

The Uganda WiseMama Study: A randomized controlled trial assessing real-time feedback to improve ART adherence among HIV- positive pregnant and postpartum women

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Abstract #380

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Conflict of Interest Disclosure

Lisa J. Messersmith, PhD, MPH
has no real or apparent
conflicts of interest to report.

Background

- High HIV prevalence in Uganda:
 - 8.1% among women of childbearing age; 7% in general population.
 - Option B+ is current standard of care in Uganda
 - 95% of HIV positive pregnant women on ART by 2015
- For full benefit, high ART adherence is critical for women's health and PMTCT.
- HIV+ pregnant and postpartum women (PPPW) face unique challenges related to retention in care and adherence.

Given the need for ART adherence support among PPPW, we wanted to know...



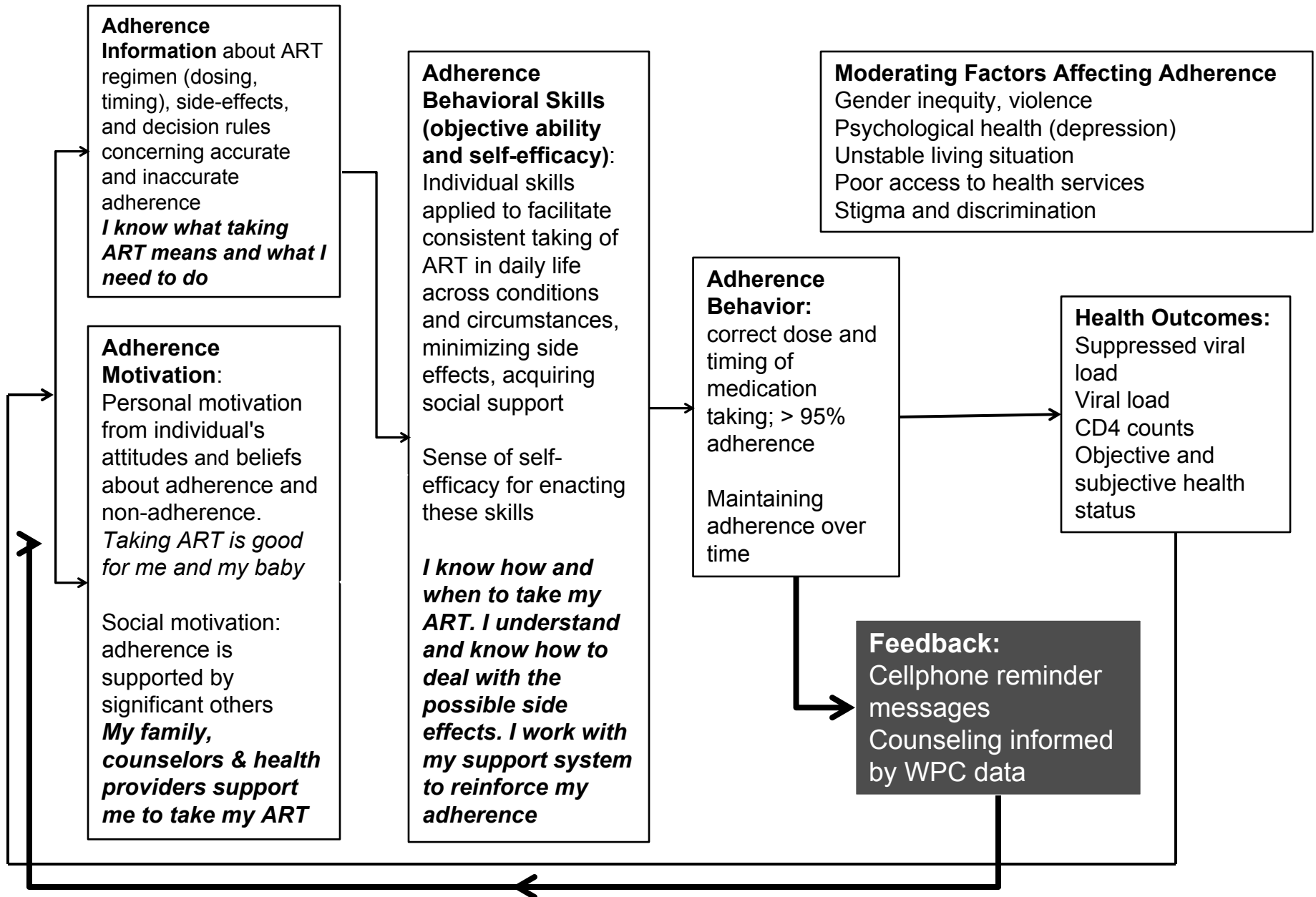
Could triggered reminders
via wireless pill container
(WPC) combined with
WPC data-informed counseling
improve ART adherence in this
vulnerable population?

