Methods Article

Effects of a video-based mHealth program for the homebound older adults: study protocol for a randomized controlled trial

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Abstract

Background: Although homebound older adults are among the highest users in hospital services, the existing health and social services that provided to them in the community are limited and fragmented. This study tries to bring this group of older adults to the providers' attention and design a health-social oriented self-care mobile Health (mHealth) program and subject it to empirical testing. The aim of this study is to shift the current reactive, cure-oriented approach to a preventive and health promoting model, empowering the homebound older adults to take an active role in their health, be responsive to their care needs, and subsequently improve their holistic health.

Methods: This is a randomized controlled trial. The study is supported by five community centers with an estimated sample size of 68 subjects. The subjects will be randomly assigned to video-based mHealth and control groups when they are (1) aged 60 or above, (2) going outdoor less than once per week in current six months, (3) living within the service areas, and (4) using smartphone. Subjects in the video-based mHealth group will receive two main elements, which include nurse case management that supported by a social service team and an individual-specific video messages covering self-care topics that delivered via smartphone. The control group will receive usual care only. Data will be collected at two time points—pre-intervention (T1) and post-intervention (T2). The primary outcome measure will be activity of daily living and secondary outcomes will include health outcomes (instrumental activities of daily living, medication adherence), perceived well-being outcomes (quality of life, self-efficacy, depression), and health service utilization outcomes (outpatient clinic, emergency room, hospital admission).

Discussion: The current study will add to the knowledge gap in using mHealth supported by a health-social team in enhancing quality of life and self-care and meeting the needs of these particularly vulnerable older adults.

Trial registration: This study has been registered at clinicaltrials.gov (identifier: NCT04304989). Registration date: 10/3/2020.

Introduction

The number of homebound older adults has been rising rapidly due to the ever-increasing growth of aging population. The latest report showed that approximately 2 million older adults aged 65 and older in the United States are considered as homebound [1]. Similar to the figures of several OECD countries (i.e. 5%-20%) [2], the prevalence rate of homebound older adults in Hong Kong has been estimated at about 8.9% of the population [3], with some estimating the percentage to be as high as 12.5% [4].

Homebound older adults are defined as those who confined to their home due to a combination of chronic conditions and physical and functional impairments, and normally not able to go outdoors more than once per week [5]. Their homebound state is considered as a barrier to gain access to the community and restrict from joining community programs. When these older adults experience health and social problems, many of them struggle to manage on their own and rely heavily on acute and tertiary care if no other help is available [2]. A statistical report revealed that homebound older adults had significantly higher rate of emergency admission use and were more likely to admit to hospital and long-term care facilities and consumed more health care expenditures when compared to their non-homebound counterparts [6]. The high use of health care services is not only related to their physical limitations and complex health and social care needs, but also reflective of the lack of a comprehensive primary health care structure to support the self-care of this population in the community [7].

Although homebound older adults have higher levels of comorbidity and physical impairments than their non-homebound cohorts do, they have shown the ability to take good care of themselves at home when they could be given opportunities to learn about their health conditions. A feasibility study showed that homebound older adults were able to access health information on the internet and managed their chronic diseases at home after attending computer-training lessons [8]. Another pilot study demonstrated that homebound older adults could successfully manage and adhere to their medicines when they were offered a self-care agenda by pharmacists [9]. Evidence suggested that people who are capable to adhere to self-care activities show a decrease in health services utilization and the healthcare cost, with increase in satisfaction level, sense of control, well-being, self-efficacy, quality of life, and most importantly, stay independently in their own community as long as possible [10, 11]. Yet, to date, there are few programs attempted to empower the homebound older adults to take an active role in their health.

