

Research Article

## Technology for Engagement and Management of Health (TEAMH) and Antiretroviral Adherence in People Living with HIV: a Mixed-Methods Pilot Evaluation Study

Paola DiMarzio<sup>1,5</sup>, Sheneiza Moore<sup>2</sup>, Barbara Martens<sup>3</sup>, Oonagh Dowling<sup>4</sup>, Joseph McGowan<sup>3</sup> and Rebecca M Schwartz<sup>5\*</sup>

<sup>1</sup>Department of Medicine, Zucker School of Medicine, Hofstra-Northwell, Great Neck, NY, USA

<sup>2</sup>Zucker School of Medicine, Hofstra-Northwell, Hempstead, NY, USA

<sup>3</sup>Center for AIDS Research & Treatment, Department of Medicine, Northwell Health, Great Neck, NY, USA

<sup>4</sup>Department of Anesthesiology, Long Island Jewish Medical Center, Queens, NY, USA

<sup>5</sup>Department of Occupational Medicine, Epidemiology and Prevention, Zucker School of Medicine, Hofstra-Northwell, Great Neck, NY, USA

### Abstract

Medication adherence remains a major barrier in the health care management of people living with HIV (PLWH). This pilot study evaluates the feasibility of a smartphone application and web-based medication adherence program, Technology for Engagement And Management of Health (TEAMH), and its potential to impact patient adherence. Nine patients were recruited using convenience sampling to pilot the TEAMH study application. Patients' ART adherence was monitored in real-time using the TEAMH app on smartphones provided by the research team. Patients then participated in a qualitative focus group and completed a survey on acceptability and feasibility of the app. Results: Participants completed the study with 92% medication adherence. The majority of participants indicated a desire to utilize the app in the future and 89% reported feeling confident using the system. The feasibility of the TEAMH mHealth system was rated satisfactory and patients felt that it could be especially beneficial for PLWH struggling with medication adherence.

**Key Words:** People Living with HIV; Medication Adherence; Mobile Phone Application

### Introduction

The use of antiretroviral therapy (ART) has dramatically reduced disease progression and mortality in people living with Human Immunodeficiency Virus (PLWH). With appropriate dosing, ART suppresses HIV replication, resulting in an undetectable plasma viral load, an arrest in disease progression to AIDS and a reduced risk of HIV transmission [1]. Nevertheless, ART is not fully effective in restoring

the immune function, and as consequence several immunodeficiency-associated complications (i.e., cardiovascular diseases, cancer) are emerging, having a profound effect on the health PLWH. Given that HIV infection is now considered a chronic disease that persists for many decades and requires sustained engagement in care and adherence to prescribed medications, it is imperative to find effective interventions to maximize adherence rates among PLWH [2]. In the United States, only half of all PLWH are actually receiving proper HIV and primary health care and of those receiving care only one third achieved complete viral suppression [3]. Since it has been shown that drug resistance is most common among patients with a medication adherence rate of <90%, PLWH must adhere to their ART regimen at a rate of >90% to prevent physiological deterioration due to HIV rebound [4].

**\*Corresponding Author:** Rebecca Schwartz, Department of Occupational Medicine, Epidemiology and Prevention, Zucker School of Medicine, Hofstra-Northwell, 175 Community Drive, Great Neck, NY 11021, USA, Fax: 516-465-2699, Tel: 516-465-7926; E-mail: rschwartz3@northwell.edu

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Poor medication adherence may have lifelong implications for PLWH, not only by reducing ART options due to cross-resistance among HIV medications, but, also by increasing the overall mortality risk which has been estimated to be 3.8 times higher than that of adherent patients [5-9]. Most methods developed to increase patient adherence to medications attempt to change patient behavior by using reminders, counseling, reinforcement, education, dosage simplification, or a combination of these methods [10,11]. Other methods include electronic systems that deliver reminders by telephone, pager, or audio-visual devices [12,13]. Meta-analyses of randomized controlled trials showed that text messaging improved adherence to ART and clinical outcomes [14,15]. A recent systematic review of several randomized controlled trials found that the most successful mobile health (mHealth) technology interventions aimed at improving medication adherence utilized psychoeducation and other approaches (i.e., reminders, pill box, and medication planners) to impact adherence self-efficacy [16]. The review also suggested that reliable, valid and objective methods, such as electronic monitoring, should be employed to measure adherence [16]. Muessig's group underscored the greater reach that mHealth technologies offer, particularly for more marginalized populations such as HIV-infected drug users [17]. Therefore, a strong understanding of the usability of this technology and its impact on medication adherence for use with PLWH is crucial for the development of optimal interventions. To date, most of the interventions developed to support and improve ART primarily employed text messaging while only few focused on apps [17].

