Effect of Medication Management at Home Via Pharmacist-Led Home Televisits: Protocol for a Randomized Controlled Trial

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Abstract

Background: Older adults are more likely to suffer from multiple chronic conditions, being prescribed multiple medications and are more susceptible to adverse reaction to their medications. In addition, older adults often use over-the-counter medications and supplements, further complicating their medication regimens. Complex medication regimens are potentially harmful to older adults. Interventions aimed at reducing medication discrepancy in the ambulatory clinic setting, such as the review of medication lists, and implementation of "brown bag" reconciliation continues to be challenging with limited success. Pharmacist led interventions to improve appropriate medication use in older adults have demonstrated effectiveness in reducing adverse drug events.

In this study [NCT04340570], we propose to utilize telemedicine to deliver medication management by pharmacists. Video visits have the potential to provide direct visualization of medications in older adults' homes, thereby reducing medication discrepancy and increasing medication adherence. Pharmacist-led management of older adults' medication regimens may improve appropriate medication use in older adults.

Objective: The objective of this study is to examine the effect of a pharmacist-led medication through home televistits compared to usual care on appropriate medication use, medication discrepancies, adherence, and adverse drug events.

Methods: We will conduct a 2-site cluster randomized controlled trial [NCT04340570]. The intervention will be a home televisit by a pharmacist including medication reconciliation and assessment of actual medication use. The cluster randomized controlled trial was iteratively adapted after a pilot test. We will examine outcomes of the pharmacist-led intervention including the primary outcome of medication appropriateness, measured by the STOPP criteria for potentially inappropriate medications at 6 months. Medication lists obtained will be compared against the medical record by a clinician reviewer to establish discrepancies in medications. The clinician will review medications using the validated Medication Appropriateness Index (MAI).

Results: This project has been peer reviewed and selected for support by the VA Health Services Research Service. We

anticipate the completion of the ongoing trial in Spring 2025. The first results are expected to be submitted for publication in 2025.

Conclusions: The cluster randomized clinical trial will provide evidence on medication management through televisits. If found to be effective in improving the use of medications, the intervention has the potential to impact oClinicalTrials.gov NCT04340570lder adults with multiple chronic conditions and polypharmacy. Clinical Trial: ClinicalTrials.gov NCT04340570

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Abstract

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Older adults are more likely to suffer from multiple chronic conditions, being prescribed multiple medications and are more susceptible to adverse reaction to their medications. In addition, older adults often use over-the-counter medications and supplements, further complicating their medication regimens. Complex medication regimens are potentially harmful to older adults. Interventions aimed at reducing medication discrepancy in the ambulatory clinic setting, such as the review of medication lists, and implementation of “brown bag” reconciliation continues to be challenging with limited success. Pharmacist led interventions to improve appropriate medication use in older adults have demonstrated effectiveness in reducing adverse drug events.

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Trial Registration: ClinicalTrials.gov NCT04340570

Keywords: Older adults; Medication management; Televisit; Polypharmacy

Introduction

Polypharmacy in older adults, and the importance of medication reconciliation:

The US population is aging rapidly; the population aged 65 and above is projected to be doubled in 2050. The most rapidly growing segment is the population of older adults aged 85 and above, which will more than triple from 5.9 million in 2012 to 18 million in 2050 [2]. Older adults aged 65 and above often suffer from multiple chronic diseases—more than 60% have 2 or more chronic diseases[3] and 17% with four or more chronic diseases[4]. Older adults with multiple chronic comorbidities often require multiple medications for management, particularly with guideline-based management of chronic diseases [5, 6]. The use of multiple medications in older adults is common, with almost 20% of older adults over age 65 taking 10 or more medications [7, 8]. Multiple medications use in older adults are associated with lower adherence rate and increased use of inappropriate medications [9, 10]. The use of multiple medications increases the risk of potential drug interactions leading to undesirable adverse drug events, which could also contribute to lower medication adherence. In particular older adults are more susceptible to adverse drug reactions due to the changes in their physiology, clearance and reserves [11], particularly with polypharmacy[9, 12] Based on the phycological changes in the older population, knowing the drug regimens with older adults is an important feature in order to provide medication safety and make adjustment to their regimen accordingly to ensure appropriate medication use. The START/STOPP criteria[13-15] and AGS Beers criteria [16 17] for potentially inappropriate medications (PIMs) were developed to provide evidence-based guides to signal clinicians regarding medications that are potentially inappropriate and to enhance medication appropriateness. These medications include those with strong anticholinergic properties which may disproportionately affect older adults and are linked to adverse outcomes of adverse drug reactions, and other medications that are demonstrated to have significant side effects in older adults.