Community health care organizations are frequently under economic constraints to provide better services with fewer resources [12]. Mobile health (mHealth) is emerging as a solution for overcoming this challenge and offering low cost, ready access, and individualized care to people [13]. mHealth not only enables information sharing across professional and organizational boundaries, it provides an easy-to-use platform for connecting older adults electronically with the health care professionals without the need of leaving home [14]. According to WHO, mHealth is defined as a medical and public health practice using the core utility of mobile and wireless technologies to support the achievement of health objectives [15]. A systematic review found that mobile instruction video is the most commonly used and successful strategy in mHealth programs to facilitate behavioral change, increase knowledge and understanding, and improve compliance with medical instructions for older adults [16]. Evidence showed that video have outperformed images or written words since they cannot convey dynamic body language and facial expressions [17]. This delivery channel proves to be particularly useful in older adults who have limited education, motivation and health literacy as video requires less reading of multiple pages of written material [18]. Recent studies integrating mobile instruction video in primary health services have demonstrated positive results on promoting physical activity [19], balanced diet intake [20], and medication adherence [21], which suggested that employing the video-format approach as a platform for promoting self-care might be a viable way forward.

Existing studies of mHealth interventions have demonstrated inconsistent results on improving self-care of older adults. A trial involved one-way video messages in a diabetes care program showed that there was a larger rate of decline in blood glucose in older adults who received the messages than those who received no messages, but the difference was not statistically significant [22]. Another study provided basic program information, video and a simple fact sheet about heart failure to a group of older adults who have heart failure with the aim of improving their self-care ability [23]. The results indicated that there were no significant differences in physical activity, health status, and health care cost and utilization between intervention and control groups. In fact, homebound older adults are a group of disabled person who have multiple health and social needs, mHealth intervention that provided self-care information alone may not be enough for them to remain living in the community. In order to promote their self-care and independent living, building a health-social team in the community that can provide individualized care is imperative. Within the team, nurse plays an important role in delivering and coordinating most of the health care services including continuous comprehensive assessment, case management, health education, and medical and social referral; while social worker is well-positioned to mobilize tangible community resources, and

provide psychological and financial reassurance. To our knowledge, there is no study investigating the use of health-social team with the support of mHealth on empowering and promoting self-care of homebound older adults. This proposal therefore endeavors to develop a mHealth program, with the integrated efforts of a health-social team, on increasing self-care ability and health among homebound older adults and submit it to empirical testing. This study adds to the knowledge gap in using mHealth supported by a health-social team in enhancing quality of life and self-care and meeting the needs of these particularly vulnerable older adults.

Aims and research questions

The aim of this study is to test the effects of a video-based mHealth program and the control group receiving usual care on health outcomes, perceived well-being and health service utilisation. Specifically, we ask:

1. Is there a difference in health outcomes (i.e. activities of daily living, instrumental activities of daily living, medication adherence) between the intervention group and the control group?

2. Is there a difference in perceived well-being outcomes (i.e. quality of life, self-efficacy, depression) between the intervention group and the control group?

3. Is there a difference in health service utilisation outcomes (i.e. outpatient clinic, emergency room admission, hospital admission) between the intervention group and the control group?

Methods/Design

The SPIRIT statement was used as a guideline for this protocol paper [24].

Study design and setting

This is a single-blinded, two-armed randomized controlled trial. The research assistant who collects the data is blinded but the subjects and the health care providers who involve in the intervention are

not. This study is supported by five community centres. The location of centres are widely scattered in Hong Kong, which help maximize the generalizability effect of this program.

Participants and recruitment strategy, and randomization

The leaders of the community centres will help draw a list of potential subjects. Simple random sampling with fixed sample size will be employed to recruit subjects. The inclusion criteria of this study include: (1) people who are aged 60 or above, (2) go outdoor less than once per week in current 6 months [14], (3) living within the service area of community centre, and (4) using smartphone. The exclusion criteria are: (1) diagnosed with dementia, (2) unable to hear, see or communicate, (3) bed-bound, (4) active psychiatric illness with recent hospital admission within last 6 months, (5) living within an area with no internet coverage, and (6) already engaged in other mHealth programs.