The purpose of this study was to obtain preliminary data regarding the usability of the Technology for Engagement and Management of Health (TEAMH) medication adherence smartphone application and to begin to assess its potential impact on patient adherence. TEAMH provided medication reminders and access to a health educator through the use of a secure two-way messaging system. The health educator was able to track patients' adherence to medications and medical appointments in real-time. Most importantly, TEAMH was customized to each patient's needs, providing specific information regarding medication regimen including dosage and side effects. Moreover, the TEAMH app also provided a comprehensive medication adherence educational component for PLWH. We hypothesized that TEAMH would be feasible and acceptable for use and would provide supplementary support for the management of PLWH's medications and care.

## Materials and Methods

### Study Design

This single-arm, mixed-methods study involved piloting the TEAMH medication adherence smartphone application with nine patients; ini-

tially 12 patients were recruited and consented, but three were lost to follow up in the interval between recruitment and launch of the app. The study was implemented at the Center for AIDS Research and Treatment (CART) part of a regional health system in the NY metropolitan area from June 1st until September 30th, 2015. Patients were recruited by a health educator during their routine visit and were followed for one month. Convenience sampling was used and the health educator approached patients with varying medication adherence histories. The participants included were: 1) HIV-infected outpatients at CART (18 years or older); and 2) prescribed ART. Exclusion criteria included an inability to provide written consent due to language or cognitive barriers. Patients were provided with a 4G Android (Samsung G6) loaded with the app and content. Patients' ART adherence was monitored in real-time. The TEAMH app and the web-based portal for the health educator were the focal points of the study. TEAMH provided the patients with: 1) ART medication reminders tailored to the patient's specific ART dosing schedule; 2) medical appointment reminders; 3) the ability to contact the health educator regarding medication side effects and other issues related to the medication regimen; and 4) educational material related to the HIV-infection as well as medication treatment related information. The intervention is based on Bandura's Social-Cognitive Theory [18] which posits that improving self-efficacy will lead to an increased likelihood of engaging in a particular behavior, in this case, adherence to medications. SCT has been the basis of numerous studies aimed at understanding and promoting adherence among HIV-infected patients [19-21]. The Institutional Review Board (IRB#15-212) approved the study protocol.

The health educator instructed patients on how to operate the Android smartphone including; navigating the TEAMH app and responding to the alerts each time it reminded the patients to take the medication. The patient has to click "yes" or "no" as to whether it was taken. The application was designed in such a manner that it provided additional notifications in case of any non-adherence. Direct contact with the health educator through online messaging to discuss patients' symptoms and side-effects was available and the health educator could, as needed, set the medication reminders as well as reminders regarding medical appointments, medication refills and laboratory testing. Furthermore, the health educator was able to regularly monitor patients' adherence to their medication regimen as patients' responses to the alerts transmitted directly to the health educator's HIPAA compliant web-based portal. In addition, the TEAMH app provided patients with feedback on their adherence to ART medications by sending the list of alerts that were missed. Screens of the TEAMH application are shown in Figure I.

A system usability scale questionnaire, adapted from the mHIMMS App Usability work group, was administered to all patient participants and the health educator at the end of the one-month study period [22]. All data

