Implementation of Text Messaging and Brief Phone Counseling to Improve Medication Adherence

by

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Abstract

Problem & Purpose: Among persons infected with human immunodeficiency virus (HIV), suboptimal adherence to antiretroviral therapy (ART) decreased treatment efficacy, increased hospital admissions, delayed viral suppression, and increased subsequent onward transmission. As of March 2020, of the approximately 350 HIV-positive patients receiving continuity HIV care at an urban public sexual health and wellness clinic, 41 (13.1%) were not virally suppressed. The purpose of this Quality Improvement (QI) project was to implement and evaluate the effectiveness of weekly medication reminder text messaging and brief phone-based counseling on adherence to ART among HIV-positive adults seen at this clinic.

Methods: Implementation, led by Registered Nurse Case Managers (RN-CMs) trained on project procedures, was conducted among a sample of new and existing HIV-positive patients aged 18 years or older who were newly initiating treatment, had sub-optimal medication adherence, had an unsuppressed viral load, had a functioning cell phone, and who agreed to participate. Following ethical approval, the intervention was conducted over 14 weeks (August 31, 2020-December 4, 2020). Data were collected and tracked weekly using a specially designed audit sheet, projected into run charts, and analyzed using Microsoft Excel.

Results: Twenty-two (n=22) HIV-positive patients, including four new and 18 existing patients, participated in this project. All 22 (100%) patients received weekly medication reminder text messages, but only seven of the 22 (31.8%) patients agreed to also receive weekly phone-based adherence counseling sessions. Adherence was measured through phone-based unannounced pill counts at weeks four, eight, and 12. The proportion of the total participants who completed pill count with an adherence level of >95% was 71.4% (n=10 of the 14 patients) at four weeks, 86.7% (n=13 of the 15 patients) at eight weeks, and 85.7% (n=12 of the 14 patients) at 12 weeks.

Conclusion: Reminder text messages and phone-based adherence counseling were feasible and potentially effective interventions to improve ART adherence. Pill count adherence completion was highly dependent on participants' availability. However, weekly phone-based counseling sessions were less acceptable to participants.

Introduction

The use of antiretroviral therapy (ART) in the management of human immunodeficiency virus (HIV) has led to a significant therapeutic advancement, slowly changing the course of the epidemic and transforming HIV into a chronic disease (Lacob et al., 2017). However, the full benefits of ART can be unattainable among patients with suboptimal adherence rates, leading to decreased treatment efficacy, increased risk for opportunistic infections (OIs), increased hospital admissions and higher emergency department visits, delayed viral suppression, and increased healthcare costs (Abara et al., 2017). If all HIV-infected individuals demonstrated optimal ART adherence, the estimated medical cost savings for preventing one new HIV infection would be between $229,800 to $338,400 (Schackman et al., 2015).

In the U.S, one in every three HIV-positive persons in care does not achieve viral suppression within 12 months of starting ART, and suboptimal adherence was a fundamental reason for the delayed viral suppression (Centers for Disease Control and Prevention [CDC], 2019; Hall et al., 2013). As of March 2020, of the approximately 350 unduplicated HIV-infected patients receiving continuity HIV care at an urban public sexual health and wellness clinic, 41 (13.1%) were not virally suppressed. The purpose of this Quality Improvement (QI) project was to implement and evaluate the effectiveness of weekly medication reminder text messaging and brief phone-based adherence counseling among HIV-positive adult patients in this clinic. It was anticipated that this practice change will enhance Registered Nurse case managers' (RN-CMs) abilities to deliver evidence-based adherence support, and thus increase the willingness among patients to take their prescribed ART medications consistently.

Literature Review

The focus of this literature review was to provide an evidence-based rationale for a practice change. The evidence review started with a broad synthesis of evidence documenting the use of mobile phone technology in supporting adherence to ART and improving patient outcomes (Tables 1 and 2). The review consisted of studies that examined the use of medication reminder text messages and phone-based adherence counseling to improve ART adherence and concluded with evidence that supported monthly phone-based unannounced pill-counts as being a validated tool for measuring medication adherence (Kalichman et al., 2016; Abdulrahman et al., 2017; Fredericksen et al., 2014). These studies were thoroughly analyzed and rated based on their strengths and quality of evidence presented (Melnyk & Fineout-Overholt, 2014; Newhouse, 2006).

Studies have shown that the use of short message services (SMS) to deliver medication reminders can enhance ART adherence among HIV-positive patients (Abdulrahman et al., 2017; Kalichman et al., 2016). Results from two randomized control trials (RCTs) found that reminder SMS text messages improved ART adherence among patients who used illicit drugs (Garofalo et al., 2015; Ingersoll et al., 2015). Further evidence showed that timing and length (short or long) of messaging could impact adherence behaviors (Ingersoll et al., 2015; Kalichman et al., 2016). However, SMS reminder messaging frequencies produced mixed results across these studies. While weekly reminder messages significantly improved ART adherence and HIV viral suppression rates, daily reminder SMS did not show any added benefit to ART adherence (Abdulrahman et al., 2017; Kalichman et al., 2016; Garofalo et al., 2015).

Behavioral and psychosocial issues are known to challenge patients' willingness to take their prescribed ART. However, two studies found that SMS reminder messages increased adherence self-efficacy and behavior modification even in patients with behavioral and psychosocial issues (Moore et al., 2018, & Ingersoll et al., 2015). The use of brief phone-delivered counseling also emerged as an effective adherence support strategy among people living with HIV (PLWHIV) (Abdulrahman et al., 2017; Kalichman et al., 2016). Counseling sessions grounded on behavior modification theories and laboratory data such as viral loads and CD4 counts had the potential to motivate patients to improve their adherence and increased the opportunity for patient-provider interaction while addressing patient-reported barriers (Kalichman et al., 2017, & Abdulrahman et al., 2017). Phone-delivered counseling and SMS text messages were shown to be effective tools to improve ART adherence rates to levels greater than 90% and increase clinic attendance while lowering OIs incidence and missed appointments (Kalichman et al., 2017, & Abdulrahman et al., 2017).

Furthermore, the ability to follow given ART dosage, frequency and achieve optimal adherence of 90-95% produced significant effects on viral suppression and patient outcomes across studies (Abdulraham et al., 2017; Ingersoll et al., 2015). In these studies, SMS was used to deliver interventions that were tailored to target adherence barriers and improve medication adherence. However, their primary outcome, adherence, was measured with varying instruments (clinic attendance, self-report, and pharmacy refill data), and self-reported adherence was often exaggerated, overestimated, and did not reflect accurate adherence levels (Abdulrahman et al., 2017). Another study that found 90% ART adherence following adherence counseling and SMS delivered by phone (Kalichman et al., 2016) used monthly phone-based unannounced pill counts to determine medication adherence levels. To corroborate this finding, Fredericksen et al. (2014) found that unannounced phone-based pill counts to be a more valid, reliable, feasible, and less costly tool to measure medication adherence.

Theoretical Framework

The Pender's Health Promotion Model (HPM) was used as the theoretical framework for implementing weekly medication reminder text messaging and brief phone-based adherence counseling (Figure 1). This model's theoretical bases were found relevant to HIV prevention and management. They were used to explore health behavior change issues among HIV-infected adults, including sexual risk behaviors and HIV transmission (Tarkang et al., 2018). The HPM model emphasized nurses' role as fundamental to health promotion and disease prevention and provided a schematic framework to assess social, emotional, and biological factors that hinder patients' ability to attain *self-efficacy* for ART adherence (Butts & Rich, 2018; Yeow Chye et al., 2016).

As presented in Figure 1, participants' personal and interpersonal factors that might influence the willingness to improve their ART adherence levels were evaluated through three empirically grounded domains (*characteristics and experience, behavior-specific and affect*, and *behavioral outcomes*). These domains guided the assessment of participants' perceived ART benefits, risk factors for poor adherence, ability to take their ART confidently, and their state of feelings after sustaining optimal adherence and achieving viral suppression. The information gathered was used to guide discussions during weekly adherence counseling sessions. Behavior change requires commitment and dedication to follow through with an action (optimal adherence). Hence, weekly check-in text messages and brief phone-based adherence counseling sessions were used to strengthen participants' adherence self-efficacy and commitment to achieve optimal ART adherence by controlling and managing their perceived barriers to adherence, including lack of insurance coverage, transportation issues, and forgetfulness.