The potential subjects will be approached and invited to participate in the study. Consent form will be signed once the subject agrees to participate. The random assignment schedule, generated using the computer software Research Randomizer, will be compiled by a research team member who is not involved in subject recruitment. The group assignments will be put in a sealed envelope and revealed sequentially at the time of randomization. The research assistant, after successfully recruited a subject, will call the research team member for the random assignment. The research team member who has no knowledge of the identity of the subject will make the assignment based on the computer number (‘1’ = video-based mHealth program; ‘2’ = control group).

Interventions

A 3-month program will be designed in this study. There will be two groups involved in this study with description as follows.

Intervention group

This group of participants will receive a video-based mHealth program which includes two main elements: 1) nurse case management supported by a social service team, 2) individual-specific video messages covering self-care topics delivered via smartphone.

Upon enrolment, each client in the intervention group is assigned to a nurse case manager. The nurse case manager will conduct a structured assessment in the client’s home by using the Omaha System [25]. The Omaha System is a comprehensive assessment-intervention-evaluation tool that

identifies 42 problems under the domains of environmental, psychological, physiological, and health-related behaviours. The Omaha System has been found to be applicable for older adults in the community and proven valid to be used in Hong Kong [26]. Following assessment, nurse case manager will guide and empower the clients to set their own goals and co-decide their own plans to manage their health problems.

Apart from monitoring the progress of the clients in accordance to the contract goals in a weekly telephone call, the nurse case manager will also send weekly, individual-specific videos of tips and reminders via smartphone. These videos cover topic of importance to clients according to the result of the Omaha System. The content of videos includes but not limits to chronic disease self-management, healthy behaviours, simple self-care practices, and medication knowledge. The selected videos are limited to ten minutes to accommodate the short attention span of older adults [27]. All videos that provided to the intervention group are originating from reliable sources such as Hospital Authority, Department of Health or credible health or charity organizations. Nurse case manager will first send a testing video to the client in the first home visit to ensure that the client can receive the video on his/ her mobile. The client can either download the videos or view online. The videos will run continuously unless the client presses the “pause” button. Videos can be replayed once clicking the “play” button again.

A protocol for referral system will be established with the full support of health-social team in accordance with the conditions and the needs of the client. The nurse can initiate client referral according to the set guidelines. The health referrals include primary care consultation and hospital service if indicated. Social referrals include home meal service, psychological counselling and the like. In this team, the nurse case manager is responsible to provide health-related services such as health education and drug compliance monitoring, while social workers can provide services including arrange home-delivered meals, provide psychosocial support, and mobilize community resources available in the district. A monthly case conference will be held in the community centre between nurse case manager and social worker. Issues such as progress and concern of the clients, suggestions for interventions, and requirement of modification or adjustment of goals will be

discussed during the meeting. The shared responsibilities are based on standardized protocols and agreed referral forms and records.

Control group

Both the intervention and control groups will receive their respective community services as usual. The most common services provided by community centres include meal and laundry services, transportation service, health check and education, and social activities, but most of them are episodic in nature. Social calls will be provided to the control group clients by a research team member who will not involve in data collection to minimize possible social effects. The social questions such as “where will you go tomorrow?” and “what is your hobby?” will be set in the protocol. The research team member will strictly follow the protocol and will not provide health advice. The clients will be asked to seek medical help whenever the older adults express concern about their health.

Data collection

Data will be collected at two time points—pre-intervention (T1) and post-intervention (T2). The baseline and the post-intervention data will be collected at the client’s home by the research assistant who is blinded to the grouping. Previous study has found that collecting data at their own home can yield the highest response from the homebound older adults since they seldom go out [28]. The research assistant will be trained and tested on the inter-rater and intra-rater reliability. Five percent of the data will be randomly selected for independent review to ensure data quality.

Figure 1 shows the schedule of enrolment, interventions, and assessments according to the SPIRIT Group [24].