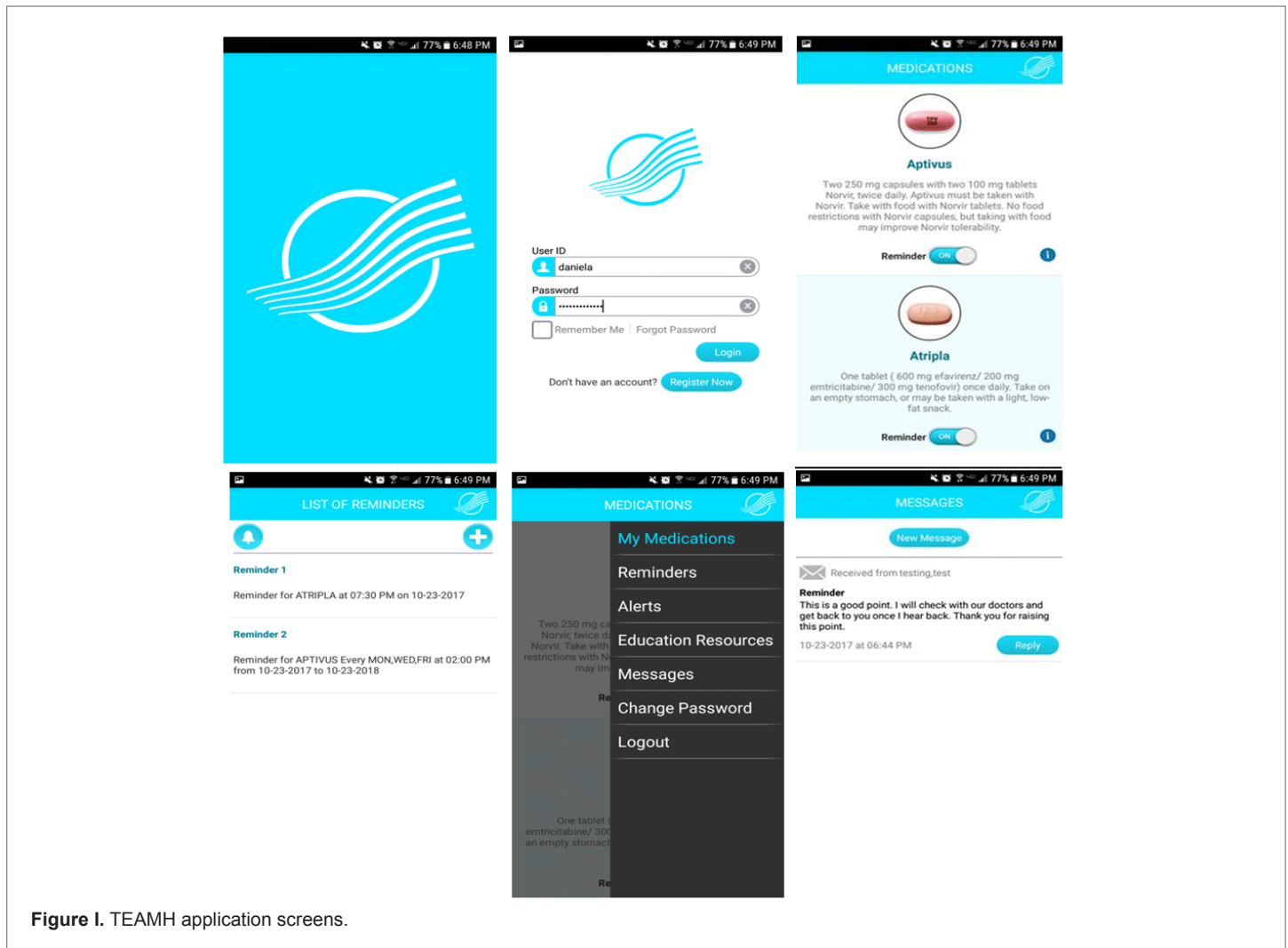


Figure I. TEAMH application screens.

were stored on a secure portal and accessed through an encrypted and secure health system network. Participants were compensated for completing the questionnaire and for their focus group participation. Patients were compensated \$25/week for completing the measures (for a total of four weeks). In addition, patients were compensated \$25 for the focus group participation and questionnaire completion.

### Quantitative Data Analysis

Descriptive statistics are presented as mean or median and as frequency/percentage wherever appropriate. In order to assess the acceptance rate, the proportion of patients that consented who then went on to accept TEAMH app was measured. To measure the acceptability rate of the TEAMH app, the proportion of patients that continued to use of the app throughout the study with no patients lost to follow up after they started using it was measured.

Medication adherence measurements were based on reports generated by the TEAMH app which recorded overall medication adherence of patients enrolled in the pilot study. Adherence was calculated based on average of the number of doses to have been actually 'taken' as reported by the app divided by the number of doses prescribed over the course of the number of functional days of app use.