Use of telemedicine to improve medication use in older adults: Telemedicine is a modern visit option enabled by advances in telecommunications technology [18]. The use of telemedicine in older adults has been examined in prior small studies that have demonstrated feasibility, acceptability and whose satisfaction [19-22]. Extending televisits to patients' homes has the potential to impact many aspects of care that rely on patient self-management such as medication use. Although telephone-based pharmacist interventions have the potential to impact medication use at home, [23,24] it still relies on accurate information reported by older adults via telephone without a mechanism for confirmation. The addition of video has the potential to further enhance the visit[25, 26] by (1) visually ascertaining actual medications taken by patients; (2) visual demonstration by the patients' actual use of medications; and (3) education of patients on proper use. Although in-person home-based reconciliation has the potential to improve accurate appraisal of medication use and reconciliation, it is not feasible for wide adoption as it is resource intensive. The proposed study will examine the impact of home televisits by pharmacists for patients at high risk for adverse drug events (i.e., with polypharmacy and multiple chronic conditions). We designed this proposed study as a mixed methods Hybrid type 1 effectiveness-implementation study where we will be testing the health impact of pharmacy televisits while also collecting data on the implementation process to facilitate subsequent scale-up efforts [27]. We included Veterans aged 65 and above as older adults have higher rates of chronic conditions and polypharmacy. The inclusion criteria of 5 or more medications is based on prior literature on polypharmacy and findings of increased risk of drug

interactions and adverse drug reactions The enrollment criteria are consistent with and exceed the criteria set in fiscal year 2019 by the Center for Medicare Services for provision of medication therapy management in Medicare Part D [51]. Among patient characteristics, polypharmacy (≥ 5 medications) and multiple chronic conditions are considered to be important risk factors for adverse drug reaction and highly prevalent among frail older adults at risk for ADR[52].

The intervention for the cluster randomized controlled trial was iteratively adapted after a pilot test with 20 Veterans [29]. Home televisits, where pharmacists conducted medication reconciliation and management were refined after which a formative evaluation [43], was conducted guided by the Consolidated Framework for Implementation Research (CFIR) [44]. Data was gathered in several ways: 1) Enrolled Veterans (n=20) were observed by study staff present within the Veterans' homes during the clinical pharmacist home televisit and 2) study staff administered a post-encounter questionnaire with the goal of improving the Veteran-based technical experience and clinical encounter. The data points were utilized to adapt and make changes to the intervention for the cluster randomized controlled trial.

Methods

Research Design Overview:

We will conduct a cluster randomized controlled trial with_a hybrid Type 1 effectiveness-implementation design [28], where we will examine effectiveness of intervention while observing information on implementation. The intervention for the cluster randomized controlled trial was iteratively adapted after a pilot test [29]. The intervention will be a home televisit by a pharmacist including medication reconciliation and assessment of actual medication use. Pharmacists will review medication appropriateness using evidence-based criteria and provide recommendations for change of medication use to the participant's primary Patient Aligned Care Team (PACT). PACTs provide team-based care and consist of a primary care provider, registered nurse, medical assistant and often time either a social worker or a pharmacist. In the control group, participants will receive usual care in which medication reconciliation and review is conducted in clinics by primary care teams. We will examine the effect of the intervention on, as primary outcome, the number of Veterans with PIMs as determined using evidence-based criteria, and, as secondary outcomes, the number of PIMs, medication discrepancy using data from record review and interviews, and medication appropriateness using validated instruments at 6 months after the intervention. We will also compare the intervention's effects on the incidence of adverse drug events using data from record review and interviews. To assess the potential for future implementation of the intervention, we will administer post-intervention questionnaires to key stakeholders, including veteran participants and PACT clinicians to examine implementation barriers and facilitators to the intervention.