Methods

This project was implemented in an urban public sexual health and wellness clinic located in a large inner-city on the East Coast. Inclusion criteria were HIV-positive patients aged 18 years or older who were on ART with sub-optimal adherence (missed >1 dose over the past 4 weeks equals <95% adherence), had a cell phone, and were not virally suppressed (having >200 copies of HIV/ml of blood). The sample size (n=22) was based on the average estimated weekly enrollment of one to two patients over a twelve-week project implementation period. Prior to implementation, formal commitments were obtained from the Clinical Site Representative (CRS) and the Administrative Sponsor. RN-CMs were identified as early adopters and change champions. The procedures for reminder text messaging, adherence counseling and unannounced pill count were developed by the Doctor of Nursing Practice-Project Lead (DNP-PL) in collaboration with the RN-CMs, and each received a password-protected iPhone.

The project was implemented over 14 weeks (August 31, 2020-December 4, 2020) and led by two RN-CMs with an anticipated goal of increasing medication adherence rates among patients with adherence issues. The DNP-PL provided the oversight and coordination of the project. During the first two weeks of project implementation (August 31, 2020, and September 8, 2020), the DNP-PL held two one-hour training sessions with the RN-CMs (Appendix A). Role-plays were used to demonstrate each RN-CM's ability and skill to implement SMS reminder text messages and phone-based counseling procedures. During these two weeks, the DNP-PL and the RN-CMs decided on the delivery times, content, and appropriateness of text messages sent to patients. These messages did not contain any confidential or personal health information. A poster consisting of the project implementation checklist and talking points was created to provide RN-CMs with a quick cheat sheet to help identify patients who could benefit from adherence support (Appendix B).

During the implementation period, verbal consents were obtained from patients who agreed to participate. RN-CMs documented completed weekly reminder text messages and brief phone adherence counseling sessions on the audit sheets (Appendix C). Key variables collected and measured by the DNP-PL included: number (%) of participants who received weekly medication reminder text messages and phone-based adherence counseling; number (%) of participants who completed adherence pill counts at weeks four, eight, and 12; and number (%) of participants with pill count adherence levels >95% (Appendix D). Each participant's adherence level was measured using unannounced phone-based pill counts at weeks four, eight and 12, and calculated as the difference between pills taken divided by the number of pills that should have been taken over four weeks multiplied by 100. Pill count adherence level was further categorized as optimal (missed </=1 dose over the past four weeks equals >95% adherence) and sub-optimal (missed >1 dose over the past four weeks equals <95% adherence). The DNP-PL projected data into run charts to track weekly changes during project implementation. Data collected were analyzed using Microsoft Excel.

The project proposal was reviewed and approved for implementation by the University of Maryland Baltimore Institutional Review Board (IRB) for Non-human subject research determination. To protect all patients' confidentiality and privacy, the weekly audit sheets did not contain any patient identifiers. The electronic audit sheets were stored on a password-protected computer and printed copies kept in a secure cabinet in the clinic's file room. Following implementation, a 5-question survey was administered to measure patients' satisfaction with the interventions (Appendix E).

Results

The implementation of the procedures for reminder text messages and brief adherence counseling took place during week three through to week fourteen. Twenty-two HIV-positive patients, including four new and 18 existing patients, participated in the project. Participants' demographic data were collected at the start of the project, and pill count adherence levels were collected at weeks four, eight, and 12. As shown in Table 3, the participants' age ranged from 18-59 years, with a median age of 31.0. Likewise, 77.3%% of these participants were within the age range of 18 and 35 years. Of the 22 patients who participated in the project, 21 (95.5%) were non-Hispanic, and one (4.5%) was Hispanic. Additionally, 20 (90.9%) were African American or Black, while two (9.1%) were of another race.

Analysis of adherence support delivered by RN-CMs showed that the total number of participants who received weekly reminder text messages was 22 (100%). In comparison, seven (31.8%) of these participants also agreed to receive weekly phone-based counseling (Table 2). Furthermore, pill count was completed for all participants who were available and picked up their calls. The proportion (%) of all participants who received interventions and completed pill counts with adherence levels of >95% were 71.4% (n=10 of the 14 patients) at four weeks, 86.7% (n=13 of the 15 patients) at eight weeks, and 85.7% (n=12 of the 14 patients) at 12 weeks (Table 4).

As shown in Figure 2, the proportion (%) of participants who received weekly reminder text messages, completed pill counts and had adherence levels of >95% were 66.7% (n=6 of the 9 patients) at four weeks, 88.8% (n=8 of the 9 patients) at eight weeks, and 75.0% (n=6 of the 8 patients) at 12 weeks. The proportion (%) of participants who received both reminder text messages and phone-based counseling, completed pill counts and had adherence levels of >95% were 80.0% (n=4 of the 5 patients) at four weeks, 83.3% (n=5 of the 6 patients) at eight weeks, and 100.0% (n=6 of the 6 patients) at 12 weeks (Figure 3). Furthermore, Figures 2 and 3 showed the observed associations between participants who received weekly reminder text messages and counseling sessions and improved pill count adherence.

Of the 22 patients who participated in this project, only seven completed the post-intervention survey. Of these, 85.7% (n=6 of 7 patients) were very satisfied with the reminder messages they received, 71.4% (n=5 of 7 patients) felt the intervention helped them stay on track, and 85.7% (n=6 of 7 patients) felt their interactions with the nurse helped them resolve other issues not related to adherence (Figures 4, 5 and 6). These participants were asked how the adherence support that they received helped them. Someone stated that “the continued communication has reminded me that I not in this fight alone. It makes me want to stay on track and adhere” (Table 5). Overall, 85.7% stated that they would like to continue to receive reminder text messages or call from their nurses or providers (Table 5).

There were no additional unexpected costs associated with the interventions. However, the coronavirus disease 2019 (COVID-19) pandemic led to some unintended consequences. The pandemic created barriers that restricted clinic operations and reduced in-person clinic visits. This unprecedented event had unintended benefits. Interventions were more relevant and facilitated increased interaction between all participants and RN-CMs. During this time, virtual case management was of utmost importance. RN-CMs consistently coordinated medication refills, insurance-related issues, psychosocial referrals, and adherence support for participants.

Discussion

Translating evidence into clinical practice is fundamental to ensuring quality health care for individuals living with HIV. Early identification and timely intervention to resolve adherence barriers can improve long-term virologic suppression and treatment success, and care retention in this population. This QI project demonstrated that reminder text messaging and phone-based adherence counseling are potentially effective interventions to ensure improved ART adherence.

Reminder text messages were acceptable to all participants and attributed to the ease of texting over phone calls. This finding is consistent with another study that found that participants were more receptive to text messaging and would recommend it for friends in need of adherence support (Garofalo et al., 2016). Most of the project participants (77.3%) who received only reminder text messages were young adults aged18-35 years. As evidenced in the study by Hightow-Weidman et al. (2015), mobile phone technology usage was higher among this population. Furthermore, a strong correlation between reported adherence rates greater than 95% and VL suppression was reported in some studies (Garofalo et al., 2016; Kalichman et al., 2016; Moore et al., 2018). However, VL was not collected during this QI project.

All participants who completed pill count showed improved adherence levels over time, and all those who received weekly text messages and phone-based adherence counseling reported adherence rates >95% at 12 weeks. This modest finding supports results from previous studies, which found both adherence counseling and reminder text messaging were more likely to enhance ART adherence and improvement from virally unsuppressed to suppressed (Abdulrahman et al., 2017; Kalichman et al., 2016). At 12 weeks, adherence rates among participants who only received reminder text messages were lower (74.7%). The reason for this was unclear; however, participants' engagement with text messaging varied throughout the intervention period. Some participants were receptive and would acknowledge the receipt of messages, while others would only reach out when they encountered challenges refilling their ARTs or other medications. There was also a trend that weekly phone-based adherence counseling sessions were less acceptable to patients, as evidenced by the percentage of participants who agreed to the intervention (31.8%).

