

PrEP, Relationship Dynamics, and Intimate Partner Violence: Findings and Tools from the CHARISMA Project

November 19, 2020

Global PrEP Learning Network



CHOICE Collaboration for HIV Prevention Options to Control the Epidemic



Opening and Introductions

CHARISMA and CHARISMA's Randomized Control Trial Overview

Randomized Control Trial Results

Results Summary and Considerations

Resources for Addressing Partner Dynamics & Violence in PrEP Services

Mobile Site Development Activities

Discussion and Final Q&A

Today's Speakers



Elizabeth Montgomery, RTI International

Elizabeth Montgomery, PhD, MHS, is a Senior Research Epidemiologist at RTI International. She is a leading expert on the role of male partners in women's HIV prevention, and she is the Principal Investigator of the CHARISMA project.



Sarah Roberts, RTI International

Sarah Roberts, PhD, MPH, is a Research Epidemiologist at RTI International whose research focuses on social and structural barriers to women's HIV prevention, including intimate partner violence, gender inequality, and stigma. She is a co-Investigator and the Monitoring and Evaluation Lead for the CHARISMA Project.



Thes Palanee-Phillips, Wits RHI

Thes Palanee-Phillips, M Med Sci, PhD, MSc, is the Director of Clinical Trials at Wits RHI in Johannesburg, South Africa. Her research priority for the last few years has been understanding the intersections between sexual/reproductive health and issues impacting adherence to PrEP-based HIV prevention interventions in the context of sexual violence. She is the co-Principal Investigator of the CHARISMA project.



Michele Lanham, FHI 360

Michele Lanham, MPH, is a Technical Advisor at FHI 360. She leads the research utilization portfolio for the CHARISMA project, including development and dissemination of the CHARISMA toolkit and other resources addressing IPV in PrEP services.



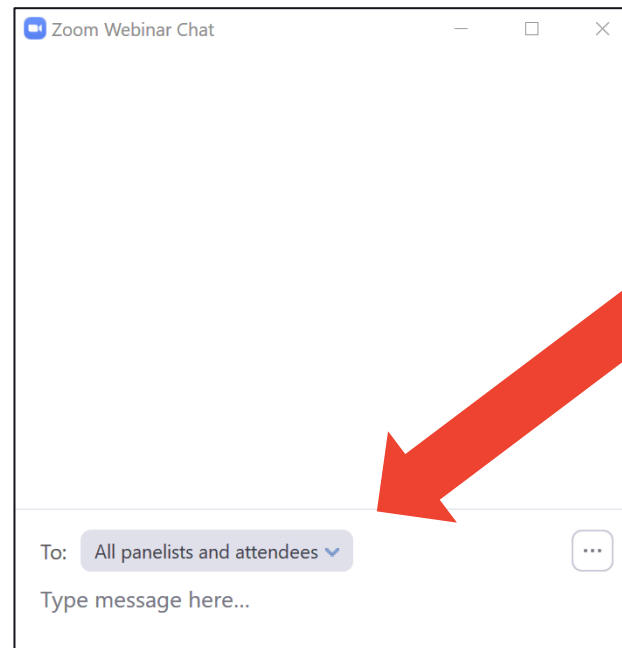
Miriam Hartmann, RTI International

Miriam Hartmann, MPH, is a Public Health Analyst at RTI International. Her body of work focuses on developing and testing interventions to address violence and gender inequalities. Hartmann is the Intervention Content Lead for the CHARISMA project.



Reminder: Use “Chat” Function

Please feel free to ask questions and add comments to the chat box at any point during today’s presentations. At the end of the session, we will dedicate time to Q&A.



Choose “*all panelists and attendees*” from the drop-down menu when adding a question or comment to the chat box.

Opening and Introductions

**Background on CHARISMA and the CHARISMA
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Background on CHARISMA and the CHARISMA RCT

Elizabeth Montgomery, RTI International



CHARISMA Team and Collaborators

- **RTI International** - Overall Project Management and Leadership
 - *Elizabeth Montgomery, PI*
- **Wits Reproductive Health and HIV Research Institute (Wits RHI)** - Clinical Site, Johannesburg
 - *Thesla Palanee-Phillips, Co-PI*
- **FHI 360** - HEART Tool Development & Research Utilization Leadership
 - *Betsy Tolley, Michele Lanham, Rose Wilcher*
- **University of Washington (UW)** - Steering Committee Leadership
 - *Jared Baeten*
- **Sonke Gender Justice** - Community Engagement (Pilot Study)
 - *Dean Peacock*
- **Project Advisory Committee (PAC):** *Sharon Hillier, Avni Amin, Terri Senn, Donna Futterman*
- **Project funded by USAID and PEPFAR as part of the Mpii Consortium:** *Lee Claypool, Benny Kotiri, Shannon Allen, Delivette Castor*

Rationale of CHARISMA Work

- 1 in 3 women globally will experience violence by a partner or sexual violence by a non-partner.
- Women have enhanced HIV risk and limited ability to negotiate HIV prevention method use.
 - Women in abusive relationships are less able than non-abused women to refuse sex or use condoms during intercourse.
- Oral pre-exposure prophylaxis (PrEP) and vaginal rings are **effective ways for women to prevent HIV**.
 - However, all women face barriers to the uptake of and adherence to HIV prevention products, including partner resistance, difficulties with covert use, and gendered norms around sexuality
 - Experience with IPV is associated with lower oral PrEP uptake, increased PrEP interruption, and lower adherence to oral PrEP and vaginal ring use

Continuum of Male Partner Involvement in HIV Prevention Product Use

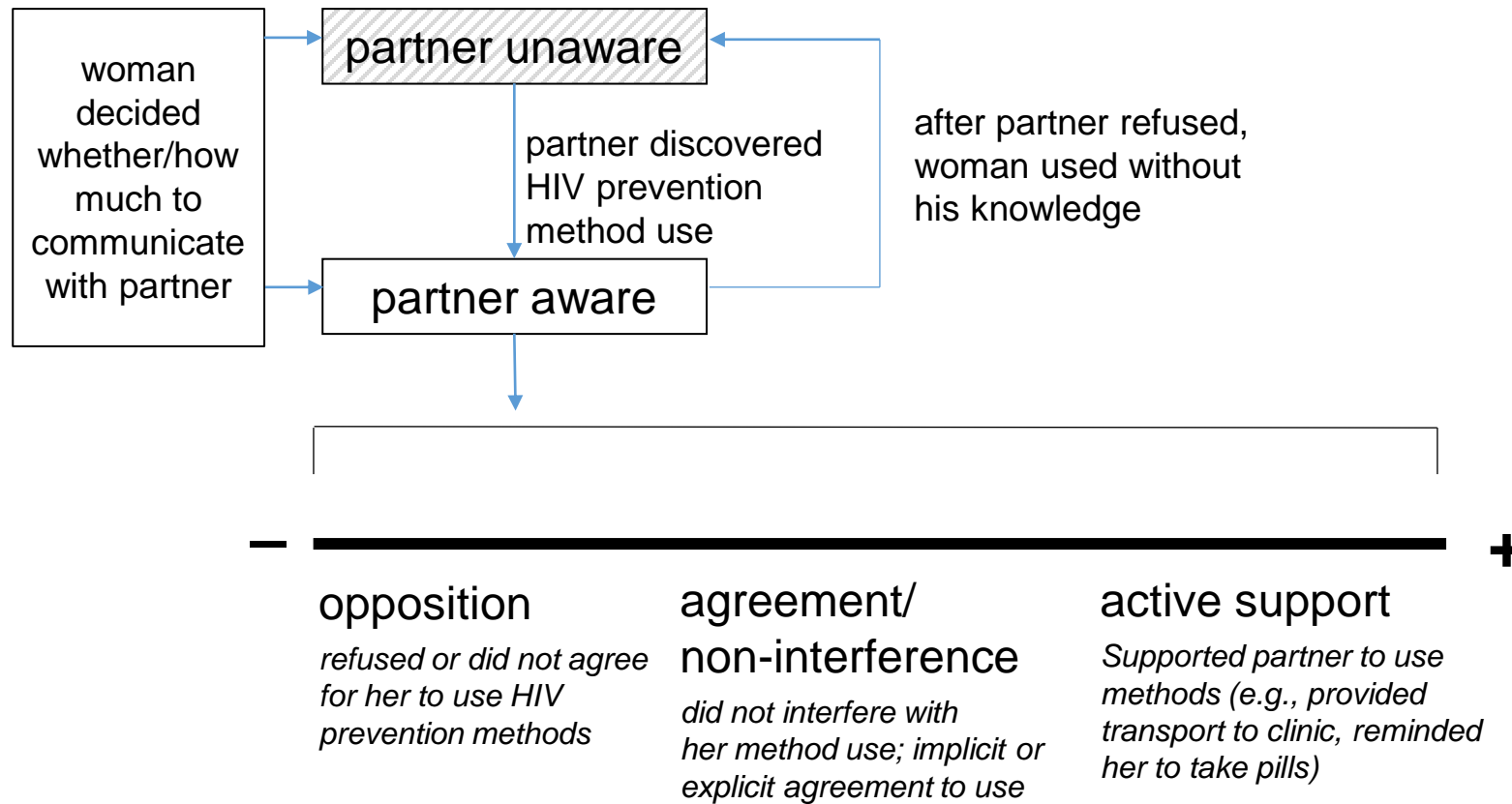


Figure adapted from Lanham et al. (2014), Journal of the International AIDS Society, 17(3 Suppl 2), 19159.

CHARISMA Question:

Can we successfully integrate approaches to address relationship dynamics with delivery of HIV prevention methods and improve method use?