Conceptual Framework of Medication Prescribing in Older Adults:

Our conceptual framework is informed by the Consolidated Framework of Implementation Research (CFIR) [30] and Steinman et al [31] on prescribing and prescription monitoring processes. The pilot phase was primarily informed by Steinman model of the prescribing process adapted to include system and provider level factors. These system level factors include VHA policy on medication management (including non-VA care use), facility level prescribing environment and practices and

decision support systems. In designing our proposed intervention, we considered the potential effect of home televisits by pharmacists to ascertain medication regimen and use, identify discrepancies and educate patients on use, and review medication appropriateness, thereby enhancing steps in the monitoring phase of the prescribing process (Figure 1).

Cluster Randomized Trial Patient Recruitment:

The inclusion criteria include: (1) Veteran must be a PACT (Patient Aligned Care Team) patient in a Bronx VA or Bedford VA geriatrics or primary care clinic; (2) Veteran must be 65 years or older; (3) Veteran must have 2 or more chronic conditions; (4) Veteran must have 5 or more medications listed on the VA medication record continuously in the previous 6 month. Patients fulfilling these criteria will be approached for study enrollment through letters of invitation after approval by human subjects' committees. To obtain informed consent, a research assistant (RA) will determine whether eligible patients have the capacity to provide informed consent to participate in the study using a screening questionnaire that assesses the four elements required for capacity understanding of study procedures, appreciation of what will happen if enrolled, communication of a choice to enroll or not, and demonstration of a rationale for that choice. Recruitment and written informed consent will take place in a location that ensures privacy and convenience for the patient.

Cluster assignment by PACT:

We will randomize patients by PACT, to prevent a team from having participants in both treatment and control groups and to reduce contamination. Prior to initiating enrollment, the project coordinator will assign PACTs to intervention and control groups, using lists of computer-generated random numbers in a 1:1 ratio, with separate lists for Bronx VA and Bedford VA, in order to maintain balance in both groups within each study site. There are 69 primary care and geriatric PACTs in the Bronx and 14 in Bedford VAMC and each PACT will keep the group assignment for the duration of the study.

Study Flow:

Study Flow is summarized in Figure 2. After enrollment, Veterans who agree to participate will be interviewed by a trained research coordinator using survey instruments that will include data elements listed in Table 2. Veterans will receive the televisit intervention or not based on the PACT team they belong to as discussed earlier. Detailed procedure for control and intervention groups are below. To observe what occurs at follow up appointments with PACT provider, subjects will be asked after the first follow up appointment post intervention about whether medication use was discussed during the appointment, if medication reconciliation was performed and how, and what, if any, medication changes were made. Electronic charts will be reviewed for documentation of medication reconciliation and management during the visit. Primary outcomes will be ascertained at 6 months after study enrollment and are described in Table 2 including subject survey and chart review. The subject survey for outcome assessment will be conducted by a research coordinator trained to take medication history with the subject and chart review will be conducted by a clinician reviewer blinded to study assignment. Survey of subjects will include confirmation of medications patients are currently taking, including names, dosages and frequency. Subjects will be asked to list

medications that they take including over-the-counter drugs and supplements. A clinician rater blinded to study assignment will review medication data from subject survey and chart review to determine medication discrepancies and appropriate use of medications.

