Evaluation Protocol for a Medication Reminder App for the Elderly

Student Name: Long Liang Student ID: 946535112 Date: May 20, 2025

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1. Introduction and Rationale

Medication non-adherence among elderly individuals is a well-documented issue, with significant health consequences. Elderly people, particularly those with chronic diseases such as hypertension, diabetes, and heart disease, often face challenges in adhering to prescribed medication regimens. According to recent studies, approximately 40% of elderly individuals do not follow their medication schedules as prescribed (Dobson et al., 2016). This non-adherence can lead to poor disease management, increased hospitalization, and an overall decline in quality of life.

Several factors contribute to this issue, including:

- 1. Cognitive Decline: Aging can lead to memory problems, making it difficult for the elderly to remember when and how to take their medications.
- 2. Complex Medication Schedules: Elderly individuals may need to take multiple medications at different times throughout the day, further complicating adherence.
- 3. Lack of Support: Although family members and caregivers may offer assistance, it is often inconsistent or insufficient for meeting the medication management needs of elderly individuals.

While traditional methods such as written calendars, verbal reminders from family members, and pillboxes have been used, these solutions are often inadequate, especially as cognitive decline progresses. Additionally, many digital tools on the market are complex and not user-friendly for elderly populations. Therefore, there is a need for a simplified, intuitive, and accessible mobile application that can serve as a reliable medication reminder tool. Such an app could significantly improve medication adherence and, consequently, health outcomes among the elderly.

This protocol aims to evaluate a new mobile application designed specifically to address these challenges. The application offers features such as medication reminders, dosage tracking, and customizable notifications, all tailored to meet the specific needs of elderly users. The goal is to assess whether using this app can improve medication adherence over a four-week period and enhance overall health management for elderly individuals.

2. Objective

2.1 Primary Objective

The primary objective of this evaluation is to determine if the medication reminder mobile application can effectively improve medication adherence among elderly individuals over a four-week period. Specifically, the evaluation will measure the impact of the app's core features on adherence to prescribed medications. These features include:

- 1. **Customizable Medication Reminders:** Users can set reminders for each medication, with different types of notifications (sound, voice, or visual) to suit their preferences.
- 2. **Simple User Interface:** The app is designed with a focus on ease of use, featuring large fonts, clear icons, and minimal navigation steps.
- 3. **Adherence Tracking:** The app tracks when users take their medications, providing an easy-to-understand log of adherence.

2.2 Secondary objectives

- **1. Usability and Accessibility:** Evaluate how user-friendly the app is for elderly users, including those with varying levels of technological proficiency. This will also involve assessing the effectiveness of accessibility features, such as text-to-speech and high-contrast modes.
- **2. User Satisfaction and Engagement:** Measure the satisfaction levels of users, including how satisfied they are with the app's features and whether they find it easy to incorporate it into their daily routines.
- **3.** Caregiver Feedback: Explore how caregivers perceive the usefulness of the app, particularly in terms of helping them manage the medication routines of their elderly relatives.
- **4. Barriers and Facilitators:** Identify any challenges or enabling factors that influence the successful use of the app. This could include technical issues, the user's physical or cognitive limitations, or the level of support from caregivers.

Achieving these objectives will allow for a deeper understanding of the app's potential to improve medication adherence and will provide valuable insights into its practical use in real-world settings. The findings can also inform future improvements and adaptations of the app to better serve elderly populations.

3. Study Design

This evaluation will employ a pre-post observational study design, which allows for a comparison of participants' medication adherence before and after using the app. The pre-post design is appropriate because it enables the assessment of the intervention's effect on the same individuals, without the need for a control group. This approach is often used in behavioral interventions, particularly when randomized trials are not feasible or ethical.

3.1 Pre-intervention (Baseline)

Initial Questionnaire: At the beginning of the study, participants will complete a questionnaire that gathers baseline data on their current medication adherence habits and any challenges they face with their medication routines. This will also include an initial assessment of usability expectations, where participants can share their views on what they expect from the app in terms of ease of use, notification types, and features.