### Qualitative Study Design

We held one focus group with all study participants at the end of the study period facilitated by an experienced qualitative researcher. The focus group used a discussion guide constructed by the authors of this paper (see Appendix 1), lasted approximately 90 minutes. The focus group was audio recorded and the audio files were professionally transcribed. The transcript was analyzed in two stages. First, a qualitative researcher manually coded transcripts for major themes and wrote an evolving qualitative memo with extended annotated interview ex-

cerpts to help coauthors verify examples and themes [23]. Given the manageable size of the data, we chose not to use qualitative analysis software. The other authors reviewed and provided feedback on the multiple versions of the memo. After reviewing each coded theme, another qualitative researcher revised the qualitative memo linking categories and subcategories to each other. Our research team regularly conferred to discuss varying interpretations of the content and meaning of patients' responses for several months until consensus was reached. In addition, a study participant reviewed results in order to validate the credibility of the data.

## Results

### Patient Participant Characteristics

In this study, 12 patients were approached by the health educator using convenience sampling and consented to participate in the study. She intentionally chose a group of patients with variable adherence histories. Only 9 of the 12 were enrolled for one month to test the use of the TEAMH application. Three patients were lost to follow up prior to initiation of the study due to reasons not related to the use of the TEAMH app. Patient rate of acceptance was 75% (n=9) while patient acceptability rate of the technology was 100% (n=9) since all patients enrolled who started using the TEAMH app completed the study. On average, these patients were 51.9 (SD 12.1) years old, 66% (n=6) were

female, 34% (n=3) were White/non-Hispanic, 11% (n=1) were White/Hispanic and 33% (n=3) were Black/non-Hispanic. The average rate of medication adherence at the end of the study was 92% ranging from 78-100% adherence. Of total doses scheduled and taken, 64% of medications were taken on time, 9% were missed and 27% were postponed by a mean of 11 (SD +/-7.7) minutes from the scheduled time.

### Usability Scale Questionnaire

A patient satisfaction questionnaire was administered to all active TEAMH patients to assess both overall satisfaction and ease of use of the technology. The scale for this survey was adapted from the Telemedicine Satisfaction and Usefulness Questionnaire [24]. As shown in Table I, an overall assessment of the results of this survey revealed that many of the patients in the study found that TEAMH was not only useful but felt confident using it. For instance, 67% (n=6) of the patients agreed that they would use the TEAMH application again and 100% (n=9) of them felt the system was easy to use, while 89% (n=8) felt confident using it. All patients agreed that, despite some technical issues encountered while using the application, such as difficulty with alarm volume, information was presented in a clear manner that could be quickly learned by any user. Although all patients responded that the system was easy to use they felt that new users would need an extensive educational session on how to use the app.

**Table I:** Usability scale patient questionnaire response frequencies.

Survey questions	Likert scale % (n)			
	strongly agree/agree	neutral	strongly disagree/disagree	no response
I think that I would like to use this system again.	67% (n=6)	33% (n=3)	0% (n=0)	0% (n=0)
I found the system unnecessarily complex.	22% (n=2)	0% (n=0)	78% (n=7)	0% (n=0)
I thought the system was easy to use.	100% (n=9)	0% (n=0)	0% (n=0)	0% (n=0)
I think that I would need the support of a technical person to use this system again.	11% (n=1)	11% (n=1)	78% (n=7)	0% (n=0)
I found the various functions in this system were well integrated.	89% (n=8)	11% (n=1)	0% (n=0)	0% (n=0)
I thought that there was too much inconsistency in this system. For example: The alarm doesn't go off all the time.	0% (n=0)	22% (n=2)	67% (n=6)	11% (n=1)
I would imagine that most people could learn to use this system quickly.	100% (n=9)	0% (n=0)	0% (n=0)	0% (n=0)
I found the system difficult to use.	0% (n=0)	0% (n=0)	100% (n=9)	0% (n=0)
I felt very confident using the system.	89% (n=8)	0% (n=0)	11% (n=1)	0% (n=0)
I needed to learn a lot of things before I could get going on this system.	11% (n=1)	0% (n=0)	89% (n=8)	0% (n=0)
The app had a clear, clean, uncluttered screen design.	89% (n=8)	0% (n=0)	11% (n=1)	0% (n=0)

The app kept screen changes to a minimum during completion of the task.	67% (n=6)	11% (n=1)	11% (n=1)	11% (n=1)
The app minimized the number of steps it took to complete tasks.	45% (n=4)	22% (n=2)	22% (n=2)	11% (n=1)
Information presented on screens was easy to understand quickly.	78% (n=7)	11% (n=1)	11% (n=1)	0% (n=0)
Information needed for a specific task was grouped together on a single screen.	67% (n=6)	11% (n=1)	22% (n=2)	0% (n=0)
Choice lists were clear and unambiguous.	89% (n=8)	11% (n=1)	0% (n=0)	0% (n=0)
Alerts were only presented at appropriate times.	45% (n=4)	22% (n=2)	33% (n=3)	0% (n=0)
Data could be entered once then used in multiple places.	22% (n=2)	0% (n=0)	0% (n=0)	78% (n=7)
I felt confident I could make a mistake without losing work.	22% (n=2)	0% (n=0)	11% (n=1)	67% (n=6)

