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Feasibility Study of a Mobile Health Intervention for Older Adults on Oral Anticoagulation Therapy

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Abstract

Background: Oral anticoagulation treatment (OAT) such as warfarin therapy is recommended for older adults with atrial fibrillation, heart failure, or who are at risk for venous thromboembolism. Despite its proven benefits, older adults report both dissatisfaction with OAT and reduced quality of life that can potentially lead to low adherence to OAT and decreased treatment efficacy. **Objective:** To test the feasibility of Mobile Applications for Seniors to enhance Safe anticoagulation therapy (MASS), a mobile-based health technology intervention designed to promote independence and self-care. **Method**s: This pilot study used a single-arm experimental pre–post design to test the feasibility of a 3-month intervention using MASS in 18 older adults (male: n = 14; White: n = 9; Hispanic: n = 7; Other: n = 2; M age = 67). MASS was available in English or Spanish. Participants completed surveys about their OAT knowledge, attitudes, quality of life with OAT, and adherence at baseline and at a 3-month follow-up. Satisfaction with the MASS intervention was also assessed at follow-up. **Results:** Anticoagulation knowledge significantly improved from baseline to follow-up (M_{base} = 12.5 ± 5.51, $M_{follow\text{-}up}$ = 14.78 ± 3.93, p = .007). Other outcomes were not different, pre- and post-tests. Participants reported they were generally satisfied with MASS, its ease of use and its usefulness. **Conclusion:** The results showed use of MASS improved older adults' knowledge of OAT. Using mHealth apps may enhance self-care among older adults with chronic conditions who are also taking oral anticoagulants.

Keywords

anticoagulation therapy, mobile health application, older adults, self-management

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Introduction

Mobile health (mHealth) applications (apps) have been used in studies focusing on enhancement of self-management of chronic diseases (de Ridder, Kim, Jing, Khadra, & Nanan, 2016; Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015). Mobile health apps and electronic tools are most commonly used among young adults and adults with chronic diseases such as diabetes, cardiovascular diseases, cancer, or chronic obstruction of pulmonary disease (Hamine et al., 2015). However, mHealth app–based interventions may also benefit older adults in managing chronic diseases.

It is recommended that older adults with cardiovascular disorders (e.g., atrial fibrillation, heart failure, venous thromboembolism) take long-term oral anticoagulation treatment (OAT) such as warfarin therapy (De Caterina et al., 2007; Go et al., 2003; Kearon, 2004). Warfarin therapy requires frequent monitoring due to its narrow therapeutic range and has numerous drug and dietary interactions (Merli, 2012). Older adults on

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warfarin therapy report low quality of life (QOL) and dissatisfaction with warfarin therapy (Corbi, Dantas, Pelegrino, & Carvalho, 2011; Sinnaeve et al., 2012) in part, due to complicated treatment regimens that affect their diet and activities. Furthermore, effectiveness of OAT is largely dependent on a patient's ability to follow a multi-component treatment regimen that might be problematic for older adults with limited health literacy and/or language barriers (Gatti, Jacobson, Gazmararian, Schmotzer, & Kripalani, 2009). Minority older adults such as Hispanic elders have been shown to exhibit poor adherence due to inadequate knowledge (Corbi et al., 2011) related to warfarin therapy in particular Latin foods containing high amount of Vitamin K (e.g., prickly pear, chilaquiles; U.S. Department of Agriculture, n.d.).

Although new oral anticoagulants (e.g., dabigatran, rivaroxaban, apixaban, or edoxaban) that do not require monitoring or dose adjustment and have no major food and drug interactions have been replacing warfarin for older adults with atrial fibrillation (AF) (Chatterjee, Sardar, Biondi-Zoccai, & Kumbhani, 2013). Health insurance coverage for these new oral anticoagulants have been are limited. This may result in older adults with low socio-economic status still having to take warfarin therapy to prevent thromboembolism. Obstacles with warfarin therapy have prompted the search for alternative strategies that enhance OAT effectiveness by improving self-management skills, especially among older adults. An mHealth technology–based intervention using medication reminders, symptom monitoring, and communication tool with care providers could be a promising approach for older adults on OAT including Hispanic elders. A multidisciplinary team including clinicians and researchers from University of California Irvine developed a culturally appropriate, age-sensitive mHealth app called MASS (*M*obile *A*pplications for *S*eniors to enhance *S*afe anticoagulation therapy) to promote independence and self-care. The MASS development has been described in details elsewhere (Lee et al., 2014).

