Acceptability and Feasibility of a Cell Phone Support Intervention for Youth Living with HIV with Nonadherence to Antiretroviral Therapy

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Abstract

A pilot randomized clinical trial of youth ages 15–24 nonadherent to antiretroviral therapy (ART) utilizing daily cell phone support was found to have significant improvement in self-reported adherence and HIV RNA. Understanding acceptability and feasibility is critical for future implementation in clinic settings. Exit interviews were obtained from participants and adherence facilitators (AF). Acceptability was assessed from content analysis of exit interviews. Feasibility was assessed via intervention retention and study retention rates. Thirty-seven eligible youth were enrolled with 19 assigned to the intervention. Seven (37%) discontinued the intervention either due to missing over 20% of calls for two consecutive months ($N=5$) or missing 10 consecutive calls ($N=2$). Sixteen participants completed exit interviews, 15 reported the call length was just right, 13 reported they would have liked to continue calls after the 24-week intervention, and all participants reported they would recommend the intervention to friends. Scheduling and making calls required less than 1 h per week per participant. Providing cell phone support to youth nonadherent to ART was acceptable and feasible. While the cost is low compared to the price of ART, healthcare systems will need to explore how to cover the cost of providing cell phones (incentive).

Introduction

Adherence to antiretroviral therapy (ART) is critical to sustain health, reduce HIV transmission,[1] and minimize the development of antiretroviral resistance.[2] Many studies have demonstrated that youth living with HIV frequently have poor medication adherence.[3] Several cross-sectional studies have described low self-efficacy, depression, poor coping styles, and poor social support as social-cognitive predictors of low adherence.[4–6] When researchers directly ask youth living with HIV why they missed taking their medication, the most common answers are, ''I forgot,'' ''I didn't have my medications with me,'' or ''I had a change in my daily routine.''[7] Other potential factors that may play a role in youth adherence include stigma and decisional capacity.[8,9]

There have been several studies of modestly successful intervention approaches for youth living with HIV who had poor medication adherence including motivational interviewing,[10] directly observed therapy,[11] personalized text message reminders,[12] and cell phone call reminders.[13] More recently, we published an initial randomized controlled trial utilizing cell phone support among nonadherent virologically detectable youth which demonstrated statistically significant improvements in self-reported adherence and reduction in HIV RNA (viral load) at the conclusion of the 24-week intervention and 24 weeks following the completion of the intervention. There were large to medium effect sizes. Adherence decreased in the control group over the 48 weeks.[14] Findings indicate a very nonadherent cohort that likely represent the least adherent youth living with HIV.

Limitations in the design of this pilot study precluded understanding if the intervention impact was attributable to the support, the reminders, or the incentive. A small pilot study of 11 extremely nonadherent perinatally infected youth

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demonstrated improved adherence during a 12-month intervention utilizing motivational interviewing and financial incentives. Four participants maintained an undetectable viral load for 12 months beyond the intervention. This may suggest that incentives play an important role in helping nonadherent youth stick to their medication.[15]

There have been limited data published on the acceptability of adherence interventions with HIV+ youth. A small pilot study ($N = 18$) found 61% preferred motivational interviews to regular office visits.[16] Dowshen's study of text message reminders for HIV+ youth retained 84% of subjects and 95% of those reported they found the intervention helpful.[12]

Authors hypothesized that many youth fail to adhere to antiretroviral therapy due to a combination of factors. As Maslow (1943) theorized, human beings are motivated by unsatisfied or unmet needs.[17] Basic needs must be satisfied before higher needs are met. Many youth living with HIV struggle with fundamental problems like housing, substance abuse, mental illness, and poor social support.[18–20] Because many youth living with HIV are preoccupied with meeting life's basic needs (either chronically or episodically), taking medications becomes a secondary priority, particularly during the asymptomatic phases of their disease.

A successful intervention to increase adherence in the adolescent and young adult population should assist patients with prioritizing medication adherence on a daily basis, habitualizing, offering real time problem solving assistance for unforeseen circumstances, and addressing ongoing needs through reinforcement or newly advised referrals to care team members.