### Focus Group Results – Overall Usability

As part of the focus group, patient participants (n=9) were asked about the intervention feasibility and acceptability, and they were encouraged to discuss any barriers to using the technology that they encountered during the study period. Any issues discussed regarding the implementation of the use of TEAMH app or the specific features of the application that required adjustment, were changed by the study team.

Overall, the focus group indicated that participants were satisfied with the app and found it easy to use. They felt that it would be extremely beneficial for all patients, especially those struggling with ART adherence or who have to manage complicated medication regimens.

One female participant enthusiastically expressed how useful she found the TEAMH app.

*...I really liked it you know... I love it, I think it's a great app. Even now I would use it...*

Another male participant felt that the app would be great not only for patients who are not adherent but also for patients who are adherent since it tightened up their dose schedules.

*...Even for adherent people because it made me aware of really trying to take my medications at the same time each day...*

Lastly, a third female participant stated that she wished she had the app for her son in college who has issues with adherence.

These were many of the common themes expressed by the focus group patients. They generally believed that once a few technological issues were worked out, TEAMH has the ability to be very beneficial to both

PLWH by supporting adherence to prescribed medications and the community by potentially supporting patients' overall health and, at the same time, decreasing the likelihood of HIV transmission given the potential for improving adherence and therefore lowering HIV viral load.

### Equipment Changes

Throughout the study there were changes made to the TEAMH app to make it easier and more functional for patients' use. Many of these changes are discussed below.

### Password Login

Initially, patients downloaded the app off the app store, but seeing this as an issue of privacy, the method of downloading changed. An email was sent to the patients that allowed them to click a URL to download the app and enter a password. Then the patient could change his/her username and password once he/she had logged in with the preset password. Some patients requested a simpler login process, where they would only have to enter one ID number and not both username and password. When this was created, patients had the option of keeping the old style or to using the new one with the ID number for their ease of use.

### Added Sound to Alerts

In the beginning, for privacy of the patients, the app did not make a noise to alert patients to take their medication. Patients suggested an alert noise to help them remember. Once added, many patients still didn't hear the alerts because of their lack of knowledge of the technology. Those patients had to be reminded as to how to use the phone and turn the volume on, in order to hear the alerts.

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## Changes to Notifications

To indicate that a patient missed a notification from the app, an alert of the number of missed notifications would show on the upper left corner of the application. Additionally, when the nurse messaged the patient, another number would appear on the screen. Patients realize missing notifications from the app such as notifications regarding medication adherence.

## Drop Down Menu

To facilitate increased ease of app use, a drop down menu was added to keep the app functional and easy to use. The font wasn't easily readable when the menu was added, so as per the request of the participants, the font size was made larger.

## Added Link for Medication information and Medication Side-Effects

Pictures of the medications were shown in the application to help patients understand what pill they had to take at which time. If the patient clicked on the pill, it would link to information on the internet about the specific medication (e.g., purpose of use, description).

## Development of an Instructional Brochure

To help patients during their use with the app, based on participant feedback, an instructional brochure was created for patients on phone and app usage. The guide helped patients learn how to properly use the application and in some cases prevented the patients from needing to contact the health educator with any questions.

## Consistent Log Out that Protected their Confidentiality

Some patients were more concerned with the log out process than others. The patients agreed, however, that the app should continually log out after each use due to privacy concerns. Many did not want their HIV status to be known to others, particularly children to whom they had not yet disclosed.

*... all of a sudden it would be there immediately... I have friends with children and they play with their parents phones and maybe their kids don't know and they don't want them to know...*

## Changing the Background to Protect Patient Privacy

Many patients were also concerned that the pill in the background would prompt questions from both friends and family that they may not want to discuss. Although the pill in the background was to remind patients of what their pill looked like, they suggested changing

the background to an emoticon or something abstract to protect privacy.

*...you get on then someone says why are there two pills there? If they were two birds or two hearts maybe they would think it's a game...*

## Reassurance that the App Understood they had taken their Medication

The bird icon in their background would change from a dull gray to a yellow. Some patients wanted to see a more drastic color change or another indication that assured them the application logged their medication as taken.