Table 2. Data Elements and Instruments		
Outcomes	**Source**	**Instrument or Measurement**
Primary: Potentially inappropriate Medication Use	Chart review, interview	STOPP criteria; assessment of medication list by blinded clinical reviewer[14]
Secondary: Medical discrepancies	Chart review, interview	Medication discrepancies (omissions, duplications, additions)
Medication Appropriateness	Chart review, interview	Medication Appropriateness Index (MAI)[32]
Patient Satisfaction, self-efficacy, and adherence	Interview	CAHPS item pertaining to medication use[33] Medication Understanding Use and Self-Efficacy Scale (MUSE)[34]
Health Related quality of Life	Interview	EQ5D-5L [35]
Adverse Drug Events	Chart review, interview	ADR determination by clinical
Baseline covariates		
Socio-demographic	Baseline survey, chart review	Gender, age, race, ethnicity; Education, income, Medicare, Medicaid
Chronic illness burden	Patient interview, chart review	Modified RAND index[36]
Medication List	Chart review, patient interview	Number and type of medications; source (VA, Non-VA, Over the counter)
Medication Use	Interview; chart review	Number and type of medications; how taken. Presence of refill gap (>90 days)
Patient's self-efficacy on medication use	Patient Interview	Medication Understanding Use and Self-Efficacy Scale (MUSE)
Health literacy	Patient Interview	Short Test of Functional Health Literacy in Adults (S-TOFHLA)[37]
Cognitive function	Patient interview	Montreal Cognitive Assessment (MOCA)[38]
Physical function	Patient interview	Katz ADL/Lawton IADL scale[39,40]
History of Acute care Utilization (Hospitalization, ED)	Patient Interview chart review	Days prior to enrollment for most recent hospitalization and ED visit; number of episodes in previous year
Health related Technology use Attitude, self-efficacy, and comfort	Patient interview	Self-reported comfort and confidence in using technology[41]

Intervention: Subjects assigned to the intervention will have a pharmacist televisit appointment made and coordinated. Subjects will be asked if they have device at home capable of supporting

televisits including home computers with cameras, tablets, smartphones, and availability of broadband or 4G connection at home. Subjects that do not have appropriate devices will be provided with VA issued internet enabled tablets on which to conduct the visit. On the scheduled day of visit, the research team will coordinate with subjects via telephone to facilitate the initialization of the televisit by the pharmacist. The content of the televisit is further described earlier and will be further adapted through Aim 1 with direct observation of televisit at home. Subsequent to the televisit, pharmacist will document visit content in EMR to note discrepancies noted during televisit, review of medications with START/STOPP criteria, and recommendations based on criteria-based review for PCP review and concurrence for adjustments of medications. Recommendations will be communicated to PCP electronically through secure email or electronic note, and telephone or face-to-face discussion if preferred by PCP. Adjustments in the medication regimen will be noted at 7 days in the EMR after recommendations are made. If recommendations are not adopted, the pharmacist will communicate with PCP electronically to request reasons for not adopting recommendations. Subjects will then continue follow up primary care with their PCP.

Design of the Televisit intervention:

We plan to use the VA Video Connect (VVC) capability introduced in fiscal year 2018 to conduct televisits between clinical pharmacists, located at the VA medical centers and study subjects at home. An appointment will be scheduled with study subject for time to conduct the home televisit. The devices, EX90s or web cameras used at the clinician side will be located at Bronx or Bedford VA; on the subject side, the device will be the subject's choice of computer, tablet, or smartphone with internet connection and webcam capability, or a VA provided tablet if the subject does not have device or home internet capabilities. Because the experience of the televisit may be different using different devices on the subject end, the use of different devices was tested in phase I of the study, strengths, and pitfalls of the use of different devices and modes of connecting were identified.

After establishing video connection, the pharmacist will conduct home-based medication reconciliations by asking subjects to show and explain the use of each of their medications.
The pharmacist will also include a brief medication focused functional assessment including asking the veteran to read aloud and interpret one or more of his prescription bottles and to demonstrate ability to open bottles. Before ending the visit, the pharmacist will educate the veterans regarding possible side effects or interactions between their medications. The pharmacist will also solicit and answer any questions the veteran has about the medications. The clinical pharmacist will note medications used and compare it against the list of medications on the subject's medical record to note discrepancies and will then generate a note in EMR to notify the primary care team of the review and information obtained. When the pharmacist finds that patients are taking medications differently, they will clarify the correct usage of the medication.

Pharmacist Review of Medications:

After the tele-visit is completed, the pharmacist will conduct a medication review using the START/STOPP criteria to review the indication of each medication (see Table 1). They will also review whether there are medications prescribed beyond the recommended duration of the medication, where treatment duration is well defined. Pharmacists will utilize evidence-based guideline to inform follow up prescribing decisions (maintaining, adjusting dose, or stopping medication) (see Figure 1). Medications noted to be not appropriate or those that do not have an indication will be flagged for consideration of deprescribing. Duplication of drug class prescriptions will also be noted. Other disease specific criteria will be reviewed based on the criteria [13-15]. Recommendations generated from the medication review based on START/STOPP criteria will be

communicated to the primary care provider for consideration of modification of medication regimen. Final decisions on medication modification will be made by primary care clinicians in consultation with their patients as it usually would in clinic settings.