There were some limitations to the generalizability of the project findings. Due to the small sample size, a detailed analysis was not conducted to determine if there was a correlation between intervention received and pill count adherence level or to check for similarities or differences between participants who received text messages and those who received both. Another limitation was that the project participants were a subset of all HIV patients with uncontrolled HIV and adherence issues at this clinic. Similarly, the adherence measure (pill count) was highly dependent on participant availability, which may have limited the generalizability of the project findings. Despite all these limitations, the risk for imprecision in intervention delivery, data collection method, and adherence measurement were minimized by training RN-CMs on the project's procedures. Future projects may expand interventions to all patients with uncontrolled HIV and incorporate other adherence measures such as viral load to validate the correlation between reported adherence and viral suppression.

Conclusions

Reminder text messaging and phone-based adherence counseling were feasible and potentially effective interventions to improve ART adherence. This QI project offered patients the flexibility of texting or calling their assigned RN-CMs whenever they had questions. Approximately 85.7% of the participants who completed the post-intervention survey would like to continue receiving reminder text messages or calls from their RN-CMs. The interventions contributed to addressing participants' individual perceived barriers to ART adherence, such as forgetfulness. Weekly text messaging and phone-based adherence counseling sessions motivated participants to take purposeful actions, increased participants' and RN-CMs' interactions, and helped address issues (such as a lack of insurance coverage) that could jeopardize participants' efforts to remain adherent.

Furthermore, this project demonstrated case management as being an integral part of HIV care. Interventions helped to address participants' specific medical, psychosocial, and continuous adherence needs. Consequently, the project outcome was achieved, and findings were useful to the practice setting. This project's sustainability will be enhanced by building RN-CMs' capacity through ongoing training and full integration of adherence screening into the current process and medical case management standard of care. The implication for practice is that telephone-based (text or call) adherence support necessitates workflow optimization tools to ensure that RN-CMs are efficient. As a result, an automated text messaging service that allows for bidirectional texting conversations with patients may be a viable option for scaling up adherence support intervention at this sexual health and wellness clinic.

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Table 1

Evidence Review Table

Abdulrahman, S. A., Rampal, L., Ibrahim, F., Radhakrishnan, A. P., Kadir Shahar, H., & Othman, N. (2017). Mobile phone reminders and peer counseling improve adherence and treatment outcomes of patients on ART in Malaysia: A randomized clinical trial. *PloS One*, *12*(5), e0177698. doi:10.1371/journal.pone.0177698					Level II (2)
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
The purpose of this randomized controlled trial (RCT) was to examine whether mobile phone reminders and peer counseling are effective interventions in improving adherence and treatment outcomes among HIV positive patients on ART.	RCT	**Sampling Technique:** Simple, complete, blinded randomization technique. **Eligible participants:** Adult HIV-positive patients who were newly initiating treatment have valid phone numbers and can read text messages. Participants' ages ranged from 18-64 years. **Accepted:** 242 participants were included in this study. **Excluded:** Adult HIV-positive patients who already initiated and patients who were previously lost to follow-up	**Control:** Standard of care **Intervention:** Intervention includes weekly SMS medication reminders (sent at 9 am every Monday), SMS reminder and a phone call before clinic appointment dates, and routine adherence counseling over 24 weeks. **Intervention fidelity:** Research assistants (two PLHIV) were trained on the study protocol for consistent delivery of SMS reminder messages and counseling	**Dependent Variable:** The researcher selected the primary outcome of adherence-related variables to include HIV viral load suppression, improved CD4, frequency of missed clinic appointment, the incidence of TB, and OIs. Good adherence was measured with the Adult AIDS Clinical Trial Group AACTG adherence questionnaire. Good adherence =missing <3 medication/month=95% Adherence. Sub-optimal=missing more than 3 pills/month=less than 95% adherence. **Measurement tool:** Adherence to ART was measured by self-report outcome via AACTG adherence questionnaire therapeutic outcome via blood analysis for viral load (VL), CD4 counts, OI index	**Statistical Procedures(s):** Chi-square test, Fisher's exact test, and Friedman's ANOVA **Results:** **At baseline:** there was a significant difference in gender, income distribution, employment distribution and the residential location between the two groups. (p = .838, .071, .473, and .554). There was no significant differences in mean CD4 count, VL and adherence between the two groups (p = .297), (p = .144), and (p = .212). There were significant differences in age, ethnicity, and educational level between the two groups

		(LTFU) and are restarting treatment were excluded. **Control:** 121 patients were randomized to the control group. These patients received standard care only. **Intervention:** 121 patients were randomized to the intervention arm. Not applicable **Power analysis:** 242 participants were required to provide 80% Beta, moderate sample size, and .05 alpha. Analysis met **Group Homogeneity:** Control and intervention group are similar in clinical characteristics and ART regimen, baseline adherence levels		was determined with the presence/absence WHO clinical stage-defining illnesses. Viral suppression=HIV RNA was less than 400 copies/ml.	(p = .031, .036 and .004). **At 6-month follow-up** The mean adherence between the two groups was statistically significant (p = .035). Participants in the intervention group reported adherence >95% compared to the control (p=.035). An increase in CD4 count values was observed in the intervention compared to the control group (p=0.17). Participants who received standard care reported frequently missed clinic appointments compared to those in the intervention group (p=.001). Incidence of TB and OIs increased among participants in Control compared to the intervention group (p=.001 and .001)

Garofalo, R., Kuhns, L. M., Hotton, A., Johnson, A., Muldoon, A., & Rice, D. (2016). A randomized controlled trial of personalized text message reminders to promote medication adherence among HIV-positive adolescents and young adults. *AIDS and Behavior*, *20*(5), 1049–1059. doi:10.1007/s10461-015-1192-x					Level II (2)
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
This RCT aims to examine whether a two-way, personalized daily text messaging is an effective intervention to improve adherence to ART	RTC	**Sampling Technique:** Non-blinded randomization by computerized block random assignment. **Eligible participants:** HIV-positive youths aged 16-29 years, who initiated ART, have cell phone access, can use text messaging functions, speak English, and have adherence issues. **Accepted:** 105 participants were included in this study. **Excluded:** Patients who were not regular for a follow-up appointment, pregnant, and unable to consent were excluded. **Control:** Participants received usual care	**Control:** Usual care **Intervention:** Daily personalize medication reminder text message delivered by Remedy Health Media **Treatment Fidelity:** The staff reviewed the study protocol. Consent was obtained before enrollment. IRB approval was obtained and approved by the awardee institution.	**Dependent variable:** Adherence was compared with viral load (VL). **Measure:** Adherence to ART was measured by self-report via using a visual analog scale (VAS). Adherence greater than 90% was used as the gold standard. Viral suppression was defined as HIV RNA less or equal to 75 copies/mL Medication taking self-efficacy was measured using HIV Medication Taking Self-Efficacy Scale **Reliability:** No reliability data was provided.	**Statistical Results:** Chi-square tests were used to analyze categorical variables. Wilcoxon rank-sum tests were used to analyze continuous variables. **Conclusion:** The average effect of the intervention on adherence greater or equal to 90%over 6-month was significant (p=.05). Adherence level greater or equal to 90% maintained 6 months post-intervention among participants who received the intervention.