The Uganda WiseMama Study

Primary Objective

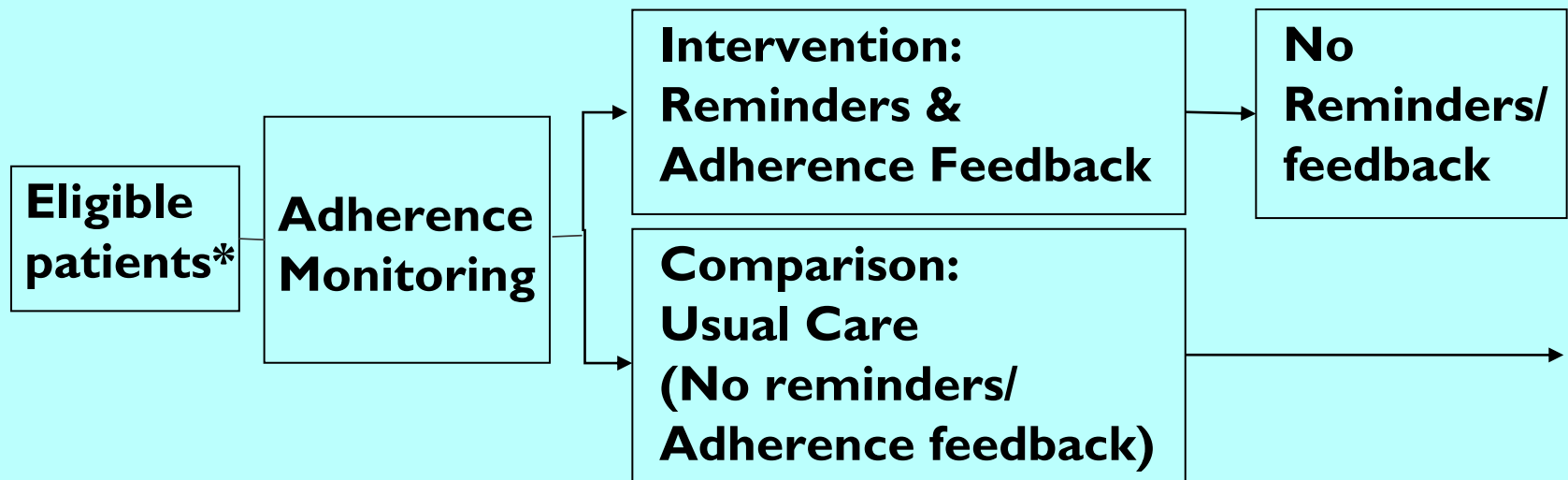
- To generate efficacy data of real-time feedback plus data-informed counseling on ART adherence among HIV-positive pregnant and postpartum women

Information-Motivation-Behavioral Skills Model



WiseMama study design (‘real-time feedback’ intervention)

Intervention design and timeline



Month 0:
Enrollment in
Study

Month 1:
Randomization of
Enrolled Patients

≈ Month 7:
End of Active
Intervention
(postpartum M3)

Month 10:
End of Follow-up
Period
Postpartum M6

*Pre-intervention
Period
(1 month)*

*Intervention
Period
(≈ 6 months)*

*Post-Intervention
Follow-up Period
(3 months)*

*HIV+
pregnant
women

Methods: Enrollment & Randomization



- 165 ART-naïve pregnant women, >18 years, 12-28 weeks gestation, attending 2 antenatal clinics:
 - Entebbe Grade B Hospital
 - Mityana District Hospital
- Once daily regimen: (tenofovir, 3TC, efavirenz)
- All women given a WPC for daily use for ~ 8-10 months total

