

SMS interventions to improve antiretroviral therapy adherence: A pilot randomized controlled trial

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Disclosures

- I am/have been a paid consultant for the International AIDS Vaccine Initiative, the World Health Organization, and FHI 360
- I receive funding from NIMH, NIAID, and the Gates Foundation
- I partner with several technology companies, but receive no financial support from them



Background



- Cellular technology may improve adherence; however, results to date have been mixed

(Lester, Lancet, 2010; Pop-Eleches, AIDS, 2011; Mbuagbaw, PLoS One, 2013; Shet, BMJ, 2014)

- Real-time adherence monitoring has been shown to be feasible and acceptable *(Haberer, AIDS Behav 2010; Haberer, AIDS, 2013)*

- Social support known to be important for adherence *(Ware, PLoS Med, 2009)*



Questions

- Can real-time detection of adherence lapses improve on the intervention effect of SMS reminders?
- Can social support be triggered by SMS technology?



Design

Individuals initiating ART
All receive real-time adherence monitoring



Months	Arm A (scheduled SMS + real-time monitoring)	Arm B (triggered SMS + real-time monitoring)	Control (real-time monitoring only)
1	Daily SMS	SMS for missed doses	No SMS
2	Weekly SMS		
3			
4	SMS for missed doses + social supporter notification (48 hr lapse)	SMS for missed doses + social supporter notification (48 hr lapse)	
5			
6			
7			
8			
9			

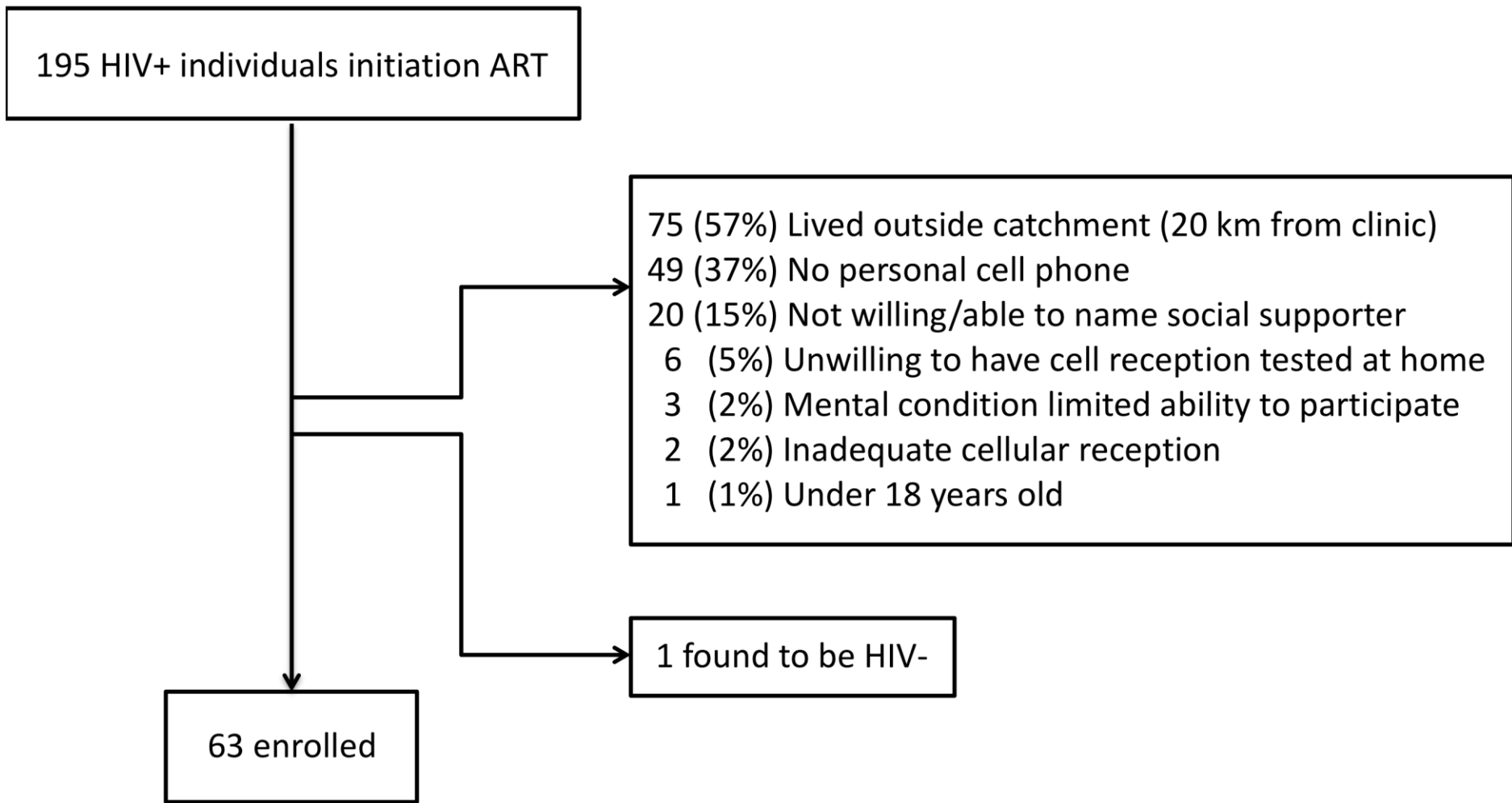
Primary outcome: Adherence (median, <80%, 48+ hr and 96+ hr gaps)