The theoretical underpinnings for this intervention were identified from literature on coping with stress and support.[21] Specifically, provider support through daily phone contact assists participants in addressing any current barriers to medication adherence in the moment through (a) interpretation of perceived barriers and challenges (appraisal support); (b) reinforcement of routinization of medication taking; (c) promotion of medication as a daily priority; (d) prompting alternative courses of action when barriers arise (problem-solving support). Second, these calls may serve to triage larger issues needing attention through identification of and referral to appropriate services, thereby addressing barriers that that cannot be resolved during a call.

To increase the probability of youth in the intervention to answer phones calls regularly, we linked the provision of free cell phones/phone service to those who answered a minimum of 80% of calls each month, as having reliable cell phone access is a critical priority for youth.

Increased understanding about the acceptability and feasibility of this intervention will assist in designing a future full scale study as well as implementing this intervention in a clinical setting.

This publication describes the acceptability and feasibility of this intervention through review of exit interviews of the subjects and adherence facilitators (AFs) and also through analysis of the cell phone call experiences and content.

Methods

A cell phone adherence support intervention guided by the theories of social support was developed by the coauthors and has been described in detail previously.[14] The study was con-

ducted between February 2010 and November 2011. Briefly, 37 participants were enrolled with 19 randomized to the intervention and 18 to the control group. Participants were 15–24 years old, with a history of nonadherence to ART defined as: (a) currently prescribed ART and reporting <90% adherence with a recent viral load over 1000 copies/mL, (b) discontinued ART while documented to have adherence <90% during last use and currently off ART, (c) agreed to start ART but never initiated. Youth were recruited from Adolescent Trials Network (ATN) sites located in Los Angeles, Washington DC, New Orleans, Fort Lauderdale, and San Francisco.

Subjects randomized to the intervention were contacted by cell phone Monday–Friday at a prearranged time by AFs either once or twice a day corresponding to the frequency of their taking ART. Calls were arranged at mutually determined times (usually, but not always during work hours, which depended on the needs of site staff and work regulations). When possible, calls were made about 1 h after the time the medication was supposed to be taken.

Primary AFs making the majority of the calls were nonlicensed staff (primarily research assistants or case managers) experienced working with youth living with HIV. Each site had one or two secondary AFs (such as licensed registered nurses or social workers) to make calls when the primary AFs were off work. For this study, AFs participated in a 2-h training session that reviewed a standardized script for conducting calls, reviewed basic HIV adherence promoting strategies and suggestions on how to encourage and provide referrals for problems that could not be addressed in a short 3- to 5-min call. A quality manager (licensed psychologist with experience caring for youth living with HIV) reviewed a subset of recorded phone calls from each site to ensure protocol fidelity and to provide practical problem solving advice to AFs during monthly conference calls.

AFs followed a standardized script during calls that included closed- and open-ended questions regarding medication review, barriers to taking medications, problem solving support, referrals provided, and scheduling relevant referrals. Participant responses were recorded on daily call forms. Medication review included the AF confirming that subjects had taken their medication or waited for the subject to take the medication if on hand. When medication was not taken prior to the call, the AFs would review why and then problem solve with the youth and reinforce the importance of taking their medications regularly. If needed, AFs would refer youth back to members of the clinical team to provide further support and AFs also reminded youth of regular upcoming appointments.

Intervention participants had the option to utilize their own cell phones and receive a payment of $45/month directly to their plan provider or receive a cell phone and have the plan paid for by the study. The paid plan included at a minimum, 400 anytime minutes, free nights and weekend calls, free unlimited texting and unlimited incoming calls from the study team. Participants were required to answer at least 80% of AF calls and if they did not meet this minimum for 2 consecutive months, they were dropped from the intervention (but continued with the study data collection). Participants were also dropped from the intervention if they missed more than 10 consecutive calls. Those participants utilizing their own phones who missed over 20% of calls in one month were switched to a study-provided phone and plan to ensure

subjects had access to all calls (in case they were not answering calls due to being out of free minutes).

