Feasibility and Acceptability Video Observed Therapy for Pre-Exposure Prophylaxis use among pregnant and postpartum women





Cape Town, South Africa





INTRODUCTION

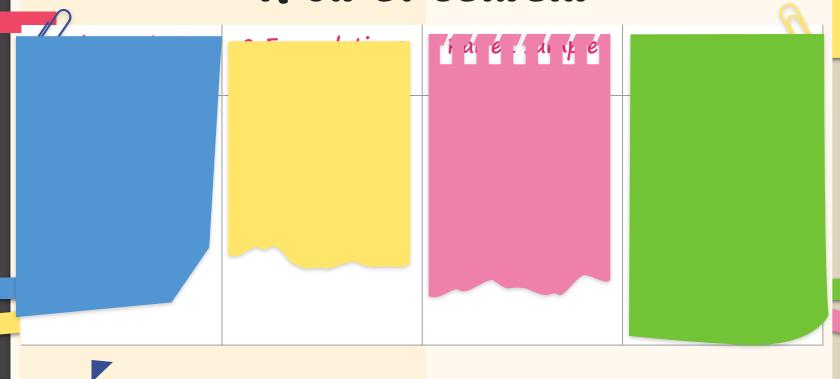
Aim:
To assess the
To assess the
feasibility and of VOTs
feasibility and
acceptability of
a

- Pregnancy and postpartum are periods of increased risk for HIV infection.
- Strict PrEP adherence is critical during these times of biological change.

INCLUSION CRITERIA:

- √ Women >= 18 years
- ✓ Confirmed HIV-negative (4th gen. antigen test)
- ✓ Attending ANC visits at Gugulethu MOU
- ✓ GA: 20-30 weeks pregnant
- √ Has a smart phone
- ✓ Consent to video observations of PrEP dosing.

A bit of context



METHODS (procedures)

01

Pregnant women enrolled into the PrEP -PK study

02

Participants
randomised to
type of oral PrEP
(Truvada/Descovy)

03

Participants
observed taking
PrEP daily via
VOTs.

METHODS (data)

04
0bservation period:
16 weeks.
8 weeks in
pregnancy + 8
weeks postpartum



Feasibility
assessed:
Reported as
fraction of
expected doses
observed (FEDO).

06

A median FEDO of ≥85% indicated VOT feasibility while <85% indicated lack of feasibility.1

Sekandi et.al. Video directly observed therapy for supporting and monitoring adherence to tuberculosis treatment in Uganda: a pilot cohort study. ERJ open research. 2020 Jan 1;6(1).

METHODS (analysis)

07

Logistic regression:
Baseline
characteristics VS.
FEDO score



08

Linear mixed
effect models:
Observation time
VS. FEDO score.
AND
Pregnancy state
VS. FEDO score.

09



Acceptability:
Qualitative, semistructured
questionnaires
and interviews.

RESULTS (Demographics)



Sample size n=53



Mean (SD) age: 28 (6)



All participants:
African/Black females
residing in Cape Town



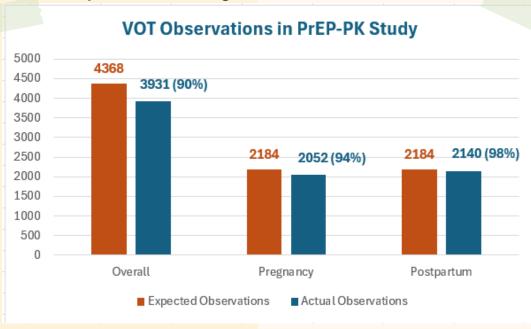
58% were unemployed/not studying at the time of enrolment.



30% of the women were carrying their 1st pregnancy.

RESULTS (VOTs)

- n= 39 (73%) completed the observation period.
- Median(IQR) observation time: 15 weeks (14-16)
- 90% OF expected videos were received after 16 weeks of PrEP dosing observation.
- This exceeds the specified feasibility threshold of 85%



RESULTS (VOTs)

Table 1: Self-reported reasons for participants failing to submit video observations during PrEP PK study, June 2022-October 2023 (n=53)

Type of Reason (%)	Reasons for missed videos	Videos missed (N=459) n (%)
	Pill not taken (dose missed)	155 (33.8%)
Person Related (50%)	Forgot to record video	30 (6.5%)
	Travelling	8 (1.7%)
	Participant uncontactable during dosing time	35 (7.6%)
Process Related (4%)	Unsure of VOT process	2 (0.4%)
	Pills finished/late for refill	3 (0.7%)
	Not in a convenient/private place to record at time of dosing	15 (3.3%)
Technology Related (46%)	Power Outages (battery dead/too dark to record)	25 (5.4%)
	No cell phone network in area	27 (5.9%)
	Phone malfunction	8 (1.7%)
	No reason specified	151 (32.9%)

Reasons for missed videos are listed in Table 1.