		Intervention: Participants revived daily personalize medication reminder text message to include the timing and number of dosages **Power analysis:** Small sample size. The probability of making a type II error increase. The Alpha level was set as 0.05 Power=80% **Group Homogeneity:** Control and intervention group are similar in clinical characteristics and ART regimen, baseline adherence levels demographic characteristics, medication viral load and mode of infection.			
Kalichman, S. C., Kalichman, M. O., Cherry, C., Eaton, L. A., Cruess, D., & Schinazi, R. F. (2016). Randomized factorial trial of phone-delivered support counseling and daily text message reminders for HIV treatment adherence. *Journal of Acquired Immune Deficiency Syndromes (1999)*, *73*(1), 47–54. doi:10.1097/QAI.0000000000001020					Level II (2)
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
The purpose of this Randomized factorial trial was to examine	Randomized factorial trial	**Sampling Technique:**	**Control:** Standard of care and counseling on general wellbeing.	**Dependent Variable:** The researcher selected the primary outcome of	**Statistical Procedures(s):**

whether brief phone-delivered counseling and daily medication reminder text messages are effective interventions to improve adherence and VL suppression.		Simple non-blinded randomization technique. **Eligible participants:** Adult HIV positive patients who were on ART and self-report adherence levels below 95% Participants were 18 years and older. **Accepted:** 600 participants were included in this study. **Excluded:** Adult HIV-positive patients who did not meet the inclusion criterion were excluded. **Control:** 151 patients were randomized to the control group. These patients received counseling on general wellbeing. **Intervention:** 149 patients were randomized to receive adherence counseling only	**Intervention:** Intervention includes 5-sessions of brief adherence counseling delivered bi-weekly and daily medication reminder text messages. **Intervention fidelity:** Study protocols reviewed and approved by the Connecticut IRB Consents were obtained from participants. Participants were trained in study protocols. Trained Bachelor' s-level prepared counselors delivered the intervention	adherence-related variables to include HIV viral load suppression and improved CD4. Good adherence equals to 90% ART adherence. Sub-optimal= adherence levels less than 90% **Measurement tool:** Adherence counseling was based on Self-Regulation Theory. Adherence was measured through monthly unannounced pill count. VL and CD4 counts were measured. Undetectable VL=HIV RNA was less than ≥ 100 copies/ml. **Reliability:** No reliability data was provided.	Chi-square test, Fisher's exact test, and Friedman's ANOVA **Results:** **At baseline:** VL suppression was significantly greater among participants who received counseling compared to the control group ($p<.05$) Counseling had a significant effect on adherence over time ($p<.01$). Participants in the intervention group showed significantly greater adherence self-efficacy. The effects of reminder text messages on adherence were also significant ($p<.05$).

		150 participants received adherence counseling and reminder text. 150 participants received text messages only. **Power analysis:** Large sample size (n=600). Minimal risk of Type I error. Power Analysis met **Group Homogeneity:** The Control and intervention group are similar in clinical characteristics and ART regimen, baseline adherence levels			
Ingersoll, K. S., Dillingham, R. A., Hettema, J. E., Conaway, M., Freeman, J., Reynolds, G., & Hosseinbor, S. (2015). Pilot RCT of bidirectional text messaging for ART adherence among nonurban substance users with HIV. *Health Psychology: Official Journal of the Division of Health Psychology, American Psychological Association*, *34S*(0), 1305–1315. doi:10.1037/hea0000295					Level II (2)
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
The purpose of the descriptive study was to examine the efficacy of theory-based bidirectional text messaging (TEXT) on ART adherence, clinic appointments, and substance use	Pilot RCT	**Sampling Technique:** Simple non-blinded randomization **Eligible participants:** HIV positive adults aged 18 or older, prescribed ART, self-report adherence level less than 95%, use	**Control:** Participants received usual care. **Intervention:** Intervention include daily text messages for medication dosing, mood assessment, and substance use. .	**Dependent variable:** Dependent variable adherence was compared with clinic Attendance and pharmacy refill rates. **Measure:**	**Statistical Results:** Adherence levels increased from preintervention to post-intervention among participants who received TEXT compared to UC (p=.04).

		illicit drugs, drank alcohol at levels considered risky and read English **Accepted:** 63 participants were recruited for this study. **Excluded:** Participants who did not meet the inclusion criterion were excluded. **Control:** 30 participants were assigned to the control group. **Intervention:** 33 participants were assigned to the intervention group. **Power analysis:** Small sample size Alpha level was set at 0.05. Power was set at 80%. **Group Homogeneity:** The control and intervention group are similar in clinical characteristics, ART regimen, and depression rates,	**Intervention fidelity:** Study protocols reviewed and approved by the Connecticut IRB Consents were obtained from participants.	Substance use disorder was assessed using the Mini International Neuropsychiatric Inventory. Adherence=Pills dispensed/pills prescribed per day/days between refills × 100% used to calculate the pharmacy refill rate. Missed appointments were used to assess attendance rates. **Reliability:** No reliability data was provided.	

		anxiety, and substance use disorder			
Moore, D. J., Pasipanodya, E. C., Umlauf, A., Rooney, A. S., Gouaux, B., Depp, C. A., Atkinson, J. H., & Montoya, J. L. (2018). Individualized texting for adherence building (iTAB) for methamphetamine users living with HIV: A pilot randomized clinical trial. *Drug and Alcohol Dependence*, *189*, 154–160. doi:10.1016/j.drugalcdep.2018.05.013					Level II (2)
Purpose/ Hypothesis	Design	Sample	Intervention	Outcomes	Results
This RCT aims to examine whether individualized reminder text messages effectively improve ART in HIV-positive individuals who use methamphetamine (METH).	RCT	**Sampling Technique:** Non-blinded Randomization. **Eligible participants:** HIV-positive patients aged 18 years and older diagnosed with METH abuse or dependence, prescribed ART, have functioning cell phones, can use text messaging functions, speak English, and have adherence issues. **Accepted:** 75 participants were included in this study. **Excluded:** Patients who did not meet the inclusion criterion were excluded.	**Control:** Usual care **Intervention:** Daily individualized texting for adherence building (iTAB) **Treatment Fidelity:** The study protocol was reviewed with participants. Consent was obtained before enrollment. IRB approval obtained	**Dependent variable:** Medication Event Monitoring System (MEMS) Adherence **Measure:** Adherence to ART was measured by computing the electronic record of Medication Event Monitoring System (MEMS) caps MEMS Adherence was defined as the percentage of taken doses. Dosing time was measured as the overall number of bottle openings within the set dosing time Viral suppression was defined as HIV RNA less or equal to 75 copies/mL	**Statistical Results:** A significant increase was observed in ART dose timing among the intervention group compared to the control group. 80% of participants in the intervention group reported adherence >90% compared with the control group There was a correlation between MEM adherence and text messages ($p<.001$). A significant correlation was observed between overall MEMs adherence, MEMS adherence based on dosing time, and reported Meth ($p<.001$)

		Control: 25 participants received usual care **Intervention:** 50 participants revived daily individualized texting for adherence building (iTAB) **Power analysis:** Small sample size. The probability of making a type II error increase. **Group Homogeneity:** Control and intervention group are similar in clinical characteristics and ART regimen, baseline adherence levels demographic characteristics, medication viral load and mode of infection.		**Reliability:** No reliability data was provided.	Adherence level lower than 90% observed in participants who used Meth.

Table 2

Evidence Rating Table

Level of Evidence	# of Studies	Summary of Findings	Overall Quality
II (2)	5	Kalichman et al. (2016) and Garofalo et al. (2016) found that daily reminder text messaging produces a significant effect on ART adherence levels in intervention groups compared with usual care in HIV positive patients with adherence levels below 90%. Adherence was measured with different instruments across these studies, but each instrument showed improved adherence levels from baseline to follow-up adherence. The effect of the intervention was sustained in two of the studies.	(B). These are RCTs. Participants were randomized to groups. The instrument (monthly unannounced pill counts and self-report) used to assess adherence levels were clearly described. Self-reported adherence may be exaggerated and introduce desirability bias. Unannounced pill count is a valid and reliable tool to measure adherence. Rigorous selection and inclusion criterion methods were useful to regulate confounding variables (age, gender, educational level, depression, substance use, and ethnicity) that could minimize the homogeneity of the groups. Non-blinded randomization could introduce selection bias. High rates of loss to follow-up and dropouts among participants may threaten the internal validity of these studies. Results from these studies showed that reminder text messaging had significant effects on adherence.
		Abdulrahman et al. (2017) found that weekly SMS reminder text messaging and peer counseling increased ART adherence at levels greater than 95% significant among participants who received the intervention compared with treatment-as-usual. Viral suppression and increased CD4 counts were higher in participants who self-reported good adherence.	(B) This is an RCT. A single-blinded randomized technique was used. AACTG questionnaire is a reliable and valid instrument to measure ART adherence among HIV-positive patients. CD4 counts were used for measuring the effects of adherence on virologic and immunological responses. The rigorous selection and inclusion criterion method was useful to regulate confounding variables but may impact the generalizability of findings. Results were consistent with the other studies.
		Ingersoll et al. (2015) and Moore et al. (2018) found that medication reminder text messages improved adherence among HIV positive patients who use illicit substances and Meth. Effect of intervention post-intervention in the two studies. Adherence level lower than 90% observed in participants who reported using Meth.	(B). These are RCTs. Non-blinded randomization was used to assigned participants to groups. (MEMS and pharmacy refill rate) are reliable instruments to measure ART adherence. These studies had a small sample size, which may increase the probability of Type II errors. The representativeness of the study's participants may impact the generalizability of findings in other populations. Rigorous selection and inclusion criterion methods were useful to

			regulate confounding variables but may impact the generalizability of findings. Results from these studies were consistent with the other studies.