Data collected by AFs during daily calls

AFs were required to attempt to reach each participant once or twice a day; corresponding to how often medication was being taken. AFs followed a standardized daily call script, which included a series of questions to assess during the call, and a checklist of pre-populated responses, as well as opportunities to capture additional responses. If the AF was not able to call the participant, the reason was recorded on a daily call form. The same is true for participants who did not answer or return calls within 30 min but were subsequently contacted. The AF also noted if the call was delayed from the regularly scheduled time. Ideally, phone calls would take place just after the time that medications were typically taken. During these calls, the AF would first assess if the participant had already taken his/her medications. If no, the reason was recorded along with the appropriate barrier issues. If the participant had his/her medications, he/she would take it during the call. If the participant did not have his/her medications available, the AF would find out why and again record the barrier.

Depending on the youth and/or barrier to taking medication (e.g., general stress; housing problems; insurance problems; job issues; and interpersonal issues with family, partners, and friends), problem solving advice and/or a referral was provided in order to troubleshoot and increase adherence. Participants were reminded of the importance of taking HIV medication.

The AF would troubleshoot additional issues as presented by the participant and remind youth of the services available to them. Twice a week, generally Mondays and Fridays, participants were asked if they received any referrals from outside the study and/or the clinic from which the study was being run, if he/she attended any visits for referrals provided outside of the study or the clinic, and if he/she attended any visits for referrals made by the AF within the last week. All types of referrals were recorded. Lastly, the AF would provide reminders of any upcoming appointments.

Exit interviews

Participant exit interviews occurred either at the end of the study intervention or when a subject was prematurely discontinued from the intervention. AFs conducted the exit interviews, utilizing a standardized script, consisting of closed-ended questions to assess the acceptability of calls (e.g., length of calls, timing of calls, frequency of calls), feeling about the impact (e.g., usefulness of calls, improved adherence, increased motivation to take ART), and suggestions to improve the intervention (e.g., longer duration, including weekends). An open-ended question assessed the most helpful aspects of having calls with AFs.

AF exit interviews were conducted by a protocol team member with primary and secondary AFs either at the end of all study interventions, or if an AF ended their participation early in the study. The exit interview utilized a standardized script, including closed- and open-ended questions, by phone and recorded the responses. Close-ended questions queried whether AFs believed that the training was adequate; youth were able to utilize problem-solving advice offered; youth were able to

problem-solve on their own; youth needed additional time, or help; and daily calls were too intrusive. Open-ended questions assessed additional issues or skills that should be addressed in the training, most challenging part of their role, and what type of staff would be best to provide this intervention.

Statistical analysis

Statistical tests were performed on closed-ended responses collected during the daily calls and exit interviews. All statistical tests were performed using SAS™ 9.3 software (SAS 9.3, 2012, SAS Institute, Cary, NC). Descriptive analyses, including means, frequencies and percentages, were generated as appropriate to describe the study population. Given the small sample size, Fisher's Exact test for was performed to compare the youth in the once-a-day call group versus those in the twice-a-day call group. Statistical tests were based on two-tailed alternatives and $p < 0.05$ was considered significant.

Qualitative analysis

A content analysis, defined as ''a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns''[23] was utilized to assess the open-ended responses from the daily phone calls, participant exit interviews, and AF exit interviews. Considering the limited number of open-ended questions and brief responses that were elicited, the content analysis primarily focused on the frequency of particular words or content. Further exploration of the underlying meaning or usage of these words or content was not always feasible given the responses provided.

A qualitative analyst reviewed open-ended text from the three data sources to develop an understanding of responses. A preliminary codebook was developed for each of the data sources that included codes, definition of codes, frequency of text coded, and examples of text coded. Codebooks were reviewed iteratively, to assess whether codes should be expanded, deleted, or merged, based on the frequency and content of text. Patterns of codes were discussed with the research team and further refinement of the codebook was conducted.