195 HIV+ individuals initiation ART

75 (57%) Lived outside catchment (20 km from clinic)
49 (37%) No personal cell phone
20 (15%) Not willing/able to name social supporter
6 (5%) Unwilling to have cell reception tested at home
3 (2%) Mental condition limited ability to participate
2 (2%) Inadequate cellular reception
1 (1%) Under 18 years old

1 found to be HIV-

63 enrolled



Participant characteristics

	N (%) or median (IQR)	p-value for comparison among arms
Female	40 (65%)*	0.003
Median age (years)	25 (30-35)	0.26
Education		
None	5 (8%)	0.16
Primary	36 (58%)	
Greater than primary	21 (34%)	
Able to read English or Runyankole	60 (97%)	1.00
Median CD4 count (cells/mm ³)	309 (231-397)	0.21
ART regimen		
TDF-3TC-EFV	60 (97%)	0.77
AZT-3TC-NVP	2 (3%)	
Severe food insecurity	23 (37%)	0.46
Depression (Hopkins)	30 (48%)	0.69
Alcohol (AUDIT-C)	14 (23%)	0.93
Social support score (Duke)	3.1 (2.8-3.4)	0.95
Stigma score (Kalichman)	3 (2-5)	0.94

*Arm A: 15 (71%), Arm B: 7 (35%), Control: 18 (86%)

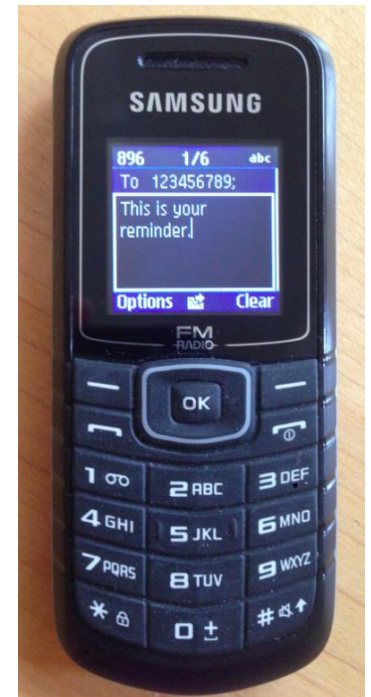
Participant characteristics

- Arm A: 21
- Arm B: 20
- Control: 21

- Median follow-up: 8.9 months (8.7-8.9)

Summary of SMS

Total SMS sent: 5,415		
Sent per protocol	3,436	63%
Sent unnecessarily	1,935	36%
SMS not sent	44	1%



Adherence summary

Arm	Mean (SD)	Median (IQR)
A (Scheduled SMS + real-time monitoring)	91% (9)	92% (88-99)
B (Triggered SMS + real-time monitoring)	79% (18)	84% (66-93)
Control (real-time monitoring only)	79% (22)	90% (72-93)

Total dataset: 16,328 participant days

Primary analysis: Data removed for the 1 ineligible participant and staff device openings (161 events)

Secondary analysis: Data also removed for probable unmonitored time (779 days, 5%). Of these, 48% were due to device non-use and 52% were due to technical problems (e.g., low battery).