CHARISMA Core Activities to Date

- CHARISMA tool development, from primary and secondary research: 2015-2016
 - HEART: HEALthy Relationships Assessment Tool
 - Counseling content (training and counseling manuals)
- CHARISMA Pilot study attached to MTN-025 HOPE open-label extension study of the dapivirine vaginal ring: 2016-2018
 - Found to be acceptable to participants, and feasible to implement (with some required adaptations)
- CHARISMA Effectiveness Study (RCT): 2018-2020
- Development of CHARISMA Toolkit

Overview of CHARISMA RCT Intervention

Enrollment
into PrEP use
visit

Step 1



Relationship
Assessment (HEART)

HEART : HEALThy Relationships Assessment Tool

Step 2
Counseling
(Module A plus
Module B, C, or D)



Module A
Healthy and Unhealthy Relationships



Module B
Partner
Communication



Module C
Discussing PrEP Use
with Partners



Module D
Responding to Intimate
Partner Violence

Step 3



Educational Materials
for Male Partners

End of visit and
1 follow-up
check-in visit

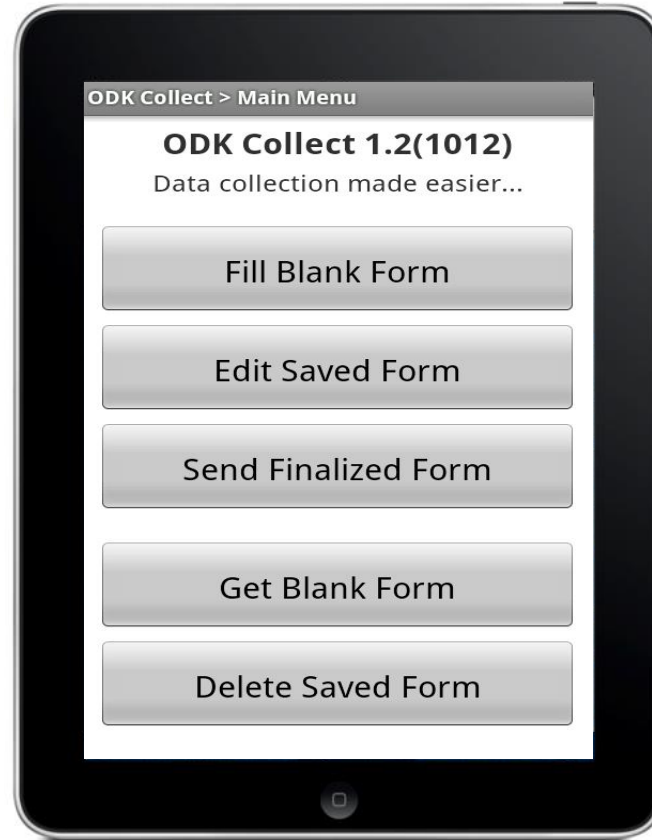
Step 4



Support
and Referrals

Relationship Assessment Tool (HEART)

- **HEART= Healthy Relationship Assessment Tool**
- Developed from primary research and pre-existing validated scales
- 5 domains:
 - Traditional Values
 - Partner Support
 - Partner Abuse and Control
 - Partner Resistance to HIV Prevention
 - HIV Prevention Readiness
- Targets counselling to participant's needs



I think that a woman cannot refuse to have sex with her husband.

My partner does what he wants, even if I do not want him to.

I can talk about my problems with my family.

Empowerment Counseling Modules



Responding to IPV

HEART indicates any controlling behaviors, emotional abuse or physical abuse



Disclosure and partner support

HEART indicates partner is *not* abusive but she has *not disclosed method* use or she has disclosed and he is *not supportive*



Partner communication

Elements of communication, “I” statements, and conflict de-escalation

All other women receive this module

CHARISMA Videos

HEALTHY RELATIONSHIPS

WHAT'S A HEALTHY RELATIONSHIP ANYWAY?

PARTNER COMMUNICATION

HOW TO TALK TO YOUR MAN?

PREP DISCLOSURE

HOW DO YOU TELL YOUR MAN ABOUT PREP?



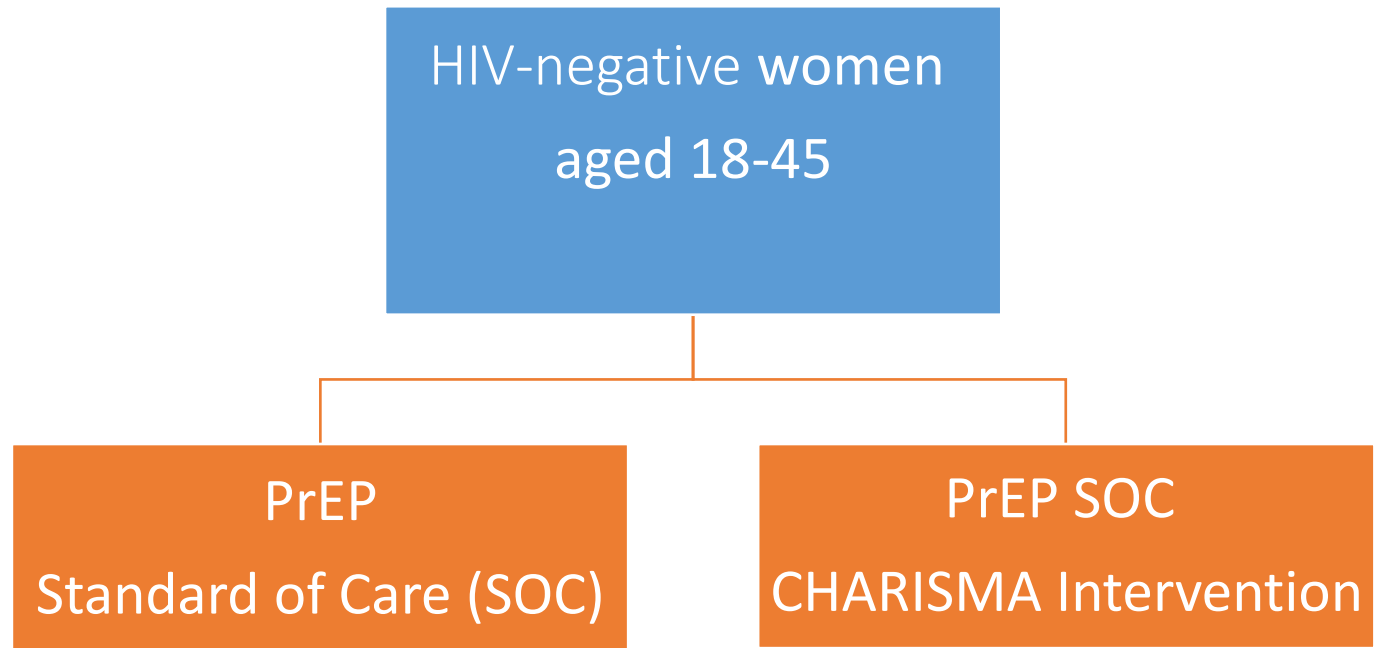
Example video link: https://youtu.be/JnxzZWaJB_E

CHARISMA RCT Study Objectives

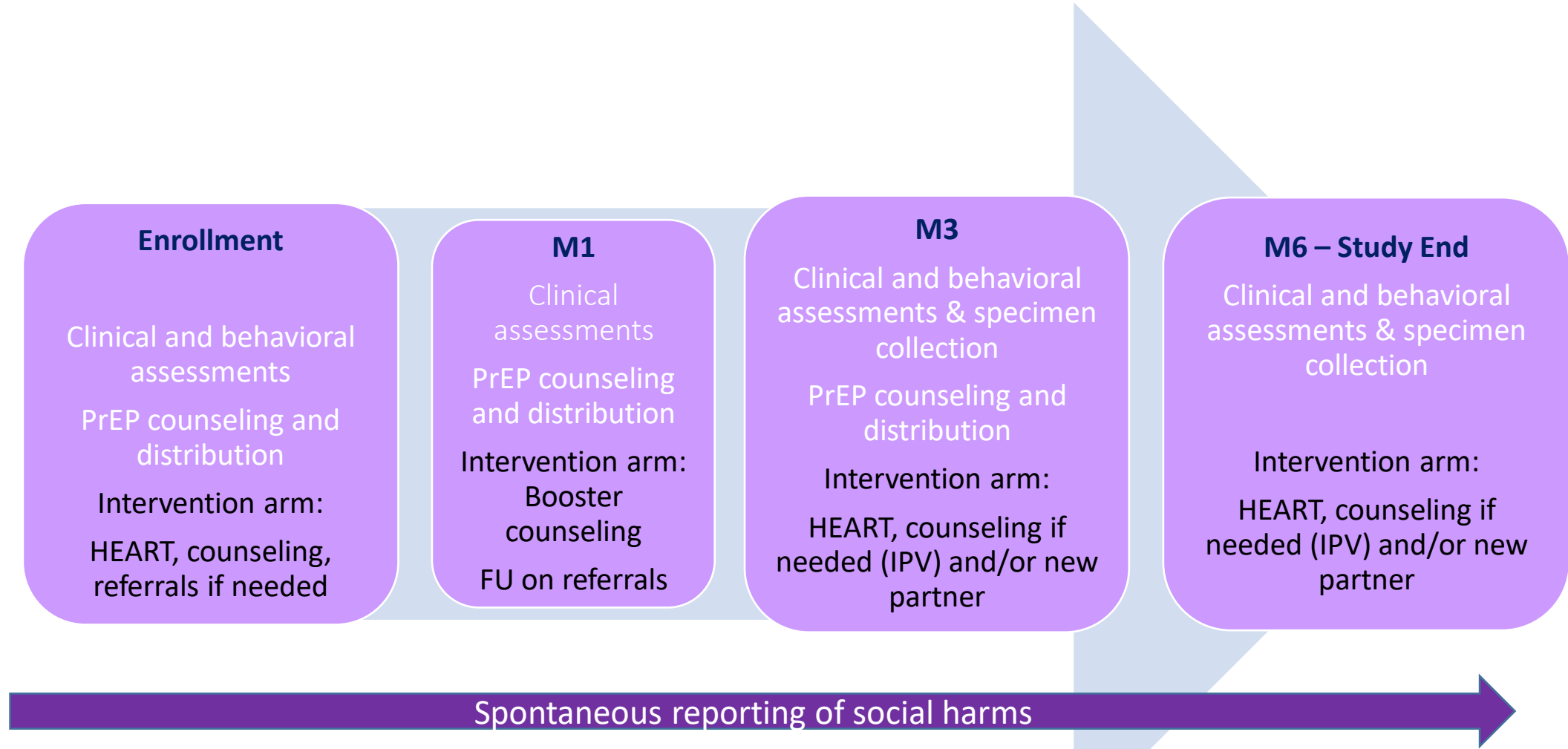
- To determine **effectiveness of the CHARISMA intervention** with regard to:
 1. Increasing PrEP adherence and persistence
 2. Reducing experiences of social harms while on PrEP
 3. Reducing experiences of IPV
 4. Improving relationship dynamics with male partners, including disclosure of PrEP use, support for PrEP use, and communication
- To measure **acceptability and feasibility of the intervention**

CHARISMA Randomized Clinical Trial (RCT): Study Design (n=407)

- Wits RHI, Johannesburg
- Sep 2018 – May 2020
- 6 months follow-up
- Oral PrEP for both arms
- Standard of care: IPV routine inquiry, first-line support and referral, offered educational materials for male partners and referrals
- CHARISMA intervention: SOC plus intervention components



