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Efficacy of an intervention with text messaging to improve early retention in HIV care for people with HIV who receive treatment at VIA LIBRE

Brief title:
Efficacy of SMS to improve retention in HIV care for PLWH in Lima

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2. INTRODUCTION

The HIV epidemic in Latin America is concentrated in men who have sex with other men (MSM) (1). In Peru, the prevalence in them is greater than 12% versus 0.5% in the general population (2). Less than 50% of people living with HIV in the country know their status, and 56% of those diagnosed receive treatment. The Ministry of Health reports 35% viral suppression (3), however, this figure could be underestimated due to: lack of a timely period of follow-up; inability to unify data between different health centers and; inadequate quality control of the data (4).

In 2017, it was estimated that globally 75% of people living with HIV knew their diagnosis, 79% were in treatment, and 81% had reached viral suppression (UNAIDS). In Latin America, 75% knew their status, 55% were in treatment and 41% achieved viral suppression. One study evaluated trends in a large cohort of Hispanics in relation to the initiation of treatment and achievement of viral suppression (5). Wolff and colleagues found that both variables have been improving over time; however, there are still significant inequalities, for example, with the youngest (5).

In VIA LIBRE during 2016, 192 people started antiretroviral treatment (ART). Viral suppression varies between 70 - 90%. This depends on whether or not we include those who do not have a viral load lab result. This is because 23% does not have a follow-up viral load result. There is still an important gap to retain in care those who receive ART and thus to have timely measures of viral suppression. Additional measures must be implemented both in Peru and in other countries of the region (6).

The World Health Organization recommends sending text messages (SMS) as a good practice to reinforce adherence to ART (7). Recent studies with MSM have shown acceptability, feasibility and preliminary efficacy to increase adherence and viral suppression with the use of mobile health (8). However, it is necessary to develop new methodologies that allow a better scalability of the approach across all the HIV continuum of care, and to be evaluated in other regions of the world such as Latin America (8).

Most interventions have used structured models, that is, with specific contents and schedules to send and / or receive SMS (9, 10). A more versatile and individualized strategy has the potential to improve the continuum of care, and to understand the perspectives, barriers and facilitators of patients; to continuously adapt the approach, and thus achieve a lasting retention (11). We propose to evaluate the acceptability and efficacy of an intervention with semi-structured SMS, to improve retention in the timely monitoring of viral load (VL) of people with HIV who receive treatment in the clinic VIA LIBRE.

In VIA LIBRE we implemented, during 2015, a research using SMS to improve early linkage to care among newly diagnosed patients. The participants of the intervention interacted for 3 months with a trained counselor who helped them to become linked. The subjects of the intervention were linked 16% more than the control group (manuscript in finalization). The exchange of SMS between counselors and participants was important to reveal concerns, challenges and solutions that had more impact shortly after diagnosis. This individualized interaction identified opportunities to provide support in relation to: (a) mental health symptoms; (b) coping behaviors; (c) interpersonal support; (d) physical symptoms; (e) knowledge of HIV; and (f) care coordination (11).

Thus, since May 2016 we implemented this strategy on a regular basis in the counseling service. During the first 4 months we found that 24% more users were linked to care (defined as having attended the 1st appointment), compared to the 4 months prior to implementation. This semi-structured strategy consists of sending some predetermined SMS messages plus an individualized interaction between users and previously trained counselors. It seems to be versatile to improve early linkage and, we suggest that it can have similar impact to improve retention in the timely monitoring of VL, for which we aim to implement a controlled study to assess this.

Our hypothesis is that participants receiving the semi-structured SMS intervention will increase their retention from 70% to 90%, compared with the control group.

3. OBJECTIVES

3.1. Primary

a) Evaluate the efficacy of an intervention through text messages to increase the retention of patients in the HIV Care Center.

Measurement of the main outcome: retention in VL monitoring (rate of participants with a second lab result of VL available 6 months after initiation of ART).

