

TEXT MESSAGING TO IMPROVE PATIENT ADHERENCE IN HAART: RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objectives. To assess the efficacy of a text messaging (SMS) strategy to improve appointment attendance, treatment adherence, and biological markers (viral load and CD4) in continuous patients with high activity antiretroviral therapy (HAART) who were late to their last scheduled appointment. **Materials and Methods.** A randomized controlled trial implemented in *Vía Libre*, a non-governmental organization (NGO) that provides services to people living with human immunodeficiency virus (HIV) in Lima, Peru, was conducted, where 166 follow-up patients were randomized: 82 participants received SMS for six months and 84 participants received standard care. **Results.** Patients in the intervention group: 93.9% were men and had a median of 5.1 years in HAART; in the control group: 94.1% were men and a median of 5.3 years in HAART. In the intervention group, patients attended their scheduled medical appointments more frequently than those in the control group (RR=1.89, 95% CI 1.21 to 2.97) during the six months of intervention. Comparing the viral load level and CD4 level, no differences were found (p=0.930 and p=0.905, respectively). Adherence to treatment measured by self-report was higher in the intervention group (p<0.001). **Conclusions.** The results of this study suggest that sending SMS for six months may improve appointment attendance and adherence to treatment in continuing patients on HAART.

Keywords: *Treatment Adherence and Compliance; HIV; Acquired Immunodeficiency Syndrome; Viral Load; CD4 Lymphocyte Count (source: MeSH NLM).*

INTRODUCTION

One of the Sustainable Development Goals (SDG) of the United Nations is to fight the Human Immunodeficiency Virus (HIV) infection and AIDS. Globally, access to highly active antiretroviral therapy (HAART) has increased steadily, averting millions of deaths and contributing to achieve the SDGs⁽¹⁾.

To assess progress in the face of the HIV/AIDS epidemic, the treatment cascade is used as the main indicator. On a global level, out of the people living with HIV, 70% knew their HIV status, 53% had access to antiretroviral therapy, and 44% achieved viral suppression by 2016. Similarly, out of the total number of people living with

HIV in Latin America, 80% knew their HIV status, 50% had access to antiretroviral therapy, and 46% achieved viral suppression⁽²⁾. In Peru, in 2014, out of the people living with HIV, 64% knew their HIV status, 46% had access to antiretroviral therapy, and 36% achieved viral suppression⁽³⁾. These figures show that in Peru there are weaknesses at all three levels of the cascade, given that, most notably, only four out of ten people living with HIV have achieved viral suppression.

Timely medical care is necessary for people living with HIV to achieve the desired viral suppression. Thanks to improvements in medical care and in treatment plans, HIV has become a manageable chronic infectious disease⁽⁴⁾. Two very important facts are that HAART

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This study is part of the thesis: Condori I. Ensayo aleatorizado controlado del envío de mensajes de texto para mejorar la asistencia a citas de los pacientes continuadores en TARGA (Randomized Controlled Trial of Text Messaging to Improve Attendance to Medical Appointments of Continuing Patients on HAART) [Master's Degree Thesis]. Lima: Post-graduate School, Cayetano Heredia Peruvian University; 2018.

Received: 20/12/2018 Approved: 28/08/2019 Online: 23/09/2019

Citation: Condori Lizárraga IR, Menacho Alvirio LA, Pérez-Lu JE, Cárcamo Cavagnaro C. Text messaging to improve patient adherence in haart: randomized controlled trial. Rev Peru Med Exp Salud Publica. 2019;36(3):400-7. doi: <http://dx.doi.org/10.17843/rpmesp.2019.363.4139>.

should be taken for life and that high levels of adherence give the patient's immune system the best results, preventing drug resistance^(5,6,7). The main indicators of disease recovery are viral suppression and increased CD4 levels⁽⁷⁾. To achieve this, it is crucial that patients take their medications, which are provided at their medical appointments.

It is estimated that In Peru, HIV prevalence in the general population in 2016 was 0.3%. In Lima, HIV prevalence among men who have sex with men was greater than 10%, and among transgender people it was greater than 20%⁽⁸⁾; which represents a major health problem that has not been addressed by the country's current policies.

