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A Randomized Controlled Trial of a Text Messaging Intervention to Promote Virologic Suppression and Retention in Care in an Urban Safety-Net HIV Clinic: the Connect4Care (C4C) Trial

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Background

- Text messaging has been shown to significantly improve antiretroviral adherence and virologic suppression in sub-Saharan Africa
- Focus in U.S. has been on ART adherence in sub-groups (substance users, MSM, youth)
- Less is known about texting to support engagement in HIV care for safety-net clinic populations



C4C Intervention

- Low-effort, clinic-wide, easily scalable
- Foster a sense of connectedness to one's health and health care
 - Promote intrinsic motivation for engaging in HIV care
 - Support enhanced psychosocial adjustment
 - Provide information about resources for healthy living



C4C Intervention Development

- Drew upon
 - Text messaging intervention literature
 - A conceptual text messaging framework that emphasized multi-faced components, interactivity, frequency, timing, and tailoring
 - Behavioral models used to understand HIV care engagement
- Focus groups with clinic patients and staff
- Messages created by a multidisciplinary team
- One-month open pilot (n=10) for refinement



C4C Intervention Messages

Table 1 Intervention domains and sample text messages

Domain	Sample text message
Improving a sense of social support	Stay strong. The clinic cares about you.
Ameliorating negative affect	Everyone feels sad sometimes. Remember you can talk to your provider about depression.
Bolstering positive affect and coping	Smile, breathe, and go slowly.
Fostering empowerment	Be active in your health care. Keep your scheduled appointments.
Supporting healthy behaviors and health maintenance	Invest in your health. Remember to get your Pap smear.
Emphasizing the value of antiretroviral adherence and persistence	Taking meds? They help, even if you can't tell they are working.



Study Design

- Randomized controlled trial
- 1:1 allocation to 12 months of C4C study exposures
- Randomization stratified on whether individuals were newly diagnosed with HIV, i.e., diagnosed in past 12 months
- Repeated measures design: outcomes assessed at 6 and 12 months



C4C Study Exposures

Control

-Monthly check-in text message from study that asked for response

Active

-Monthly check-in text message from study that asked for response

-Intervention text messages three times per week; participants asked to respond at least once per week

Standard of Care Background for Both Arms

Primary care appointment reminder calls from clinic
Reminder text messages 48 hours prior to appointment

Automated platform provided by Mobile Commons by Upland Software



Study Setting

- Recruitment at Ward 86, the safety-net HIV clinic for San Francisco
 - 2,500 patients
 - ~85 % male (mostly MSM), 25% black, 20% Latino
- Enrollment and study questionnaires (baseline and follow-up) conducted at a community research site so as not to influence attendance at clinic appointments



Eligibility Criteria

- HIV-infected
- Receiving primary care at Ward 86
- English-speaking
- Have a cell phone, able to read a text message, willing to send/receive up to 25 text messages per month
- Viral load >200 copies/mL in past month
- At high-risk for continued viremia
 - New to clinic (no more than 2 primary care visits)
 - OR
 - Poorly retained (in care for at least 12 months with either ≥ 1 missed visit or lack of six-month visit constancy)



Outcomes

- **Primary: Virologic Suppression**
 - Viral load <200 copies/mL at 12 months
- **Secondary: Retention in Care**
 - Visit adherence rate: kept/scheduled visits over 12 months



Quantifying Exposures

- % of text messages successfully received (sent/sent +fail)
- Self-reported service interruption
- Response to study text messages



Study Follow up

- Study Visits (0, 6, 12 months)
 - Questionnaires
 - HIV viral load drawn at 6 and 12 month visits if no value available in electronic medical record (EMR) in past 28 days
 - Abstraction of primary care appointment attendance from EMR
- Check-in Calls (3 and 9 months)



Statistical Analysis

- Intent to treat, adjusting for stratification factor
- Primary outcome
 - Generalized estimating equation modified* Poisson model to estimate 12-month mean (95% CI) virologic suppression rate by arm and relative risk between arms
- Secondary Outcome
 - Generalized estimating equation Poisson model to estimate 12-month mean (95% CI) visit adherence by arm and relative rate between arms

*With robust variance estimation



August 2013 – November 2015: Assessed for Eligibility = 569

Excluded = 339

- Inclusion criteria not met: = 224
- Declined = 81
- Eligible but not enrolled = 34