Measurement of the secondary outcome: retention in HIV care (rate of participants attended the 2nd and 3rd appointments for HIV care at the study clinic).

4. METHODS

4.1. Design

Interventional, randomized controlled trial with two parallel arms. Participants linked to HIV care at the study clinic will be randomized to interact with a nurse through text messages (intervention group); or only receive standard care information (control group). Participants of both groups will have access to HIV care services.

4.2. Variables

Variable	Definition	Categories	Source
Age	Date of birth	18 or more	Medical record, self-report
Civil status	Civil status of the patient when starting the study registered by self report	Single, married, widower, divorced, cohabiting	Medical record, self-report
Education	Degree of education of the patient when starting the study	Less than high school, high school, technical, superior	Medical record, self-report
Sexual identification	Self-reported sexual identification	Heterosexual Homosexual	Self-report

Variable	Definition	Categories	Source
		Trans Bisexual	
Retention in viral load monitoring	Result available of VL 6 months after initiation of ART	Yes No	Medical record, lab appointment book
Retention in care	Attendance of the third medical appointment at the HIV care center.	Yes No	Medical record, appointment book
Arm	Assigned arm	Intervention Control	Randomization
Diagnosis	Date of diagnosis	Date	Medical record
Visit 1	First medical appointment after diagnosis (linkage)	Date	Medical record
Visit 2	Second medical appointment after diagnosis (usually to start ART)	Date	Medical record
ART start	Date of initial of ART	Date	Medical record

4.3. Population

Study population:
Men diagnosed with HIV at VIA LIBRE (the study clinic) and people referred from other centers to start treatment.

Unit of analysis: men linked to HIV care at VIA LIBRE.

Sample size:

With a power of 0.80, and an alpha level of 0.05, we will need 72 participants in each arm (i.e. 144 in total) to evaluate a retention increase from 70 to 90%.

4.4. Eligibility criteria.

4.4.1. Inclusion criteria

a) Male 18 years old or older.
b) Linked to HIV care at the study clinic.
c) Have a cell phone.
d) Diagnosed at the study clinic of referred from other center to start ART.
e) Give consent to participate.

4.4.2. Exclusion criteria

a) Enrolled in other HIV study using text messages.
b) Have started ART.
c) Enrolled in a clinical trial.

4.5. Overview of the intervention.

This is a randomized controlled pilot study with a parallel 2-arm design. It will evaluate the effect of a text message-based strategy to improve retention in HIV care at the study clinic, compared to the standard of care. Trained counselors will deliver the text messages. After a block randomization, the trained counselor (a nurse) will send the first welcoming message to participants in the intervention arm. The nurse will send 2 tailored text messages per week. In addition 2 to 4 days before an appointment, the nurse will send a message reminder. In addition, the nurse will have bilateral communication with participants using text messages according to their needs. The participants of the intervention arm will interact with the nurse during 3 months with a semi-structured strategy, that is, with template text messages (predesigned) and open messages (for which the nurse will be trained). Three and six months after started the intervention the variables of interest will be assessed (Figure 1).