Visit schedule and core activities



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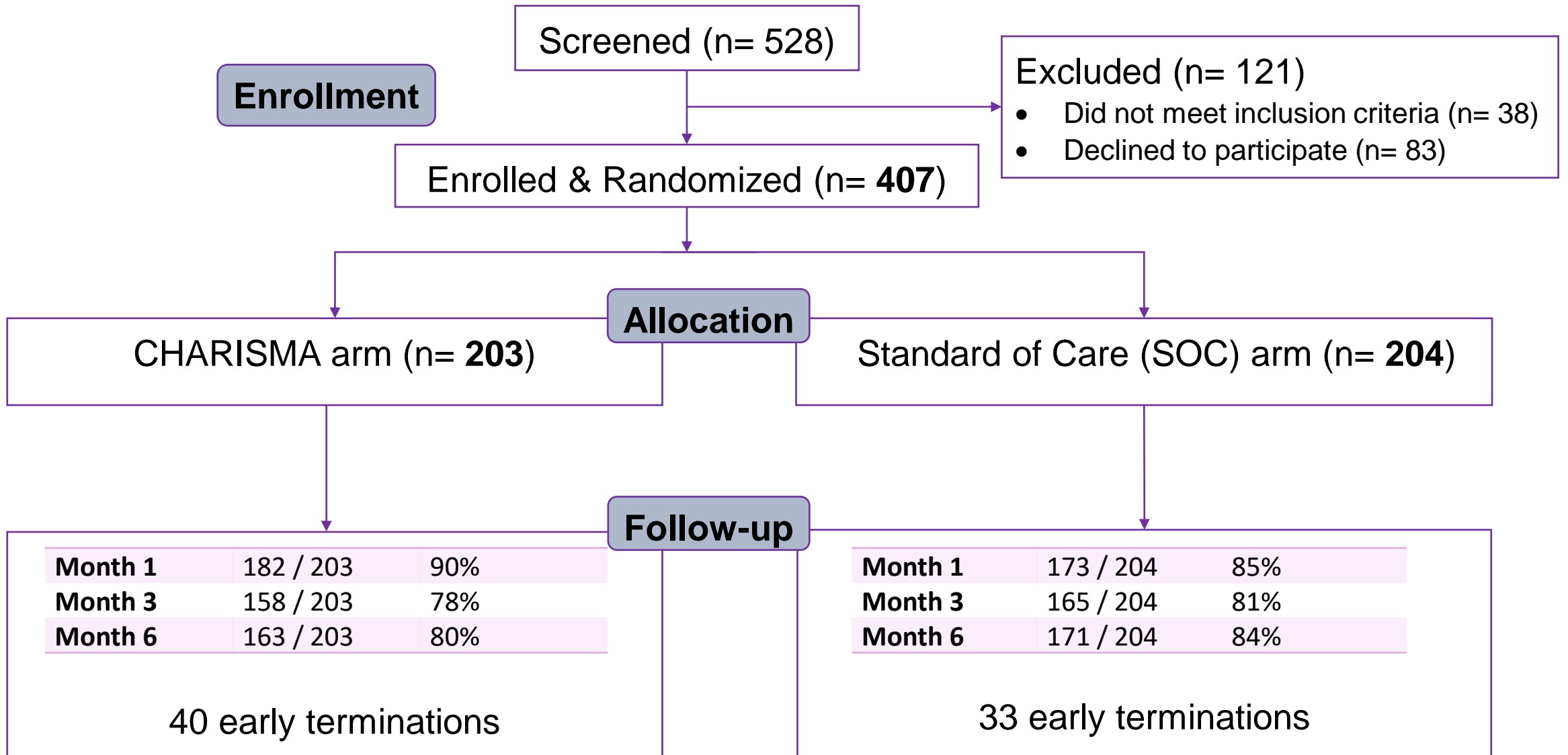
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Results

Sarah Roberts, RTI International



Participant Characteristics

Age (median, IQR): 27 (22-34)
Ages 18-24: 39.6%
Has a regular partner: 99.5%
Married: 9.1%
Cohabiting: 23.5%

Lifetime IPV: 39.6%
Recent IPV (past 3 months): 27.3%
Controlling behavior*: 22.4%



Partner aware of PrEP use: 64.9%
Participant disclosed PrEP use: 62.6%

Partner reaction:

Supportive: 57.7%
Neutral: 27.3%
Opposed: 3.5%
Don't know: 11.5%

Any CHARSIMA risk factor: 59.9%

- *Recent IPV*
- *Controlling behavior*
- *Non-disclosure of PrEP*
- *Partner opposed to PrEP*

*Restricts contact with family or friends, per Durevall & Lindskog, Lancet GH 2015

Differences by study arm

Characteristic	CHARISMA	SOC
	%	%
Age [Median, (IQR)]	27 (22-34)	26 (22-34)
Recent IPV	23.6	30.9
Controlling behavior	19.2	25.5
Partner reaction to PrEP		
Supportive	50.4	64.7
Neutral	35.4	19.5
Any CHARISMA risk factor	55.0	64.7

Feasibility and Acceptability

Intervention delivery requirements

- **Staffing and resources:**

- Lay counselors are suitable for implementation
- Private space for counseling sessions needed
- Referral network in place
- (Ideally) oversight and mentorship from staff with IPV counseling experience
- (Ideally) tablets or computers for administration of HEART relationship assessment tool
 - In low resource settings a paper version may be used

- **Training:**

- Lay counselor training and certification via mock counseling sessions
- Sensitization training for all clinic staff
- Periodic refresher training sessions and routine observation

Counseling duration (minutes)

Counseling Module	Enrollment visits			Month 1 visits			Month 3 visits			Month 6 visits		
	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
A. Partner Communication	130	56.1	12.1	0	--	--	3	43.0	12.0	2	43.5	7.8
B. PrEP Disclosure	52	53.1	11.3	1	28.0	--	3	40.3	15.6	1	49.0	--
C. Responding to IPV	20	74.0	19.0	0	--	--	3	43.3	20.0	1	51.0	--
NO Module Provided*	--	--	--	180	27.8	10.1	147	22.1	7.4	125	20.3	5.8

* Check-in + HEART at M1; HEART only at M3 and M6

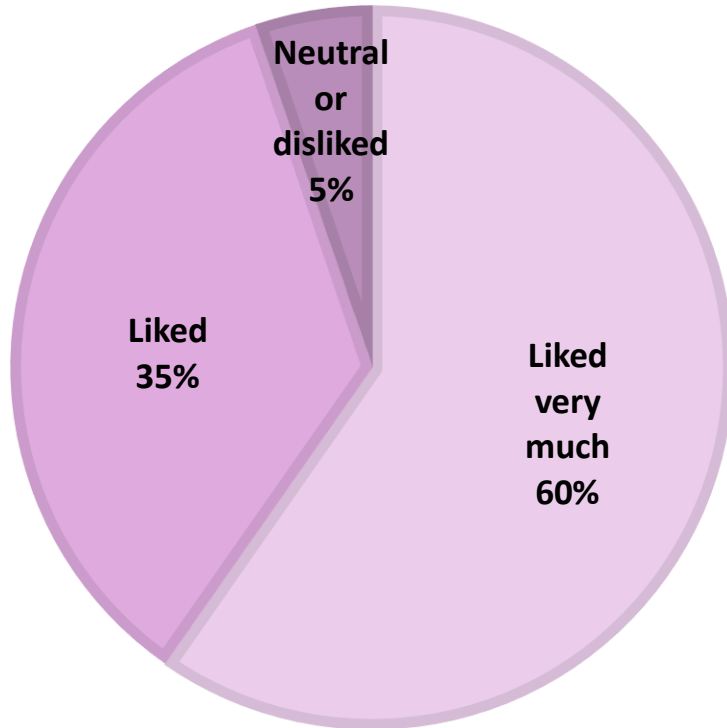
Intervention delivery

Enrollment module received	N	%
A. Healthy and Unhealthy Relationships	203	100
<i>Tailored modules:</i>		
B. Partner Communication	131	64.5
C. PrEP Disclosure	52	25.6
D. Responding to IPV	20	9.9

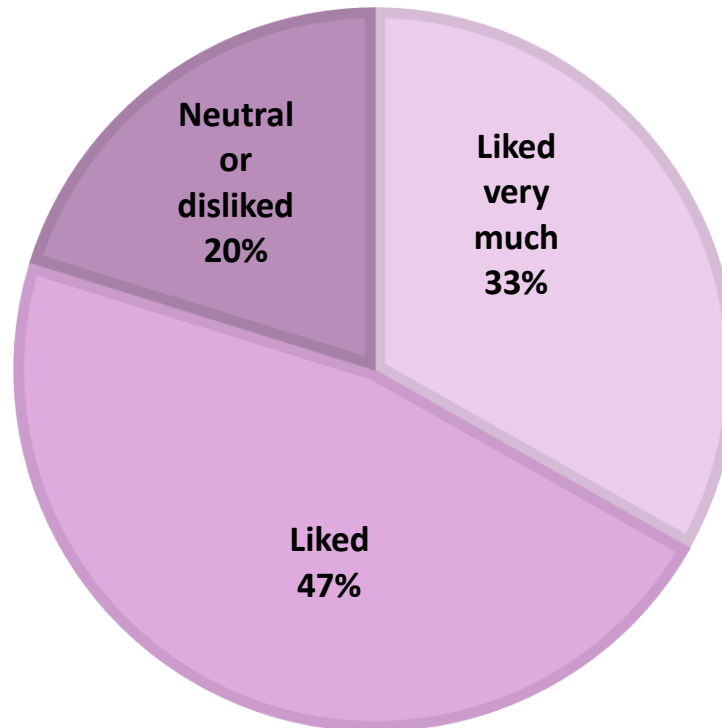
- Quality: Median score 4 of 5 (IQR 3.5-4.5) based on 23 observed sessions
- Fidelity: >90% of expected activities conducted at enrollment sessions
 - Exception: Participants receiving IPV module less likely to receive Healthy Relationship module activities (78%)