App Setup: Participants will install the app and go through an onboarding process, which includes setting up medication schedules, selecting reminder preferences, and configuring accessibility features. They will also have the opportunity to interact with a caregiver or receive assistance during the setup phase if needed.

3.2 Intervention Period (4 Weeks)

App Usage: Over the course of four weeks, participants will use the app to receive medication reminders and log their medication intake. They will be encouraged to engage with the app daily and track their adherence, with reminders sent based on their medication schedule.

Mid-study Check-in: An optional support check-in will be conducted halfway through the study period to ensure users are consistently using the app and to offer any additional support. This will help address any potential issues that arise during the intervention.

3.3 Post-intervention (After 4 Weeks)

Follow-up Questionnaire and Surveys: After four weeks, participants will complete a follow-up survey, which includes the same medication adherence questionnaire (MMAS-8) used in the baseline assessment, a System Usability Scale (SUS) survey to evaluate the app's usability, and a user satisfaction survey to gauge overall satisfaction with the app. Caregivers will also be asked

to complete a feedback form to evaluate their involvement and perceptions of the app's impact.

Qualitative Interviews: A subset of participants will be selected for semi-structured interviews to gain in-depth feedback about their experiences using the app, any barriers they faced, and suggestions for improvements.

This study design is practical, cost-effective, and appropriate for real-world settings. It enables a comprehensive evaluation of both behavioral outcomes (medication adherence) and user experience, while keeping the intervention period manageable. Furthermore, the inclusion of qualitative interviews allows for deeper insights into users' perspectives and experiences, which can inform future improvements to the app.

4. Population and Inclusion Criteria

4.1 Target Population

The study will target elderly individuals aged 60 years and above who have been prescribed at least one daily medication for chronic disease management, such as hypertension, diabetes, or heart failure. This population is at a higher risk of medication non-adherence due to age-related cognitive decline and the complexity of medication regimens.

4.2 Inclusion Criteria

- 1. Individuals aged 60 and above.
- 2. Currently taking at least one prescribed daily medication.
- 3. Possession of or access to a smartphone or tablet.
- 4. Ability to operate the device independently or with the help of a caregiver.
- 5. Willingness and ability to provide informed consent.

4.3 Exclusion Criteria

- 1. Diagnosed with severe cognitive impairment or dementia.
- 2. Severe visual or hearing impairments that cannot be mitigated through app accessibility features.
- 3. Lack of access to a digital device or internet connection.
- 4. Participation in other ongoing medication adherence studies.
- 5. Residing in care facilities where medication administration is managed entirely by staff.

5. Recruitment Methods

Participants will be recruited through a combination of community outreach and healthcare provider networks. Recruitment strategies include:

- 1. Posting informational flyers at community centers, pharmacies, general practitioner (GP) clinics, and libraries that serve elderly populations.
- 2. Engaging local health practitioners and geriatric specialists to refer eligible patients.
- 3. Publishing digital announcements through local senior-focused online groups or social media pages.
- 4. Hosting short information sessions or app demonstrations at retirement communities and senior wellness events.

A dedicated phone line and email address will be set up to handle inquiries and pre-screen potential participants. Interested individuals will complete a brief eligibility survey either in person or over the phone. Eligible participants will then receive a Participant Information Sheet and Consent Form to ensure understanding and voluntary participation.

6. Intervention

The intervention in this study is a mobile application developed specifically to support medication adherence among elderly users. The application is designed with a focus on simplicity, clarity, and accessibility, taking into account the common challenges experienced by older adults.

