Protocol:

Impact of Pillboxes on Medication Adherence
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SUMMARY OF THE RESEARCH

This study uses an experimental design to test the impact of different types of pillboxes on medication adherence. Participants in this study will randomized to receive one of the three pillbox interventions: 1) A standard seven day a week, one-dose per day pillbox with training 2) an off-the-shelf pillbox that was purchased specifically for the individual's needs with training and education, or 3) a customized 3D printed pillbox that was designed and manufactured specifically to the individual's needs with training and education. Participants will have three visits with the research team to collect baseline data, receive the pillbox, and collect follow up data.

Risks to the study include loss of time, boredom, invasion of privacy, and medication errors. We have taken precautions to mitigate these risks. This study will improve understanding of medication adherence and potentially help us better address poor medication adherence which needlessly causes morbidity, mortality, and costs over $300 million in unnecessary healthcare costs each year.

BACKGROUND

Scientific Background & Literature Review

Many individuals do not take medicine as prescribed resulting in declines in health and function. Pillboxes are a cost effective and easy to implement intervention that can help people better take their medications as prescribed. While some studies find that pillboxes can increase medication adherence as much as 5% other studies find that pillboxes have no effect. We hypothesize that to be effective pillboxes must be customized to the client's needs and be part of a package of services involving training on the device and education. The purpose of this study is to understand the impact of customized pillboxes on medication adherence.

1.Vlasnik, J. J., Aliotta, S. L., & DeLor, B. (2005). Medication adherence: factors influencing compliance with prescribed medication plans. The Case Manager, 16(2), 47-51.

2.Bartlett, R. J. (2018, September). Characteristics of Adults Managing Vitamins/Supplements and Prescribed Medications- Who Is Using, Not Using, and Abandoning Use of Pillboxes?: A Descriptive Study. PubMed, 32(5), 231-239. doi: 10.1097/NUR.0000000000000395

3.Defanti e Souza, F. and da Silva Santana, C. (2013) A descriptive study about the use of pillboxes by older adults. Health, 5, 103-109. doi: 10.4236/health.2013.512A014

4.Bartlett, R. J., Knisely, M. R., Boyer, K., & Pike, C. (2017). Pillbox intervention fidelity in medication adherence research: A systematic review. Nursing Outlook, 65(4), 464-476. doi:10.1016/j.outlook.2016.12.011

5. Schwartz, J.K., Fermin, A., Fine, K., Iglesias, N., Pivarnik, D., Struck, S., Varela, N., & Janes, W.E. (2019) Methodology and feasibility of a 3D printed assistive technology intervention. Disability and Rehabilitation: Assistive Technology.

RESEARCH OBJECTIVES

The purpose of this study is to:

•Understand the impact of pillbox customization on medication adherence
•Understand the impact of pillbox customization on device satisfaction
•Test the feasibility of the research methodology

SUBJECT POPULATION

Duration of participation

Interaction 1: Screening: .5 hrs
Interaction 2: Informed Consent & Evaluation: 2 hrs
Interaction 3: Dispersion of pillboxes: 1 hr
Interaction 4: Follow-up Data Collection: 1.5 hrs
Total time commitment- approximately 5 hrs

Number of Participants

We seek to enroll as many as 40 participants in the study. This means we may screen as many as 120 individuals to identify the 40 study participants.

Inclusion & Exclusion Criteria

To be included in this study participants must be 18 years of age or older, speak English, and be prescribed to take two or more medications per day, and manage their own medications.

Participants will be excluded if they have a significant cognitive impairment, unwilling to use a novel pillbox, or are unable to meet with the research team.

SUBJECT RECRUITMENT

Identification of Subjects & Recruitment

We will recruit through word of mouth, by sharing study information with local organizations that serve adults who take medications, and snowballing (asking participants to share the recruitment flyer with other individuals who take medications). We will also post electronic flyers on social media.

Incentives

Participants who complete all study procedures will earn up to $20 in gift cards and a pillbox. On the 1st and 3rd visit, participants will receive a $10 gift card. On the 2nd visit, the participant will receive a pillbox worth no more than $15.

METHODS & ACTIVITIES

Instrumentation & Data Collection

Below is a description of each data collection tool.

- Screener Survey - ensures that the individual meets the eligibility criteria for the research study. This also allows the individual to describe their preferred contact method.
- Adherence to Refills and Medication Scale - 12 question Likert-like survey investigating medication adherence
- Demographics Questionnaire (Characteristics of Respondents [CORE] Survey) - Describes the participants background including race, ethnicity, gender, diagnoses, family situation, etc.
- Performance Assessment of Self Care Skills Medication Subtest - This performance-based assessment asks participants to sort a placebo medication. Participants are scored on their independence, safety, and adequacy in performing the task.
- Canadian Occupational Performance Measure - Participants discusses their daily routine. They score their performance of everyday activities on their importance, satisfaction, and performance.
- Quebec User Evaluation of Satisfaction with Assistive Technology - 12 item Likert-scale questionnaire evaluates how satisfied participants are with their assistive device and their related services that they experience.
- Medication Management Instrument For Deficiencies in the Elderly - Examines how much the participant knows about their medications, if they know how to take their medications, and if they know how to procure their medications. Also provides their complete medication list.
- Exit Interview - Participants will be interviewed regarding their experiences within the study.
- Audio recordings - All interactions will be audio recorded. The PI will assess the researcher assistant’s fidelity to the protocol.

