

Title of Project: ***Use of mHealth Technology for Supporting Symptom Management in Underserved Persons Living with HIV***

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Principal Investigator and Team Members:

Principal Investigator: **Rebecca Schnall, RN, PhD**

Co-Investigators: Suzanne Bakken, RN PhD, Susan Olender MD, Haomiao Jia, PhD

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STUDY PURPOSE AND RATIONALE:

HIV has changed from an acute illness to a chronic disease. The success of HIV medications and treatments has significantly altered the course of the disease. While AIDS-related illnesses are no longer the primary threat, a new set of HIV-associated complications have emerged, resulting in a chronic disease that for many will span several decades of life. The ability to self-manage adverse symptoms of HIV illness has been shown to improve patient-centered outcomes. In response to this need a team at UCSF developed a paper-based symptom management manual with self-management strategies for 21 common HIV/AIDS adverse symptoms (PCOR evidence). The efficacy of the manual was demonstrated in a 775-person RCT over three months at 12 sites. However, subsequent use of these strategies has been very limited; mHealth offers an ideal platform for the implementation and dissemination of evidence-based strategies for HIV symptom management. Due to the high incidence of HIV among racial and ethnic minority populations, it is appropriate to develop mHealth tools tailored to the needs of these populations. mHealth technology has the potential to address many of the healthcare needs of persons living with HIV/AIDS (PLWH) including symptom management. In response to these current issues, our proposal seeks to inform the development and testing of a mHealth application that will incorporate findings from PCOR studies to improve the outcomes of PLWH.

To improve outcomes for those most in need, our study activities are focused on communities with the greatest burden of HIV in the US, including racial and ethnic minorities and those of low socioeconomic status.

The goal of this study is to facilitate the dissemination and implementation of PCOR using mHealth technology to improve self-management of adverse symptoms in persons living with HIV/AIDS (PLWH). Symptom management in PLWH is especially important because the US HIV epidemic continues to exact a huge toll, especially among AHRQ priority populations including racial, ethnic, and sexual minorities and low-income persons. The incorporation of HIV symptom management strategies into patient's lives through the use of mHealth technologies has the potential to advance the effective dissemination and implementation of PCOR finding. The overall research question is to test the efficacy of the mVIP app which will be created as part of this study.

SPECIFIC AIMS

- 1) Apply participatory design, heuristic evaluation, and end-user usability testing (using eye tracking software) and think-aloud protocol method to incorporate PCOR evidence for HIV symptom management into a mobile health application (mVIP) for use in patient self-management.
- 2) Using a randomized design, examine the effect of mVIP as compared to an attention control group on primary outcomes of symptom frequency and intensity.
Hypothesis: Study participants who use the mVIP system to access symptom strategies are more likely to have decreased symptom frequency and intensity at the end of 12 weeks.
- 3) Guided by the PRECEDE-PROCEED model of health program planning and evaluation,

examine PLWH's perceptions of the predisposing, enabling, and reinforcing factors for mVIP use.

Overview of Design, Methods, Target/Accrual Enrollment, Recruitment/Enrollment Status				
Aim	Design/Methods	Target Enrollment	Enrolled/Accrued	Enrollment Status
1	A) Participatory design using card sorting activity	40	31	Closed to further enrollment. Study-related procedures ongoing.
	B) heuristic evaluation	5	5	Closed to further enrollment. Study-related procedures ongoing.
	C)End-user usability testing Utilizing eye tracking software and think-aloud protocol	20	20	Closed to further enrollment. Study-related procedures ongoing.
2	Randomized controlled design	80 (Intervention:40, control: 40)	80	Closed to further enrollment. Study-related procedures ongoing.
3	Descriptive: focus groups/in-depth interviews	Focus groups: 40 In-depth interviews: 12	0	Closed to further enrollment. Study-related procedures ongoing.

Subject Population: We anticipate two categories of research subjects in our study:

- 1) Persons living with HIV/AIDS
- 2) Experts in human computer interaction.