Table 1. Scope of Pharmacist Intervention Visit lays out the steps, content, and approximate duration of each step.

Step	Content and sample questions (See additional questions in Appendix 1)	Approximate duration (60-75 minutes)
Set up	Establish connection; preparation for visit	5- 10 minutes
Introduction	Identify individuals in the visit and discuss purpose of visit	5 minutes
Identification of medication regimen & visualization of medications	What medicines do you currently take? How about over the counter medicines? How about vitamins and supplements? Where do you keep your medications? Can you show me?	15 minutes
Description and visualization of how to take the medications	What do you take this medicine for? When do you take this medicine? Can you show me how much you take each time?	15-20 minutes
Clarify medication instructions	If medications are taken incorrectly, ask about why; educate & use teach back method to confirm understanding	15 minutes
Questions and Closing	Answer questions from subjects; Discuss next steps of review and communication with PCP	5-10 minutes

Control Arm (Usual Care):

After baseline MoCA and technology comfort assessment, medication reconciliation and management will be conducted by the Control primary care teams in the manner they usually do. PACT teams are guided by the VHA Directive on Medication reconciliation[42], which includes in clinic assessment of medication information provided by patients via lists, recall or actual medication review, comparing information obtained to VA electronic medical record to note discrepancies and educating patient on updated medication. PACT PCPs may also request assessment of medication regimens by pharmacists embedded in their clinic based on clinical decisions regarding the needs on the individual patient and availability of such services. Prescription of new medication may trigger review by a VA pharmacist, guided by EMR based interaction alerts. We considered using an active control group with pharmacist review (in clinic or chart review); however, the intervention with pharmacist home televisits informing medication review represents a bundled intervention and the study will examine the effectiveness of the intervention as an enhancement of care to what currently occurs (usual care). This design involving subject interviews and chart reviews will also allow us to characterize current “usual” medication management for older adults in PACTs.

Outcomes:

Primary Outcome: Potentially inappropriate medication (PIM) use, which is the primary outcome, will be assessed by the blinded clinical reviewer using the medication data obtained from home visit surveys employing the STOPP criteria [14]. Proportions of subjects in the intervention group with PIM will be compared to proportions of subjects with PIM in the control group. Secondary Outcomes: Medication lists obtained through survey will be compared against the medical record by a clinician reviewer to establish discrepancies in medications. Discrepancies will be characterized as "no potential harm", "monitoring or intervention potentially to preclude harm", or "potential harm" similar to prior approaches to assess potential clinical impact [43]. In addition, the clinical reviewer will assess the medications using the validated Medication Appropriateness Index (MAI)[32]. Each medication will receive a score based on the 10-item tool to determine appropriateness of medications. Patient satisfaction will be ascertained using an item pertaining to medication use from CAHPS 3.0 [33], a 7-item 5-point Likert scale on medication management by pharmacists adapted from a validated instrument [44,45]; self-efficacy on medication use will be assessed using the MUSE tool to assess change from before and after intervention[34]. Health related quality of life will be assessed using the EQ 5D-5L instrument, a brief validated instrument with good test, retest reliability [35,46].

Implementation Factors:

Post-intervention questionnaires to key stakeholders, including veteran participants and PACT clinicians will be administered to assess the potential for future implementation of the intervention. This will allow us to examine implementation barriers and facilitators to the intervention. Invitation to complete the post-intervention questionnaires will be emailed to PACT providers in the Intervention arm. To ensure we understand PCP decisions on pharmacist recommendations, we will track PCP adoption of recommendations provided by pharmacist review and examine PCP reasons for adoption or non-adoption of recommendations, as well as provider factors that can influence these decisions. Patient and clinician interview and questionnaires will provide perceived barrier and facilitator on a Likert scale. Knowledge and attitude on prescribing for older adults will also be obtained using validated Likert questions. While attitude and behavior in clinician communication with pharmacists will be gathered using Home Medicines Review Inventory (HMRI).