Results

Demographics

The mean age of youth was 20.43 (STD = 2.57) years (range 15–24 years). The majority were male (62.2%) and African American (70.3%). Fifty-four percent had acquired HIV sexually and 46% perinatally. There were no differences between demographic characteristics between the intervention and control participants (Table 1).

Study acceptance

At four of five sites, all but one youth who were approached and found to be eligible participated in the study. At one site, 20 youth who were eligible declined participation in the study. Of these 20, 11 stated they were not interested, 5 expressed interest but never returned to consent, 3 stated they were too busy, and 1 did not participate due to parental concerns. It is unclear why this one site's experiences were so different from the other four sites.

TABLE 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS BY STUDY GROUP

	Overall N=37	Intervention N=19	Control N=18	p Value
Age at baseline (years), mean (std)	20.43 (2.57)	19.84 (2.52)	21.06 (2.53)	0.14
Gender, n (%)				
Male	23 (62.16)	11 (57.89)	12 (66.67)	0.74
Female	14 (37.84)	8 (42.11)	6 (33.33)	
Race/ethnicity, n (%)				
Non-Hispanic black/African American	26 (70.27)	13 (68.42)	13 (72.22)	0.80
Hispanic	7 (18.92)	3 (15.79)	4 (22.22)	
Non-Hispanic white/other	4 (10.81)	3 (15.79)	1 (5.56)	
Most likely mode of transmission, n (%)				
Perinatal transmission	17 (45.95)	12 (63.16)	5 (27.78)	0.09
Heterosexual contact	5 (13.51)	1 (5.26)	4 (22.22)	
Male-to-male sexual contact	15 (40.54)	6 (31.58)	9 (50.00)	
Viral load (copies/mL), mean (std)	264,643 (725876)	87,553.1 (109181)	451,572 (1015436)	0.86
Log_{10} viral load, mean (std)	4.54 (1.00)	4.39 (0.90)	4.71 (1.10)	0.52
History of non-adherence				
Currently prescribed HAART and reports to care provider less than 90% adherence in previous month and has viral load greater than 1000 copies/ml when last evaluated (within the last four weeks), n (%)				
Yes	14 (37.84)	9 (47.37)	5 (27.78)	0.31
No	23 (62.16)	10 (52.63)	13 (72.22)	
Discontinued HAART in the past while documented to be less than 90% adherent during the most recent antiretroviral treatment, n (%)				
Yes	22 (95.65)	10 (100.0)	12 (92.31)	1.00
No	1 (4.35)	0 (0.00)	1 (7.69)	
Agreed to initiate antiretroviral treatment in the past, but never initiated, n (%)				
Yes	1 (100.0)	0 (0.00)	1 (100.0)	–
No	0 (0.00)	0 (0.00)	0 (0.00)	

    For continuous variables, the mean, standard deviation, median and range (min, max) are provided; *p*-value is from non-parametric (Kruskal-Wallis) test.
    For categorical variables, the count and % are provided; *p*-value is from Fisher's exact test.

Cell phone usage

Of the 19 youth assigned to the intervention, 15 received once daily calls and 4 received twice daily calls, which corresponded to the ART dosing frequency. Using one's own cell phone and plan was 57.9% at entry, 47.1% at week 6, 37.5% by week 12 and 27.3% by the end of the 24-week intervention. This decline was primarily due to the study requirements of having participants switch to a study phone and plan when missing over 20% of calls for 1 month (*n*=4).

Length of calls

AFs were queried as to the length of calls. Four sites reported average length of calls were 2–5 min, with calls being shorter when subject had already taken their medication prior to the call. At one site that utilized two different primary AFs (primary AF changed due to change in employment), one reported calls averaged 6–7 min and the other 3–5 min.