Intervention vs. Comparison Arm

Intervention Arm

- SMS reminder to cell phone if WPC was NOT opened within 2 hours +/- dose time
- Patients chose one of 10 possible reminders e.g.:
 - *Time for prayers*
 - *Hello, it's time*
- Wisepill data used in monthly counseling sessions
 - Report of adherence behavior in previous month
 - Patients <95% adherence: counseling focused on improving adherence
 - Patients with $\geq 95\%$ adherence: counseling encouraged but not required

Comparison Arm

- No reminder messages; Wisepill report NOT shared with patient and no data-informed counseling

Methods: Adherence Measures (Analyses using ITT approach)

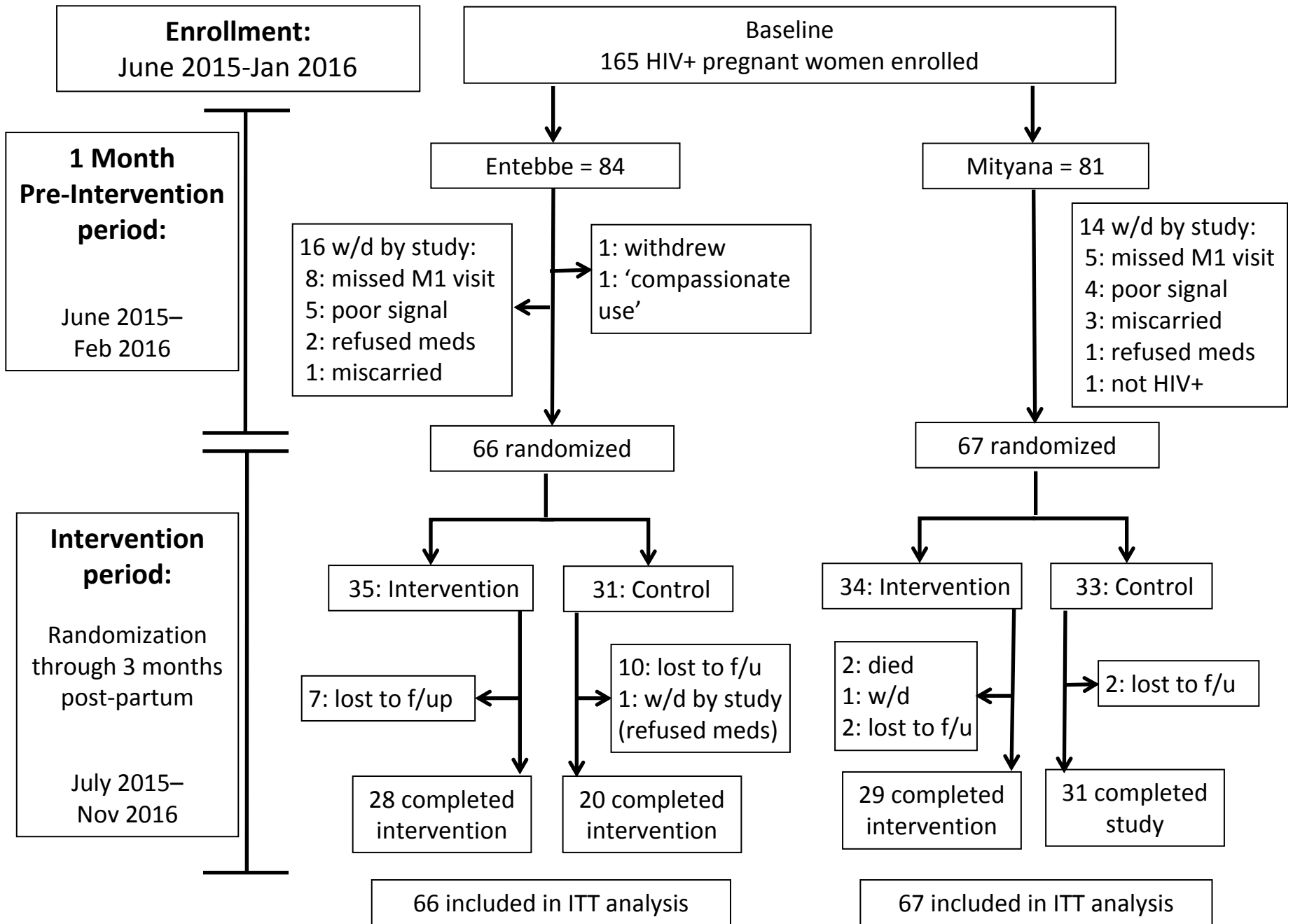
$$\text{Adherence measure ('on time' measure):}$$
$$\frac{\# \text{ doses taken } \pm 2 \text{ hours of scheduled time}}{\# \text{ prescribed doses}}$$