Results

This project has been peer reviewed and selected for support by the VA Health Services Research Service. We anticipate the completion of the ongoing trial in Spring 2025. The first results are expected to be submitted for publication in 2025.

Discussion

The complex medication regimens of many older adults contribute to increased risk of drug interactions, adverse drug events and other poor health outcomes. A number of studies have found that the use of potentially inappropriate medications is associated with adverse outcomes, such as falls, acute care utilization and other negative outcomes.[47,48] Improving medication prescribing using START/STOPP criteria have been found to reduce adverse effects and improve patient outcomes in a number of studies, although mostly in institution-based settings (acute care hospitalization, nursing

homes).[48] Pharmacist based interventions have been demonstrated to have beneficial effects[49,50] but often do not reach the majority of those who would most benefit from them. Leveraging the advances of telemedicine, clinicians can provide medication management services to older Veterans at home. The televisit intervention with pharmacists in medication management has the potential to bridge the current gaps in older adult care and provide a scalable solution to improve medication use in older adults.

The study's pilot phase refined the procedure for pharmacists to conduct home televisits. It is possible that Veterans will consider televisits to home cumbersome or invasive, and that VA primary care staff will consider tailoring medications for older adults an additional task burden that competes with other mandated tasks. Our prior experiences of home televisits suggest that they are well accepted, and our hybrid effectiveness implementation study will enable us to identify potential implementation challenges and thus can inform future implementation. To ensure we understand PCP decisions on pharmacist recommendations, we will track PCP adoption of recommendations provided by pharmacist review to identify PCP reasons for adoption or non-adoption of recommendations, as well as provider factors that can influence these decisions.

The older adults population have increased the use of technology allowing the VA to utilize technological advances for VA televisits overcoming previous barriers and we expect future changes in technology will further facilitate use. Our study design will allow us to observe older adults using technology at home to enhance our understanding of barriers to use, and qualitative interviews with clinicians and patients will further identify factors to guide future implementation. We elected to use 2 separate sites in the randomized trial phase in order to enhance understanding of contextual issues and to enhance external validity.

Strengths and limitations:

This study design includes both a pilot phase trial and hybrid effectiveness implementation trial, which ensures that we would observe and be able to address challenges prior to the randomized trial. While the results from the hybrid implementation effectiveness trial would allow us to determine its effectiveness while preparing to spread the intervention, if effective, in the health system. We aim to limit crossover contamination for providers with cluster randomization. Lastly the standardized intervention and structured pharmacist protocol ensures consistency and reliability. The study design also has a few limitations. One such limitation is that the study is conducted in urban and suburban settings, which may limit generalizability Another limitation is that this study is being conducted during the COVID-19 pandemic that introduced unique challenges in recruitment due to factors such as travel restrictions and increased risk for participants however the study team tackled these challenges and completed the pilot phase of the study despite limitations introduced by COVID-19 pandemic. This study will contribute towards literature regarding pharmacist medication management through home televisit procedures as well as interventions aimed at improving medication use in older Veterans.

Conclusions

This study design is to demonstrate how medication management will be beneficial through televisits. The effectiveness is to show how it will improve the use of medications and interventions regarding the potential impact to older adults with multiple chronic conditions and polypharmacy. Clinicians can offer elderly Veterans medication management services at home by utilizing telemedicine's advancements. The employment of pharmacists in televisit medication management interventions has the potential to close existing gaps in older adult care and offer a scalable way to

enhance older individuals' medication utilization.

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Conflicts of Interest

None declared.