Randomized = 230

Allocated to control = 114

Allocated to intervention = 116

6 Month Follow Up
LTFU = 9
Declined = 4
Moved = 3
Deceased = 2
Incarcerated = 1

6 Month Follow Up
LTFU = 5
Withdrew = 2
Treatment = 2
Moved = 2
Incarcerated = 2
Deceased = 1

12 Month Follow Up
LTFU = 8
Moved = 5
Declined = 3
Deceased = 2
Incarcerated = 2

12 Month Follow Up
LTFU = 8
Withdrew = 2
Moved = 2
Incarcerated = 2
Deceased = 2

Included in Primary Analysis = 107[†]

6 month viral load data = 99

12 month viral load data = 92

Included in Primary Analysis = 110^{†*}

6 month viral load data = 108

12 month viral load data = 100

[†] Includes participants with EMR viral load data

* Includes 3 participants who withdrew from text messages



Baseline Characteristics	Total (N=230)	Control (N=114)	Intervention (N=116)
Median age, years (IQR, range)	45 (36-51, 21-74)	44 (35-51, 21-74)	45.5 (38-50, 22-65)
Male Gender	83%	82%	84%
Race/Ethnicity			
White	35%	35%	34%
Black	31%	31%	31%
Latino	21%	24%	18%
API/Mixed Race/Other	13%	10%	16%
Non-Gay/Lesbian Sexual Orientation	51%	52%	50%
No money for basic necessities daily, weekly or monthly	51%	52%	51%
Homeless in Past 6 Months	48%	49%	47%
IDU Ever*	52%	52%	52%
IDU Past 30 Days*	23%	22%	24%
Stimulant Use in Past 6 Months*	66%	65%	67%
Hazardous Drinker (AUDIT)	23%	23%	22%
Problem/Dependent Drug User (TCU)	36%	38%	35%
Current Depression (CES-D \geq 16)	68%	67%	69%
Median Years Since HIV Diagnosis (IQR)	11 (5-19)	11 (5-20)	11 (4-18)
Median CD4 Cell Count (range)*	351 (3-1041)	335 (3-1041)	353 (7-1019)
Currently Taking ART	75%	75%	75%
Care Status			
Poorly Retained	75%	77%	72%
New to Clinic Not New Diagnosis	14%	12%	16%
Newly Diagnosed	11%	11%	12%

*Missing data: IDU ever (n=1), IDU past 30 days (n=8), stimulant use (n=1), CD4 cell count (n=9) and current ART usage (n=5)



Technology Use at Baseline

Type of Phone	
iPhone	38 (17%)
Android	118 (51%)
Other	74 (32%)
Type of Plan	
Month to Month/Prepaid	145 (63%)
Contract	41 (22%)
Assurance Wireless/Other	34 (15%)
Phone Service Cut Off in Past Six Months	84 (37%)
Comfortable Sending Text Messages	
Extremely/Quite A Bit	180 (77%)
Somewhat	32 (14%)
A Little Bit/Not At All	18 (8%)
Do Not Have Email Address	44 (19%)
Did Not Use Internet At All in Past Six Months	31 (13%)