The purpose of the study was to test the feasibility of the MASS program in older adults on warfarin therapy and to evaluate changes from baseline to 3-months in oral anticoagulation knowledge (OAK), medication adherence, and emotional well-being (e.g., QOL, depressive symptoms, anxiety).

Method

This prospective, quasi-experimental study with a single-arm pre–post design was conducted at a single university-affiliated medical center. Participants were recruited between June 2014 and June 2015 from two outpatient anticoagulation clinics affiliated with an academic medical center in Southern California. A sample size of approximately 20 to 25 was chosen based on feasibility (i.e., the number feasible to recruit within our given time frame) and recommendations for the optimal *N* for use in a pilot study (Evangelista et al., 2015).

Study Participants

To be eligible, patients had to be (a) 55 years old or older, (b) taking an oral anticoagulant (e.g., warfarin), (c) English or Spanish speaking, (d) not cognitively impaired according to Mini-Cog^{TM} (total score ≥ 3; Borson, Scanlan, Chen, & Ganguli, 2003; Borson, Scanlan, Watanabe, Tu, & Lessig, 2006, p. 5) without a diagnosis of irreversible conditions which is likely to affect 6-month survival or ability to participate in the study, and (e) not living in a long-term care facility.

Passive and active recruitment strategies were used including (a) posting study fliers on bulletin board outside the waiting room in the anticoagulation clinics, (b) anticoagulation specialized pharmacists in clinics referring eligible participants to the research team, and (c) the research team calling and introducing eligible participants who were previously referred to the study. The study protocol was approved by the institutional review board at the University of California Irvine. Written informed consent was waived by the institutional review board (IRB) due to the nature of the study's minimal risk. However, a summary of study details (study procedures, potential risks, and benefits) was provided.

Procedures

Patients who agreed to participate in the study were instructed by trained research assistants on the use of the MASS system (described below) and its components. Family members willing to support the senior participating in the study were also instructed on the use of MASS program.

Participants were provided with a 10″ screen, Android tablet that included the MASS program for 3 months. Telephone calls were scheduled at Weeks 1, 2, 4, and 8 to evaluate and provide technical support on use of the MASS program. Participants were asked to complete questionnaires at baseline and 3 months later that assessed OAT convenience and satisfaction, OAT medication adherence, QOL, and depressive and anxiety symptoms. Satisfaction with the MASS app was measured at 3 months. Participants received US$50 cash at baseline and an additional US$100 cash after the 3-month MASS intervention for completing the study.

MASS Program

The MASS program was developed by researchers, clinicians, and engineering scientists from the University of California Irvine based on the patients and caregivers' feedback and comments on existing mHealth apps (Lee et al., 2014). The MASS was designed specifically for older adults who spoke English or Spanish. The modules of the MASS app for warfarin therapy include (a) education about anticoagulation therapies and safety tips, (b) medication self-monitoring and reminders, (c) Vitamin K content of foods including common "Hispanic foods,"

(d) monitoring of signs and symptoms of bleeding/bruising, (e) monitoring blood (i.e., international normalized ratio [INR]), (f) connecting with trusted other people (e.g., family caregivers, friends), and (g) message to tell doctors which includes information (e.g., bleeding episode, time, images taken, and description) that may be helpful at doctor's appointments. Participants were encouraged to use the MASS app every day to log bleeding or bruising, to set up daily reminders to take warfarin on time and to search Vitamin K content of foods.

Measures

Demographics. Participants reported on their gender, age, race/ethnicity, marital status, living arrangements, employment status, and highest level of completed education. They also reported on their smoking history and current alcohol consumption and height and weight (used to calculate body mass index [BMI]).