RESULTS (Feasibility)

FEDO vs. TIME

- FEDO increased over weeks of observation: FEDO at week 1 (81%); week 7 (92%) and week 15 (97%).
- LME modelling: every additional week of observation time was associated with a 0.5% (95% CI: 0.20%, 0.89%) increase in median FEDO score (p value=0.002).

FEDO:

fraction of expected doses that were observed. Used as a measure of feasibility.

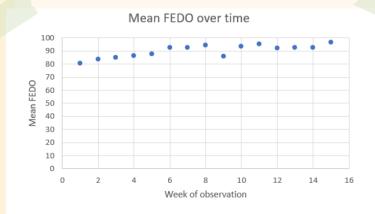
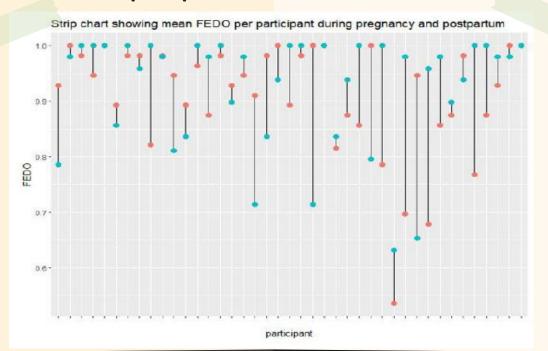


Fig. 1 Scatter plot depicting median FEDO at each study week

RESULTS (Feasibility)

FEDO vs. Pregnancy

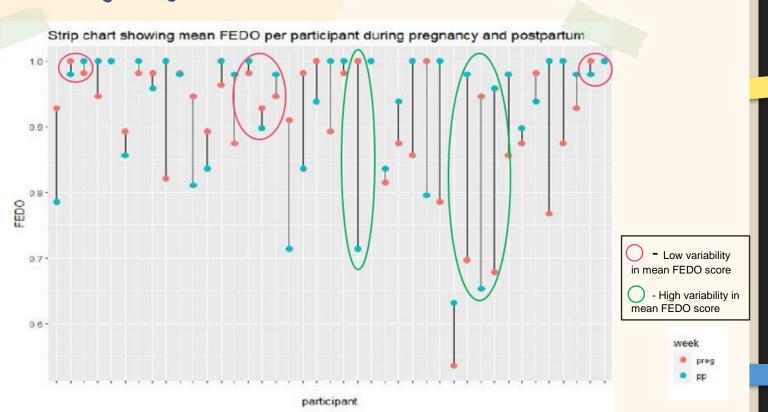
- No significant association between pregnancy state and median FEDO score in LME modelling (P value= 0.523).
- Strip chart shows lots inter-participant variation.



week

RESULTS (Feasibility)

FEDO vs. Pregnancy



RESULTS (Acceptability)

VOTs helped me to take my PrEP daily

98%

I felt that the process was confidential

77%

VOTs was convenient for me

79%

The process was easy for me

947

"It helped with

(cellphone) data a lot

and also if I was not

sending video everyday I

easy for me to take my

Prep everyday." PID:

nuch to send the much to send there's videos now there's nothing that is nothing aging me to encouraging me take my prep as take my prep still much as I'm pID: 027 taking it."—PID: 027

"If you want to see if I'm taking my Prep the blood test times I was not comfortable to take OO4"

VIDEO OBSERVED THERAPY

Technology

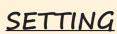
Technology comfort/proficiency and owning a smartphone was not a barrier

→ FACTORS

RELATING TO

ACCEPTABILITY

OF VOTS



Adaptation needed. Resources used in the study may not be available in the South African public health system.



<u>Infrastructure</u>

Poor cellphone network and frequent loadshedding (rolling blackouts) were barriers.



Majority of censorships occurred within the first 3 weeks enrolment.



Acknowledgements:

The PrEP-PK team

University of Cape Town

A/Prof. Dvora Joseph Davey

CONCLUSION!

Short-term vot may be feasible and acceptable in pregnant and Postpartum women for the monitoring and supporting of daily oral prep adherence.

VOT may be useful for assuring daily dosing and can be applied to future PK studies that require strict adherence.