1. Mean adherence

- Over entire intervention period
- Over pre-delivery and post-delivery periods
- In final 30 days of the intervention

2. Proportion whose mean adherence reached selected thresholds (in each of the above periods):

- $\geq 95\%$ adherent
- $\geq 80\%$ adherent

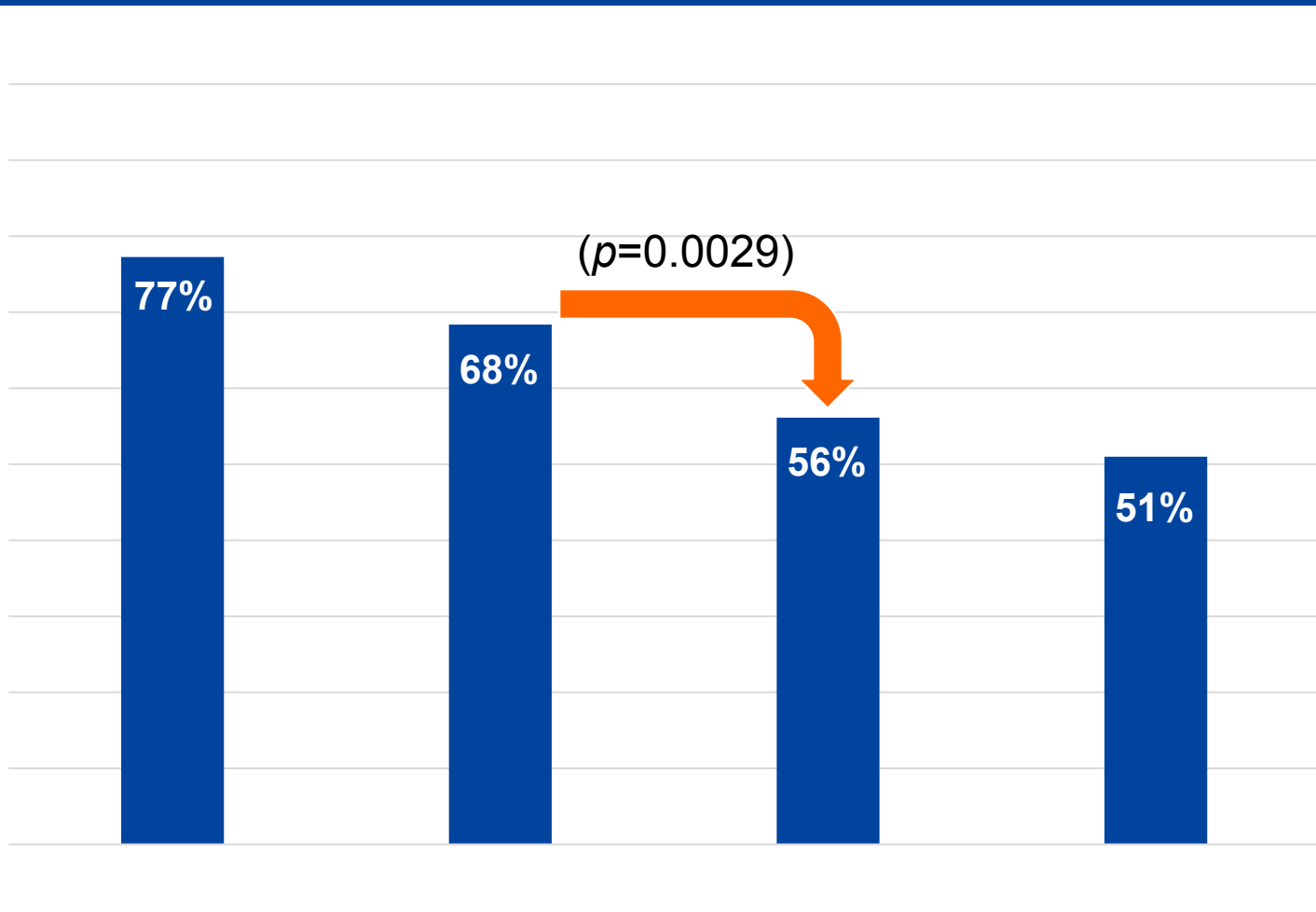


Characteristics at randomization (N=133)

Table: Characteristics at randomization, by arm (n=133)

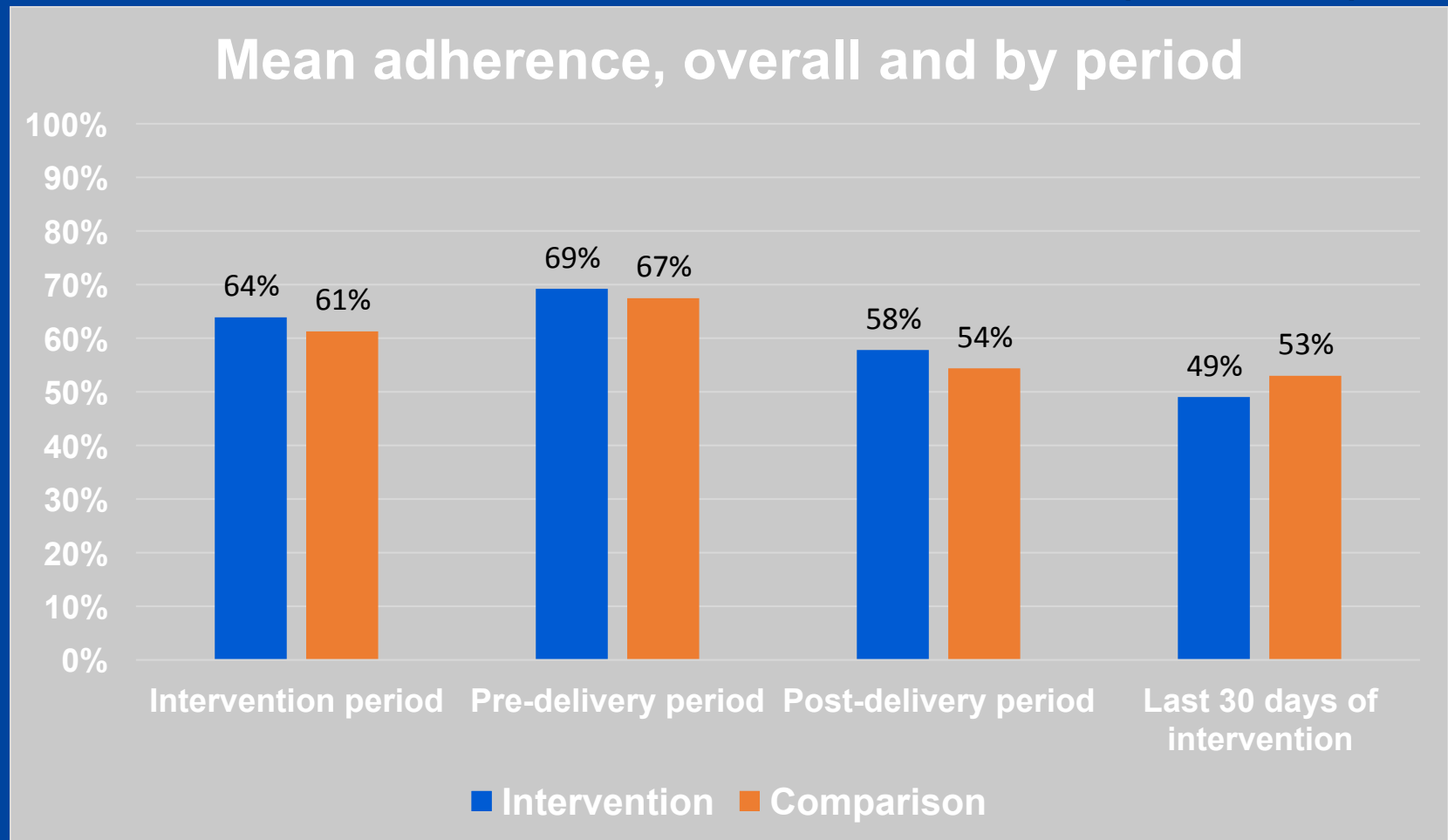
	Intervention Arm (n=69)		Comparison Arm (n=64)		p-value
	Mean/%	(SD)	Mean/%	(SD)	
Age (years)	25.6	6.8	25.2	4.6	0.73
Gestation age (in weeks)	20.4	(5.0)	21.9	(4.2)	0.06
Married	71	(45.7)	76.6	(42.7)	0.47
Education level completed					
Primary	44.9	(50.1)	39.1	(49.2)	0.50
Secondary	49.3	(50.4)	54.7	(50.2)	0.54
First pregnancy	24.6	(43.4)	31.3	(46.7)	0.40
Multiparous women, previous pregnancies	2.2	(1.4)	3.0	(2.1)	0.02
Someone else knew status at enrollment	43.5	(49.9)	40.6	(49.5)	0.74
Disclosed to husband/partner at enrollment	31.9	(46.9)	23.4	(42.7)	0.28
Adherence, pre-intervention period	78.55	(23.9)	75.89	(24.5)	0.52