Results: Primary Outcome

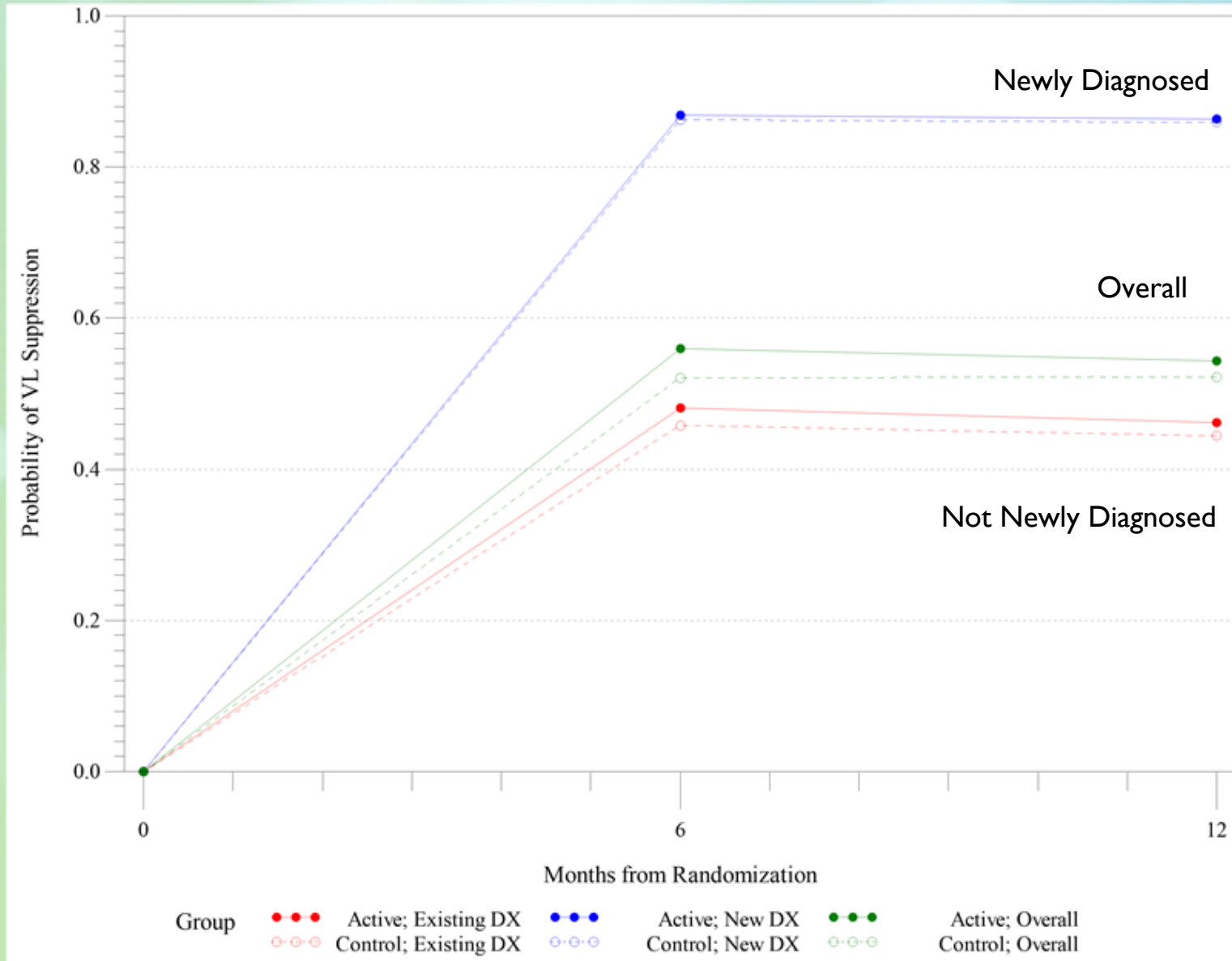
Viral Suppression at 12 Months

	Active (n=100)	Control (n=92)	Relative Risk (95% CI)	p
Overall, unadjusted, n(%)	51 (51.0%)	45 (48.9%)		
	% Suppressed (95% CI)			
Overall, adjusted*	54.4 (43.2-63.3)	52.2 (40.5-61.6)	1.03 (0.78-1.36)	0.82
By Stratification Factor				
Newly Diagnosed (n=22)	86.4 (64.1-94.8)	85.9 (62.5-94.7)		
Not Newly Diagnosed (n=170)	46.2 (34.7 -55.7)	44.4 (32.5-54.2)		