Several strategies have been implemented to improve adherence to treatment and appointments among HIV patients. An innovative and cost-effective method is the use of information and communication technologies (ICT), especially the sending of text messages (SMS) to patients. Some randomized controlled trials have demonstrated that this intervention is beneficial for HIV patients^(9,10,11). However, there are other studies where the intervention did not improve patient adherence^(12,13). New research is required, especially in Latin America, that focuses on improving adherence to medications, adherence to appointments and emotional support for the patients, among others.

The objective of the study was to evaluate the effectiveness of an SMS strategy to improve appointment attendance, adherence to treatment and biological markers (viral load and CD4) in patients who continued with HAART and had attended their last scheduled appointment at the wrong time.

MATERIALS AND METHODS

DESIGN AND STUDY POPULATION

A randomized controlled trial was conducted in Vía Libre, an NGO that provides sexual, reproductive, and HIV healthcare in Lima, Perú. Consultation and screening for sexually transmitted diseases are provided at a cost, which is why it's usually people from the middle socioeconomic level that receive treatment, although treatment is free, as it is throughout the country. Its patients, mostly men who have sex with men (MSM) and trans women, constitute the concentrated epidemic in Peru⁽¹⁴⁾. In this institution, the HAART medicines are handed during the medical appointment. For continuing patients, medical appointments are every three months, and viral load and CD4 determinations are scheduled every six months, or as the physician deems necessary.

KEY MESSAGES

Research motivation. Adherence to treatment is crucial to reducing morbidity and mortality in HIV-infected patients; however, many patients do not adhere to their visiting schedule.

Main findings. This study found that sending SMS helped improve attendance to medical appointments and reported adherence to treatment.

Implications. Sending text messages can be an alternative for health facilities to optimize compliance with appointments and adherence to the treatment by their patients.

In Vía Libre, following our protocol, a few months after patients miss their appointments they are given a call to check if they will resume their therapy, but in many cases the calls are not answered.

INCLUSION CRITERIA AND SAMPLING

The following were considered inclusion criteria: to be over 17 years of age, to have received HAART in Vía Libre for at least six months, to have arrived late (one day or more) at the last scheduled appointment and to have a cell phone with an active SIM card.

Using version 7.2.1 of the Epi-Info™ program it was determined that a sample size of 166 participants (between the control and intervention groups) was required to detect a 20% improvement regarding appointment attendance^(10,11), with an 80% power and a significance level of 5%.

RECRUITMENT AND ENROLLMENT

The patients from the NGO Vía Libre who continued with HAART and showed up late to their appointments (at least one day later) were contacted by the organization's nurses, and if they met the inclusion criteria they were invited to take part in the research from May 29, 2017 until they reached the sample size, on September 29, 2017. Those who agreed voluntarily to take part signed an informed consent form. Once the patient was recruited we proceeded with randomization; using complete randomized blocks of size four, previously developed in an Excel document, the participants' code was placed in the order in which they had been recruited, to assign them to the intervention group or to the control group.

SMS SENDING SYSTEM

An SMS sending system for computers, with PHP programming language, compatible with Windows and

Linux, was designed. With a portable modem and a mobile SIM card, this system allows the programmed sending and the reception of SMS to mobile phones. It has a security system with password and allows for the definition of user privileges.

SMS VALIDATION

The acceptance of SMS in *Vía Libre* was assessed with three focus groups and 17 in-depth interviews; in most interviews it was reported that the messages would be well received as long as they were discreet, did not mention anything explicit regarding their condition or were not too frequent. The content of the SMS was validated with four focus groups and validation interviews, and each participant was shown a printed list of the SMS. Immediately after the facilitator proceeded to examine with them each SMS in terms of overall impression, substance, form and usefulness. In general terms, the SMS with motivational and general messages were all well received. The participants, young and old, mentioned it would be nice to receive motivational messages on their cell phones. Those messages would have to be general, not mentioning any particular situation so that they could be sent to anyone.