Adherence to the intervention

Of the 19 intervention participants, 12 completed the 24 weeks of the intervention. Five were dropped from the intervention due to missing greater than 20% of calls for 2 consecutive months, and two were discontinued due to missing 10 consecutive days (one due to hospitalization and the other due to incarceration). Of the five who dropped due to missing over 20% of calls for 2 consecutive months, only two missed over 25% for 2 consecutive months and none missed over 33% for 2 consecutive months. No-one asked to be dropped from the intervention. Youth completing the intervention had significantly more completed first calls (mean=98.25) compared to those with premature discontinuation of the study intervention (mean=26.86) *p*<0.001.

Over the 24-week intervention, 83.97% of calls were completed (85.21% of first calls and 78.4% of second calls, *p*=0.005). Only 6% of all calls were delayed with 2.9% due to AF schedules, 2.3% were rescheduled by mutual agreement, and 1.2% were due to delays made by subjects without permission and were counted as missed calls when calculating the 80% requirement. Participants met the required minimum of answering 80% of monthly calls on time in 79.6% of the intervention months.

Call content

Self-reported (to AF) medication usage before and during AF calls. AFs regularly asked participants if they had taken their ART prior to the call. Participants reported that they had taken the scheduled dose of ART prior to 93.7% (*n*=1281 of 1367) of completed AF first calls (i.e., the first call of the day, corresponding to the first or only dose of ART, depending on regimen). The most common reasons participants did not take ART prior to the first call were forgetting to take medication (*n*=23, 21.5%), change in schedule or routine (*n*=17, 15.9%), sleeping through their designated time to take medication

($n = 7, 6.5\%$), not having medication on hand ($n = 6, 5.6\%$) and feeling ill ($n = 5, 4.7\%$). Participants on a twice-daily regimen reported taking the second dose of ART prior to 90.99% ($n = 212$ of 233) of completed second AF calls. The most common reasons participants named for not taking ART prior to the second call was lapse in insurance coverage ($n = 21$, 52.5%), or that they were busy with other things ($n = 5, 12.5\%$).

Participants also had the option to take their dose of ART during the call if they had not taken it prior to the call. Participants reported taking ART during 45.4% ($n = 39$ of 86 calls) of completed first AF calls when medications had not previously been taken. The most common reasons for not taking ART during these first AF calls were not having medications available or with them (20.6%), lapse in insurance coverage (16.4%), and a change in routine (6.85%). Participants took ART during 14.3% ($n = 3$ of 21) of second AF calls. The most common reason for not taking ART during the second call was insurance lapse ($n = 11, 30.6\%$), or that they did not have their medications with them ($n = 4, 11.1\%$).

Additional AF call content. Problem-solving advice was offered by the AF during $n = 92$ of all completed first AF calls (6.7%) and $n = 27$ (11.6%) of all completed second AF calls. For the first AF calls, the most frequent types of advice related to strategies to increase medication adherence ($n = 45$, 48.9%). For example, AFs reported that they suggested that participants to use alarms, pill boxes, travel pill bags, or keeping a backup dose on hand to prevent missed doses. Other strategies included incorporating medication into participants' daily routine, such as taking medication when waking up, or utilizing visual reminders, such as keeping medication next to toothbrushes or keys. AFs also provided advice on how to manage side effects of medication ($n = 10$, 10.87%), such as nausea and stomach aches, by taking medication with food and maintaining a consistent medication schedule. AFs emphasized the importance of continuing to take medication despite these side effects. For second AF calls, strategies to increase medication adherence were also frequently discussed ($n = 7, 25.9\%$), as well as resolving insurance issues ($n = 5, 18.5\%$), including completing Medicaid paperwork and strategies to find transportation to the Medicaid office.

Referrals were given during $n = 69$ (5.1%) of first AF calls and $n = 4$ (1.7%) of second calls. The most frequent types of referrals were medical ($n = 42, 40.4\%$) and case management ($n = 40, 38.5\%$) for first AF calls. All referrals offered for second AF calls were for case management.