6.1 Key Features of the App

- 1. **Medication Reminders and Notifications:** Timely alerts in the form of push notifications or voice reminders are sent to users at scheduled medication times. Users can choose their preferred method and sound profile to match their needs.
- 2. **User-Friendly Interface:** The design prioritizes ease of use, with large fonts, high-contrast colors, and intuitive navigation. A simplified dashboard allows users to easily view and manage their medication schedules.
- 3. **Recording and Tracking Function:** The app records each instance when the user confirms medication intake. This data is stored securely and can be viewed in daily, weekly, or monthly summaries. Missed doses are also flagged.
- 4. **Accessibility Support:** The app includes support for users with low vision or hearing impairment, offering text-to-speech options, customizable text size, and high-contrast themes. Audio instructions and haptic feedback are also available

6.2 Initial Setup and Configuration

Upon installation, users are guided through a step-by-step setup process:

- 1. Enter prescribed medications including name, dosage, and schedule.
- 2. Choose preferred reminder type (visual, sound, or voice).
- 3. Set up caregiver access if needed.
- 4. Complete a short orientation/tutorial on how to use the app.

Technical support will be available via a dedicated helpline and in-app help center to assist users with troubleshooting or onboarding questions.

Caregivers may also assist during setup or routine use.

7. Measures

To assess the effectiveness and usability of the app, a combination of quantitative and qualitative measures will be used.

7.1 Primary Outcome Measure

Medication Adherence Rate assessed using the Morisky Medication Adherence Scale (MMAS-8), a validated self-report questionnaire, and corroborated with in-app adherence logs. Adherence rate will be calculated as the percentage of doses taken on time relative to the schedule.

7.2 Secondary Outcome Measures

- 1. **User Satisfaction:** Measured via a custom survey consisting of Likert-scale questions and open-ended feedback to assess user opinions on app usefulness, ease of use, and impact on daily routine.
- 2. **Usability:** Evaluated using the System Usability Scale (SUS), which provides a reliable benchmark of usability across various systems and platforms.
- 3. **Caregiver Engagement:** Assessed through a caregiver feedback form that collects information on how the app supported their involvement and whether it reduced their burden.

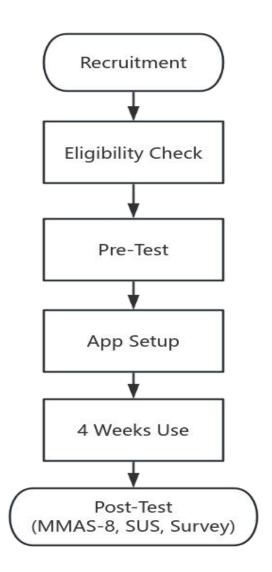
7.3 Measurement Instruments and Methodology

- 1. Surveys will be available in both paper and electronic formats to accommodate users' preferences.
- 2. Questions will be provided in plain English, with bilingual options available if needed.
- 3. Interviews will be semi-structured and conducted in person or via video call, recorded with permission, and transcribed for thematic analysis.

7.4 Measurement Timeline

- 1. **Day 0 (Pre-test):** MMAS-8 administered; app setup and baseline expectations captured.
- 2. **Day 14 (Mid-check):** Optional user support check-in to ensure ongoing engagement.
- 3. **Day 28 (Post-test):** Repeat MMAS-8, SUS survey, user satisfaction survey, and caregiver feedback collection.

7.5 Study Flow Diagram



8. Analysis

In the data analysis section, we will employ a combination of quantitative and qualitative analysis methods to ensure a comprehensive assessment of drug compliance and application availability. Specific analysis methods include:

8.1 Quantitative Analysis

Descriptive Statistics: Descriptive statistics will be used to summarize participants' basic demographic data (e.g., age, gender, disease type), app usage data (e.g., daily usage frequency, reminder response rate), and adherence data (e.g., percentage of on-time medication intake). This will help understand the sample's basic characteristics and usage patterns.

Adherence Analysis: Medication adherence will be assessed using the Morisky Medication Adherence Scale (MMAS-8), a self-report questionnaire, and corroborated with in-app adherence logs. The adherence rate will be calculated by comparing the self-reported data and the in-app data, quantifying any changes in on-time medication intake.