Results: Overall mean adherence (n=133)



Mean adherence is low and decreases over time, significantly between pre- and post-delivery.

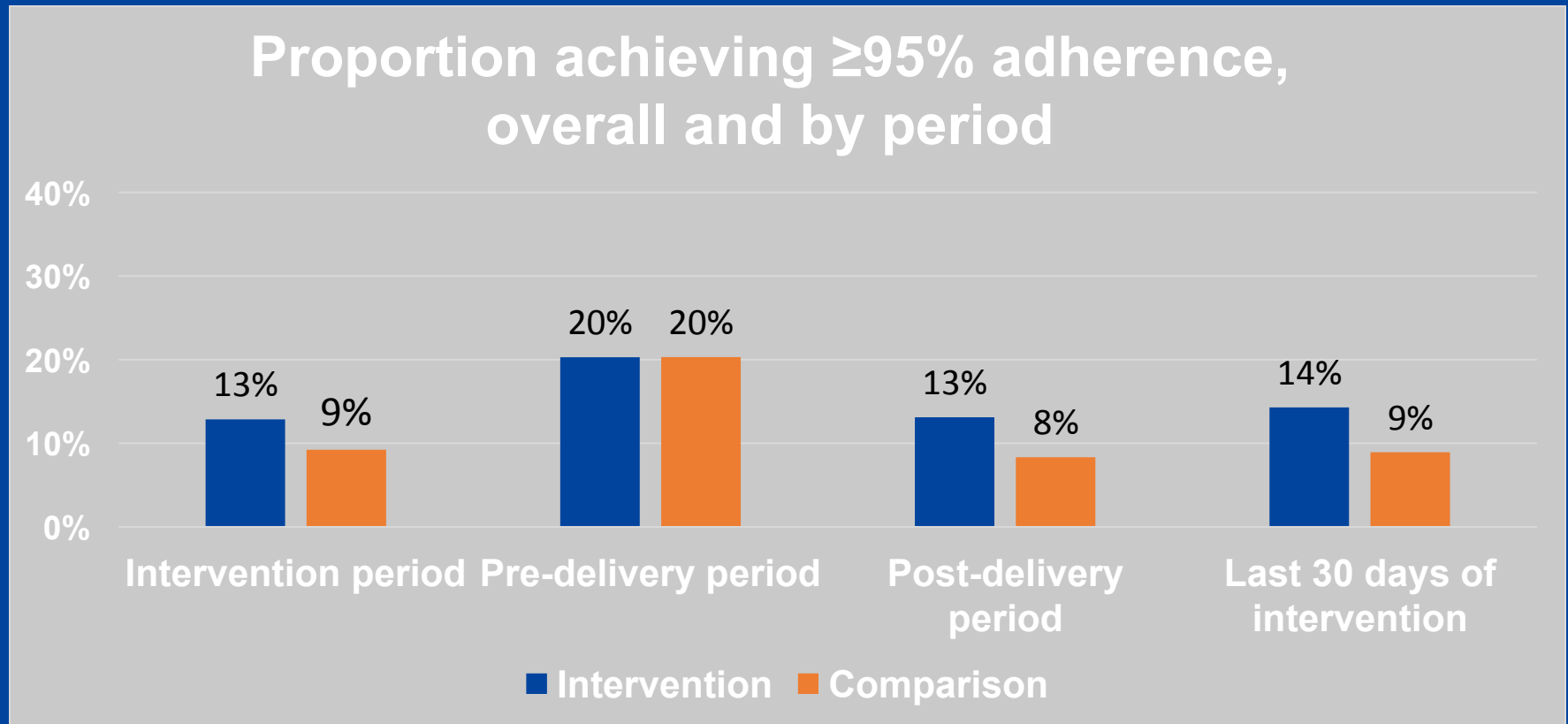
Intervention results: Mean adherence of intervention vs. control arms (n=133)