*Poisson GEE repeated measures model, adjusted for stratification factor



Virologic Suppression at 6 and 12 Months





Results: Secondary Outcome

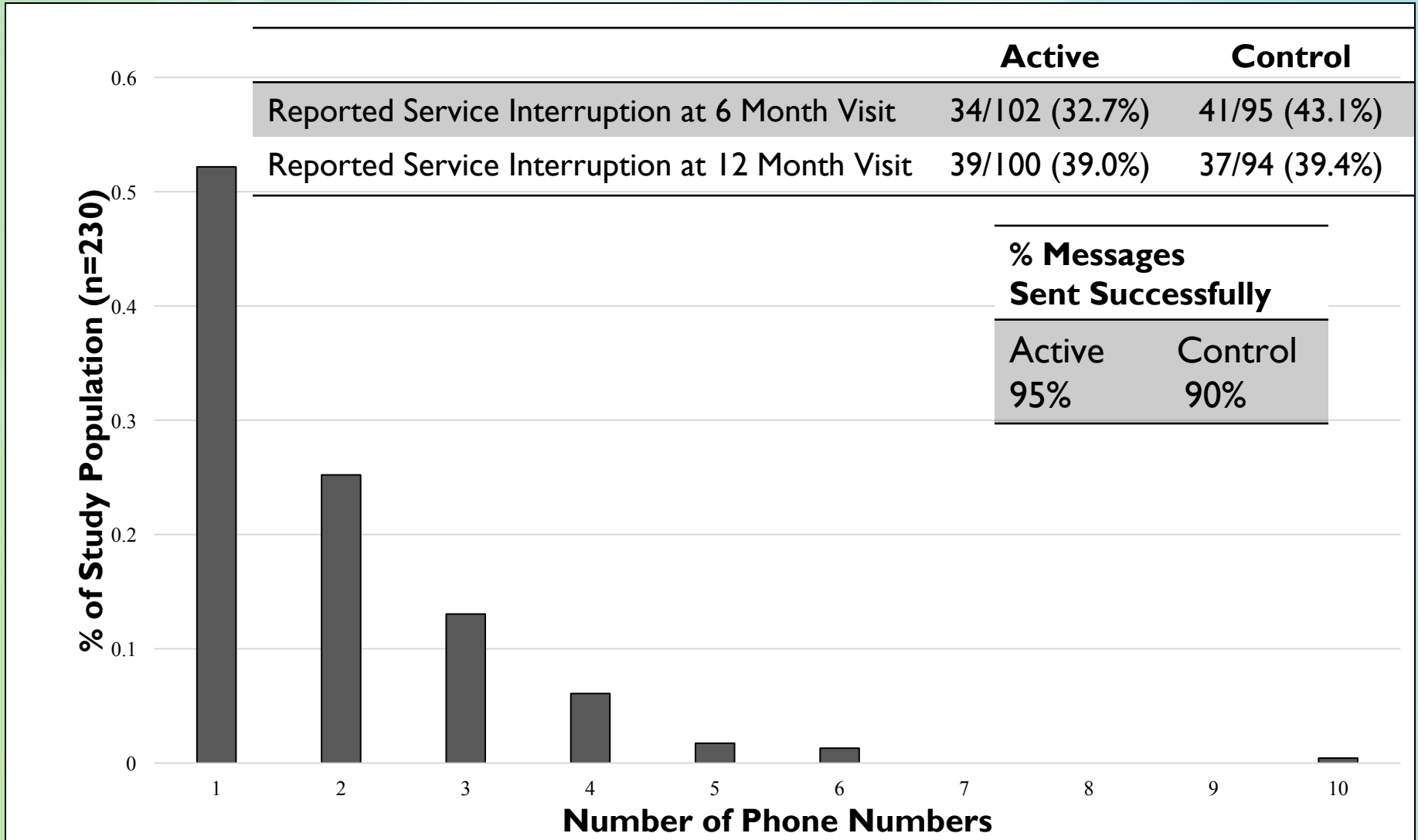
Mean Primary Care Visit Adherence at 12 Months

	Active (n=116)	Control (n=114)	Relative Risk (95% CI)	<i>p</i>
	% Visits Kept (95% CI)			
Overall, adjusted*	52.0 (45.4-59.6)	53.9 (47.1-61.7)	0.97 (0.80-1.17)	0.71
By Stratification Factor				
Newly Diagnosed (n=22)	53.6 (43.2-66.3)	55.5 (44.6-69.0)		
Not Newly Diagnosed (n=170)	51.8 (45.1-59.5)	53.7 (46.8-73.6)		
Median Number of Scheduled Visits (min, max)	7 (0,17)	7 (0,20)		