Acceptability of study topics and counseling

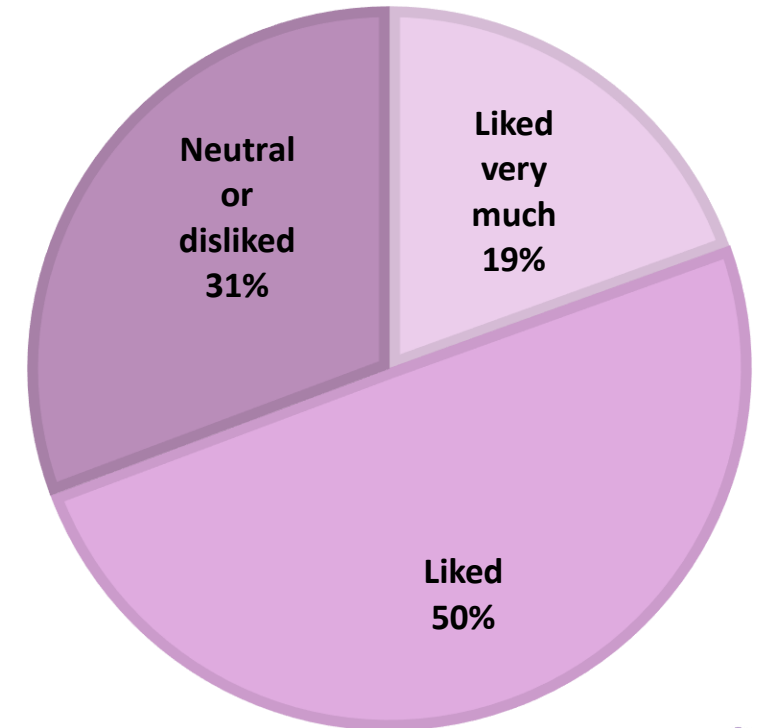
Counseling about HIV risk and PrEP use



Being asked about intimate partner violence

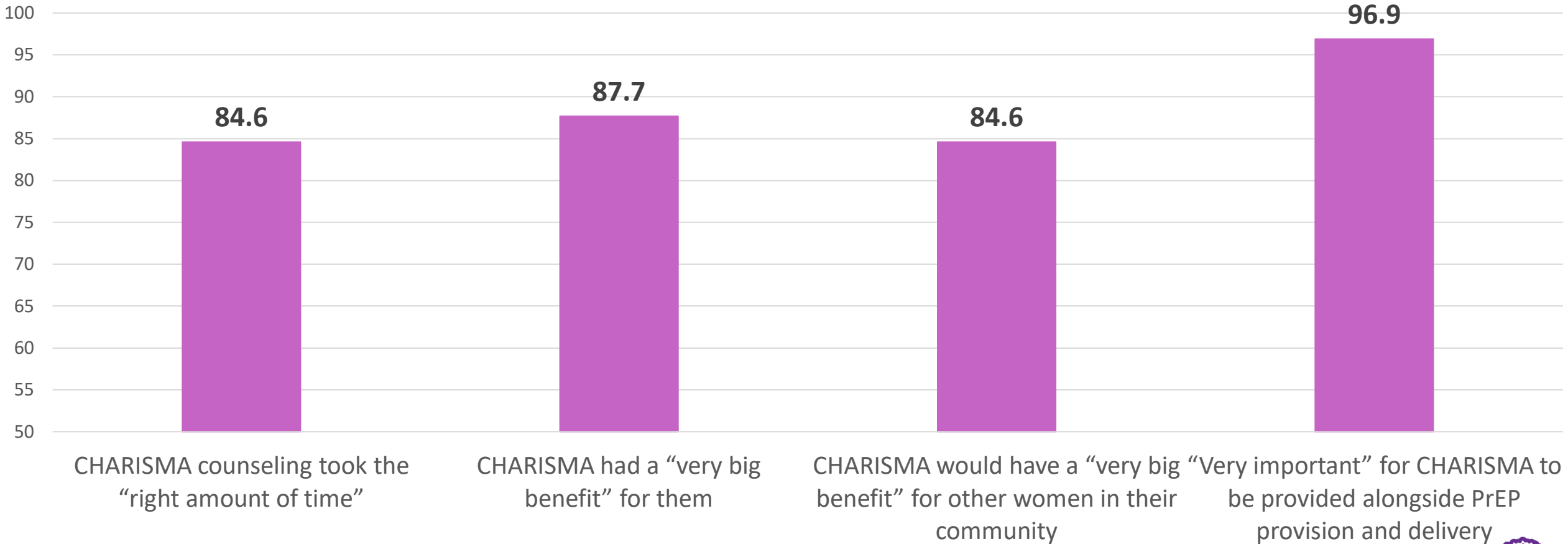


Being asked other sensitive questions about relationships and behaviors



Acceptability of CHARISMA intervention

% of participants who shared the following opinions:

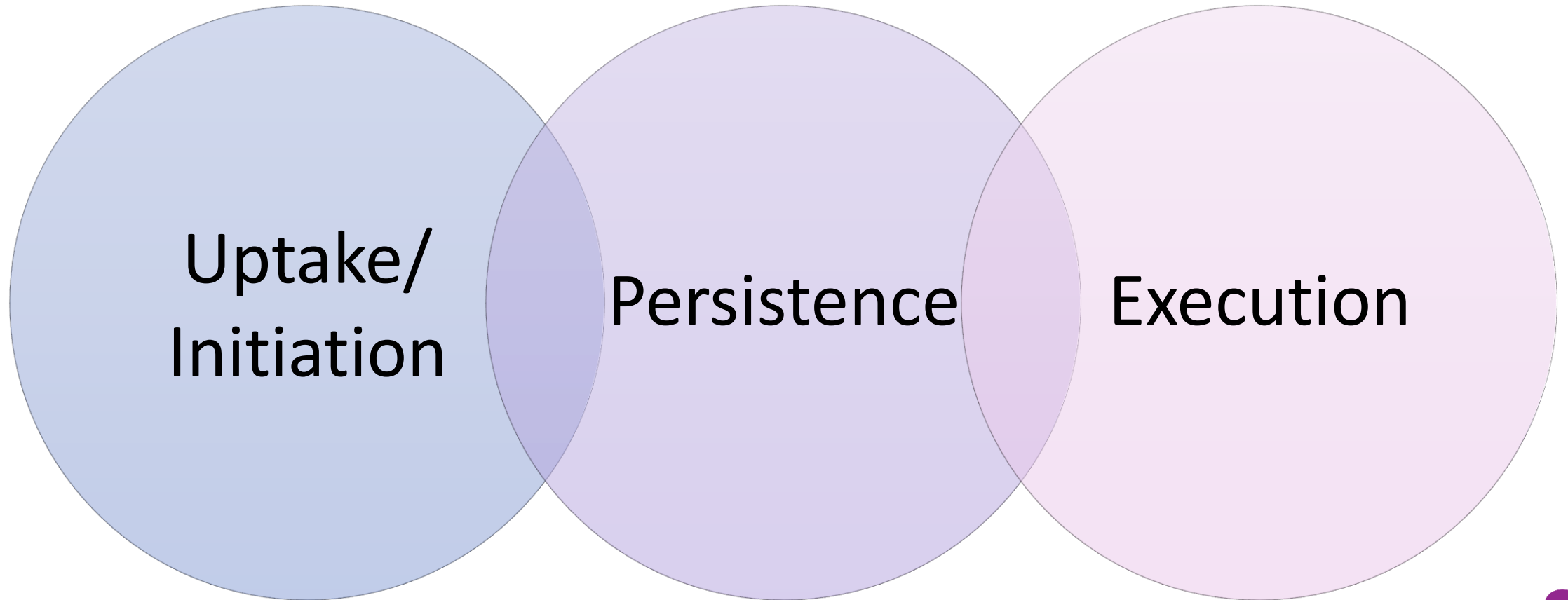


Acceptability and feasibility: summary

- The CHARISMA intervention was perceived as highly acceptable to participants and participants felt it would benefit others
- Delivery of the CHARISMA HEART tool and counseling took time, although the majority of participants felt it took the right amount of time
- Intervention can be delivered well by lay counselors

Aim 1:
PrEP adherence

Three components of adherence



Definitions in CHARISMA

- **Persistence:** Time from initiation to discontinuation
 - *Discontinuation:* Self-reported stop, lost to follow-up, >14 days late for refill
 - Analysis based on time to first discontinuation
 - Re-initiation can occur upon receipt of new PrEP refill after discontinuation
- **Execution:** TVF-DP level >1064 fmol/punch *during periods of persistence*
 - When participant is not >14 days late for refill or on product hold/self-reported stop
 - 1064 fmol/punch corresponds to 6-7 doses/week

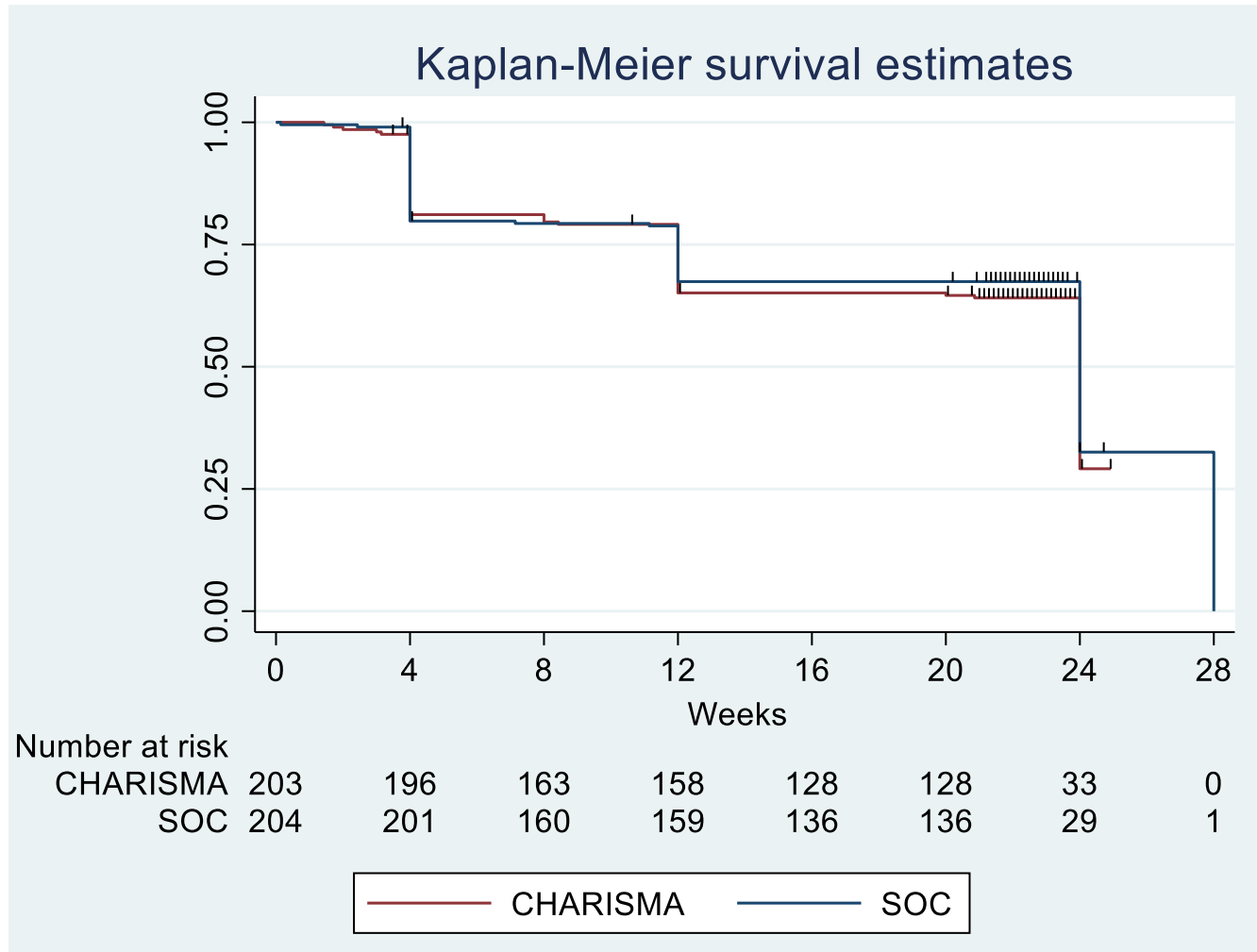
Persistence outcome: Discontinuation

- PrEP discontinuation: >14 days late for refill, LTFU, or self-initiated stop
 - Defined mainly by late refills
 - 14 (3%) ppt-initiated stop