Rating System for Hierarchy of Evidence

Level of Evidence	**Type of Evidence**
I (1)	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT and/or reports of expert committees.
III (3)	Evidence obtained from well-designed controlled trials without randomization.
IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative study
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities

Rating Scale for Quality of Evidence (Newhouse)		
High (A)	Scientific	Consistent results with sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence
	Summative Review	Well-defined, reproducible search strategies; consistent results with sufficient numbers of well-defined studies; criteria-based evaluation of overall scientific strength and quality of included studies; definitive conclusions
	Experiential	Expertise is clearly evident
Good (B)	Scientific	Reasonably consistent results, sufficient sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
	Summative Review	Reasonably thorough and appropriate search; reasonably consistent results with sufficient numbers of well-defined studies; evaluation of strengths and limitations of included studies; fairly definitive conclusions.
	Experiential	Expertise seems to be credible.
Low Quality (C)	Scientific	Little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn
	Summative Review	Undefined, poorly defined, or limited search strategies; insufficient evidence with inconsistent results; conclusions cannot be drawn
	Experiential	Expertise is not discernable or is dubious
Newhouse, R. (2006). Examining the source for evidence based nursing practice. JONA.Volume 36, Number 7/8, pp 337-340		

Table 3

Demographic Characteristics of Participants who Received Reminder Text Messaging and Brief Phone-Based Adherence Counselling, (N=22)

Variable	N=22	%	Range	Median	Mean (SD)
Total HIV+ clients	22	100%	18-59	31	32.4 (10.1)
Age					
18-27	6	27.3%			
28-37	13	59.1%			
38-47	1	4.5%			
48 and above	2	9.1%			
Ethnicity					
Non-Hispanic	21	95.5%			
Hispanic	1	4.5%			
Race					
Black/African	20	90.9%			
American	2	9.1%			
Other					
Gender					
Male	20	90.9%			
Female	2	9.1%			

Table 4

Total Participants Pill Count Adherence

Variable	N=22	%	Range	Median	Mean (SD)
Total adherence support	22	100%			
Text only	7	31.8%			
Text/Counseling					
Total pill count completed	14	63.6%			
Week 4	15	68.2%			
Week 8	14	95.5%			
Week 12					
Total with adherence levels >95%					
4 weeks >95%	10	71.4%			
8 weeks >95%	13	86.7%			
12 weeks >95%	12	85.7%			

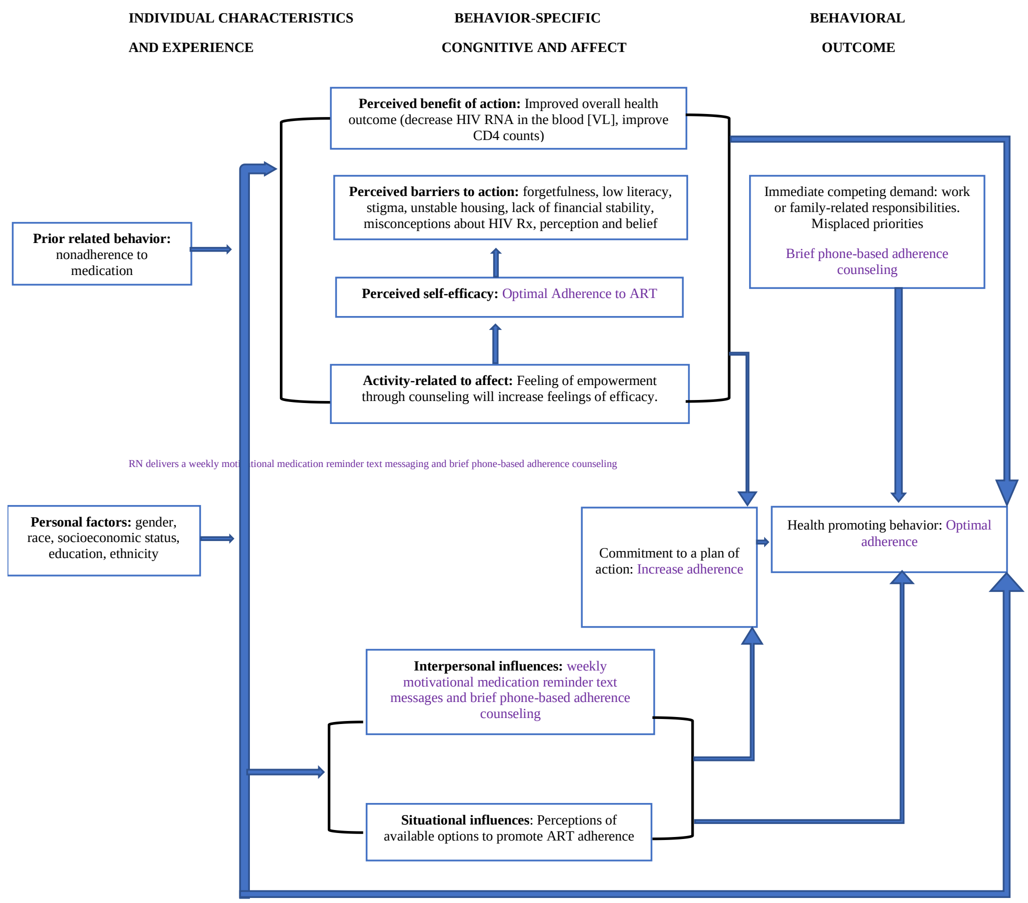
Table 5

Participants who Completed the Post-Intervention Survey

Question 4. Tell us how this support has helped you stay on track with your medications.		
ID	**Name**	**Responses**
1	Anonymous	A good reminder can keep you on top of things. Very helpful.
2	Anonymous	Weekly reminders
3	Anonymous	The support that I have received has been phenomenal. The continued communication has reminded me that I not in this fight alone. It makes me want to stay on track and adhere.
4	Anonymous	I'm reminded of appointments and to regard my health in general due to the text messages. Medication adherence is positively impacted, but isn't an extreme challenge, personally. However, I appreciate them and they are very useful reminders
5	Anonymous	It helped a way for me to keep updated on my meds for the most part even though it is ultimately my responsibility to do so....but as long as everything is good on my health I'm not worried as much.
6	Anonymous	I have not missed any, and text helped mw
7	Anonymous	Having a direct line of communication with someone who's aware of my condition has helped tremendously with staying on track and quickly resolving issues that arrive. Especially during the pandemic. I've built a relationship that has improved my mental and physical health. I am very thankful for my connection with my provider
Question 5. Would you like to continue to receive reminder text messages or call from your nurse or provider?		
1	Anonymous	Maybe
2	Anonymous	Yes
3	Anonymous	Yes
4	Anonymous	Yes
5	Anonymous	Yes
6	Anonymous	Yes
7	Anonymous	Yes