Usability Analysis: The System Usability Scale (SUS) will be used to evaluate the app's usability. This standardized tool is widely used to measure the ease of use of various systems and platforms. By comparing pre- and post-test SUS scores, we will gauge changes in users' satisfaction and ease of use.

User Satisfaction Analysis: User satisfaction will be measured through a custom survey with Likert-scale questions to assess users' overall satisfaction, ease of use, and impact on their daily routines.

Caregiver Engagement Analysis: Feedback from caregivers will be collected via a caregiver feedback form to assess how the app supported their involvement and whether it reduced their caregiving burden.

8.2 Qualitative Analysis

Interview Feedback Analysis: Thematic analysis will be applied to feedback from participant interviews to explore in-depth user experiences, perceived outcomes, and any unexpected challenges or facilitators encountered during the use of the app. This feedback will provide valuable insights into the real-world context of app usage.

Paired t-tests (or non-parametric alternatives): Paired t-tests will be used to compare pre- and post-intervention adherence and usability scores. If the data

does not meet normality assumptions, non-parametric tests (e.g., the Wilcoxon signed-rank test) will be applied as an alternative.

Handling Missing Data: For participants who do not complete all surveys or app usage, Intention-to-Treat analysis will be used to include all participants in the analysis, regardless of whether they completed the study, reducing bias in the results.

9. Reflection

Based on the constructive feedback received for Assignment 2, several key improvements were integrated into Assignment 3, which presents the evaluation protocol for the medication reminder app. The aim was to strengthen the proposal's clarity, theoretical grounding, and evidence base.

9.1 Clarifying Programme Logic

The feedback indicated a need for "an explicit programme logic to show how the intervention leads to the desired outcomes." In response, Assignment 3 details a comprehensive evaluation protocol. While not presented as a standalone "program logic model" diagram, the Study Design (Section 3), the description of the Intervention and its Key Features (Section 6), and the defined Outcome Measures (Section 7) collectively articulate the intended pathway. These sections explain how the app's specific functionalities—such as customizable reminders, a user-friendly interface, and adherence tracking—directly address known barriers to medication adherence. This structure implicitly outlines how the intervention is expected to lead to improved medication adherence and other positive health outcomes for elderly users.

9.2 Addressing Theoretical Framework

It was suggested that "specifying the theoretical framework that informed the design of the digital tool—and explaining how it influences health behaviours—would strengthen the proposal." As an evaluation protocol, primarily focuses on the methodology for assessing the app's effectiveness and usability. While a single, explicitly named behavioral theory (e.g., Health Belief Model, COM-B) is not extensively detailed as the overarching driver of the app's initial design in this document, the app's features are nevertheless informed by an understanding of established challenges in medication adherence among the elderly. The Introduction and Rationale (Section 1) identifies critical factors like cognitive decline, the complexity of medication schedules, and insufficient traditional support. The app's features are designed to directly counteract these barriers by simplifying medication management, providing reliable and customizable reminders, and enabling adherence monitoring. These design choices align with general principles of behavior change, focusing on making the desired behavior (medication adherence) easier to initiate, perform, and sustain.

9.3 Strengthening Supporting References

A crucial piece of feedback was that "more references should be included to support the claims made throughout...This would add validity to the claims being made about the issues of medication adherence." Assignment 2 had limited references, some of which were not directly focused on medication adherence. Assignment 3 addresses this by incorporating relevant

scholarly literature. For instance, the Introduction (Section 1) already cites Dobson et al. (2016) in relation to adherence rates. The evaluation protocol itself is structured based on established research methodologies in health technology assessment. Furthermore, Section 10 (References) is designated for a comprehensive list of sources. Additional pertinent references that validate the prevalence of medication non-adherence, the specific challenges encountered by the elderly population, the potential of mHealth interventions, and methodologies for usability and effectiveness testing have been identified to bolster the claims made and provide a more robust evidence base for the proposed study.

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