

"PrEP my Way": A novel PrEP delivery system to meet the needs of young African women

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Background

- Young women face numerous barriers to pre-exposure prophylaxis (PrEP) adherence
- Novel, supportive communitybased delivery systems that offers privacy and convenience may improve PrEP uptake when needed and desired





Developing PrEP My Way

- Client-centered approach to optimally design PrEP My Way
 - Kit with instructional materials
 - Peer delivery system (including phone communication and kit delivery plans)
- Iterative design through IDIs and FGDs
 - Young women & men
 - Community health volunteers
 - Clinical staff
- Supported by Ark (Nairobi-based design firm)





Recruitment & PrEP My Way kit

- Clinic-based initiation of PrEP and contraception
- Community-based peer delivery of a visually appealing kit with pictorial and video guidance
 - HIV self-test (oral or finger prick)
 - PrEP
 - STI self-sampling (Cepheid)
 - Pregnancy test
 - Choice of contraception (condoms, oral pills, self-injection medroxyprogesterone)



Instructional Guides

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Prep Pills



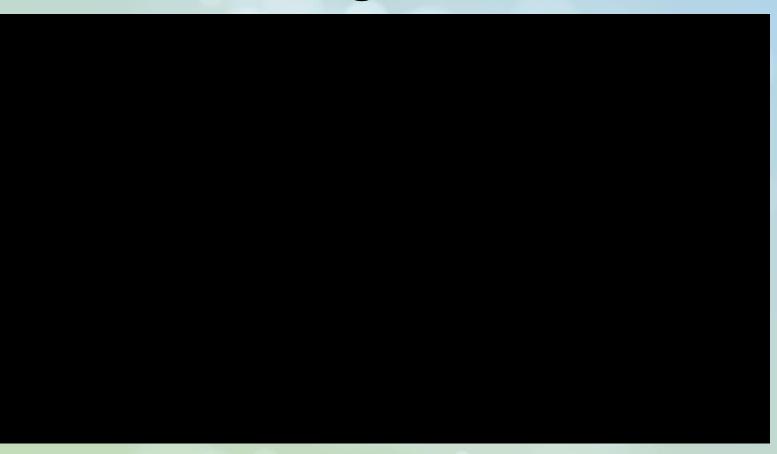
Prep Pill Pack



Instruction card inside the prep pill pack

Video guidance





Evaluation

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Objective: To assess *PrEP My Way* for feasibility, acceptability, and preliminary impact on PrEP adherence and program retention

- 150 women randomized 1:1 to PrEP My Way vs Standard of Care and followed for 6 months
- <u>Feasibility</u>: Receipt of the kit and ability to use its components
- Acceptability: Mixed-methods interview
- <u>Preliminary</u> impact: Kit use/clinic attendance (retention) and DBS tenofovir-diphosphate levels (TFV-DP; persistence) at 6 months
- Potential influencing and mediating sociobehavioral factors explored







Participants

- Inclusion criteria
 - Young woman (age 16-24 years)
 - Reported sexual activity within the past 3 months
 - Initiating PrEP
 - Residence in the Kisumu region
 - Phone ownership
 - Ability to understand KiSwahili, DhoLuo, and/or English
- Exclusion criteria
 - Inability to provide informed consent (e.g., intoxication, mental disability)
 - Provider discretion (e.g., co-enrollment in some studies)





Trial flow

Participants initiate PrEP at Lumumba Clinic or Kisumu County Hospital

- Enrollment, consent, and randomization occur
- Baseline questionnaire completed

PrEP, STI testing, and/or contraception as desired PrEP My Way kit delivered (Month 1) per routine care at Lumumba or KCH (Month 1) PrEP, STI testing, and/or contraception as desired PrEP My Way kit delivered (Month 3) per routine care at Lumumba or KCH (Month 3) PrEP, STI testing, and/or contraception as desired PrEP My Way kit delivered (Month 6) per routine care at Lumumba or KCH (Month 6) Participant returns to clinic for DBS and Participant seen by the study for DBS and exit questionnaire completion +/- interview exit questionnaire completion +/interview



Baseline characteristics

Characteristic	PrEP My Way	Standard of care
Median age in years (IQR)	21.6 (20.7, 23.1)	22.6 (20.9, 23.9)
Median years of education (IQR)	12 (12, 14)	12 (12, 14)
Median number of current sexual partners (IQR)	2 (1, 3)	2 (1, 3)
History of an STI (N, %)	4 (5%)	6 (8%)
>60 minutes to clinic (N, %)	4 (5%)	2 (3%)
Finding time to get to clinic "very difficult" (N, %)	3 (4%)	3 (4%)
Problem alcohol use (N, %)	9 (12%)	7 (9%)
Moderate to severe depression (N, %)	42 (56%)	48 (64%)
Median sexual relationship power score (IQR; possible range 1-4)	2.7 (2.5, 2.7)	2.6 (2.3, 2.6)
Median HIV stigma score (IQR; possible range 4-20)	12 (9,12)	12 (9,12)
Median PrEP stigma score (IQR; possible range 7-35)	46 (40, 50)	46 (42, 50)

High acceptability and feasibility





Feasibility

- Of 225 anticipated kit deliveries to date, 198 (88%)
 have been successful
 - Month 1 (92%)
 - Month 3 (87%)
 - Month 6 (85%)
- Sexually transmitted infections have been diagnosed in 50 women (26%); none diagnosed in the Standard of Care arm

Acceptability

- 81% prefer it to clinical care
- 91% would use it in the next 12 months
- Median systems usability scale of 69 (IQR 61-77) indicating good performance

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Effective delivery system; low adherence



No difference detectable TFV-DP at Month 6 (p=0.18)

- 50% of samples available to date
- PrEP My Way: 5/36 (14%)
- Standard of Care: 2/34 (6%)

Qualitative quote





It's quite good; it has reduced that burden of having to come to the hospital. You know I'm a student, so that burden... that time I would use coming to the hospital to queue – you know with a public hospital that queue has got to be long – so it has reduced that time for me

Female participant, 20 years



Conclusions

- PrEP My Way is a novel PrEP delivery system with high feasibility and acceptability
- It is highly promising for delivery of PrEP and other sexual health services to a population with suboptimal engagement in traditional health systems
- Impact on PrEP persistence may depend on alternative PrEP formulations
- Future research should explore scalability in routine care and involving emerging new PrEP formulations

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Thank you, Erokamano!