- Mean adherence is low and decreases over time
- No significant differences between intervention and comparison arms

Results: Intervention effect

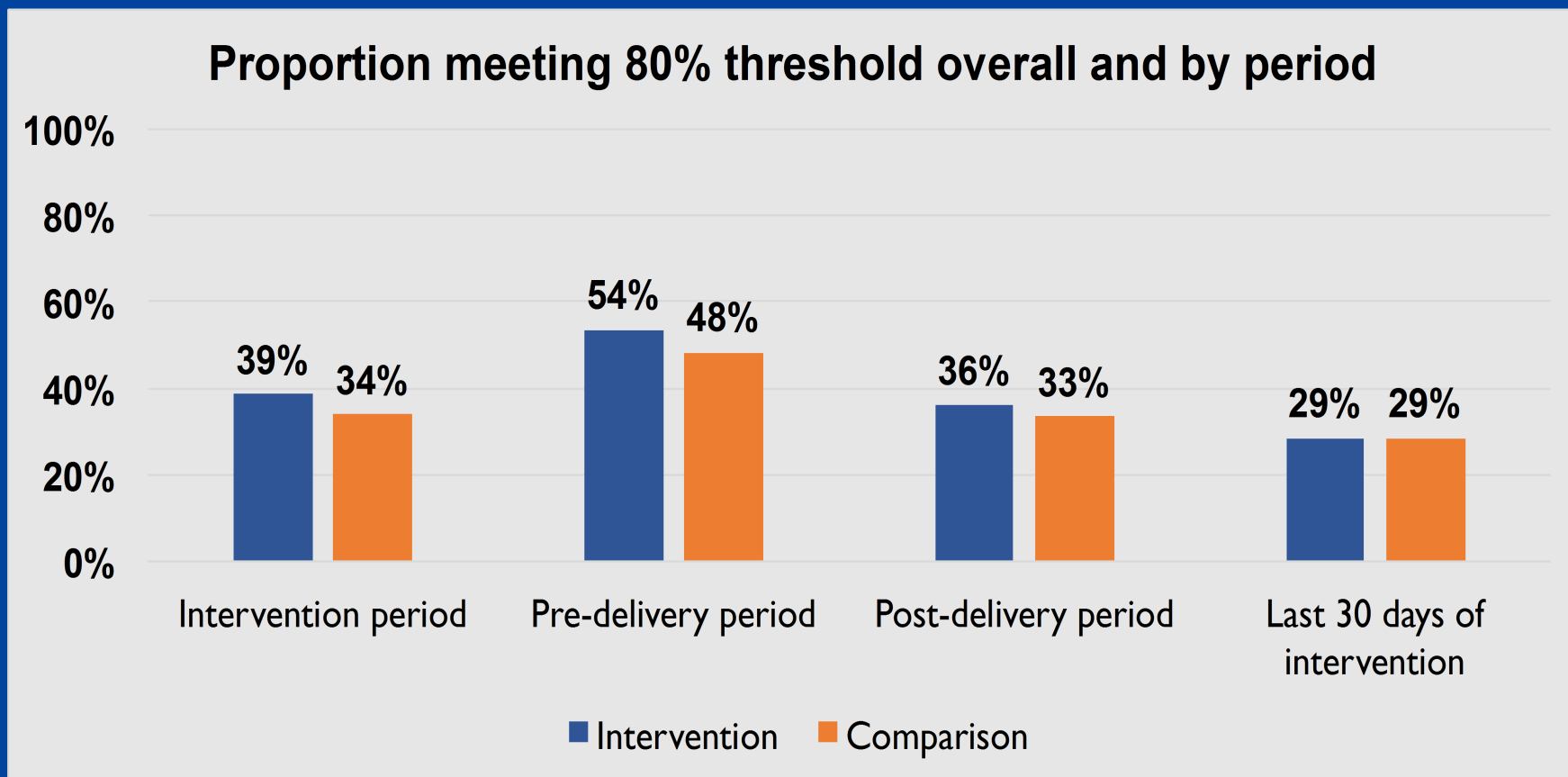
95% Threshold



- Very few women reach the 95% threshold, especially in the post-delivery period.
- No significant differences between intervention and comparison groups.

Results: Intervention effect

80% Threshold



- Very few women were even 80% adherent, especially postpartum

Why no improvement in adherence?

- Real-time feedback did not address interpersonal and structural barriers to adherence.
- Major barrier: Lack of disclosure to male partners:
 - 24.8% of women had disclosed at enrollment
 - Only 56% had disclosed by postpartum month 3 ($n=100$).
 - Major reasons for not disclosing:

	At enrollment	At PPM3
Fear husband will blame her for HIV	47%	32%
Fear of divorce	68%	16%

Qualitative analysis of post-intervention in-depth interviews and FGDs:

- Motivation to stay on ART is high during pregnancy: women want to prevent HIV transmission to their babies.
- Lack of disclosure to male partners prevents women from taking their medication openly and on time.
- After delivery women found it difficult to get to the clinic, especially if did not disclose to partner.
- Transport to clinics is expensive, women had to ask partners for money to travel to the clinic, time-consuming, and burdensome.
- Lack of food prevents women from taking their medications.

Qualitative Results

Need to hide status and medication from partner

- *...some men are so furious and rude so the women fear to tell them and the women have to take their medication in secrecy and fear that they might be caught. When we come to the hospital you hear women talking about how they have to hide their medication and always lie to where they are going because they are afraid of the husbands..*