Figure 1

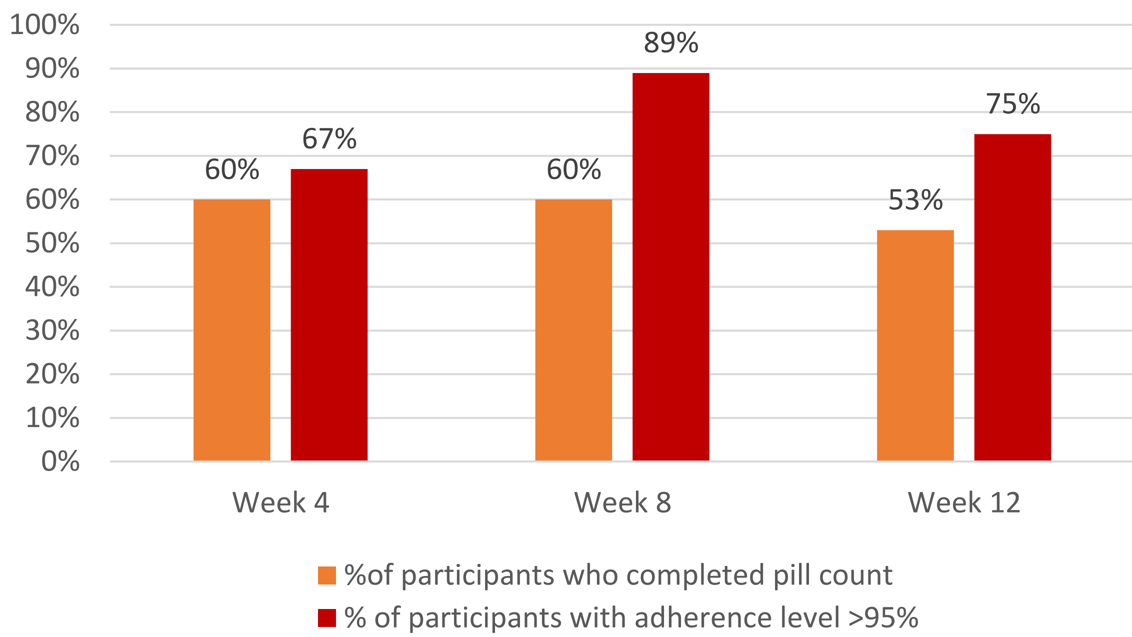
The Health Promotion Model (Adapted)



Note: The Health Promotion Model (Revised): (Adapted from Pender, N. J., Murdaugh, C.L, & Parsons, M. A. (2015). Health Promotion in Nursing Practice (7th ed.). Upper Saddle River, NJ: Pearson Education Inc

Figure 2

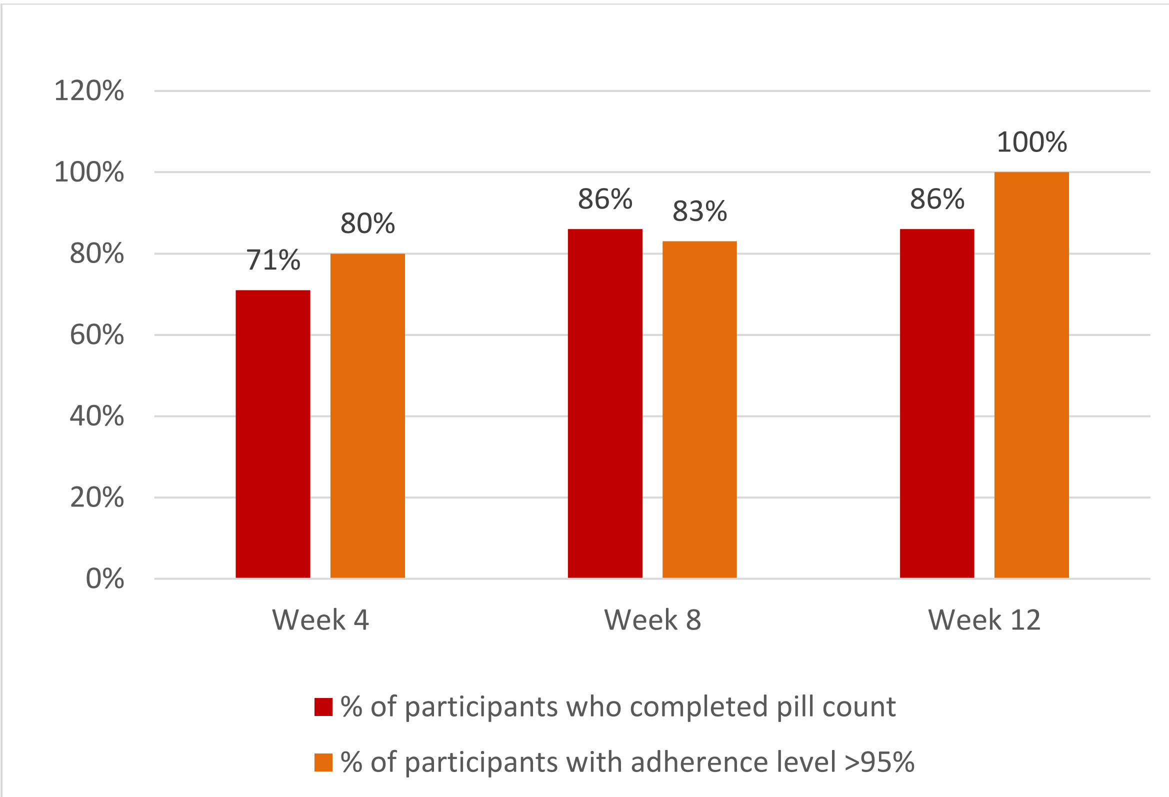
Participants who Received Weekly Reminder Text Messages Only, (N=22)



Note: the proportion (%) of participants who completed pill who completed pill count with adherence level >95%, 66.7% (n=6 of the 9 patients) at 4 weeks, 88.8% (n=8 of the 9 patients) at 8 weeks, and 75.0% (n=6 of the 8 patients) at 12 weeks

Figure 3

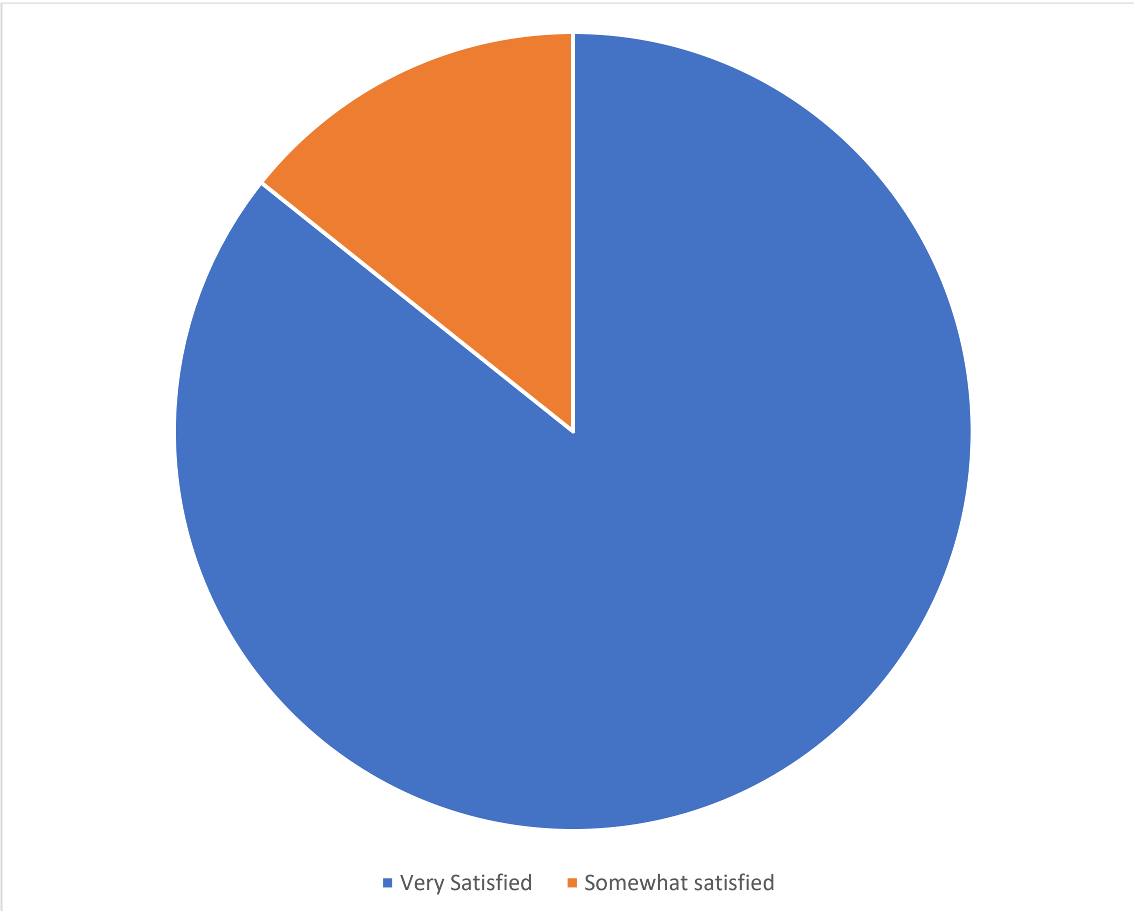
Participants who Received Weekly Reminder Text Messages and Phone-Based Adherence Counseling, N=7