The SMS about appointment reminders would have to be neutral so that if someone else read the phone they would have no way of knowing the reason for the appointment. There were discrepancies regarding the messages about taking medications. The older participants, who had family members and friends who knew about their serostatus, were quite receptive to the messages with direct content, while the younger participants, with recent diagnosis, were uncomfortable regarding messages with explicit language. Furthermore, it was suggested not to use the terms medication or "HAART", but an equivalent, like vitamins. The three text messages sent more frequently were: a) Did you take your vitamins? Let's go all the way! Remember! You have an appointment on (DD/MM/YY) at (HH/MM); b) You are the most important thing! Persistence is the secret of success; and c) Take your vitamins every day. You'll see the results. The messages that were sent are listed in the supplementary material.

VARIABLES OF INTEREST AND MEASUREMENT

Epi-Info and Excel tables were used to record patients that received SMS after randomization. Using medical records and nursing notes, the date on which the patient went to the medical appointment was determined, which was reported dichotomously (either attended two appointments or attended less than two appointments); in addition, if the patient was late for an appointment, the number of days of the delay was also reported. The patient's viral

load and CD4 levels were obtained from reports from the National Institute of Health (INS). Adherence to treatment was assessed through the SMAQ (Simplified Medication Adherence Questionnaire) survey, which is found in the Technical Standard of the Ministry of Health of Peru (15), which classifies each participant at different levels, from poor adherence (<30% adherence) to optimal adherence (>95%). At the end of the study, participants completed a satisfaction survey about the intervention with seven questions. The level of satisfaction was categorized using the average values on a Likert scale for low (1-2.33), medium (2.33-3.66) or high satisfaction (3.66-5).

INTERVENTION

The control group received only standard care, which consisted of appointments with the doctor and nurse, every three months, in which they also received their treatment. During the intervention, the nurses did not know which group each participant belonged to; only the principal investigator had access to that information, since that was necessary to search the clinical data of the participants. The intervention group participants received messages within days of being recruited, while the control group did not receive any messages. The intervention group participants received standard care and were sent two messages reminding them of their appointments one and three days prior to the date of each scheduled appointment, plus two SMS per week (every Wednesday and Saturday) for 24 weeks. The first weekly message promoted adherence. The second weekly message alternated between a motivational message and a general health information message. Participants received messages that were designed to be one-way, i.e., they could not ask questions or respond to the messages they received; however, if they wished to leave the study, they had the option to send an SMS with the word "Finish" to the sending number, which they could do at any time during the intervention. The SMS sending system was managed entirely by the main investigator, who, as a way of confirmation, received a copy of the messages sent by the study's modem.

FOLLOW-UP

The follow-up lasted a period of six months, in which they had two medical appointments, which included the provision of medicines. Using information from medical records and laboratory records it was determined whether the participants had gone to their appointments on time, their viral load level, and their CD4 count.

In the second appointment, i.e., six months later, they completed the SMAQ survey of adherence, found in the Technical Norm of the Ministry of Health (MINSAs)⁽¹⁵⁾.

Participants who did not attend their scheduled appointments were able to complete the survey at a later date, either when they went to *Vía Libre* to get their medication and/or to be seen by a doctor. During the analysis, those who had not completed the survey before the end of the study were assigned the lowest level of adherence. Regarding the viral load level and basal CD4, the most recent value as regards the date of recruitment (maximum six months before that date) was recorded. Similarly, for the end-of-follow-up visit, the most recent value in relation to the date of that visit (maximum six months after the date of recruitment) was considered. Only viral load and CD4 count results processed by INS were included.

STATISTICAL ANALYSIS

For the description of the variables, medians, means, and interquartile range (IQR) were used, according to the distribution of the variables. The measurement of the results was done through an intention-to-treat analysis. The Haenszel Mantel, t-student and chi-square tests were used to compare variables in the baseline. To evaluate the effect of the intervention, the relative risk (RR) was calculated with its respective confidence interval and p-value. Regarding the effect of the intervention on the number of days a scheduled appointment was delayed, the Wilcoxon sign-range test was employed. All analyses were performed with the Epi-Info program version 7.2.1.0.

ETHICAL CONSIDERATIONS

This study's protocol was evaluated and approved by the ethics committees of the Universidad Peruana Cayetano Heredia and the Asociación *Vía Libre*. Informed consent was obtained from all participants. The SMS messages sent did not contain words that could reveal sensitive information about the participant, nor the name of Asociación *Vía Libre*. When referring to antiretroviral drugs, the word "vitamins" was used in the messages. The messages were designed as messages about any regular medical appointment.