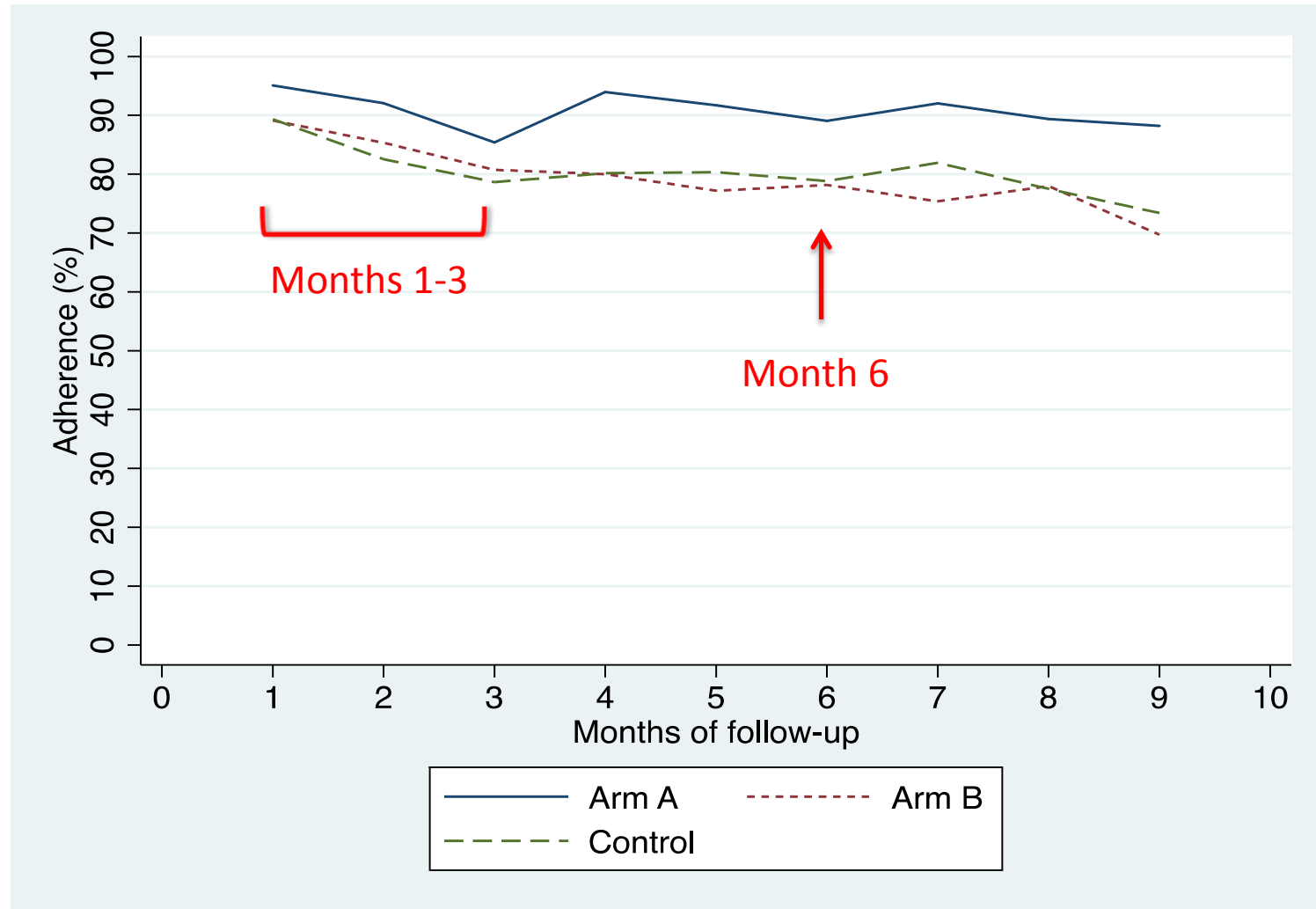
Intervention effects

GEE regression analysis

Outcome	Model	Arm	Effect	p
Percent adherence	Linear	A	11.13	0.021
		B	-0.74	0.898
		Control	<i>ref</i>	
Adherence <80%	Logistic	A	0.35	0.036
		B	1.06	0.898
		Control	<i>ref</i>	
48+ hour gap	Poisson	A	0.59	0.017
		B	0.95	0.790
		Control	<i>ref</i>	
96+ hour gap	Poisson	A	0.27	0.000
		B	0.72	0.231
		Control	<i>ref</i>	

Findings were similar when removing probable unmonitored time (secondary analysis) and when adjusting for gender.

Effects over time



Effect over time significant for all arms (Months 1-3) and overall (Months 1-9) for Arm B and Control only ($p < 0.05$)

Limitations

- Real-time adherence monitoring may have influenced adherence, thus making it difficult to distinguish effects between arms
- Small sample size
- Experience with technology and social support may vary in other settings

Conclusions

- Highly feasible intervention
- Adherence improved with daily/weekly scheduled SMS at ART initiation
- No clear effect of triggered SMS for missed doses; however,
 - There was a trend toward decrease in adherence gaps
 - Addition of SMS to social supporters may have stabilized adherence
- Unknown how real-time monitoring itself influences adherence

Conclusions

- Meaning of SMS explored through qualitative interviews in this study
 - Norma Ware: oral presentation Monday 11:30
 - Emily Pisarski: oral presentation Monday 10:15, poster #42
 - Melanie Tam: poster #44
- Effect with Arm A (scheduled SMS) suggests daily/weekly SMS may help develop a habit of good adherence
- SMS for missed doses may have been viewed less favorably than daily/weekly SMS

Next steps

- Further evaluation of the social supporter aspect of the intervention is ongoing
- Future research needed to confirm these findings; ideally powered by viral load to discern effects of SMS and real-time monitoring (i.e., no real-time adherence monitoring in the control group)

Acknowledgements

- Funding: R34MH100940
- Study participants
- Additional study team members: Justus Ashaba, Judith Namanya, Moonlight Sheila, Moran Owembabazi
- Wisepill Technologies, Yo! Voice Solutions, Dimagi