Any discontinuation	Total		SOC		CHARISMA	
	n	%	n	%	n	%
Total	407	100	204	100	203	100
Yes	172	43.0	82	40.2	90	44.3
No	228	56.0	120	58.8	108	53.2
NA – clinician-initiated hold*	7	1.7	2	1.0	5	2.5

*censored in analysis

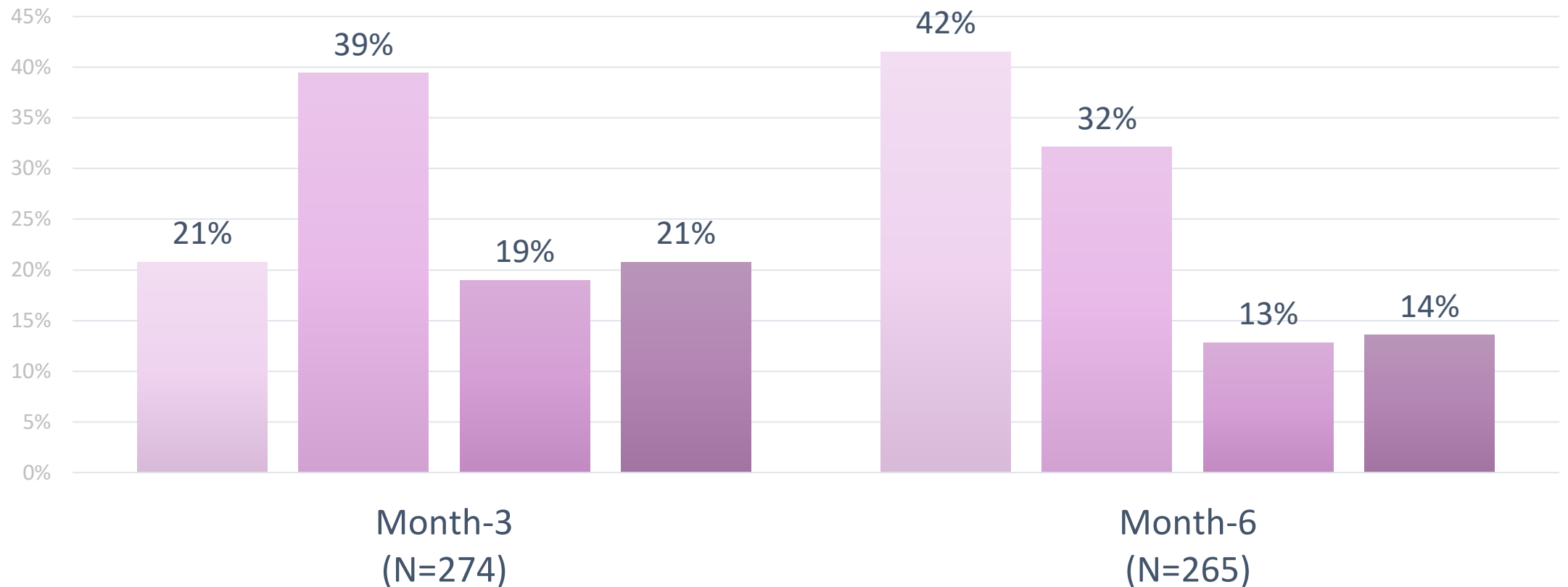
Persistence outcome: Time to first discontinuation



	Hazard Ratio	95% CI	p
CHARISMA vs. SOC	1.09	0.81 – 1.47	0.57

Time to self-initiated stop, lost to follow-up, or >14 days late for refill

Execution: TVF-DP levels during periods of persistence (fmol/punch)



■ <16.6 (No use) ■ 16.6-700 (<4 doses/wk) ■ >700-1064 (4-5 doses/wk) ■ >1064 (6-7 doses/wk)

Execution – Primary analysis

	SOC		CHARISMA		Total	
	n	%	n	%	n	%
Total samples	274	100	265	100	539	100
High execution (TFV-DP >1064 fmol/punch)	46	16.8	47	17.7	93	17.3

	Risk Ratio	95% CI	p
CHARISMA vs. SOC	1.08	0.69 – 1.71	0.73

Also no significant difference in secondary analyses:

- Stratified by visit month (Month 3 and Month 6)
- With "high execution" defined as TFV-DP > 700 fmol/punch

Summary

- Proportion with high execution was 17% overall
 - 21% at M3 and 14% at M6
 - *This is similar to PrEP adherence in other studies and settings*
- 56% persisted with PrEP throughout the study while 43% discontinued at least once (>14 days without PrEP).
- At visits with persistence, 60-80% had evidence of some PrEP use
 - *Women are taking PrEP, but not consistently, which may reflect intermittent PrEP use*
- No effect of CHARISMA on execution or persistence
- No seroconversions occurred in the study
 - *This could reflect the study population, intermittent PrEP use, an intervention effect on both arms*

Aim 2: Social Harms

Social Harms Results

- Outcome: Any partner-related SH during the study
 - SH: non-clinical adverse event related to study participation
- Only 4 SH reported
 - 1 partner related (in CHARISMA arm): Related to concerns of infertility due to contraceptive use
- Incidence of partner SH:
 - Study overall: 0.60 per 100 person-years (95% CI 0.08-4.25)
- Conclusion
 - *Neither study nor intervention resulted in high rates of partner SH*

Aim 3:
IPV

IPV Measurement: WHO Violence against Women Survey Items

- Emotional (none are severe)

- Insult
- Belittle or humiliate
- Scare or intimidate
- Threaten to harm

- Sexual (all are severe)

- **Physically force**
- **Had sex because afraid of what he might do**
- **Forced to do something degrading or humiliating**

- Physical (bold = severe)

- Slap or throw something at
- Push or shove
- **Hit with fist or something else**
- **Kick, drag, or beat up**
- **Choke or burn**
- **Use or threaten to use a weapon**

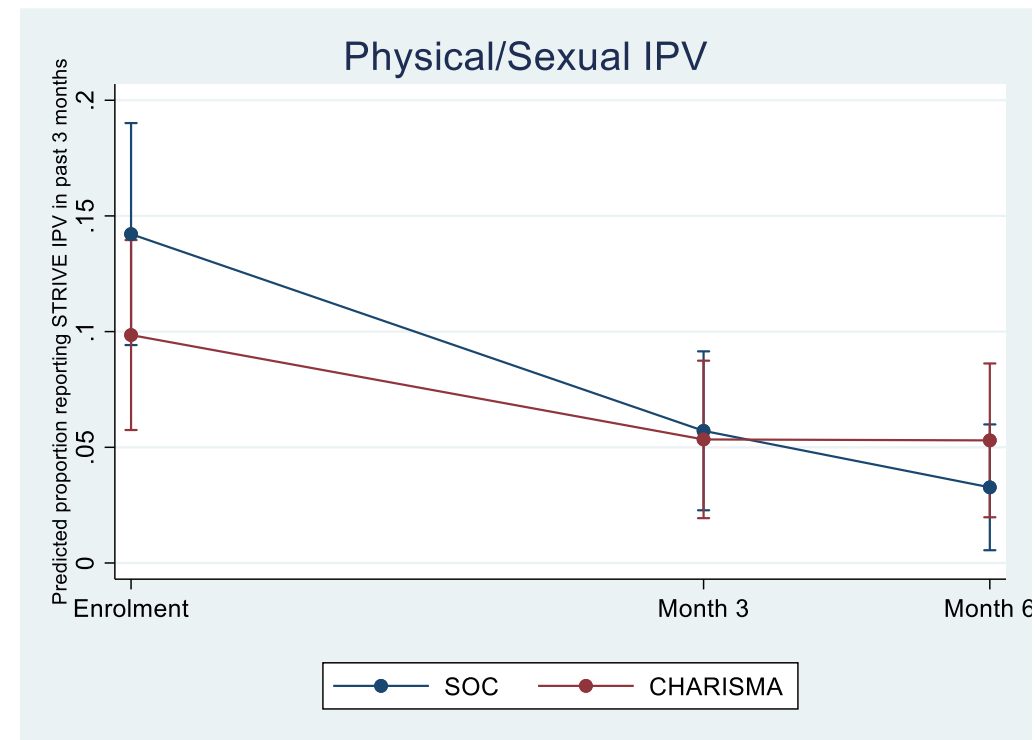
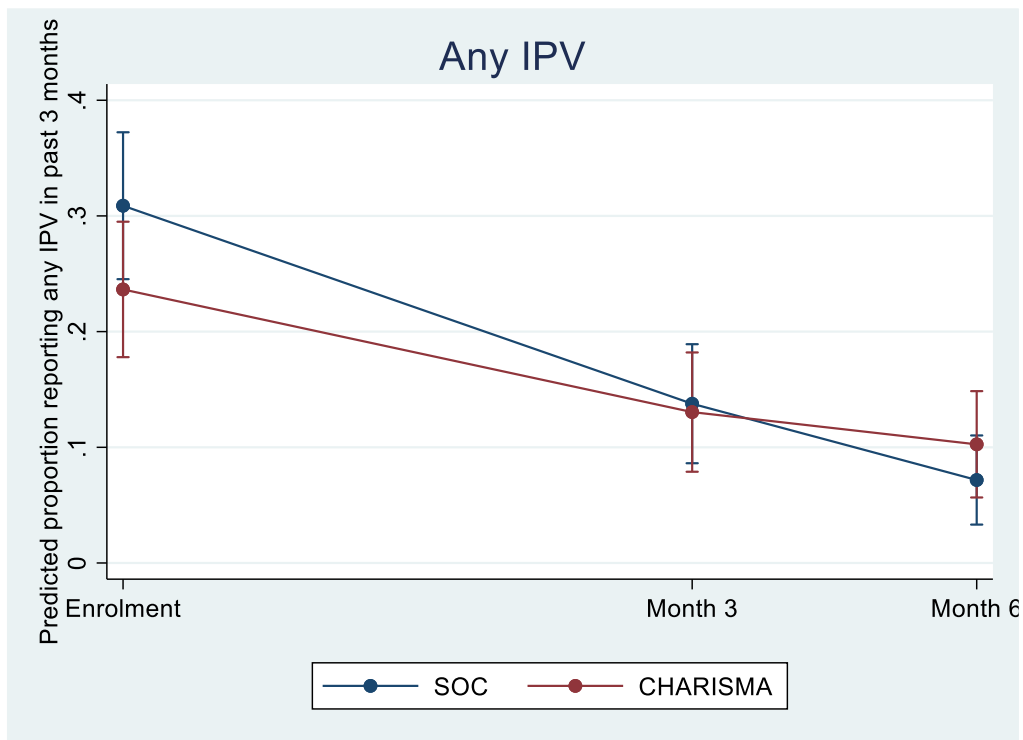
For all: Reference period: past 3 months; frequency: once, few times, or many times

Primary IPV Outcomes

- Any IPV during study participation
- Any physical or sexual IPV during study participation¹ :
 - at least one act of severe physical violence
 - at least one act of sexual violence, and/or
 - at least two acts of moderate physical violence.