Note: the proportion of participants who completed pill count with adherence level >95%, 80.0% (n=4 of the 5 patients) at 4 weeks, 83.3% (n=5 of the 6 patients) at 8 weeks, and 100.0% (n=6 of the 6 patients) at 12 weeks

Figure 4

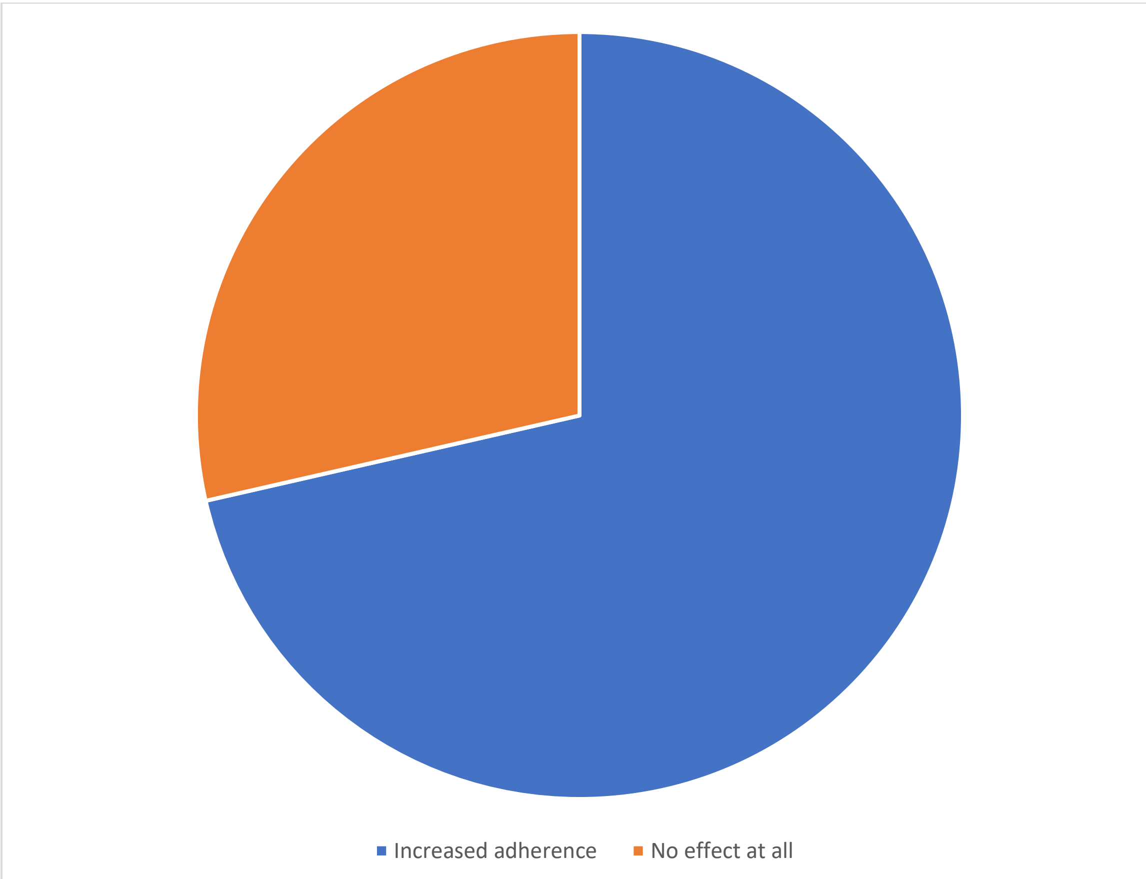
Participants who Completed the Post-Intervention Survey, N=7



Note: Question 1: How satisfied were you overall with the medication reminder messages that you received?

Figure 5

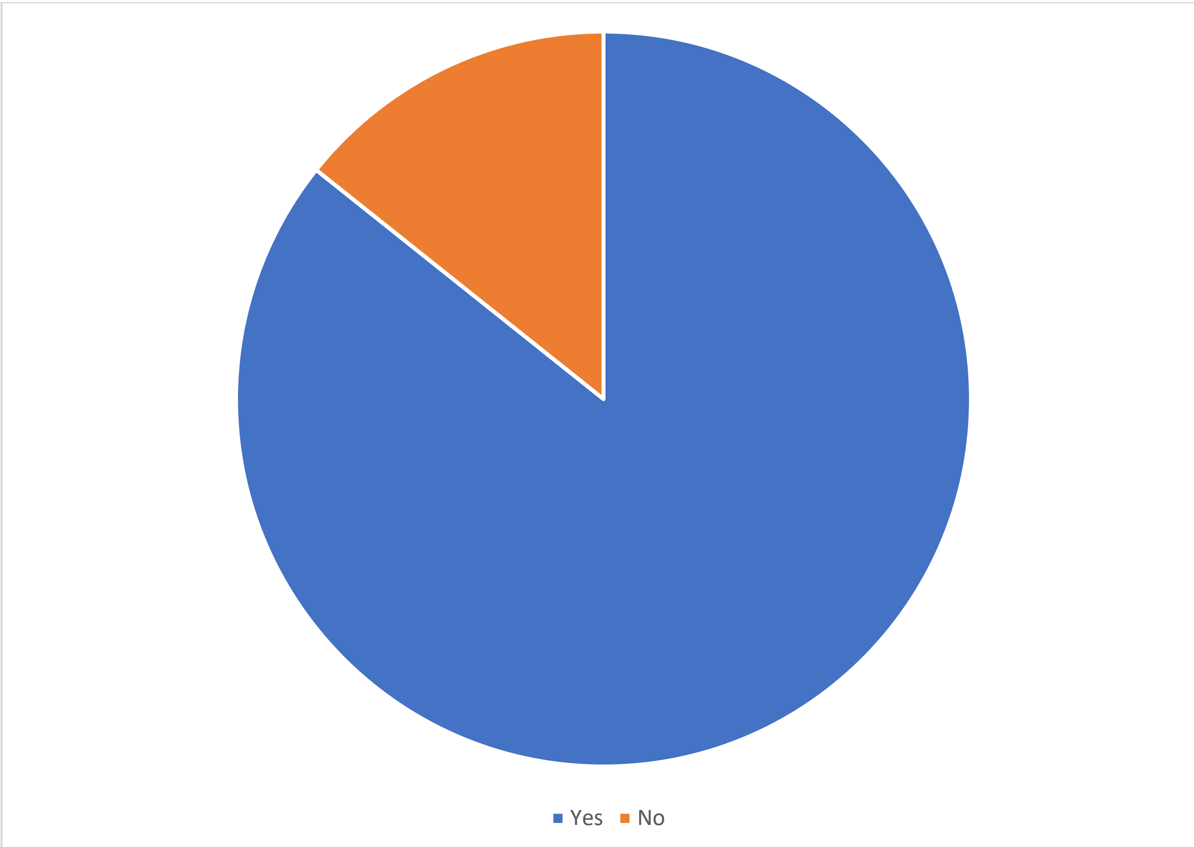
Participants who Completed the Post-Intervention Survey, N=7



Note: Question 2: Did the support have any effect on helping you stay on track with taking your medication?