Adherence facilitators were also provided an opportunity to indicate any other issues that were raised during the calls. These other issues were reported $n = 350$ (25.6%) for first AF calls and $n = 75$ (32.2%) of second AF calls. Of the first AF calls, the majority of issues discussed related to missed, rescheduled, or confirmation of calls ($n = 85, 30.0\%$). Other health issues ($n = 56, 19.8\%$) were also discussed, such as headaches, vomiting, hospitalization, and missed medical appointments (e.g., dental and psychiatric appointments). In these cases, AFs often communicated with participants' case managers and therapists to reschedule appointments, and reminded participants to attend these appointments. Study visit schedules were also discussed ($n = 39, 13.8\%$), as AFs often confirmed study visit schedules, arranged visit appointments, and rescheduled visits for participants.

For the second calls, the majority of issues discussed also related to missed, rescheduled, or confirmation of calls ($n = 21, 28.8\%$). Other health issues ($n = 18, 24.7\%$), such as fatigue, flu, and vision problems were also discussed. AFs often encouraged participants to communicate to their case workers about these health issues and to schedule medical appointments as needed. Employment was also discussed ($n = 12, 16.4\%$), as participants discussed the job application, interviewing, and training process to their AFs.

TABLE 2. PARTICIPANT EXIT INTERVIEW
RESPONSES ($N = 16$)

Response	N	%
Talking to my AF about my problems was:		
Very difficult/difficult	0	0
Neither	1	6.25
Easy/very easy	15	93.75
Getting calls made taking my medications regularly:		
Very difficult/difficult	0	0
Neither	2	12.5
Easy/very easy	14	87.5
Talking to my AF changed my motivation to take my medications regularly It made me:		
Less motivated	0	0
About the same	5	31.25
More motivated	11	68.75
What were the most helpful things about the calls?		
Having reminders	12	75
AF providing strategies to remember medication	2	12.5
Positive relationship with AF	2	12.5
Was the length of the calls:		
Too short	0	0
Just right	15	93.72
Too long	1	6.25
If you had a choice, would you like to continue or restart the AF calls?		
Yes	13	81.25
No	1	6.25
Doesn't matter	1	6.25
Don't know	1	6.25
While on this study, the AF did not call you over the weekends. How did you feel about this?		
I wish I could have received calls from the AF over the weekend	10	62.5
I liked having my weekend free without getting called by the AF	6	37.5
Would it have been helpful to gradually reduce the frequency of the calls before stopping altogether?		
Yes	9	56.25
Don't know	1	6.25
No	6	37.5
Would you recommend having a similar phone-based support from an AF to a friend who was having problem taking HIV medications regularly?		
Yes	16	100
No	0	0

AF, adherence facilitator.

Participant exit interviews

Table 2 describes select questions asked during exit interviews. Despite efforts to recontact youth, exit interviews were conducted with 16 participants. Fifteen participants reported very positive feedback, stating that it was easy to talk to AFs, and participants expressed that they found reminders to be helpful, and had a ''positive relationship with their AF.'' The majority of participants also reported that getting calls made it easier to adhere to their medication

TABLE 3. AF EXIT INTERVIEW RESPONSES (*N* = 13)

Response	N	%
Did the training prepare you to deliver the phone calls?		
Yes	13	100
No	0	0
What other issues or skills should be addressed in the training?		
Problem solving (e.g., lack of motivation, distractions)	7	53.85
Pre-call activities (e.g., meet with participants, clinical team)	1	7.69
Therapeutic listening	1	7.69
Safety plan (e.g., identify services for referral)	1	7.69
None	3	23.08
Did you feel that youth were making use of the problem solving discussion/advice that you offered?		
Yes	12	92.31
No	1	7.69
Were youth able to eventually problem-solve on their own?		
Yes	11	84.62
No	2	15.38
Did you feel that the youth needed more of your time, attention or help than you were able to provide?		
Yes	5	38.46
No	8	61.54
Do you think daily calls were too intrusive to youth?		
Yes	4	30.77
No	9	69.23
What part of being an AF was the most difficult? (choose more than one)		
Scheduling calls to accommodate youth's schedule	9	64.29
Follow-up on referrals	1	7.14
Getting participants to open up	1	7.14
Issues with recording equipment	1	7.14
Non-response from youth	1	7.14
None	1	7.14
Who do you think would be the best person to take on the role of an AF? (choose more than one)		
Social worker	6	33.33
Case manager	4	22.22
Peer advocate	2	11.11
Someone with HIV/AIDS knowledge	1	5.56
Volunteer close to youth	1	5.56
Research assistant	1	5.56
Patient care assistant	1	5.56
Adherence facilitator	1	5.56
Someone not in primary care team	1	5.56