¹ Definition recommended by STRIVE Consortium. Women who report just one act of moderate physical IPV are excluded.

	SOC		CHARISMA		Total	
	n	%	n	%	n	%
<i>During follow-up (n=368)</i>						
Any IPV reported	28	15.0	30	16.6	58	15.8
Any physical or sexual IPV reported	12	6.4	16	8.8	28	7.6



IPV results

	Primary: Adjusted for time in study only (n=368)			Adjusted for time in study and baseline IPV (n=368)		
	Risk Ratio (CHARISMA vs. SOC)	95% CI	p	Risk Ratio (CHARISMA vs. SOC)	95% CI	p
1. Any IPV	1.11	0.69 – 1.78	0.67	1.28	0.82 – 2.02	0.28
2. Any physical or sexual IPV	1.37	0.67– 2.82	0.39	1.73	0.88 – 3.41	0.11

Summary: IPV

- IPV decreased in both arms during the study
 - Decrease from Enrollment to Month 3
 - Decrease continued to Month 6 in SOC arm, leveled off in CHARISMA arm
- No evidence that CHARISMA reduced the risk of IPV
 - *CHARISMA arm may have had increased IPV reporting*
 - *Measurable effect may have been observed in a higher risk population*
 - *Both arms received quality IPV counseling response*

Aim 4:

Relationship Dynamics

Relationship dynamics: Outcomes

- Disclosure: % who have told their male partner they are using PrEP
- Support: % who report partner supports or accepts their PrEP use
 - His response was supportive, neutral, or don't know (versus opposed)
- Communication: 3 separate scales
 - Relationship Self-Efficacy Scale (subset of items)
 - Decision-Making Subscale of Sexual Relationship Power Scale
 - Communication: 4 questions from WHO Violence against Women Survey
- All analyses look separately at Month 3 and Month 6 visits

PrEP Disclosure to Male Partner

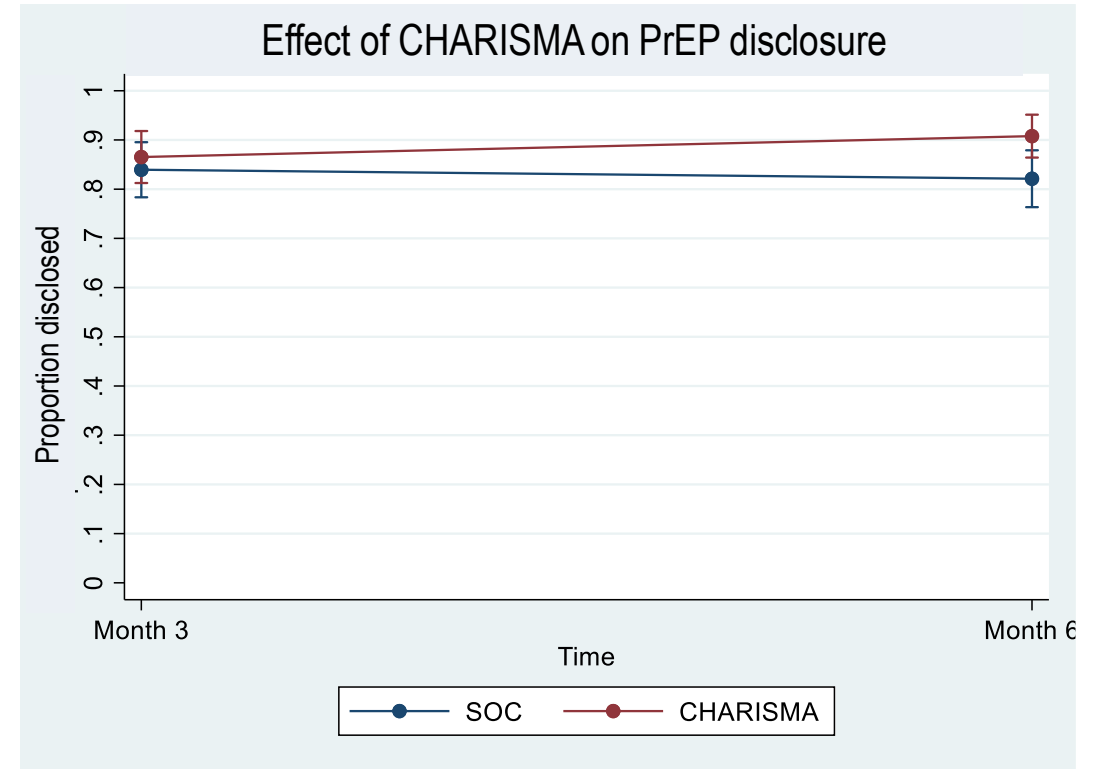
	SOC		CHARISMA		Total	
	n/N*	%	n/N*	%	n/N*	%
Baseline	27/203	62.6	125/202	61.9	252/405	62.2
Month 3	132/156	84.6	132/152	86.8	264/308	85.7
Month 6	135/164	82.3	142/155	91.6	277/319	86.8

*Among participants with a primary partner

** Missing data for 3 participants: CHARISMA (2) and SOC (1)

PrEP Disclosure to Male Partner

	Risk ratio (CHARISMA vs. SOC)	95% CI	p
Month 3	1.03	0.94 – 1.13	0.51
Month 6	1.11	1.02 – 1.20	0.02



Partner Supports or Accepts PrEP Use (vs Opposes)

	SOC		CHARISMA		Total	
	n/N*	%	n/N*	%	n/N*	%
Partner supportive/ neutral/don't know						
Baseline	125/131	95.4	122/122	97.6	247/256	96.5
Month 3	130/134	97.0	132/132	100.0	262/266	98.5
Month 6	141/141	100.0	142/142	100.0	283/283	100.0

- Model not estimable because all partners supportive at M-6
- No difference between proportion supportive vs. neutral in post-hoc analyses

*Among participants whose partner is aware of her PrEP use

Communication scales

	SOC Mean (SD)	CHARISMA Mean (SD)	Mean difference (CHARISMA vs. SOC)	95% CI	p
Relationship self-efficacy (8 items, total score range 8-40)					
Month 3	27.5 (4.3)	28.6 (4.8)	0.98	-0.02 – 1.99	0.06
Month 6	28.8 (4.0)	29.2 (4.7)	0.41	-0.54 – 1.35	0.40
Decision making (8 items, mean score range 1-3)					
Month 3	2.04 (0.29)	1.98 (0.25)	-0.05	-0.11 – 0.01	0.08
Month 6	2.04 (0.25)	2.03 (0.22)	0.00	-0.05 – 0.05	0.96
Communication (4 items, total score range 0-4)					
Month 3	3.6 (1.0)	3.7 (0.9)	0.15	-0.05 – 0.35	0.15
Month 6	3.7 (0.8)	3.8 (0.7)	0.05	-0.11 – 0.21	0.52

Summary: Relationship Dynamics

- Most ppts disclosed PrEP use to partners (~86%); disclosure higher in CHARISMA arm at M6 (although not M3)
 - *This result is promising, may be attributed to skills-building counseling*
- Male partner support high in this population throughout the study, and there was no difference between arms
 - *Results may be different in a different study population/setting*
- No evidence that CHARISMA increased relationship self-efficacy, decision making, or communication.

Subgroup analyses

Subgroup Analyses

Goal: To explore whether CHARISMA worked differently for certain populations:

1. Age group (18-24 or 25+ at baseline)
2. Cohabitation with partner (yes/no)
3. Any CHARISMA risk factor (yes/no):
 - Any IPV in the past 3 months
 - Partner controlling behaviors
 - Non-disclosure of PrEP to partner
 - Partner opposition to PrEP

Subgroup Analysis Results

CHARISMA may work better among women who cohabit with their partners

- For cohabiting women, CHARISMA (vs. SOC):
 - ↑ PrEP persistence
 - ↓ any IPV
 - ↑ self-efficacy* and communication scores*
- For non-cohabiting women, CHARISMA (vs. SOC):
 - ↓ PrEP persistence
 - ↑ physical/sexual IPV*

CHARISMA may work better among women with any CHARISMA risk factor

- For women with any risk factor, CHARISMA (vs. SOC):
 - ↑ PrEP execution
 - ↑ self-efficacy** and communication scores*
 - ↓ partner support**.
- For women with no risk factors, CHARISMA (vs. SOC):
 - ↓ PrEP execution
 - ↓ decision-making scores**

No clear trends by age group:

CHARISMA (vs. SOC) for women >25: ↑ physical/sexual IPV*, no other differences

CHARISMA vs. SOC for women 18-24: No differences

* $p < 0.1$; ** $p < 0.05$

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Thesla Palanee-Phillips, Wits RHI

Discussion and Summary

- CHARISMA: feasible and acceptable approach to IPV and relationship counseling in context of PrEP delivery
- Adherence “low”: 17% and 33% at different DBS TFV levels. Intervention had no impact on increasing persistence or execution of PrEP.
- No seroconversions in 6 months of follow-up among these 407 women
 - women may have been at lower risk of HIV
 - intermittent PrEP use around periods of risk
- IPV decreased in both study arms.
- IPV reporting may have been differential by arm.
- Disclosure to male partners significantly higher among CHARISMA women at M6, although not M3.
- Male partner support: “supportive” and level of support was not impacted by intervention

Reflections in hindsight

- To what degree were results impacted by intervention length and content?
- How would results have been different if the study population was more “vulnerable” in their relationships?
- How was level of effect diminished by SOC participants receiving an elevated SOC relative to non-research settings?
- Why is PrEP persistence and execution so low in this setting (and yet seroconversions nil)?