Outcome measures

There are 4 sets of measures, including the demographics, health, perceived well-being and health service utilization outcomes.

Primary outcome

The primary outcome is the activity of daily living of the older adults. Activities of daily living will be measured by the Chinese version of Barthel index. This 20-item questionnaire was validated with a reported inter-rater reliability of 0.99 [29].

Secondary outcomes

The secondary outcomes include health outcomes (instrumental activities of daily living, medication adherence), perceived well-being outcomes (quality of life, self-efficacy, depression), and health service utilization outcomes (general outpatient clinic, emergency room admission, hospital admission).

Instrumental activity of daily living will be measured by the Chinese version of Lawton Instrumental activity of daily living [30]. The scale covers tasks such as telephone, shopping, meal, and transport. The Cronbach's alpha internal consistency and the inter-rater reliability was 0.86 and 0.99 respectively [30]. Medication adherence will be measured using the Adherence to Refills and Medication Scale [31]. The 12-item self-reporting questionnaire was designed to assess the respondent's ability to take and refill all prescribed medications under different circumstances. It has been shown to be highly valid in identifying medication adherence issues of community-dwelling older adults [31].

Quality of life will be measured by the Short Form 12 item (version 2). The scale has been translated and proven reliable for use among the Hong Kong Chinese older adults [32]. The internal consistency and test-retest reliabilities were good, and the SF-12v2 summary scores explained more than 80% of the total variances of the SF-36v2 summary scores [32]. Self-efficacy will be measured by General Self-Efficacy Scale. High Cronbach's alpha internal consistency (0.89) was shown in this scale [33].

Depression will be measured by the Chinese version of the Geriatric Depression Scale. Good validity and reliability were reported [34].

Health service utilization will be measured by the number of attendance to government out-patient clinics and the emergency department, and the number of hospital admissions. The information will be collected by the subjective reports of participants.

Background demographic data

The background demographic data that collected at baseline include age, gender, education level, marital status, years of using smartphone, work status, accommodation type, financial status, family living in the same household, and caretaking support. The entire set of baseline measures has been validated in a previous study [27].

Quality assurance mechanism

This study will adopt a number of measure to ensure that the intervention delivery is valid and reliable. The nurse case manager employed in this study will have extensive experience in community elderly care, with competent level in using a smartphone, good communication skills, and the ability to work with a team. A training session will be given to providers in the areas of case management, referral system, the Omaha system, telephone counselling skills and guideline for telephone follow-up. During the training session, providers require to provide interventions to a simulation client in front of the research team to ensure they understand and comply with the set protocols prior to actual implementation of the study. Research team member who will not involve in intervention and data collection will pay random home visit with providers to ensure the interventions are given according to the protocols and guidelines. The health-social team and the research team will meet regularly to review and discuss the progress of cases.

Ethical considerations

The present study was granted ethical approval from the Human Subjects Ethics Sub-Committee (HSESC) of the University before the commencement of the study. This study will not cause any discomfort or painful sensation to participants. Information about and an explanation of the ethical observations of the study will be provided to all eligible participants and they will be asked to sign an informed consent. Participants will be reassured that they can withdraw from the study any time

without any adverse consequences. They will remain anonymous and all data will be identified by a case number only. All data collected from questionnaires will be stored in a cabinet that required password to open.

Sample size

The sample size calculation is based on power analysis. Assuming a two-tailed alpha of 0.05, a probability of 0.2 for beta error (80% power), and an effect size of 0.436 after taking reference of previous video-based mHealth programs with the same primary outcome measure (activity of daily living) [26], eighty-four per group are required. With reference to the 10% to 15% attrition rate reported in the previous programs [35, 36], we assume a 15% drop-out rate in this study, thus the total sample size needed is 97 participants per group, i.e. a total of 194 participants. However, since this is a pilot study, according to a study [37], at least 9% of the sample size of the main planned trial should be used. To ensure the power is enough to estimate the group difference, 35% of the main planned trial is set [38]. The total number of clients required therefore is 68. The flow of this study will follow the Modified CONSORT Statement extension for individual randomized controlled trials of non-pharmacological treatments [39] (Fig. 2).