*Poisson GEE repeated measures model, adjusted for stratification factor

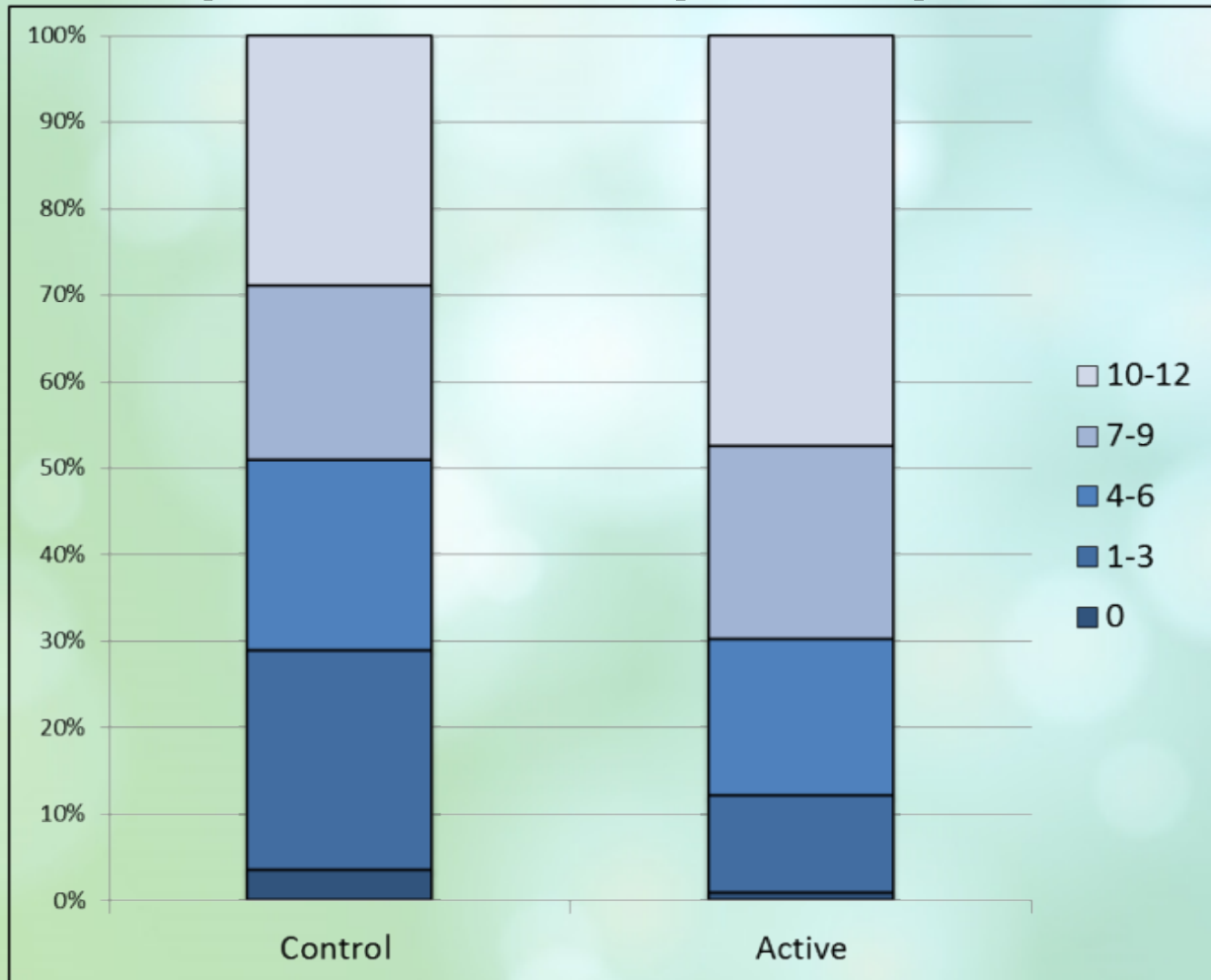


Number of Phone Numbers During Study





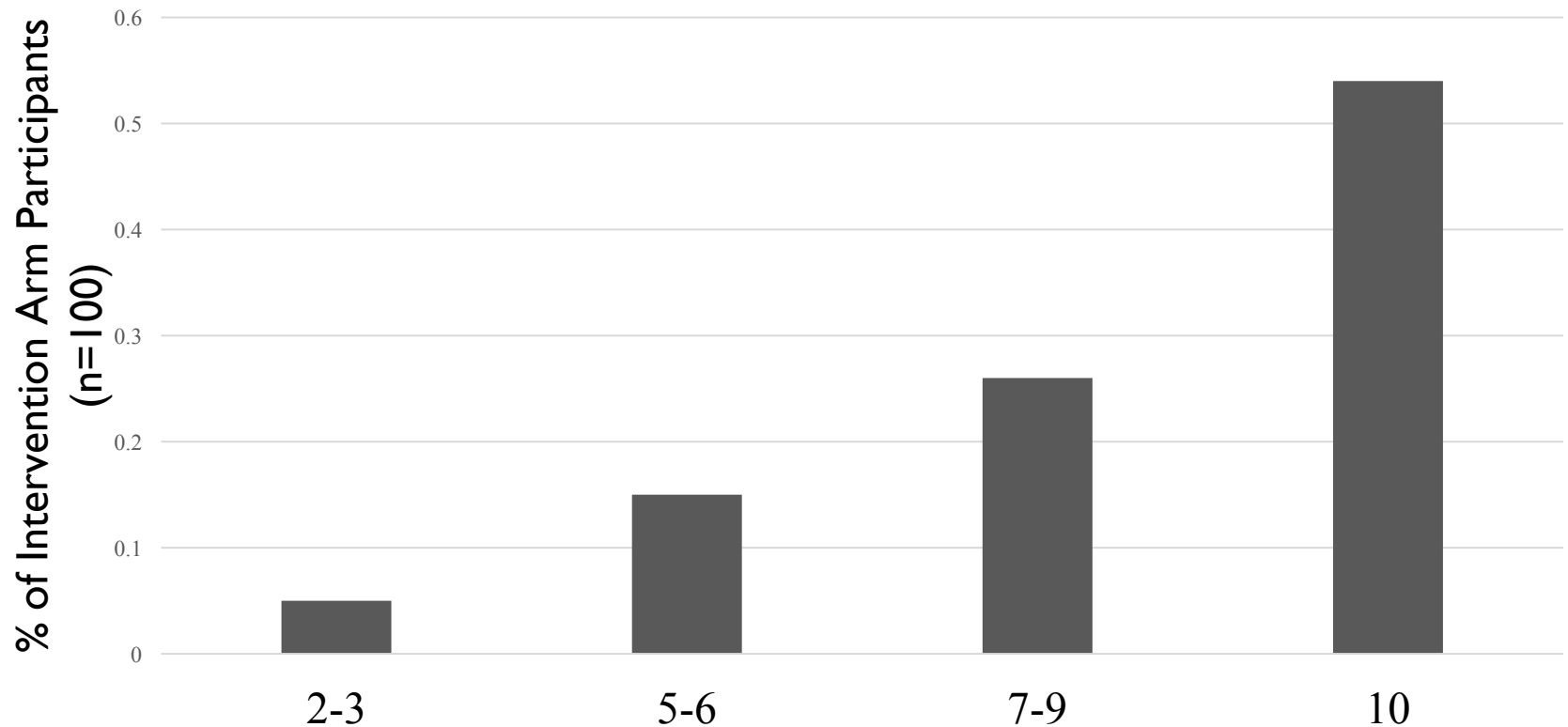
Distribution of Number of Months With Response to Any Study Text





Acceptability of Intervention Messages

On a scale of 0 – 10, how likely would you be to recommend the text messages to a friend?





Participant Perspectives on Intervention Text Messages

- “Made me feel like I wasn’t alone – someone was texting me about my health”
- “It seemed like people were concerned about me and that made me feel better”
- “It made me feel like somebody was there, that I wasn’t just somebody at the clinic but that somebody was there to care for me, that there were nice people in the world.”



So Why Didn't It Work?

I don't have an actual home right now, I'm bouncing around a lot, and sometimes I have my meds with me, sometimes I don't. Other times I have [them] with me, I just forget to take them....

I know some of the text messages were like, "Make sure you take your meds around the same time, blah, blah." Well, my life never revolves on the schedule. So trying to take something at the same time is a little difficult. But with moving, I also was working two full-time jobs, I really didn't have time to go see my doctor. So I just kind of put that on the back burner, and it just kind got lost back there.

When my friend that jumped in front of BART, it was like, well, why are you not taking your meds when you're doing virtually the same thing ...And it's like I'm consumed by something that just gets placed on the back burner. I know it's important and all...but it's really hard to be throwing out your ex for beating your dog...It's like "Oh, I'm going to take my meds now?!"



Conclusions

- Retention in study and satisfaction with intervention texts was relatively high, but there were no significant differences in virologic suppression or retention in care by study arm
- Virologic suppression was higher for newly diagnosed individuals, although the intervention effect was similar
- Interruptions in phone service (loss of phone, inability to pay for service) were common and turnover in phone numbers was high



Implications

- Mobile phone interventions with vulnerable urban HIV-infected populations in the U.S. may be stymied by lack of continuous phone service and up to date telephone numbers
- Virologic suppression in individuals with a history of poor retention in care is challenging
- Intensive, tailored, multi-pronged efforts are needed to support this group in achieving virologic suppression



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