Conclusions and Next Steps

- CHARISMA was not superior to SOC in context of impacting PrEP persistence.
- Possible considerations: Benefits of established feasibility and acceptability of intervention
- Much was learned, created, refined and implemented – skills development of the staff extensive: lay counsellors, nurses
- CHARISMA Toolkit – intervention materials to be posted online

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Resources for addressing partner dynamics and violence in PrEP services


Michele Lanham, FHI 360

CHARISMA Toolkit



**CHARISMA
Toolkit guide**

Empowerment counseling
to improve women's ability to
use PrEP safely and effectively

**CHARISMA
Counselor Training
Curriculum**



SAMPLE FOUR-DAY AGENDA (FULL TRAINING)
Prior to training ask counselors to review the Counseling Manual and Counseling Job Aid

Section	Time required	Activity	Activity name
DAY ONE			
Welcome			
	8:30-8:40 a.m. (10 min)		
	8:40-9:10 (30 min)	A.1	What is CHARISMA
A. CHARISMA and Why We Need It	9:10-9:40 (30 min)	A.2	Why We Need CHARISMA
	9:40-10:40 (60 min)	A.3	Relationships and PrEP
<i>Break</i>			
<i>10:40-10:55 (15 min)</i>			
B. Counselor Skills	10:55-11:35 (40 min)	B.4	The Counselor Role
	11:35 a.m.-12:20 p.m. (45 min)	B.5	Counselor Challenges
<i>Lunch</i>			
<i>12:20-1:10 (50 min)</i>			
B. Counselor Skills	1:50-2:00 (10 min)	B.6	Active Listening
	2:00-2:40 (40 min)	B.7	Listening Skills
<i>Break</i>			
<i>2:40-2:55 (15 min)</i>			
C. Gender Exercises	2:55-3:25 (30 min)	C.8	Who Has Power
	3:25-3:55 (30 min)	C.9	Sex and Gender
	3:55-4:25 (30 min)	C.10	Where Do You Stand?
Wrap-Up			
	4:25-4:40 (15 min)		
DAY TWO			
Welcome Day Two			
	8:30-8:40 a.m. (10 min)		
D. Counseling: Healthy and Unhealthy Relationships	8:40-9:40 (60 min)	D.11	Happy and Unhappy Relationships
	9:40-10:10 (30 min)	D.12	What Makes a Good Relationship
	10:10-10:40 (30 min)	D.13	Tree Activity
<i>Break</i>			
<i>10:40-10:55 (15 min)</i>			
D. Counseling: Healthy and Unhealthy Relationships	10:55-11:25 (30 min)	D.14	Types of Abuse
E. Counseling: Partner Communication	11:25-11:55 (30 min)	E.15	Relationship "I" Statements
<i>Lunch</i>			
<i>11:55-12:45 (50 min)</i>			
E. Counseling: Partner Communication	12:45-1:15 (30 min)	E.16	Conflict De-Escalation
F. Counseling: Discussing PrEP Use with Your Partner	1:15-2:30 (75 min)	F.17	Discussing PrEP Use with Partners



CHARISMA Toolkit



CHARISMA Counseling Manual

Empowerment counseling to improve women's ability to use PrEP safely and effectively



CHARISMA Counseling Job Aid

Empowerment counseling to improve women's ability to use PrEP safely and effectively



Step 2 - Module C

TIPS FOR TELLING YOUR PARTNER



OBJECTIVE

Encourage the client to think about all aspects of telling her partner in order to make that discussion as safe and comfortable as possible.



TIME

5 to 7 minutes



INSTRUCTIONS AND CONTENT

Show the Counseling Job Aid page titled "Tips for Telling Your Partner."



Frame the activity: *I'm glad to hear you're interested in talking to your partner. (Or: I know, for now, you are only considering discussing PrEP with your partner.) It can sometimes be difficult to bring up the issue of HIV prevention. I'd like to help make that easier. Let's start by talking about some best practices to make the conversation as easy as possible.*

Discuss the following best practices.

How to tell your partner

- Use clear and simple language.
- Maintain eye contact; remain confident and calm.
- Have prepared answers for anticipated questions.
- Listen objectively to your partner's concerns.
- Avoid blaming others for why you decided to use PrEP.
- Observe his body language.
- Be sensitive to his emotions and feelings.



Module C Discussing PrEP Use with Partners

Tips for Telling Your Partner

HOW



WHEN



WHERE



OTHER ISSUES



Icons created by Aneque Ahmed, Guilherme Furtado, Enkha, and Lisele from Noun Project

Educational materials for male partners

CHARISMA Toolkit

HEART Relationship Assessment

HEART

Page 1 of 5

Record ID _____

READ: I would like to ask you some questions about you and about your relationship with your partner(s) and your readiness to use an HIV prevention product. These questions will help determine what kind of counseling and support you might need from us.

Before we begin, I would like you to take a moment to think about the partner or partners you have been involved with sexually during the last year.

I would like to ask you some questions about what you have told your partner about your PrEP use and his reaction. Yes No

Does your primary partner know that you are taking tablets for HIV prevention?

If you don't have a primary relationship, think about your partner who has the most "say" or more influence over your ability to use HIV prevention products.

What was his reaction when he first found out? Supportive Neutral Opposed Don't know

PrEP Fact Sheet

TAKEN DAILY, PrEP IS AN ADDITIONAL PREVENTION OPTION FOR HIV-NEGATIVE PEOPLE.

PrEP is another option for prevention. Prevention options include:

- Condoms
- PrEP
- Counseling
- PEP
- Healthy lifestyles
- Treatment for STIs
- Male medical circumcision
- ART for partners living with HIV

What is the difference between PrEP, PEP, and ART?

All three contain antiretroviral medicines in different combination for different purposes:

- **PrEP** is a pill that has 2 anti-HIV medicines taken daily to prevent HIV for HIV-negative people
- **PEP** is taken within 72 hours after exposure to HIV (eg after rape) for 28 days to prevent HIV
- **ART** is a 3-medicine treatment for HIV-positive people to reduce the levels of HIV in a person's body

PrEP is only for people who are HIV-negative.

PrEP is recommended for people at high risk for HIV infection.

Give Support!

You have a right to live free of violence.

Changing is hard - but we help each other

If we don't reach out to them it's like we agree with the violence.

and our family is happier!

She can't provoke you to use violence. It's YOUR choice.

Talk with your partner -- decide together how to stay safe.

SASA

www.raisingvoices.org/sasa.php

Templates for referral directory and referral letter

SOCIAL SERVICES	HEALTH SERVICES	LEGAL SERVICES
Crisis counseling	Mental health support and counseling	Law enforcement
Financial aid	Forensic exam	Legal aid
Shelter	Additional HIV and contraception services	
Services for children		

Toolkit available at <https://www.prepwatch.org/charisma/>



CHARISMA Videos

HEALTHY RELATIONSHIPS

WHAT'S A HEALTHY RELATIONSHIP ANYWAY?

PARTNER COMMUNICATION

HOW TO TALK TO YOUR MAN?

PREP DISCLOSURE

HOW DO YOU TELL YOUR MAN ABOUT PREP?



Available on the [RTI International YouTube channel](#)

Asking about IPV as part of PrEP services is a PEPFAR requirement

PEPFAR 2020 Country Operational Plan: To improve effective use of PrEP, new or suspected cases of intimate partner violence (IPV) must be identified and provided necessary gender-based violence (GBV) response services per WHO clinical guidelines. This must be done by integrating routine enquiry* for IPV into PrEP service delivery.

Each setting where AGYW and adult women are counseled on and prescribed PrEP should have the following:

1. Counselors trained on:

- a) How to ask about violence using a standard set of questions where counselors can document responses;
- b) The provision of age-appropriate first-line support (LIVES) when violence is suspected or disclosed;
- c) Referrals for clients who disclose experiencing violence to local clinical and nonclinical GBV response services using discrete referral cards, or the provision of post-violence clinical care at the site itself.

2. A simple **standard operating procedure, job aid**, or algorithm that outlines the steps that PrEP counselors take if a client discloses experience or fear of violence.

3. Privacy and confidentiality ensured.

**routine enquiry — an approach to identifying cases of IPV among all clients who present for specific services, without resorting to the public health criteria of a complete screening program. It is recommended in certain services for populations that may be at a higher risk of experiencing violence.*

Standard Operating Procedures (SOP) and Job Aid for Addressing Intimate Partner Violence in PrEP Services

Includes procedures for:

- IPV routine inquiry, including suggested questions for cisgender women and key populations
- Providing first-line support using LIVES to clients who disclose violence
- Establishing/maintaining a referral network and facilitating warm referrals
- **PrEP counseling for clients who disclose violence**
- Supporting staff experiencing vicarious trauma
- Adaptations during COVID-19

Available on PrEPWatch.org ([link](#)) and USAID.gov ([link](#))

Summary of steps for discussing partner relationships and PrEP use

START

- Share any limits to confidentiality (if relevant)
- Administer a standard set of questions to identify clients experiencing IPV

No to all questions → Inform client about violence response resources available (provide resource list as indicated)

Yes to any question → Respond to the violence disclosed (LIVES)

Recent (<72 hours) sexual violence may require immediate access to post-exposure prophylaxis (PEP) and emergency contraception

Document disclosed violence, services provided, and referrals made on <insert form title>

- Counsel on PrEP use within abusive and controlling relationships
- Decide whether to tell partner about using PrEP

Does not want to tell partner → Review strategies for taking PrEP without partner's knowledge

Wants to tell partner → Review tips for telling a partner

Client describes abuse → Decide whether to tell partner(s) about PrEP use

No abuse described → Decide whether to tell partner(s) about PrEP use

Wants to tell partner → Review tips for telling a partner

Does not want to tell partner → Review strategies for taking PrEP without partner's knowledge

- Brainstorm what to do if partner discovers PrEP use and becomes angry
- Schedule an appointment for the client and partner if the client wants the provider's help telling partner about PrEP use

Document that provider asked about IPV as part of PrEP counseling in the PrEP registry

- Final counseling and decision regarding PrEP

PrEP Job Aid for discussing partner relationships

Overview

- This job aid is designed to be used with the standard operating procedure (SOP) *Addressing Partner Relationships and Intimate Partner Violence in Pre-Exposure Prophylaxis (PrEP) Services*.
- Providers initiating a client on PrEP or helping a client who is struggling to use PrEP as prescribed can use this job aid to ask about a client's relationships with their partner(s). This includes asking about intimate partner violence (IPV), responding to IPV (as needed), and counseling on how to use PrEP with or without a partner's knowledge. For more on provider training, managing spontaneous disclosures of violence, and establishing violence response referral networks, please see the SOP.

Instructions for Use

- Begin at the arrow labeled "Start" on either the summary or detailed version of the job aid, depending on your preference. Complete each step indicated by the tick boxes before moving on to the next step.
- When decisions are required, follow the relevant arrow according to the client's wishes or responses.
- Text in *italics* on the detailed flow chart is a suggested script.

Instructions for Adaptation

- Questions about IPV and other local specifications, such as mandatory reporting requirements if any, should be revised per national/clinic guidance.
- The boxes outlined with dashed borders describe the monitoring process that should be undertaken after the interaction with the client has ended. Revise as needed according to clinic processes.
- Text that will require review and/or adaptation, including the titles of forms/materials used at your site, is underlined.
- Delete these "Instructions for Adaptation" before printing a final version of this job aid for your clinic.
- To print, copy the job aid/cover and the detailed flow chart two-sided on an A3-sheet and fold the sheet (finished/folded size: A4).

This work was made possible by the generous support of the American people through the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). It is the result of a collaboration between the Community Health Clinic Model for Agency in Relationships and Safer Microbicide Adherence (CHARISMA) project; the Meeting Targets and Maintaining Epidemic Control (ETAC) project; the Teaching, Impact, Saturation, and Epidemic Control (TISE) project; and the Collaboration for HIV Prevention Options to Control the Epidemic (CHOICE) activity. The contents are the responsibility of CHARISMA, ETAC, TISE, and CHOICE and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government.