Data processing and analysis

The research assistant and the research team member will independently enter the data into the SPSS software (version 25.0, IBM). The inconsistencies between these two files have to be resolved by retrieving the raw data from the questionnaires. Descriptive statistics will be used to detect potential outliers.

The participants' baseline characteristics will be compared using chi-squared test or Fisher's exact test (in case the expected frequencies in one of the cells are less than 5) for categorical variables and two samples independent t-test for continuous variables. The p-value is set less than 0.05 as significant result for two-tailed test.

Comparisons of outcome variables with the intervention group before and after the intervention program will be analysed using the paired t-test or Wilcoxon signed rank test. The outcome variables between the intervention and control groups in T2 will be analysed using the independent t-test when the data is normally distributed; or otherwise, Mann-Whitney U-test will be used. Logistic regression and chi-squared test will be used for analysing the use of health service (health service

use/ no unplanned service use) in dichotomized outcomes. Odds ratios with 95% confidence intervals will be calculated and reported. Multiple imputation procedure will be employed to impute the missing data. All analyses will be conducted according to Intention-to-treat (ITT) method.

Discussion/Conclusion

Homebound older adults are an understudied population that often lives with multiple chronic diseases. Without regular access to primary preventive care, these frail older adults have high risk of moving into long-term care facilities rather than staying in the community. As for the older adults themselves, they would prefer living independently in their own homes rather than receive institutional care due to their emotional attachment to their familiar and comfortable environment.

Currently, the health and social services provided to the homebound older adults are both manpower-intensive and episodic in nature. This study aims to facilitate age in place by providing holistic care to these vulnerable group of people with the support of technology and a health-social team in the community. To our knowledge, this program is one of the few to not only include the homebound older adults who are traditionally excluded from the benefits of mHealth, but also empower them to take care of themselves so as to increase their self-efficacy, quality of life, maintain basic and instrumental activities of daily living, and reduce unnecessary hospital admission and expenditure.

Although the study is well-planned, there are barriers the research team can anticipate during the implementation of the program. Firstly, it is not guaranteed that the sample size required can be met. The homebound older adults can be difficult to reach since they seldom participate and engage in community services due to these physical and functional limitations. However, the community centre staff will call every potential clients who meet the eligibility criteria from the member list to participate in the study in order to secure enough sample size. Secondly, it is difficult to ensure the intervention group participants have watched the video at home. In light of this, the nurse case manager will ask the participants about the content of the video during telephone follow-up. Suitability and complexity of the video content can also be clarified during their conversation in a weekly basis.

When the health care system lacks the necessary structure to effectively and efficiently support the homebound older adults in the community, the use of health care services tend to be higher. In response to this, this study initiates a video-based mHealth program with the support of a health-social team to enhance their quality of life and improve health condition, as well as arouse the

interest of other community stakeholders, researchers, and policymakers to pay more attention to these vulnerable, but usually neglected group of people. If the program is proved to be effective, the accomplishment of the goal of aging-in-place for these older adults can be a step closer.

Statements

Acknowledgement

We would like to thank all the community centers for their collaboration with the research team.

Statement of Ethics

The present study was approved by the ethic committee of the university (reference no: HSEARS20190922002). Written informed consent will be obtained from the participants before commencement of the program.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

AW and FW had the initial idea, developed the original study plan and supported the development and implementation of the interventions. AW is responsible for developing the content of protocols and organizing training workshops. KC and SW will be involved in data collection and conducting the study. All authors have revised the draft manuscript critically and have approved the final manuscript.

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Figure Legends

Fig. 1. The schedule of enrolment, interventions, and assessments.

Fig. 2. Modified CONSORT flow diagram for individual randomized controlled trials of nonpharmacologic treatments.