Charlson comorbidity index (CCI). Participants reported whether or not they have had or currently have 19 conditions including asthma, cancer, diabetes, rheumatoid arthritis, and other diseases. The CCI is a summary index that weights each conditions based on its association with mortality (Kastner et al., 2006).

OAK test. The OAK test is a 20-item measure that assesses knowledge of anticoagulation medication, including its utility and proper usage (Winans, Rudd, & Triller, 2010; Zeolla, Brodeur, Dominelli, Haines, & Allie, 2006). A summary score is calculated that ranges from 0% to 100% correct responses. In the current study, Cronbach's α was .54 at baseline and .79 at follow-up.

Perception of Anticoagulant Treatment Questionnaire (PACTQ). The PACTQ includes 13 items that assess how convenient patients perceive their treatment to be (e.g., "How bothered are you by taking your anticoagulant treatment?") and seven items that assess satisfaction with treatment (e.g., "Overall, how satisfied are you by your anticoagulant treatment?") administered using five response categories (Prins et al., 2009). All items are answered on a 5-point Likert-type scale. The items for each component are averaged, and higher scores indicate greater treatment convenience and treatment satisfaction, respectively. Cronbach's alphas in the current study were as follows: treatment convenience: baseline = .68, follow-up = .74; treatment satisfaction: baseline = .85, follow-up = .67.

Duke Anticoagulation Satisfaction Scale (DASS). The DASS consists of 25 items that collectively assess the impact of anticoagulant treatment on QOL (Samsa et al., 2004). Example items include "Overall, how much does your anti-clot treatment affect your daily life?" and "How frustrating do you find your anti-clot treatment to be?" Items are rated on a scale from 0 (*not at all*) to 7 (*quite a bit*). An average score is calculated across all items with higher scores indicating worse QOL. In the current study, Cronbach's α was .80 at baseline and .82 at follow-up.

Patient Health Questionnaire (PHQ-9). The PHQ-9 assesses patients' depressive symptoms using nine items focused on the past 2 weeks (Martin, Rief, Klaiberg, & Braehler, 2006). Sample items are "Little interest of pleasure in doing things" and "Feeling down, depressed, or hopeless." Items are rated on a 0 (*not at all*) to 3 (*nearly every day*) scale. An average score is computed with higher scores indicating greater depression symptoms. In the current study, Cronbach's alphas were as follows: baseline = .39, follow-up = .86.

Brief Symptom Inventory (BSI). The Anxiety subscale of the BSI asks participants how much they were distressed by six different symptoms.(Derogatis & Melisaratos, 1983) Sample items were "nervousness or shakiness inside" and "feeling fearful." Items are rated on a scale from 0 (*not at all*) to 4 (*extremely*). Average scores were computed with higher scores indicating greater anxiety. In the current study, Cronbach's αs were as follows: baseline = .72, follow-up = .80.

Morisky Medication Adherence Scale (MMAS). The MMAS assesses patients' self-reported adherence to their anticoagulant medication (Morisky, Ang, Krousel-Wood, & Ward, 2008). The scale consists of eight items: seven yes/no items (e.g., "Did you take your blood thinner medicine yesterday?") for which *yes* responses are coded as 1 and *no* responses are coded as 0, and one item with a 5-point response scale (i.e., "How often do you have difficulty remembering to take all your blood thinner medicine?") for which the response was divided by four to standardize the item. All eight items are summed, with higher scores indicating greater medication adherence. In the current study, Cronbach's αs: baseline = .52, follow-up = .18.

Perceived Health Web Site Usability Questionnaire (PHWSUQ-12). The PHWSUQ-12 assesses patients' perceptions of the MASS intervention (Nahm, Resnick, & Mills, 2006). It consists of three separate components that ask about patients' satisfaction with the intervention (e.g., "Overall quality of graphics"), the ease of using the MASS (e.g., "I found this MASS easy to learn"), and its usefulness (e.g., "Using this MASS will help me understand specific health problem(s)"). All items are rated on a 1 to 7 scale. Responses are averaged for each component and across all items, with higher scores indicating greater satisfaction with, greater ease of using, greater usefulness, and greater overall usability of the MASS intervention, respectively. In the current study, Cronbach's αs: satisfaction = .95, ease of use = .69, usefulness = .98, and overall usability = .94.