RESULTS

PATIENT FLOW AND CHARACTERISTICS OF THE STUDY POPULATION

A total of 197 patients from *Vía Libre*, who had attended their last appointment with tardiness, were interviewed to be part of the study (Figure 1). Twenty-eight of these patients did not agree to be part of this research for fear that someone else could check their SMSs or that these messages could cause them stress if somebody else checked their phone. Other reasons for declining this invitation were a lack of interest in receiving these messages or that they reported not having time for this type of intervention. Three of the patients that were interviewed did not meet the inclusion criterion, i.e., to be a HAART patient for a minimum of six

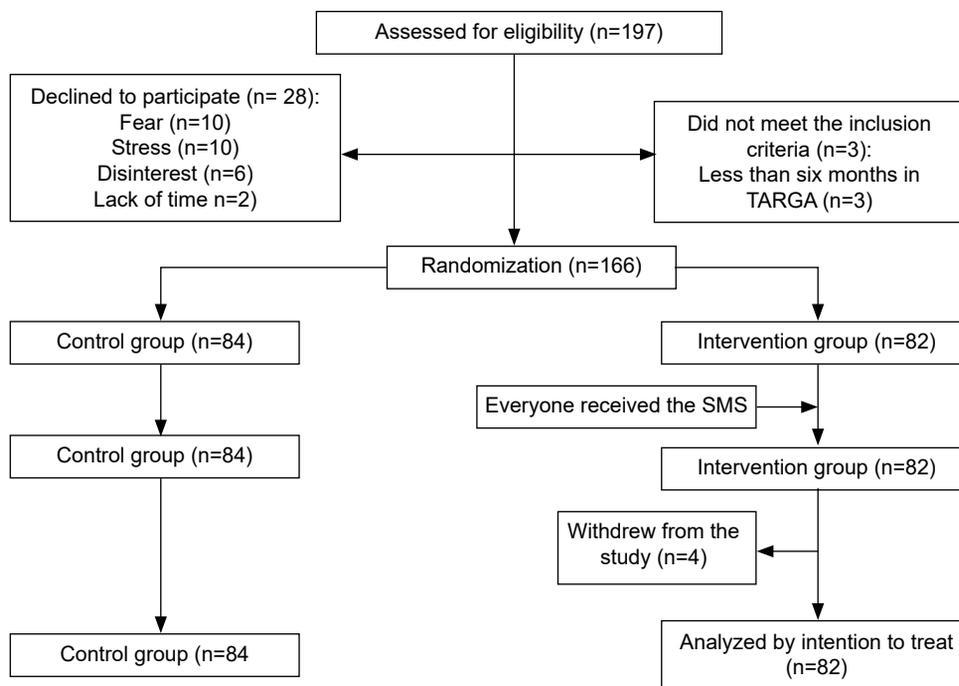


Figure 1. CONSORT flow diagram of the study

months. 166 participants were enrolled, 84 of which were assigned to the control group and 82 to the intervention group. Four participants in the intervention group withdrew from the study before completing the six-month follow-up.

In Table 1 we note that no differences were found between groups in the baseline of sociodemographic data nor in the variables regarding health status. The participants were mostly men, over 35 years old and single. About 50% had higher education and a similar percentage of participants reported being dependent workers. The median of the years the participants had spent in HAART was slightly over five years. Of the 75 participants at the start of the study, the average viral load in the control group was 20,716 copies/ml, and in the intervention

group it was 17,058 copies/ml. The average CD4 of 79 participants at the start of the study was 516 cells/mm³. As to the self-reporting of adherence to treatment, 64.3% of the control group and 58.5% of the intervention group reported optimal adherence.

KEEPING APPOINTMENTS, ADHERENCE TO TREATMENT, AND BIOLOGICAL MARKERS

When comparing timely attendance to appointments in the control group and in the intervention group (Table 2) it was found that the group that received the SMS for six months attended the two appointments in a timely manner 89% more than the control group (RR=1.89, 95% CI 1.21-2.97).