Setting and Sample

Eligibility Criteria (Aim 1a): In order to participate in Aim 1a of this study, participants must be:

- 1) Diagnosed with HIV/AIDS
- 2) Over the age of 18 years
- 3) Able to provide written informed consent
- 4) Able to communicate in English
- 5) Report at least 2 HIV related adverse symptoms in the past week
- 6) Cognitive state (as assessed by a modified version of the standard Mini Mental State Exam (MMSE): total score of 3 or higher)

This process, which is an accepted and necessary component prior to final mVIP implementation, will include an electronic survey. After survey completion we will conduct a card sorting exercise utilizing a

think –aloud protocol in which the participants will be presented with a stack of cards, representing the content of mVIP app, while they are encouraged to share their insights with us and sort/group the cards in a way that would make sense to them.

Data Analysis: A hierarchy analysis will be conducted for establishing the rank order of symptoms and self-management strategies.

Eligibility Criteria (Aim 1b): Five informaticians will participate as usability experts.

Study participants must be at least a masters-level prepared in human computer interaction, clinical informatics or public health informatics.

Each usability expert will be asked to evaluate the system using the Heuristic Evaluation Checklist and to think-aloud while performing the usability testing. The process will be recorded using Morae software™, which allows the researcher to record and analyze the audio recording and screen shots that are captured during the heuristic evaluation.

Data Analysis: At the end of this evaluation, the frequencies of usability issues will be calculated according to Nielsen's heuristic principles. Following the heuristic evaluation, the mVIP app will be refined.

Eligibility Criteria (Aim 1c):

- 1) Diagnosed with HIV/AIDS
- 2) Over the age of 18 years
- 3) Able to provide written informed consent
- 4) Able to communicate in English
- 5) Report at least 2 HIV related adverse symptoms in the past week
- 6) Be the owner of a smartphone and/or tablet.
- 7) Cognitive state (as assessed by a modified version of the standard Mini Mental State Exam (MMSE): total score of 3 or higher)

For end-user usability testing, we will conduct end-user usability testing on 10 Android smartphone users and 10 OS smartphone users.

Data Analysis: The analysis will be based on the Tobii recordings of user sessions including voice/screen and eye movement/fixation, transcriptions, notes, and the user surveys. Mean task performance time will be calculated. Critical incidents characterized by comments, silence, and repetitive actions will be identified with eye movement. We will review these incidents in detail using Tobii Eye-tracking software. The incidents identified and the users' written comments will be summarized. Eye-tracking analysis, and content analysis, a technique for making objective, replicative and valid inferences from data, will be performed.

Eligibility Criteria (Aim 2)

- 1) Diagnosed with HIV/AIDS
- 2) Over the age of 18 years
- 3) Able to provide written informed consent
- 4) Able to communicate in English
- 5) Report at least 2 HIV related adverse symptoms in the past week
- 6) Be the owner of a smartphone and/or tablet.
- 7) Cognitive state (as assessed by a modified version of the standard Mini Mental State Exam (MMSE): total score of 3 or higher)

Aim 2: Using a randomized design, examine the effect of mVIP as compared to an attention control group on primary outcomes of symptom frequency and intensity. We will conduct a 12 week trial of the mVIP. We will recruit 80 HIV+ persons with the proposed sample size of 40 in each of the following two groups:

- 1) Intervention group: mVIP app with access to symptom strategies
- 2) Control group: mVIP app without access to symptom strategies

The symptom frequency and intensity will be compared between the two groups aiming to test the effectiveness of improvement in symptom intensity score for the mVIP group over the control group.

Randomization: Patients will be randomized (1:1) to mVIP or an attention control group. Both groups will receive the mVIP app on their smartphones. The allocation sequence of participants will be concealed from the research assistant who will be responsible for randomizing study participants. This will be a single-blinded study and control group participants will not have access to the symptom strategies. We had initially planned to give a smartphone to each study participant as a compensation. However, during the first aim of our study, we learned that many of our study participants already have smartphones. For those who do not, the learning process for the basic use of a smartphone, in addition to the training needed to use our intervention, will be too difficult. Thus, we have decided to change the initial compensation plan. Instead, we will be giving our participants a token of appreciation for their participation in the study. Both groups will report their symptoms on their smartphone app every week. Participants in the mVIP (intervention) group will receive targeted symptom strategies from the UCSF symptom management manual (PCOR evidence) based on the symptoms that they report.

Contact information will be retained and used by study staff to remind participants about their follow up appointments. Contact information will be kept in a separate database from research data.