Intervention

Participants in this study will randomized to receive one of the three pillbox interventions:

1.Standard Pillbox - Participants will receive a standard seven day a week, one-dose per day pillbox. The participant will receive basic training on using the pillbox.

Figure 1. Standard Pillbox

2. Off-the-Shelf Pillbox – Participants will receive an off-the-shelf pillbox that was purchased specifically for the individual's needs from a store like CVS, Walgreens, or Amazon. The participant will also receive with training and education on using the pillbox.

3. Customized 3D printed Pillbox – The participants will receive a customized 3D printed pillbox that was designed and manufactured specifically to their individual needs.

Interactions

Research participants will occur in 4 interactions.

1. Screening
Up to .5 hrs on participant's own time on computer or the participant may be screened verbally at a time of their choosing Assessments: screener survey

2. Informed Consent and Evaluation
Up to 2 hrs
Lab at FIU or preferred location where both parties (participants and evaluators) agree on Assessments: COPM, QUEST, PASS, MedMaIDE, ARMS, and Demographics Questionnaire

3. Dispersion of pillboxes
Up to 1 hr
Lab at FIU or preferred location where both parties (participants and evaluators) agree on

4. Follow-up Data Collection
Up to 1.5 hrs
Lab at FIU or preferred location where both parties (participants and evaluators) agree on.

Data Analysis

Researchers will evaluate all variables using descriptive statistics. We will also explore the relationship between variables using approaches such as Pearson's product-moment correlation. Using this information, we will evaluate the appropriateness of the data against the assumptions for commonly used statistical approaches. Data may be normalized to increase appropriateness for the test. Then we will engage in means-testing using approaches such as t-tests, ANOVAs, Mann-Whitney U, Kruskal-Wallis analysis of variance, etc. as determined by looking at the appropriateness of the variable for that procedure. Specifically, we aim to compare means within and between groups on scores from the COPM & QUEST.

For qualitative data, we will use a grounded theory approach, consisting of open, axial, and selective coding to generate themes describing the participants answers to open ended questions.

Corbin, J., Strauss, A., & Strauss, A. L. (2014). Basics of qualitative research. sage

BENEFITS & RISKS

Benefits to Subjects

There are no direct benefits to participants.

Benefits to Society and/or Others

Information learned from this study will be used to progress research and improve medication adherence for adults.

Reasonably Expected Risks, Harms, and/or Discomforts

Risk 1) Loss of time, low likelihood, low severity
Risk 2) Boredom, low likelihood, low severity
Risk 3) Invasion of privacy, low likelihood, low severity
Risk 4) Leakage of information, low likelihood, moderate severity Risk 5) Medication errors, low likelihood, moderate severity

Minimizing Risks, Harms, and/or Discomforts

Risk 1) Loss of time: Participants can select when and how they participate to limit loss of time related to travel. Research team will work with participants in an expedient manner.

Risk 2) Boredom: Participants will be informed that they can stop the survey or interview at any time. Participants will be informed that they can take breaks as needed during the survey or interview.

Risk 3) Invasion of privacy: Participants will be educated that they do not have to talk about topics or answer survey items that feel invasive.

Risk 4) Leakage of information: Electronic data will be stored on secure devices and servers. Identifying information (e.g., informed consent) will be stored separately from survey and interview data.

Risk 5) Medication errors: Participants will be required to verbalize how to use the pillboxes. They will also be required to correctly demonstrate how to use the pillboxes with placebo medication (i.e. tic-tacs or similar candy). Participants who cannot verbalize and demonstrate correctly use of the pillbox will be removed from study participation.

INFORMED CONSENT

Informed consent will be provided in a quiet and private environment. Participants will be given as much time as they need to consider participation and ask questions of the research team. Signed informed consent forms will be stored in the PI's office.

CONFIDENTIALITY & PRIVACY

Provisions to Protect Privacy

- Data will be de-identified
- Identified information (i.e. informed consents and the master key) will be stored separately from the study data.
- Physical data will be stored securely in a locked filing cabinet in the PIs locked office.
- Electronic data will be stored on the secure FIU OneDrive and backed up on an encrypted and password protected external hard drive which is stored in a locked filing cabinet in the PIs office.
- Only members of the research team will have access to the data

Confidentiality of Data

- Informed consents will be stored in a locked filing cabinet in the PIs locked office.
- Study data will be collected with the assistance of Qualtrics and will be stored in FIU Qualtrics during data collection. After data collection, the data will be removed from Qualtrics and stored on FIU One drive. The study data will only be associated with the participants ID Code.
- Audio recordings will be stored on FIU One Drive.
- The Master Key will be stored on FIU One Drive separate from all study data.
- The study data and audio/video recordings will be backed up on to an encrypted and password protected external hard drive which will be stored in a locked filing cabinet in the PIs office.
- Only members of the research team will have access to the data.

Breaking Confidentiality

If participant's interview suggests abuse or neglect to themselves or others, it is necessary to break confidentiality. In the unlikely event that a participant reports is at serious risk to harm themselves or others, the participant will be reported to the appropriate authorities.