When comparing viral load levels and CD4 difference no differences were found. The mean viral load of the control group after the intervention was 28.2 copies/ml and that of the intervention group was 26.3 copies/ml, $p=0.930$. The mean CD4 difference of the control group was 14.3 (95% CI -19.3 to 48.0) and that of the intervention group was 20.1 (95% CI -67.7 to 107.8, $p=0.905$). With regards to adherence to treatment measured by self-report, significant differences ($p<0.001$) were found between the two groups.

Among those who did not attend on the day of their first appointment, in the intervention group the median number of days of delay was higher than in the control group (28 vs. 14 days), although this difference was not statistically significant (Table 2). For those who did not attend on the day of their second appointment, the median was more than 90 days in the intervention group and of 23 days in the control group, with no significant differences.

LEVEL OF SATISFACTION

At the end of the study, participants who received SMS filled out a satisfaction level survey with the Likert scale. A total of 11 participants did not complete the survey because they did not attend their last scheduled appointment. Table 3 shows that 72.0% of the 82 participants who received messages reported a high level of satisfaction with the intervention.

DISCUSSION

This study found that an intervention consisting of sending reminders and information on adherence to medical appointments of continuing patients receiving management guidance on HIV infection; however, when evaluating the relationship between the number of days

Table 1. Characteristics of the participants included in the study

Variable	Control n (%)	Intervention n (%)	p value
Gender			
Male	79 (94.1)	77 (93.9)	0.969
Female	5 (5.6)	5 (6.1)	
Age group (years)			
18-24	7 (8.3)	3 (3.7)	0.267
25-35	27 (32.1)	34 (41.5)	
36 or more	50 (59.5)	45 (54.9)	
Marital status			
Single/Domestic Partner	78 (92.9)	76 (92.7)	0.579
Married	6 (7.1)	5 (6.1)	
Widowed	0	1 (1.2)	
Educational level			
Primary	4 (4.8)	4 (4.9)	0.718
Secondary	39 (46.4)	33 (40.2)	
Superior	41 (48.4)	45 (54.9)	
Occupation			
Student	14 (16.7)	11 (13.4)	0.931
Employee	44 (52.4)	43 (52.4)	
Self-employed	20 (23.8)	22 (26.8)	
Unemployed	6 (7.1)	6 (7.3)	
Years in HAART, median (RIC)	5.3 (2.50-7.50)	5.1 (2.30-8.00)	0.192
Average basal viral load*	20,716	17,058	0.833
Basal CD4 (IQR)*	477.0 (316-635)	555.3 (369-733)	0.579
Average basal viral treatment (%)			
95-100	54 (64.3)	48 (58.5)	0.676
85-94	17 (20.2)	22 (26.8)	
65-84	5 (6.0)	3 (3.7)	
30-64	0 (0.0)	0 (0.0)	
<30	8 (9.5)	9 (11.08)	

IQR: interquartile range.

* Viral load and CD4 available for 75 and 79 participants respectively.

Table 2. Effects of intervention on appointment attendance, viral load level, CD4 and adherence to treatment.

Variable	Control n (%)	Intervention n (%)	RR (95% IC)	p value
Timely attendance to appointments				
Two	20 (23.8)	37 (45.1)	1.89 (1.21 to 2.97)	0.004
Under two	64 (76.2)	45 (54.9)		
First Appointment - Days Late (IQR)	14 (7 to 39)	28 (10 to >90)	-	0.064 [†]
Second Appointment - Days Late (IQR)	23 (8 to >90)	>90 (22 to >90)	-	0.074 [†]
Average viral load*	28,2	26,3	-	0.930
Average CD4* difference (95% CI)	14.3 (-19.3 to 48.0)	20,1 (-67.8 to 107.9)	-	0.905
Adherence to treatment				
95-100%	39 (46.4)	60 (73.2)	-	<0.001
85-94%	34 (40.5)	18 (22.0)		
65-84%	7 (8.3)	0 (0.0)		
30-64%	2 (2.4)	0 (0.0)		
<30%	2 (2.4)	4 (4.9)		

CI 95: confidence interval; RR: relative risk; IQR: interquartile range.

