

ATN 078

**The Acceptability and Feasibility of a Cell Phone
Support Intervention for Youth Living with HIV
with Nonadherence to ART**

Conflict of Interest

- No Conflicts
- Thanks to the ATN for funding this study

Protocol Team

- Protocol Chair- Marvin Belzer MD
- Protocol Co-chair- Johanna Olson MD
- Protocol specialist- Sarah Thornton
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- Protocol Team: Sylvie Naar-King, Leslie Clark, Shoshana Kahana, Karen Kolmodin-MacDonell

Introduction: Nonadherence

- Youth adherence to Antiretrovirals is often poor and yet is critical to long-term health, secondary prevention of transmission and prevention of resistance.

Youth Adherence Interventions

- PACTG 1036B- Directly Observed Therapy (Guar et al 2010)
- ATN 004- Motivational Interviewing (Naar-King 2009)
- Daily Personalized Text Messages (Dowshen and Garofalo 2012)
- Cell Phone reminders (Puccio and Belzer 2006)

ATN 078 Presentation Objective

- Evaluate the acceptability and feasibility of providing cell phone support to youth nonadherent to ART

Methods of Efficacy Study

- Longitudinal Experimental Design
- Randomized 40 subjects ages 15-24 to 24 weeks of cell phone support vs. usual care
- Subjects recruited from 5 ATN sites
- Primary Adherence facilitators (BA level case managers/research personal and not RN or licensed therapists) were provided standardized training

Inclusion Criteria

- Documented HIV-positive infected age 15 to 24 years
- Enrolled in care at an AMTU or affiliated site.
- History of non-adherence to one or more components of antiretroviral therapy, defined as meeting one of the following criteria:
 - 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=14
 - Discontinued HAART in the past while documented to be less than 90% adherent during the most recent antiretroviral treatment; N=22
 - Agreed to initiate antiretroviral treatment in the past, but never initiated. N=1
- Able to speak and understand English.
- Willing to provide informed consent or assent.

Procedures- cell phone plans

- Intervention subjects either used own phone and received \$45/month deposited directly to their cell phone account or received cell phone plan and phone that provided at least 400 anytime minutes, free nights and weekends, and unlimited texts. Sites tried to use plans that minimized the risk for supplemental charges and these were not a problem during the study.
- Youth with less than 80% adherence to calls for two consecutive months were dropped from the intervention and cell phone incentive was terminated.
- Youth using own service with <80% adherence to calls for one month had to switch to study provided phones to ensure phone access.

Phone Calls

- Calls were made Monday through Friday (QD or BID corresponding to medication dosing)
- Time for calls was negotiated but tried to be 1 hour post taking medication
- Scripted calls averaged 3-5 minutes and addressed (**The Intervention**):
 - Confirmation that youth took their medication
 - Discussing new or ongoing life problems
 - Reinforcing prioritizing medications
 - Scheduling referrals as needed (MD, case manager, therapist, etc.)
 - Appointment reminders
 - Assessing service utilization

Measures

- During calls AFs collected:
 - 1. Call completion
 - 2. Did youth take medication prior to or during call
 - 3. Reasons why youth didn't take medication (barriers)
 - 4. Problem solving provided
 - 5. Service utilization assessed on Mondays and Fridays
- Subject exit interviews
- AF exit interviews

Demographics

	Overall N=37	Intervention 19	Control 18	P Value
Age	20.43	19.8	21.0	0.14
Male	23	11	12	0.73
Female	14	8	6	
AA Race	26	13	13	1.0
Hispanic	7	3	4	0.69
Transmission	17 Perinatal 20 Behavioral	12 7	5 13	0.09
Log 10 viral	4.54	4.39	4.71	0.31

ATN 078- efficacy results

- Significant improvements in self-reported >90% adherence (last 7, 30 or 90 days) over 48 weeks
- Absolute self reported adherence in last 30 days went from 38% at baseline to 78% at week 24 and 74% at week 48 (P=.007)
- Intervention group had significant drop in viral load compare to controls at 24 (1.7 log, Cohen's d= 1.28) and 48 weeks (1.0 log, Cohen's d= 0.8)
- (Belzer et al 2013 AIDS and Behavior)

Feasibility Intervention Completion

Premature Discontinuation from Intervention related to call nonadherence (7/19)

Non-Adherence to phone calls $\geq 20\%$ for 2 consecutive month (N=5)

- **Week 8 (n=1)**
- **Week 12 (n=4)**

Missing calls for 10 consecutive business days (N=2)

- **Week 6 (n = 1) Death**
- **Week 12 (n=1) Incarceration**

Call Completion Rates

	Overall	Once-a-day Call	Twice-a-day Call	p-value
Number of first completed calls				
Yes	84.0%	85.2%	78.4%	0.0050
Was the first call delayed?				
No	94.0%	94.4%	92.2%	0.2781
Did Participant take medication prior to call?				
Yes	93.7%	93.92%	92.7%	0.4597

Cell Phone Plan

	Personal Phone	Study Phone
Week 0	11 (57.9%)	8
Week 6	8 (53.3%)	7
Week 12	6 (37.5%)	10
Week 24	4 (33.3%)	8

Participant Exit Interviews N=16)

- Talk to AF was easy/very easy 94%
- Getting calls made taking my meds easy/very easy 88%
- Talking to AF improved my motivation 81%
- Call length was just right 94%
- Would you like calls to continue past 24 weeks 81%
- Would you have preferred weekend calls 63%
- Would you have liked calls to have tapered off 56%
- Would you recommend this intervention to a friend 100%

- What was most helpful about the calls:
 - 1. Reminders 75%
 - 2. AF providing strategies 13%
 - 3. Relationship with AF 13%

AF Exit Interviews N=13

- Was the training adequate ? 100%
- What additional skills training would be helpful?
 - Problem solving 54%
- Did the youth utilize problem solving discussions ? 92%
- Were youth eventually able to problem solve on own? 85%
- Did youth need additional time from you? 38%
- Were calls intrusive at times? 31%
- What was most difficult about the intervention?
- Scheduling calls to accommodate youth schedule 69%

- Who is the best person to take on role of AF?
- Social worker 46%
- Case manager 23%
- peer advocate 23%

Intervention Costs

- Calls averaged 3-7 minutes (only one AF took longer than 5 minutes)
- Intervention would require about 1 hr/week/patient (\$20/week for case manager?)
- Cell phone plans varied from \$25-74/month but currently can get plans for \$45-50/month for unlimited phone/text/data

Conclusions

- 24 week intervention was completed by 12/19 (very nonadherent subjects). Unclear if more flexibility on adherence to intervention might improve percent sticking with the intervention without reducing impact.
- Participants and AF's found this intervention acceptable but unclear if patients would accept intervention without phone/plan incentive
- \$125-150/month to assist youth nonadherent to medications is extremely cost effective in the light of medication costs, as well as cost of disease progression or HIV transmission

Thanks and Questions!!!

- Thanks to the CAB who provided excellent input into how to operationalize the study, especially around cell phone plans.
- Thanks to the subjects!
- Thanks to all the adherence facilitators and site study coordinators!
- Thanks to our protocol team!