Table 1. Demographic Information for Study Sample (*N* = 18).

	Sample descriptors	
	M or frequency	(*SD*) or %
Gender		
Male	14	78
Female	4	22
Age (year)	67.28	(8.72)
Ethnicity		
Caucasian	9	50
Hispanic	7	39
Other	2	11
Education		
Less than high school	5	28
High school degree or more	13	72
Employed		
Full-time/part-time	4	22
Not employed	12	67
Other	2	11
Comorbidity (Charlson index, 0-8)	3.4	(2.5)

Data Analyses

First, descriptive statistics were computed for patient characteristics and all outcome variables. Second, Wilcoxon signed rank tests for non-parametric data were used to assess pre- to post-treatment differences in oral anticoagulant knowledge, anticoagulant treatment expectations, convenience, satisfaction, QOL, and depressive and anxiety symptoms. All analyses were conducted using SPSS v.21 for Windows (IBM Corp., Armonk, NY).

Results

During the first year of this pilot study period, 21 eligible patients enrolled in the study and completed the baseline questionnaires and MASS app training. Eighteen participants completed the 3-month MASS intervention and the 3-month follow-up outcome evaluation. Three participants were lost at the 3-month follow-up. Two participants had their health condition change (e.g., hospital admission); these changes were not related to the study. One participant voluntarily dropped out explaining no more interest in using the health app.

Participants' Information

Complete demographic information for all participants who completed the study is shown in Table 1. Overall, participants were primarily male of Caucasian or Hispanic descent. Most individuals obtained a high school degree or higher degree, were married or cohabitating with a partner/spouse, and were not employed.

The amount of time participants had been taking warfarin ranged from 4 months to 29 years, with a median duration of 5 years (M = 8 years, SD = 9 years). During the 3-month study enrollment period, none of the study participants' anticoagulation therapy changed. The average BMI score was 34 (SD = 8; range = 21-44.). Participants included 10 former smokers and eight individuals who never smoked. The majority of participants reported never drinking alcohol (n = 12; 67%), with six participants (33%) reporting drinking ≤1 alcoholic drinks per week. The average CCI was 3.4 (SD = 2.5).

Pre- to Post-MASS Outcomes

Results are shown in Table 2. Only one significant intervention effect was found: Oral anticoagulant knowledge was significantly higher post-treatment than at baseline.

Patient-Reported Usability of MASS Intervention

As shown in Table 3, the overall usability of the intervention was slightly above the mid-point of the 1-7 scale. Participants rated their satisfaction with and usefulness of the MASS intervention higher relative to the ease of use of the MASS intervention.

Discussion

The MASS, mHealth app–based intervention was implemented for older adults with chronic conditions who received warfarin treatment to enhance their self-management skills regarding medication adherence and self-care for safe daily life with anticoagulation therapy. Older adult patients using MASS warfarin app showed a significant increase in anticoagulation knowledge after the 3-month intervention while there was no significant

Table 2. Comparison of Outcomes Between Baseline and Follow-Up by Wilcoxon Signed Rank Tests.

	Baseline		3-month follow-up		Wilcoxon signed rank test	
Outcomes	*M* (*SD*)	Range	*M* (*SD*)	Range	*z*	*p* value
OAT knowledge	62% (28%)	10%-90%	74% (20%)	35%-100%	−2.69	.007
OAT convenience	4.34 (0.44)	3.38-5.00	4.32 (0.47)	3.08-5.00	−0.26	.793
OAT satisfaction	3.79 (0.83)	1.83-5.00	3.91 (0.54)	3.14-5.00	−0.06	.954
Poor quality of life	2.09 (0.59)	1.04-3.08	2.24 (0.65)	1.40-3.40	−.63	.530
Depressive symptoms	3.00 (2.66)	0-8.00	3.17 (4.83)	0-16.00	−0.32	.752
Anxiety symptoms	1.28 (1.87)	0-7.00	2.28 (3.16)	0-12.00	−1.53	.126
OAT medication adherence	7.18 (1.10)	4.75-8.00	7.15 (0.90)	5.00-8.00	−0.27	.786