* Viral load and CD4 available for 75 and 79 participants respectively.

[†] Wilcoxon sign-range test

by which the appointment was delayed with respect to the intervention, no differences were found in the first and second appointments. The intervention also improved adherence to treatment measured by self-report. Most participants in the intervention group reported a high level of satisfaction with the intervention. portaron un nivel de satisfacción alto con la intervención.

This would be the first randomized controlled trial on the sending of SMS to improve appointment attendance among HIV patients in Peru. The findings are consistent with studies conducted in other countries that focus on appointment attendance among patients with HIV^(9,11,16,17) and other medical conditions^(18,19). Unlike other studies^(9,10,11) with positive results, interventions in this research were only done through the sending of SMS, not telephone calls.

In general, interventions with two-way messages in this type of strategy have obtained better results compared to interventions with one-way messages^(20,21). In this study, one-way messages were sent, which have the following advantages: their implementation requires fewer financial resources; they do not require highly trained staff; and they

Table 3. Satisfaction level measured by a Likert scale (n=82).

Satisfaction level	n	%
High	59	72.0
Neutral	11	13.4
Low	1	1.2
Did not attend appointment	11	13.4

Average values on the Likert scale for low (1-2.33), medium (2.33-3.66) and high (3.66-5) level of satisfaction.

represent a strategy that can be combined with other support services provided at health centers. Two-way messages, while providing greater interaction with the patients, require a health worker that responds to them at all times and is trained on the wide range of possible questions. The use of one-way SMS is an important alternative that can be considered depending on the context and the resources available.

Secondary variables, such as biological markers (CD4 and viral load), were not affected by the intervention. It's possible that six months of intervention have not been enough to measure a significant change in biological markers.

On the other hand, adherence to the treatment, measured by self-report, improved in the intervention group as a result of the sending of SMS. This coincides with other research with positive findings^(10,22,23). However, only SMS was used in this research, and no other strategies, such as telephone calls or counseling complementary to the standard care.

Several studies have found that a high level of adherence (higher than 95%) can achieve the desired viral suppression in patients living with HIV⁽²⁴⁾. The fact that a patient achieves a level of adherence greater than 95% means that he or she must take the medication for at least 86 of the 90 days. If a patient attends his or her appointments five or more days after the scheduled day, he or she will not be taking the medication during those days and will have suboptimal adherence, decreasing his or her chances of achieving viral suppression and increasing the possibility of drug resistance. The public health importance of this type of research lies in identifying interventions that improve appointment attendance and adherence to therapy.

This study had several limitations. First, the SMS system allowed us to know if the participant had received the message, but we couldn't know if the participants had opened or read the content of the message. Second, the measurement of viral load, CD4 and adherence to treatment was only performed on the participants who kept the appointments, which can be seen as the most responsible and, therefore, the ones who adhere the most to the treatment; giving the impression that better results are obtained only among participants who go to the appointments, and not on the entire sample. Third, the follow-up of the participants lasted six months and what was evaluated was the attendance to two medical appointments, so the results are limited to this period of time and to those two medical controls. Fourth, this SMS intervention has had positive results regarding the attendance to two medical appointments at this health facility, but this strategy may not be as effective in much longer periods of intervention. Fifth, viral load and CD4 were not measured for each participant at the first and last follow-up appointments; instead, what was used was the patient's information obtained from the INS, analyzing the viral load and CD4 values taken on the

dates closest to those appointments. Finally, the self-report on adherence is prone to memory bias.

The study shows that sending SMS for six months improved appointment attendance and adherence to treatment in HAART patients. The intervention did not affect the number of days by which appointments were delayed. Biological markers like CD4 and viral load were not affected by this intervention. A high percentage of participants who received the SMS reported a high level of satisfaction with the intervention.

Authors' Contributions: ICL, LMA, JPL and CCC participated in the concept of the article and in the analysis, drafting, and approval of the final version. In addition, ICL was in charge of data collection, instrument drafting, and the procedural manual.

Funding: Fondecyt-Concytec

Conflicts of Interest: The authors have declared that no competing interests exist.

Supplementary Material: Available in the electronic version of the RPMESP.

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