Eligibility Criteria (Aim 3):

For Aim 3: They must have participated in AIM 2

PROCEDURES

Aim 1: Participatory Design, Heuristic Evaluation and End-User Usability Testing.

During the initial stages of designing a mVIP health management app Inclusion of stakeholders throughout the app design process is vital to ensure that patient needs unknown to the investigators are taken into account. This process, which is an accepted and necessary component prior to final mVIP implementation.

Aim 1a) Participatory Design: Participants will complete an electronic survey, on site, containing demographic questions, technology use, medication adherence, and health-related quality of life. Upon survey completion they will be asked to perform a card sorting exercise/think aloud protocol. They will be presented with a stack of cards that represent the content and functionality for the mVIP app. They will be encouraged to try and sort the cards into groups that make sense to them and share their insights with our team.

Aim 1b) Heuristic Evaluation: Five informaticians will participate as usability experts. Study participants must be at least a masters-level prepared in human computer interaction, clinical informatics or public health informatics. The usability experts will be provided with a prototype of mVIP. Each usability expert will be asked to evaluate the system using the Heuristic Evaluation Checklist and to think-aloud while performing the usability testing. The process will be recorded using Morae software™ (Techsmith Corporation, Okemos, MI) (102), which allows the researcher to record and analyze the audio recording and screen shots that are captured during the heuristic evaluation. At the end of the evaluation, each expert will be compensated \$150. Each heuristic will be evaluated by one or more items and the overall severity of the identified heuristic violations will be rated.

Data Analysis: The frequencies of usability issues will be calculated according to Nielsen's heuristic principles.

Following the heuristic evaluation, we will refine the mVIP.

Once the mVIP prototype is refined and implemented by the programmer, we will conduct an evaluation: Aim 1c) End- User Usability Testing.

Aim 1c) End-User Usability Testing. Usability testing of a Beta version of mobile Video Information Provider (mVIP). We will be conducting usability testing of a Beta version of the mVIP app. The purpose of the usability testing is to improve the effectiveness, efficiency and user satisfaction of the mVIP app. To achieve this goal, we will be using eye-tracking and think-aloud method to examine the end-user task performance to assess mVIP system validation and human- communication interaction (HCI) in a laboratory setting. We will recruit 20 persons living with HIV (PLWH) (10 PLWH for the usability testing on Android smartphones and 10 PLWH for the usability testing on iPhones. All participants will be provided with scenarios and asked to complete tasks using mVIP system on a smartphone. While they are doing the tasks, their eye movements and smartphones screen will be recorded using Tobii Pro Eye-tracker. During each task, the start and stop times of tasks will be also measured. After completing the tasks, they will be asked to think aloud and verbalize their thoughts about the tasks they completed, through a replay of the screen recordings. Participant's reactions and verbal comments will be video and audio recorded. As part of the usability assessment, participants will complete electronic surveys containing demographic questions, health literacy, technology use, medication adherence, and health-related quality of life.

Aim 2) Randomized controlled design: Examine the effect of mVIP intervention as compared to an attention control group on primary outcomes of symptom frequency and intensity.

We will recruit 80 PLWH to participate in a 12 week trial. The sample size and statistical power calculation is based on the hypothesis test of improvement of the symptom frequency and intensity after the implementation of the mVIP system. The effect size is based on our 12 week feasibility study with 42 participants. The criterion for significance (alpha) has been set at 0.05 for the two- sided test. We will recruit 80 HIV+ persons with the proposed sample size of 40 in each of the two groups (assuming a 1:1 allocation ratio). To account for a potential attrition rate of 20%, we propose to achieve a final sample of 64 patients (32 per group). Additionally, each patient will have 20% chance to miss any one of the symptom reporting opportunities between week 2 and week 10.

For the symptom frequency outcomes, this study will have 87.9% power to detect 20% decrease in symptom frequency (for example, from an average 8 symptoms to average 6.4 symptoms) from the

baseline to the end of study (i.e., 12th week). For the comparison between the mVIP group and the control group, this study will have 85.4% power to yield a statistically significant result (assuming an intention-to-treat principle for the analysis) to test 15% improvement in one group over another group (i.e., the mVIP group decreases 20% in symptom frequency and the control group decreases 20%+15%=35% in symptom frequency). For the symptom intensity outcomes, this study will have 96% power to detect decrease in symptom intensity score of a medium effect size of 0.6 from the baseline to the end of study. For the comparison of the two groups, this study will have about 95% power to yield a statistically significant result to test an effective size of 0.6 improvement in symptom intensity score for the mVIP group over the control group.