AF, adherence facilitator.

schedule. Eleven reported improved motivation, stating that the AF was supportive, and made the medication process routine. Most reported reminders as the key feature of the AF calls, although support was also reported as important. Fifteen reported the call length as ''just right'' and 13 reported they would have continued AF calls if given a choice. Ten would have preferred to receive calls on weekends, whereas 9 reported it would have been preferential to have tapered the frequency of calls over time. All would recommend this intervention to friends with adherence problems.

AF exit interviews

Thirteen AFs completed exit interviews, and select questions are presented in Table 3. All reported feeling adequately prepared to deliver the intervention after the 2-h training, but 7 would have liked more training on problem solving. Twelve reported they felt youth made use of the problem solving discussions, and 11 felt that they were able to do more problem solving as the intervention calls progressed. Five AFs reported that at least once, youth needed more time than they were able to provide, particularly to devote time for referrals, consulting with social workers, and connecting youth with case managers or youth advocates. Four AFs reported that that daily calls were occasionally intrusive to some youth and suggested to consider reducing the volume of calls to every other day or weekly. Nine reported that the most difficult part of being an AF was scheduling calls to accommodate youth schedules. When asked who would be the best person to take the role of AF in their particular setting, 6 said social worker and 4 case manager and 2 peer advocate.

Cost analyses

The cost of cell phone plans varied at each site based on institutional requirements. For example, some sites utilized individual plans and others purchased family plans. Costs varied from $25/phone (including cost of site having one plan to make calls) at one site, to $39, $53, $55, and $75/phone line at other sites. Youth who utilized their own phones and plans reported the cost to be approximately $45/month.

The phone call duration was generally reported at 3–5 min, which did not include additional time for repeating calls when participants didn't answer the initial call, as well as relaying important information and developing appointment reminder strategies with team members. The study also required higher levels of documentation than would be required if this intervention was purely a clinical tool. We estimate that this intervention could be administered and documented in actual clinics with about 1 h/patient per week. If an AF salary and benefits cost $40,000/year then the cost would be $1000/year or about $500 for this 6-month intervention.

Discussion

One of the most critical aspects of any successful intervention is evaluating feasibility and if the intervention can be implemented in the real world. This study intervention has demonstrated a fairly robust impact when compared to previous interventions for youth living with HIV who demonstrate poor adherence.[10–13] This study evaluated a very nonadherent population based on low baseline adherence (33% in past month) and very high baseline viral loads

(> 200,000 copies/mL). The control participants had no improvements over the 48-week duration of the study, further indicating a highly nonadherent group.[14] Participants and staff reported this intervention was very acceptable. Almost all youth (who completed the intervention) found this study to be useful and would recommend it to a friend experiencing adherence difficulties.

Many youth reported they would have liked the intervention to continue past 24 weeks and to have included weekends, while some would have preferred the intervention be tapered. Eleven of the 16 youth completing exit interviews reported increased motivation to take their medication, indicating that support and not just the reminders were important. However, an acceptability issue for this intervention is that only 12 of 19 participants were able to complete the 24-week intervention. This cohort was small and very nonadherent so this level of acceptance may be promising given this context. Future studies or clinical practice could reduce the requirements for 80% adherence or termination for missing 2 consecutive weeks of the intervention. Reducing the adherence requirement to 75% would have maintained 3 of 5 subjects dropped from the study intervention due to missing too many calls and would likely have little impact on intervention success

AFs also reported the intervention to be useful and found that youth improved their problem solving abilities over time. They believed social workers and case managers were the best suited staff to administer the intervention and it was reassuring that costs could be contained through the successful use of nonlicensed staff.