Note. OAT knowledge: percentage score of correct answers; possible range = 0%-100%; higher scores indicate greater OAT knowledge. OAT convenience: average score; possible range = 1-5; higher scores indicate greater convenience of their treatment. OAT satisfaction: average score; possible range = 1-5; higher scores indicate greater satisfaction with their treatment. Quality of life: average score; possible range = 1-7; higher scores indicate lower quality of life. Depressive symptoms: summary score; possible range = 0-27; higher scores indicate greater symptoms. Anxiety symptoms: average score; higher scores indicate greater symptoms. OAT medication adherence: summary score; possible range = 0-8; higher scores indicate greater adherence to OAT medication. OAT = oral anticoagulation treatment.

Table 3. Patient-Reported Usability of MASS Intervention.

	Descriptors		
	M	*SD*	Range
Usability of intervention	4.94	1.42	2.75-7.00
Satisfaction	5.16	1.54	2.33-7.00
Ease of use	4.30	1.66	1.00-7.00
Usefulness	5.15	1.44	3.00-7.00

Note. Average scores; possible range = 1-7; higher scores indicate greater overall usability of, greater satisfaction with, greater ease of using, and greater usefulness of the MASS intervention. MASS = Mobile Applications for Seniors to enhance Safe anticoagulation therapy.

change in self-reported medication adherence and treatment effectiveness. Participants also reported satisfaction with MASS regarding ease of use and usefulness.

Mixed results have been found in studies evaluating mHealth technology interventions directed at treatment adherence in patients with chronic diseases (Hamine et al., 2015). The current study shows improvement in anticoagulation (i.e., warfarin therapy) knowledge in 18 older adults who used mHealth tools. Knowledge about warfarin therapy was assessed, including controlling INR level within therapeutic range and understanding drug–drug interactions and food–drug interactions (Tang et al., 2003).

Major bleeding episodes or other adverse effects during the intervention periods were not reported. Information about anticoagulation treatment was available on mobile device (i.e., MASS) at any time when patients might have sought answers to questions about their medication or illness. In particular, MASS food search included a popular food list that Hispanic people eat and provided Vitamin K amount contained in each food based on the food and nutrition data from U.S. Department of Agriculture (n.d.).

The majority of mHealth interventions in the literature target children, adolescents, or younger adults. However, our study specifically focused on older adults with chronic diseases who were taking anticoagulants. While older individuals are often not considered as frequent mobile device (e.g., smartphones or tablets) users, use by older adults has increased by about 60% in a recent decade (Pew Research Center, 2016). Incorporating age-sensitive aspects (e.g., bigger screen, bigger fonts, ease of navigation) into the design of mHealth tools would be one way to encourage use of such apps (The National Institute on Aging and the National Library of Medicine, 2016). MASS has a simple layout and big navigation buttons for older adult users. Inviting family members in training sessions was effective for older adults to continue to adopt the mHealth tools in their daily life. Based on our findings from the previous interview study with older adults and their family caregivers (Lee et al., 2014), we learned that family-oriented culture should be considered in conducting mHealth interventions for ethnic minority older people with chronic diseases. Indeed, in our study, Hispanic participants preferred to get trained with family members including grandchildren or daughters.

Mobile health apps have been used to enhance patient-provider engagement (Healthcare Information and Management Systems Society [HIMSS], 2016). Users of mHealth apps have used these apps to track symptoms, understand and manage their conditions such as medication reminders via SMS (short text message service) and the communication tools to connect with health care providers or to get a refill are common usage for mHealth app users (HIMSS, 2016). In our study, a component (i.e., "Message to tell doctors") of MASS was designed to increase effective communication with doctors. Older adults might forget to mention important aspects of their conditions to their doctors during medical appointments; therefore, MASS can provide a way to help older adults to prepare clinical important information (e.g., bleeding or bruising history). Participants in our study were asked to log their

INR results and episodes of bruising or bleeding to share with doctors at their medical appointments. Participants were also able to share their logged information with the people whom they trust most such as family members or close friends who could help them during their medical appointments.