*...if it was going change colors it was like from some sort of mute color to another mute color. No, I wanted it to go from red to green and say hooray...*

## Incentives to Keep Patients using the App and Adherent

Some of the patients recommended creating incentives such as free phone cards, etc. to keep patients who are having difficulty with adherence using the app.

*...unless there is an incentive of some kind how will this help the person that is having difficulty taking their meds...*

## The Health Educator requested Direct Access to Patient Information

The health educator also had to open the browser quite often to see patients' adherence to all their medications, and she suggested that if a patient had missed a dose of a certain medication that it should be sent to her directly so she would not have to complete the login and periodically sift through all of their medications.

As part of the focus group, patient participants (n=9) were asked about the intervention feasibility and acceptability, and they were encouraged to discuss any barriers to using

## Discussion

The main purpose of the study was to evaluate the feasibility and usability of the TEAMH mHealth system to support medication adherence of PLWH. Patients in this study who used the medication adherence smartphone application, TEAMH, found it to be very useful and indicated that it has the potential to be quite beneficial to those who struggle with medication adherence. Some agreed that even though they were already adherent to medications, it helped them stay on

track and be more consistent with their medication adherence. Ultimately, all patients were satisfied with the application and would recommend its continued use. The application was associated with relatively high adherence rates among a group of patients with varying adherence according to clinic staff.

Previous studies utilizing similar technological interventions also found that patients were generally satisfied and that their apps were easy to use, and in some cases, improved medication adherence [25-28]. However, in most of these studies patients didn't have to respond to medication alerts in real-time and medication adherence was self-reported. Although these studies have used mobile phones for reminders [25] TEAMH is the first to use a direct alert system instead of a phone text message-based system. In fact, one of the successes of this pilot study has been the ability to send scheduled medication reminders to patients' phones independently of the phone text message system thereby adding an extra layer of protection from privacy breaches.

Although these studies share many common features with TEAMH, some important differences still exist. For example, our TEAMH intervention did not include the use of motivational messages sent to patients such as, "This is your reminder. Be strong and courageous," "We care about you" or "Stop, drop and pop. Take your meds now", however, these messages could be implemented, in our TEAMH app system, by a health educator reaching out directly to the patient to engage in motivational interviewing strategies [29,30].

The role of mHealth systems for medication adherence has been investigated in several studies, yielding different results [25,31-34]. Meta-analyses and systematic reviews have shown that mHealth supports medication adherence of patients with chronic conditions and is an effective tool for long-term care of [35-38]. However, some of these studies should be interpreted with caution given the short trial duration, reliance on self-reported medication adherence measures and the different methodological approaches used [31,32,39]. Another recent review showed that less than 40% of the studies evaluated significantly improved medication adherence when assessing clinical outcomes in mHealth interventions [33]. Badawy's recent systematic review showed that text messages and mobile phone app interventions are feasible and well accepted among adolescents, but there is limited indication that they support medication adherence [34]. Despite these mixed findings, Smartphone apps provide an efficient way to promote communication between patients and health care professionals, are easy-to-use, cheap, widely distributable, small in size, and usually commercially available.

One limitation of our study was its small sample size, however, for a formative evaluation a small sample size can be sufficient to highlight system usability issues [40]. Due to the formative nature of this study

and the small sample size, conclusions regarding efficacy cannot be achieved. Future studies should evaluate the efficacy of smartphone technologies aimed at improving medication adherence by investigating clinical outcomes and long-term retention in care.

This pilot represented a first step toward the development of technology for engagement and adherence to treatment for PLWH. We believe that our monitoring-informed counseling offered an opportunity for focused discussions about barriers to adherence, particularly for non-adherent patients. Moreover, having direct access via the TEAMH app to information related to their current medications is an important feature of the app since a number of studies have demonstrated that the more informed and educated patients are about their treatment, the more likely they are to be adherent and proactive in their health care [38]. Our TEAMH technology has the potential to be effective for use with other chronically ill patient populations. To date, none of the studies performed so far, have assessed the efficacy of the smartphone technologies by measuring the influence of these technologies on patients' viral load and cell counts via a randomized controlled trial. Future research should examine the efficacy of the intervention when rolled out on a larger scale in terms of its impact on adherence as well as on the HIV viral load and CD4 cell counts.

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