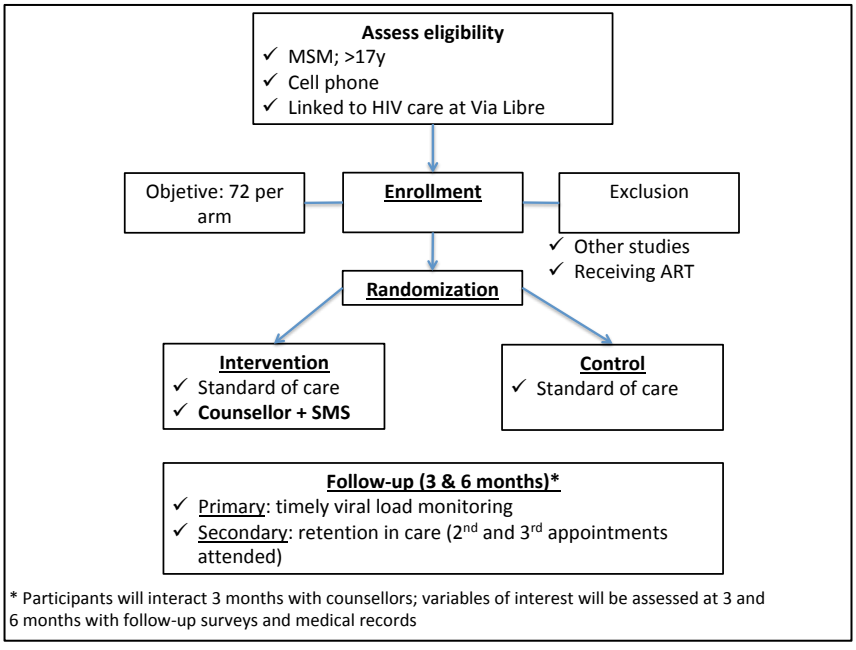

Figure 1. Intervention.

4.6. Standard of care.

After pre-test counseling, diagnosis is performed with two positive rapid tests. Those who test positive receive post-test counseling including emotional support and are link to a facility for ART initiation, ideally, within one week. ART, CD4 and viral load lab tests are provided for free. During the first year they recommend to have 2 measurements of CD4 and viral load. At the beginning, ART is provided for 1 month. If clients are adherent the next visits for pick-ups are every 3 months. Nurses are in charge of delivering the medication and assessing adherence. At VIA LIBRE, the study clinic, during the first medical appointment (linkage) after being diagnosed, the clinician performs a clinical assessment and requests lab tests. During the second (retention) appointment, most patients receive for the first time ART for 30 days. During the third (retention) appointment, patients receive for the first time ART for 90 days, and the clinician requests monitoring of viral load and CD4.

4.7. Procedures.

a) Semi structured interviews.
   In order to explore and understand the reasons why previously linked users and those who are under treatment do not have a timely monitoring of their viral load, we will perform up to 30 in-depth semi-structured interviews of 1 hour each. Participants will go through verbal informed consent.

b) Design of the content of the intervention.
   Based on the results of the in-depth interviews, and previous studies (14, 15), we will design 24 template messages that will be the core of the intervention. Following the guidelines of previous studies, such messages will be short and neutral (that is, without words that can reveal that it is an HIV study). The messages will be informative and motivating to improve retention in HIV care and the timely attendance to the laboratory for viral load monitoring. Also, providers will send reminder messages before the appointments.

c) Training of counselors and pilot of the intervention.

In addition to the template messages, a nurse will interact with the participants to provide support; information about treatment benefits, and importance of monitoring viral load; and to send appointment reminders (15, 16). Likewise, other general health topics may be addressed in these messages to arouse interest and create rapport with the participants (17). The intervention will be carried out for 12 weeks. The interaction with all the participants will not be simultaneous but according to the continuous enrollment that will be carried out in the period of 6 to 7 months until reaching the sample size.

Before beginning the intervention, a ***nurse will be trained*** in the following topics: HIV continuum of care; studies with text messages to improve the continuum of care; strategies for communication with mobile health; delivery of the intervention; reasons for not being retained in care; and logistical aspects of the intervention. Based on the experience of Young and collaborators, we estimated that each counselor could spend half an hour a week to interact with each participant (with the cell phone). If one nurse were in charge of 18 to 20 participants simultaneously, he/she would spend 10 hours a week for the interactions. Therefore, one nurse would use 25% of his/her time for delivering the intervention to 18 to 20 participants.