Following randomization of participants, both the intervention and control groups will receive the mVIP on their phones. All participants will complete all study-related questionnaires electronically on their smartphone. All subjects will complete a demographic questionnaire as well as the Newest Vital Sign instrument to measure health literacy at baseline in addition to the judgment of a team member that they are cognitively intact. Similar to our feasibility study, participants will use the system at least once every week and will receive a reminder email or phone call if they have not used the system in more than 1 week. Symptom frequency and intensity will be collected every week. The remainder of the measures will either be collected at weeks 0 and 12 or week 12 only. See the outcome measures table below for details.

Aim 3) In-Depth Interviews and Focus Groups to evaluate PLWH's perceptions of the predisposing, enabling, and reinforcing factors for mVIP use

In-Depth Interviews will be approximately 30 minutes in length and will occur immediately following a participant's follow up appointment. We will include a \$10 reimbursement for participants' time. After obtaining informed consent, study staff will audio record a structured interview aimed at collecting feedback on usage habits, potential technical or usability issues, and the session reminder structure. Each interview recording will be transcribed and transcripts will be analyzed independently for content by research team members.

The focus groups will be 60-90 minutes in length. We will include \$40 reimbursement for participants' time. Following completion of the informed consent process, all focus group sessions will be audio-recorded. The focus group guide will be informed by the Predisposing, Reinforcing, and Enabling Constructs in Evaluation (PRECEDE) portion of the PRECEDE-PROCEED Model of health program planning and evaluation. The integration of these frameworks for application in HIT implementation evaluation has been proposed by a number of authors as a strategy for assessing predisposing, enabling, and reinforcing factors for use and acceptance of HIT.

The team will adhere to qualitative research processes to ensure the credibility, confirmability, dependability and transferability of the qualitative data from these analyses. To support the credibility of the data, we will conduct peer debriefing and triangulate findings across multiple data sources (surveys, focus group data). In addition, we will use "member checks," i.e., sharing of initial data interpretations with participants, to ensure accurate interpretations. Triangulation of findings, along with reflexivity, will enhance the confirmability of the interpretations. The investigators will carefully record an audit trail and keep extensive field notes to facilitate transferability of study findings into

other contexts. Each focus group recording will be transcribed; transcripts will be analyzed independently for content by research team members.

Overview of Study Instruments

Please note that all study instruments for the trial are included as attachments entitled [mVIP Baseline](#)

[12-9-2016](#) and [mVIP Follow-up 12-2-2016](#)

Primary Outcome Measure: Change in HIV related symptom status as measured by the PROMIS-29.

Baseline Measures:

- Demographics
- PROMIS-29
- PROMIS-GI
- SF-12
- RAND-36
- Case adherence index and ART adherence VAS
- TOFLHA
- NVS
- Symptoms distress module
- Healthcare Provider Engagement
- Non-CPT/Study Medical and Other Services (CTN-0051)
- Health ITUES
- PSSUQ

Follow-up Measures:

- PROMIS-29
- PROMIS-GI
- SF-12
- RAND-36
- Case Adherence Index and ART adherence VAS
- Symptom distress module
- Healthcare Provider Engagement
- Non-CPT/Study Medical and Other Services (CTN-0051)
- Health ITUES
- PSSUQ

Data Analysis

The study analysis followed an intention-to-treat approach. Intervention and control characteristics collected at baseline were summarized with descriptive statistics (mean \pm SD or frequency). To assess the effect of the intervention on symptom burden during the follow-up period, we used linear mixed model to analyze repeated measured data, and the models controlled for age, sex, race, education and CD4 count.

For all secondary outcome measures, which were collected at baseline and 12 week follow-up, we used a same linear mixed model or a generalized linear mixed model. We used linear mixed model for continuous outcomes (e.g. PROMIS score); generalized linear mixed model (Poisson or Negative binomial model) for count outcomes (e.g. number of ER visits); the generalized linear mixed models (logistic model) for binary outcomes (e.g. CASE Adherence Index). All models were controlled for age, sex, race/ethnicity, education and CD4 count.