Incorporating mHealth tools into medical practice is still challenging. Not all clinicians are receptive to their patients using mHealth apps to change their health behaviors or improve disease management (Digital Health, 2013). According to an mHealth app consumer survey, less than half reported they shared their data with care providers (Digital Health, 2013). Barriers in adopting mHealth in health care included health technology literacy of mHealth users, financial incentives for providers and patients, work flow for providers, and privacy and security of information. People used mHealth tools mostly for health maintenance such as calorie intake, weight, and physical activity, and more recently, wearable devices to track health and fitness are popular in these people (HIMSS, 2016). Integrating data from multiple mHealth apps/tools is challenging due to data consolidation (Lewis & Wyatt, 2015). Patients may like to use a health app to manage a specific condition. Few mHealth apps available in the market are tested by health care experts, and the regulation of mHealth apps has not been fully developed or discussed (Yasini & Marchand, 2015).

There are limitations to our study and findings. First, the study used convenience sampling, and the number of patients was small, both of which limit the power to detect differences. Those who were referred by their anticoagulation pharmacists or were willing to participate in our study may not represent the full range of older adults receiving warfarin. However, this study was designed to examine the acceptability of the mHealth intervention in older adults with chronic diseases that are often excluded from technology-based studies. These pilot data are helpful in guiding future more extensive studies of its efficacy.

We provided tablets and data services during the intervention. The participants in this study will not be representative of those who do not use mobile devices. Second, the majority of participants in our study were on long-term oral anticoagulant therapy (median of taking warfarin was 5 years) to treat their cardiovascular or cerebrovascular-related chronic diseases that also limits the generalizability to other patient populations. It should be noted that outcomes (e.g., depression and anxiety) showed no improvement during the 3-month mHealth intervention. This is to be expected for several reasons. The intervention was not targeted to improve these outcomes, and if there was improvement, it might not be evident these changes in such a short 3-month period. Participants in this study had chronic conditions having more than three co-morbidities, which may affect outcomes of depression and anxiety.

We did not design the inclusion criteria to create a more homogeneous sample controlling for the role of numerous extraneous factors that could affect intervention outcomes. More tightly controlled studies where the impact of potential predictors of the outcomes could be examined could provide important information in understanding the effectiveness of MASS. We are not able to examine similarities and differences between those who were dropped and those 18 participants who remained.

An important but frequently faced challenge in a study of this kind is the reliance on self-report outcome measures. Data from these measures could be substantiated with more objective observations. For example, we used a self-reported medication adherence tool to examine medication adherence. Older adults taking multiple medications might not accurately report medication use due to poor memory and confusion. We attempted to avoid this problem by screening for cognitive impairment using Mini-Cog™. Patients with total scores <3 were excluded from the study. The medication adherence literature recommends one of several approaches to maximize the validity of self-report measures of medication adherence: medical record review, clinical judgment, family reports, or electronic monitoring, and others not all of which are appropriate for our patient population or feasible within the limited scope of the study.

Future research should be conducted with a larger sample and matched comparison group. In addition, more objective measures of medication adherence (e.g., medical record review and pharmacy records) to supplement self-reported measure can be used. In future studies, in-depth interviews can provide valuable insight into the usability of MASS and can supplement questionnaire data at the exit interview post completion of the program. These data would be particularly useful in identifying the specific concerns or barriers in using MASS and other mHealth tools.

Conclusion

Self-management in this vulnerable population is important in ensuring health and QOL during their course of treatment. Mobile health apps can be helpful in enhancing their self-care skills in managing their chronic disease. The findings from this study showed improvements in knowledge only. Still, these findings support the potential usefulness and effectiveness of mHealth intervention (i.e., MASS) in improving self-management among older adults with chronic disease conditions who are undergoing anticoagulant therapy. In an era with increasing use of mobile devices across all age groups, there is ample support for developing and testing user-specific mHealth intervention programs.

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Authors' Note

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Declaration of Conflicting Interests

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