Figure 6

Participants who Completed the Post-Intervention Survey, N=7



Note: Question 3: Did the communication with a nurse help resolve other issues that you had aside medication adherence?

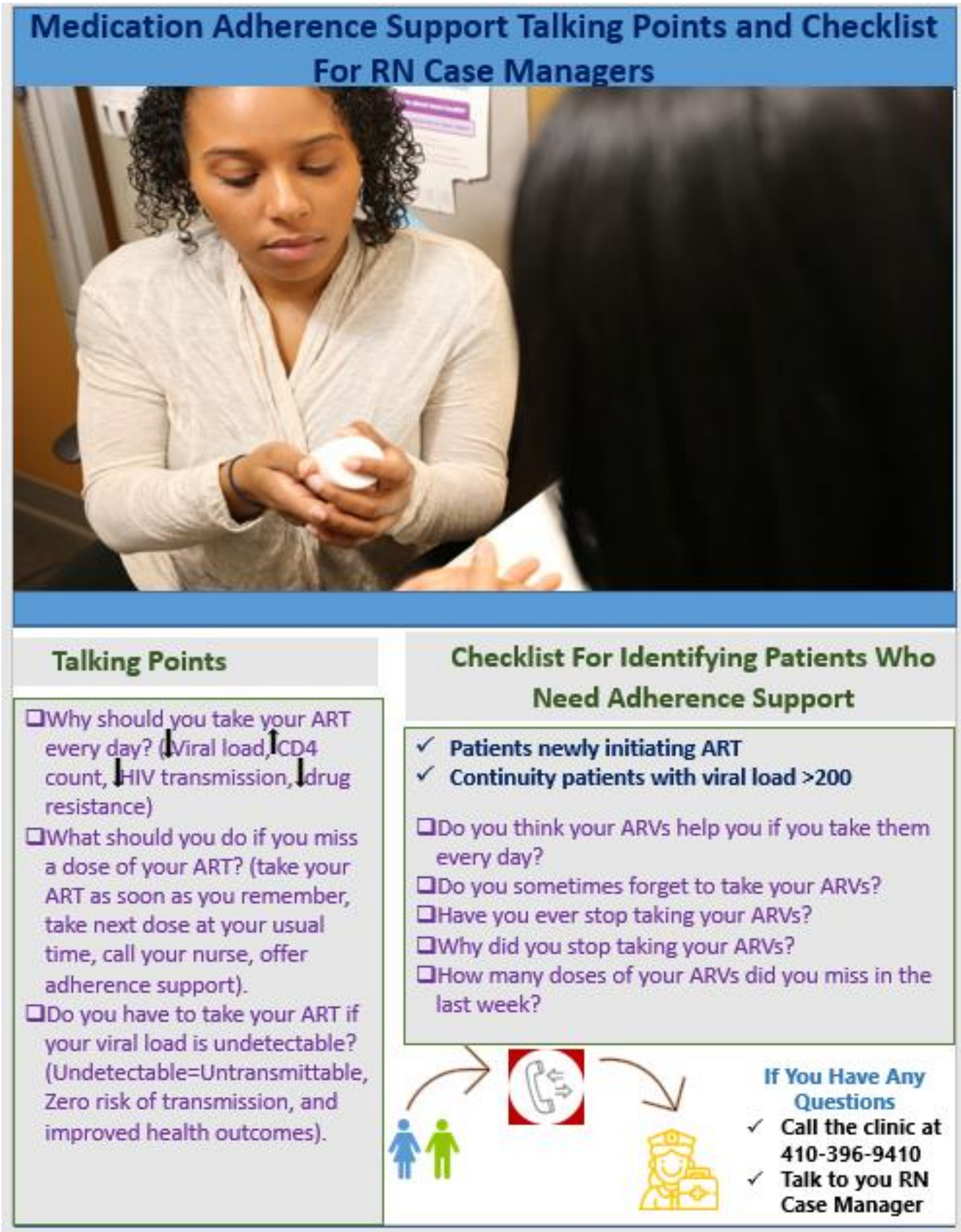
Appendix A

Lesson Plan For RN-CMs Training

Learning Objectives	Content Outline	Method of Instruction	Time Spent	Method of Evaluation
RN-CMs will describe 1. How to update contact information and cell phone numbers in Insight (EMR). 2. How to add participants to the nurse schedule in Insight for reminders. 3. How to deliver adherence counseling and what to discuss during each session. 4. When to send reminder text messages to participants. 5. What information to document on the audit sheet. 6. How to perform pill counting over the phone.	DNP-PL will discuss 1. Project procedures 2. Project participants 3. Human subject protection 4. Audit forms. 5. Data collection 6. EMR documentation.	Presentation Discussion via Webex and in-person.	1 hour	Observation
RN-CMs will demonstrate 1. Ability and skill perform tasks	DNP-PL will 1. Give feedback 2. Address any questions or concerns about project implementation process.	Roleplay Discussion	1 hour	Observation

Appendix B

Medication Adherence Support Talking Points and Checklist



Appendix C

Audit Sheets for Weekly Reminder Text Messages and Phone-Based Adherence Counseling

Audit Sheet: Implementation of Weekly Text Messaging and Phone-Based Adherence Counseling				
Data Collection Form				
Date (MM/DD/YY)	De-identified Patient Number	Text Message Yes=1 No=2 Failed=7	Adherence Counseling Yes=1 No=2 Not reachable=9	Code for RN-CM

Variable Names	**Variable Labels**
Text Message	RN sent Reminder Text Message? Yes=1, No=2, Message Failed=7
Counseling	RN completed adherence counseling? Yes=1, No=2, Patient could not be reached=9
Code for RN-CM	Code for participating RN-CM (01, 02, 03…)

Appendix D

Audit Sheet for Unannounced Phone-Based Pill Count

Variable Names	Variable Labels
De-identified Patient Number	De-identified Patient Number
ART Regimen	What ART regimen is the patient taking? Regimen as Reported
Pharmacy Pick up	Did patient pick up ART bottle from the pharmacy? Yes=1, No=2
Pill Count Completed	RN completed unannounced pill count? Yes=1, No=2
Pill Losses Pill Gains	Lose in medication can occur if the patient throws out or misplaces medication (Losses=1) Gain in medication can occur if the patient misses doses, borrows pills or adds pills from prior ART (Gains=2)
Adherence Score (%)	Adherence score is calculated based on the difference between pills taken divided by the number of pills that should have been taken multiply by 100. Example 28/28 x 100 =100% Patient took 95-100% of pills =Adherent Patient took less than 95% of pills= Non-Adherent
Code for RN-CM	Code for participating RN-CM (01, 02, 03…)

Audit Sheet: Implementation of Unannounced Phone-Based Pill Count							
Data Collection Form							
Date (MM/DD/YY)	**De-identified Patient Number**	**ART Regimen**	**Pharmacy Pick Up Yes=1 No=2**	**Pill Count Completed Yes=1 No=2**	**Pill Losses =1 Pill Gains =2**	**Adherence Score**	**Code for RN-CM**

Appendix E

Post-Intervention Survey

1. How satisfied were you overall with the medication reminder text messages that you received weekly?
    - Very satisfied
    - Somewhat satisfied
    - Neither satisfied nor dissatisfied
    - Somewhat dissatisfied
    - Very dissatisfied
2. Did the support have an effect on helping you stay on track with taking your medications?
    - Decreased my adherence
    - Increased my adherence
    - No effect at all
3. Did the communication with a nurse help resolve other issues that you had aside medication adherence?
    - Yes
    - No
4. Tell us how this support has helped you stay on track with your medications. (Free text)
5. Would you like to continue to receive reminder text messages or call from your nurse or provider?
    - Yes
    - No
    - Maybe