In addition, while the intervention demonstrated statistically significant improvements in self-reported medication adherence and viral load reductions during the 24-week intervention and for 24 additional weeks, these improvements waned in the 24 weeks after the intervention. In clinical settings, consideration for ongoing support, such as booster sessions (periods of reinitiating call support), beyond 24 weeks is likely required. This study did not evaluate the acceptance of this intervention beyond 24 weeks. Exploring the impact of a longer or perhaps tapered intervention beyond the first 24 weeks might be a successful approach for sustaining improvements in adherence and viral load in highly nonadherent youth living with HIV.

The feasibility of reproducing this intervention in clinical settings is based on the cost and sources for reimbursement. Staff time is about $80/month (assuming $20/h) and about $50/month for phones (current phone plans are available for $40–$50/month that provide unlimited calls, texts, and data plans). This intervention's direct cost is comparable to 1–2 counseling sessions per month and is well under 10% of the current cost of ART.[22] There may be hidden costs based on increased service utilization (these analyses have not yet been completed).

Data on the cascade of care in adolescents and young adults suggests that only 6% of youth infected with HIV in the United States have suppression of viral load,[24] thus intervention costs are more than compensated by the potential for reductions in HIV transmission due to suppressed or reduced HIV viral loads. The current conundrum for most clinical sites involves how to obtain funding for cell phones and plans. Funding for staff, psychological counseling, and medications are typically built into the system of care. Thus, the uptake of nontraditional services, such as the provision of cell phones and service by insurance providers will likely

require confirmation in larger studies to assess whether the provision of phones and plans as an incentive is critical to the success of the intervention. Future work could benefit from formal cost/benefit calculations.

Future analyses of this study will explore how this intervention impacted variables, such as depression, substance abuse, service utilization, social support, coping and adherence self-efficacy, but the small sample size will preclude determining for which subset of patients this intervention is best suited. Future studies will need to ascertain if the provision of the incentive of the cost of a cell phone and plan is critical to the success of the intervention, or if it is as feasible and effective to require youth to utilize their own phones and plans. We also need to determine for whom it is feasible and effective to utilize less costly interventions, such as text messaging. Other outstanding questions include the duration of calls required by individual subjects, whether calls can be tapered and increased as needed, whether training of AFs in motivational interviewing or cognitive based strategies increase both short term and long term adherence, and lastly, how we help youth for whom this intervention is not helpful.

The present study has several limitations. The study had a small sample and generalizability of the findings is unclear. Relatedly, inclusion and exclusion criteria at participating sites in the study resulted in an extremely nonadherent study population, and it is unclear if this intervention would have resulted in different findings with respect to feasibility and acceptability in more moderately nonadherent youth. In addition, the present study did not include a comparator arm of youth who did not receive the incentive of free cell phones and/or plans as part of the intervention, we are also not certain the degree to which provision of cell phone in our intervention contributed to (perceptions of) acceptability and feasibility. Another limitation was that subject exit interviews were conducted by AFs, rather than a third party exit interviewer or administered by an anonymous questionnaire, and could have created bias towards positive assessment of the intervention experiences. Finally, parts of the cell phone technologies that were included in the current study are continually evolving. Future research might examine if more youth-friendly options (e.g., video chatting, avatars) on cell phone would contribute to intervention acceptability, feasibility, and effectiveness.

Conclusions

Providing cell phone support to youth nonadherent to ART was found to be feasible and acceptable. Reproducing this study in larger populations may determine for whom this intervention is best suited and how long to continue the intervention. Developing funding mechanisms should be prioritized given the high cost of ART nonadherence both in terms of disease progression and HIV transmission.

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Author Disclosure Statement

No conflicting financial interests exist. The views and opinions expressed in this report are those of the authors and should not be construed to represent the views of the National Institute on Drug Abuse or the US governmnet.

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