMSRS: Health Self-Management Skill for Adults

AI: artificial intelligence

AUT: autonomy

BMI: body mass index

BI: Barthel Index

CDSS: clinical decision support system

CONSORT: Consolidated Standards of Reporting Trials

DAD: death and dying

IADL: instrumental activities of daily living

ICT: Information and Communication Technology

ITT: intention-to-treat

INT: intimacy

MFES: Modified Fall Efficacy Scale

MICE: Multiple Imputation by Chained Equations

OR: odds ratios

PP: per-protocol

PPFA: past: present: and future activities

QOL: quality of life

RCT: randomized clinical trial

SAB: sensory abilities

SD: standard deviation

SOP: social participation

SSRS: Social Support Rating Scale

WHO: World Health Organization

WHOQOL-OLD: World Health Organization Quality of Life Instrument - Older Adults Module

Data availability statement

The data that support the findings of this study is available from the corresponding author upon reasonable request.

Ethics Statement

The study was approved by the Institutional Review Committee of the Capital Medical University (Approval No. 2015SY49U).

Multimedia Appendix

Multimedia Appendix 1：CONSORT-EHEALTH checklist

Multimedia Appendix 2：Detailed imputation methods, subgroup analysis results and sensitivity analysis results

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Supplementary Files

Multimedia Appendixes

Detailed imputation methods, subgroup analysis results, and sensitivity analysis results.
URL: http://asset.jmir.pub/assets/4b2c4cd5d5beb45271a7539c2cae57de.docx

CONSORT (or other) checklists

CONSORT EHEALTH Checklist.
URL: http://asset.jmir.pub/assets/b9e6a494571fe1127b3caee84017e905.pdf