If requested by the participant, the counselor could make a ***voice call*** to clarify some of the issues addressed through text messages. The counselor can see the participants in person only at the study clinic, and to discuss topics related to the project. The counselor will keep a weekly record of the number of text messages / chats, calls made to each participant, and appointments (missed and attended) at the study clinic.

d) Recruitment, enrollment and randomization.
Potential participants will be contacted the day they go for their first medical appointment after having been diagnosed (that is, the day they are linked). They will be explained about the study through an informed consent process. After consenting, participants will be randomly assigned to the intervention or control with a 1:1 ratio and random block sizes of 2 and 4 using computer generated random numbers. Block sizes will not be disclosed. Allocations will be sealed in individual, sequentially numbered opaque envelopes. The recruiter, who will be masked to the group assignment, will give instructions to all participants on how they should interact if they start receiving SMS. We will emphasize that, by chance, a counselor through text messages will contact only half of them during 3 months. After completing the baseline survey, one of the principal investigators will assign the participant to a group by opening the corresponding envelope. The PI will report to one of trained providers in charge of delivering the intervention (different from recruiters) when a new participant of the intervention arm is enrolled. Because of the nature of the participation, providers and participants will not be masked to group assignment. At the time of enrollment the recruiter will send a text message to the cell phone of the participant who consents to participate to confirm that it is a valid number. On the same day of enrollment, the responsible counselor will send the first welcome text message.

e) Baseline and follow-up surveys.
At the time of enrollment (after providing written consent), at the end of the intervention and 3 months after the intervention is completed, participants will complete a survey with three sections: socio demographic, history of utilization of HIV care services at the study clinic and adherence to ART. The surveys will be completed through a survey platform (such as surveymonkey.com) by sending the link of the survey by email. Participants will also be able to complete surveys at the study clinic, using one of the computers or tablets designated for the project. After completing each survey, they will receive an incentive of 17 soles (5.3 US) for transportation.

f) Follow-up.
The follow-up and retention of participants of the intervention arm will be in charge of the nurse who will interact weekly with them. For participants in the control arm, the verification of the outcomes (to know if they attended their appointments) will be done through medical records, and laboratory and nursing records. In addition, the follow-up surveys will collect additional information about retention.

4.8. Ethical aspects.

In order to protect the confidentiality of the participants, the following procedures will be carried out:

- One of the potential risks is the loss of confidentiality due to receiving text messages related to HIV. To avoid this, they will be explained that the text messages will be neutral in case they lose the cell phone or someone else reads the messages. For example, these words will not be used: HIV, AIDS, treatment, infection, VIA LIBRE, virus, homosexual, among others. Also, the messages will not be massive or sent at inappropriate times. They will be able to stop receiving messages when they want.

- In addition, there is a potential risk of ***discomfort*** due to receiving some messages related to HIV (intervention arm, or by answering some questions from the surveys. To address this, counselors will be trained to provide emotional support and more information about related topics. For the surveys, most of the questions will be optional.

- The ***personal information*** as name, telephone number, email, as well as the information of the surveys, will be kept ***confidential***. It will be kept in a database with a password that will only be accessed by the research team. Likewise, the computers containing the databases will be protected with a password.

- "Survey monkey" stores the data of the survey encrypted. In addition, the cell phone used by the counselors will be a smart mid-range or high-end cell phone that will need a key and fingerprint in order to open it and view the content.

- The benefits of participating in the study are receiving additional support to improve their HIV care (intervention arm). In addition, the satisfaction of contributing to the evaluation of an innovative strategy to improve the health of people with HIV. Finally, participants will receive a modest incentive after completing each survey for transportation.

- The publication of the results of the study will be done without names or any information that can identify the participants.

5. ANALYSIS PLAN

We will use Fisher's exact test for the univariate analysis of binary variables. T Student and Mann-Whitney tests will be used for the analysis of continuous variables. The analysis of the randomized controlled trial will be conducted using the intention-to-treat analysis. For the primary analysis, the adjusted relative risk between both arms will be calculated with the Mantel Hanzel test. The analysis will be carried out with the statistical program Stata v13. Audios of in-depth interviews will be transcribed and along with the interactions with text messages will be reviewed and codified. We will use theoretical framework analysis. After identifying concepts, we will create categories and themes. The analysis will be carried out with the Atlas.ti program.

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