Abbreviations

ADR: Adverse Drug Reaction
CFIR: Consolidated Framework for Implementation Research
HMRI: Home Medicines Review Inventory
JMIR: Journal of Medical Internet Research
MAI: Medication Appropriateness Index
MOCA: Montreal Cognitive Assessment
S-TOFHLA: Short Test of Functional Health Literacy in Adults
PACT: Patient Aligned Care Team
PCP: Primary Care Providers
PIM: potentially inappropriate medications
RCT: randomized controlled trial
VVC: VA Video Connect

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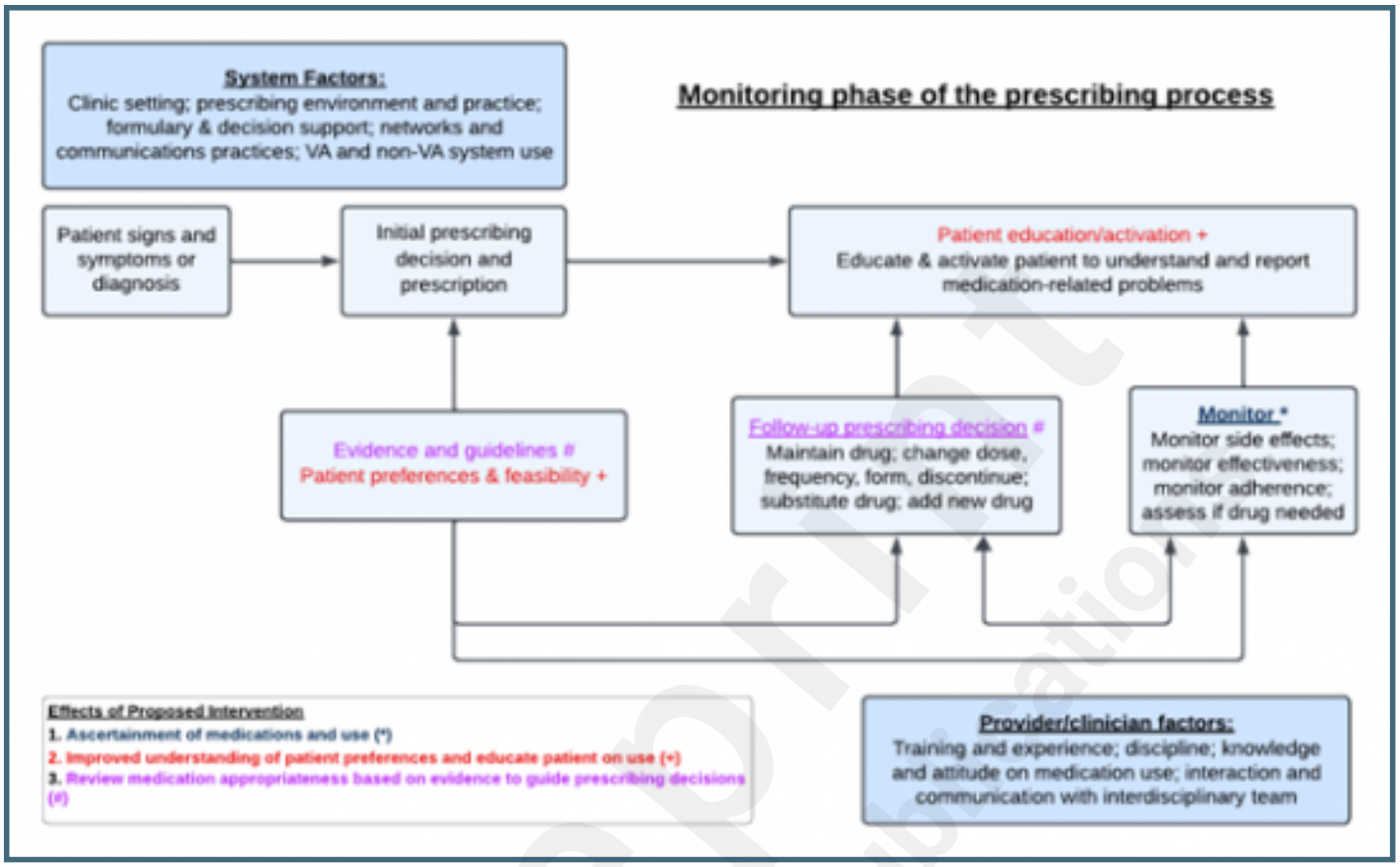
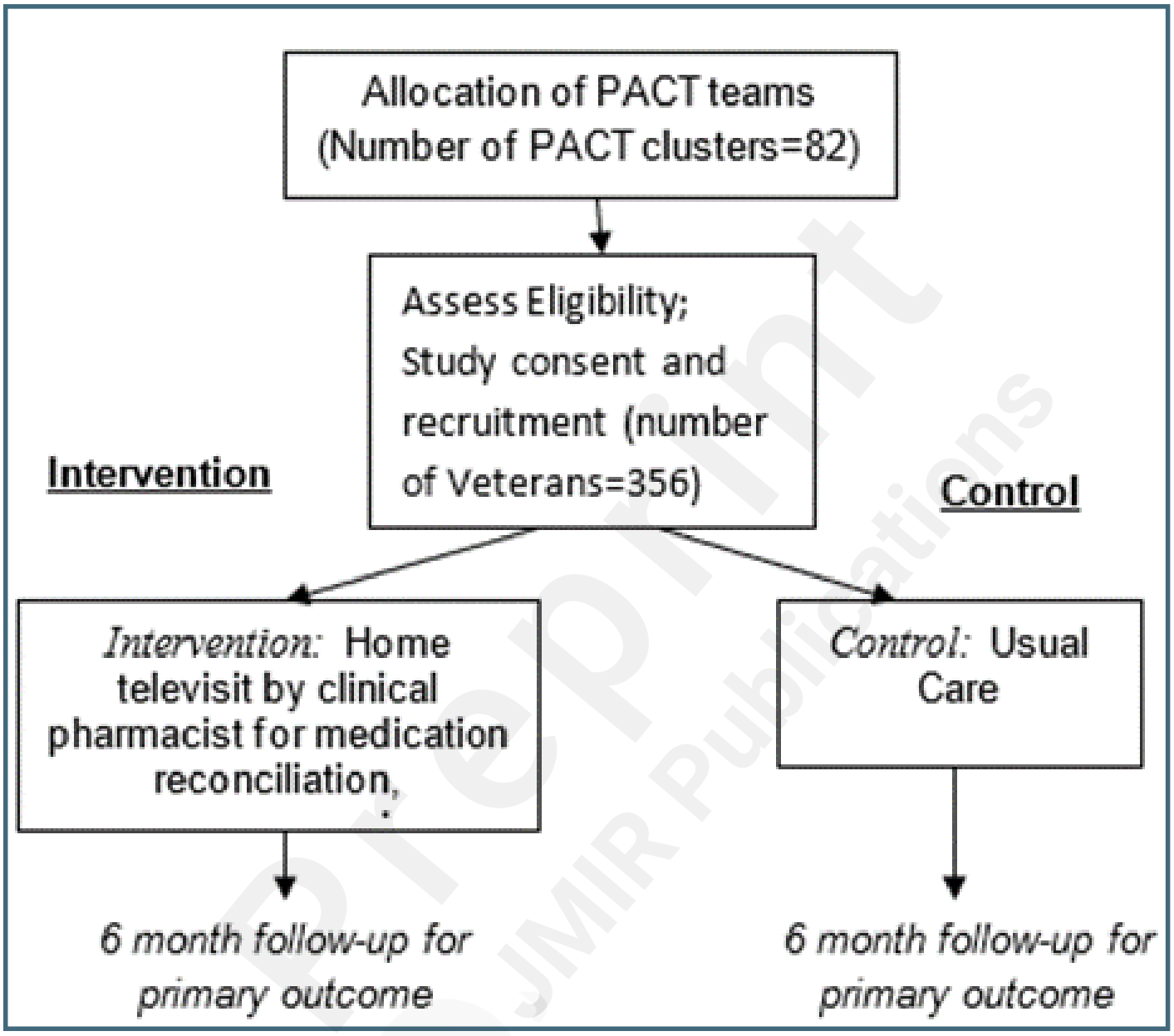
Supplementary Files

Figures

Conceptual framework of prescribing and prescription monitoring process- Modified from Steinman et al [31].



The study design steps, as it shows the specific steps included in both the Intervention and Control group.



Multimedia Appendixes

Approved Grant Proposal.
URL: http://asset.jmir.pub/assets/e51300c89ea1d0c50fed80b7a5a2b639.pdf