- *Whenever I don't take my medication on time, it is because my spouse is around and so I have to wait for him to sleep. Then I take my medication.*
- *If he is away, I easily take my medication, but trouble comes when he comes back.*

Qualitative Results

Economic dependence

- *So, I wait for what my husband gives me to buy the daily food and the truth is that if he doesn't give me money on certain days, I don't take my drugs. I wait till the next day when I can get some posho (food), then I take my drugs.*
- *... if at all I tell him that I am HIV positive and he chases me, where will I get my daily bread or shelter? I can even not feel at home in my own household? So I decide to take my drugs secretly as he also goes on with his adultery. (Laughter)*

Conclusions

- Real-time feedback combined with data-informed counseling did not result in improved ART adherence among pregnant and postpartum women in our study.
- Women may have the knowledge, motivation and behavioral skills to be adherent, BUT interpersonal, structural, and social factors, especially gender power dynamics, pose major barriers to adherence.
- Our WiseMama Study intervention did not address these factors, BUT we learned a lot!
- Lack of disclosure to male partners, economic dependence, and fear of violence and abandonment must be addressed to improve health outcomes for women and babies.

WiseMama Study Team & Acknowledgements

- BU CGHD

- Lisa J Messersmith (PhD)
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- Mary Bachman DeSilva (ScD)
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