PEPFAR USAID FROM THE AMERICAN PEOPLE CHARISMA EpiC Health Program and Epidemic Control RISE Health Program and Epidemic Control

Opening and Introductions

CHARISMA and CHARISMA's Randomized Control Trial Overview

Randomized Control Trial Results

Results Summary and Considerations

Resources for Addressing Partner Dynamics & Violence in PrEP Services

Mobile Site Development Activities

Discussion and Final Q&A

Mobile Site Development Activities

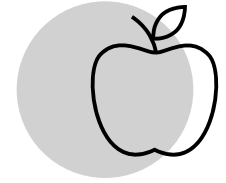
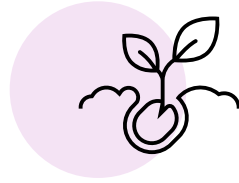
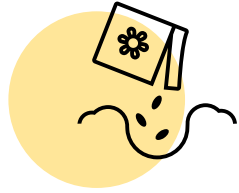
Miriam Hartmann, RTI International

Why create a mobile site?

- Current delivery of the HEART relationship assessment tool and counselling require **substantial counselor time**, which is **not feasible** for limited time/resource scenarios
- **A need exists for more accessible relationship/IPV counselling and support**

It's not always feasible for women to attend a clinic/see a counselor in person. This was particularly salient during the COVID lockdown, where we saw increased reports of IPV to police and hotlines and movement was restricted.

What's our development approach?



Content adaptation

- ✓ Use human-centered design workshops to adapt in-person counselling content into mobile friendly tools
- ✓ 2-3 2-day workshops with women split by age, 18-24 and 25-45
- ✓ Ideas further reviewed in one-on-one cognitive interviews with 24 women

Beta testing

- ✓ Beta-test rough prototyped version(s) with 80 women
- ✓ Evaluate useability and functionality
- ✓ Make further modifications

Field testing

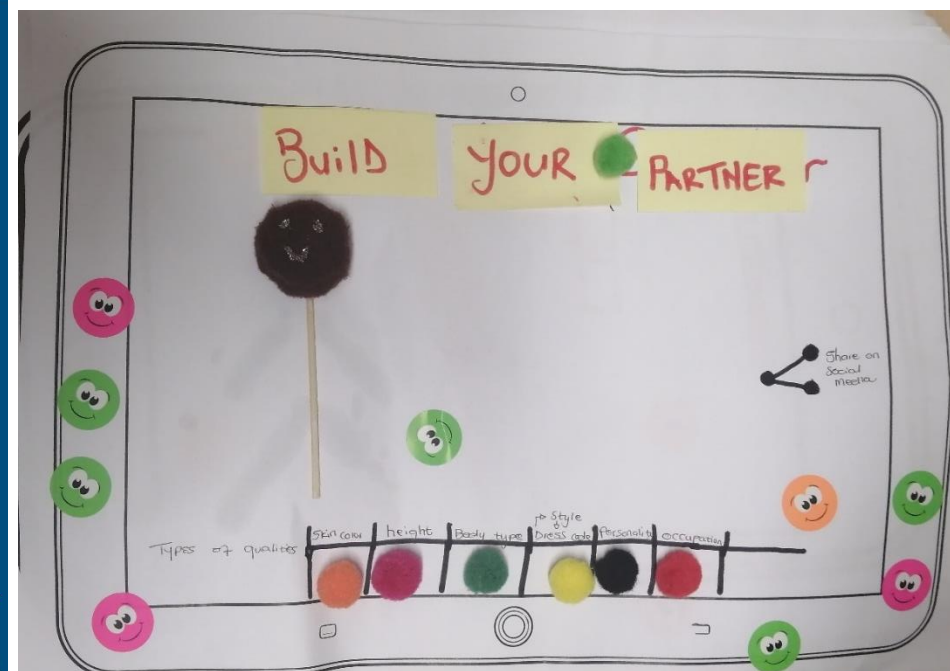
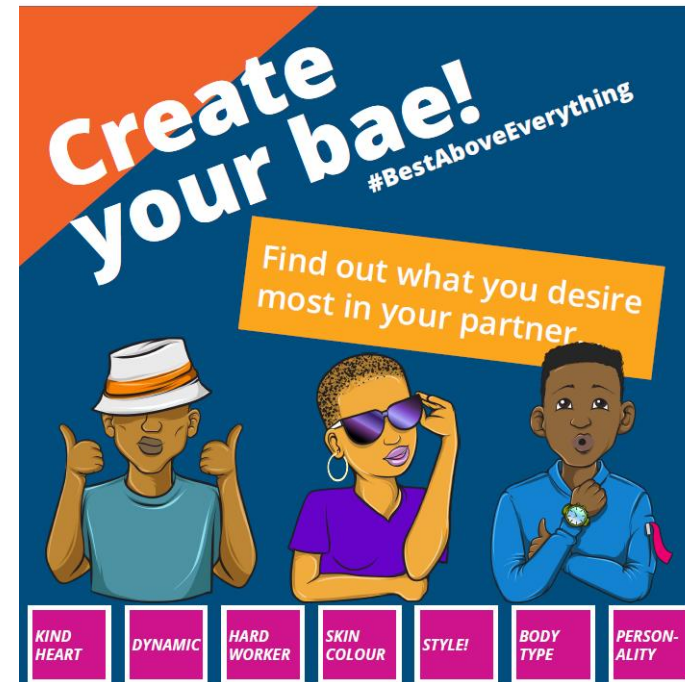
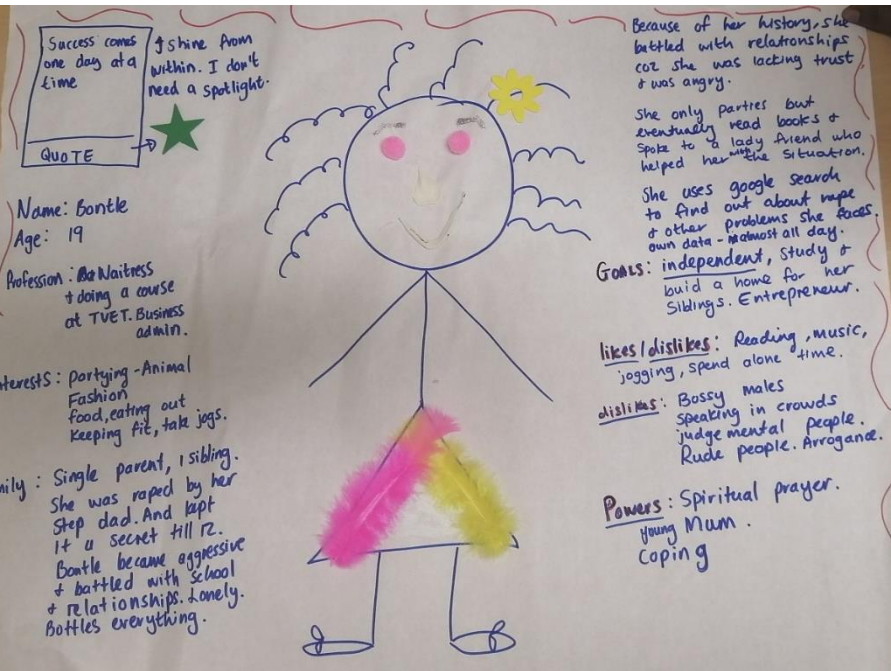
- ✓ Launch and evaluate acceptability and feasibility among 160 women in 4 public health PrEP clinics
- ✓ Women interact with content on their own, followed by an interview
- ✓ Technical feasibility monitored during use

Final product

- ✓ Final product available

What did we learn from our first workshop?

- Through activities such as persona creation and other creative prototyping, we learned:
 - Young women identify patterns of historical abuse among their peers and subsequent mental health and relationship challenges needing support
 - They have a desire for opportunities to create their own life and (healthy) relationship journeys
 - They're creative and have suggested alternative needed content for protection (e.g. self-defense and associated physical strength skills)



Thinking about the future

- Aiming not to reinvent the wheel and therefore drawing from **existing features/tools**, such as chat bots (e.g. Hi Rainbow)
- We are engaging with NDOH product teams in South Africa to **consider technical feasibility and alignment of values/needs** for possible **future integration**
- Considering **other sources of input** for valuable adaptations to **meet broader needs** of young women across South Africa (e.g. DREAMS)

CHARISMA Wrap-up

- CHARISMA RCT did not show statistically significant results for most outcomes, BUT...
 - Impacted PrEP disclosure
 - Suggested trends towards a positive intervention effect among those with "CHARISMA risk" (most vulnerable)
 - Was HIGHLY acceptable and perceived as highly valuable to participants for themselves and others in their communities
- CHARISMA Toolkit offers several materials to PrEP programs that can be tailored to meet resource needs
- Mobile CHARISMA will offer new resources to reach a broader audience

Thank you



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Q&A



Upcoming Sessions

**NOV
19**

**JAN
21**

**FEB
25**

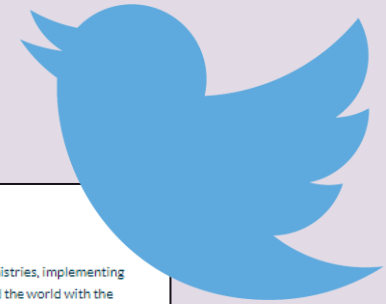
**Determining ‘Substantial
Risk’ and the use of Risk
Assessment Tools for PrEP**

TBD

Visit www.prepwatch.org/virtual-learning-network for up-to-date information.

Follow Us & Visit PrEPWatch

- Follow **@PrEP_LN** on Twitter!
- All **webinars are recorded** and will be accessible on PrEPWatch within a week post-presentation date.
- Complementary **resources** will also be shared on PrEPWatch—including relevant research articles and tools.
- Registration for **upcoming webinars** is also located on PrEPWatch.



Virtual Learning Network

The PrEP Learning Network, hosted by CHOICE, provides national and sub-national ministries, implementing partners, community-based organizations (CBOs), and others working with PrEP around the world with the tools and resources, best practices, and opportunities to learn from others to help to advance PrEP scale-up. Prior to July 2020, the PrEP Learning Network was hosted by OPTIONS, EpiC and RISE.

Its monthly webinar series features presentations from experts in specific content areas, lessons learned and insights shared from implementing partners and government ministries, and new tools or research on specific topics related to PrEP scale-up, ranging from demand creation to continuation.

The following pages include links to register for upcoming PrEP Learning Network webinars, watch previously recorded webinars and access complementary resources, research and tools on webinar topics.

Upcoming Webinars

- Expanding Access to PrEP through Community-based Delivery
Thursday, August 27, 2020, 9:00am EDT | 15:00 CAT | 16:00 EAT
[Register here.](#)

Previous Webinars

- Addressing the Elephant in the Room: Stigma and PrEP Rollout
Thursday, July 23, 2020
Research shows that stigma is an important barrier to the uptake of most services along the HIV prevention cascade, including PrEP. In this webinar, we heard about evidence-based approaches to address provider-level stigma, so clients feel comfortable and supported when accessing PrEP services. We'll also heard how Kenya has tried to de-stigmatize PrEP use by positioning it as an HIV prevention option "for all."
[Recording / Slides](#)

Visit www.prepwatch.org/virtual-learning-network for up-to-date information.

**Thank
You!**

