

# Empowerment clubs did not increase PrEP continuation in AGYW in South Africa & Tanzania - results from EMPOWER trial

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STRIVE webinar, November 2018

# Background

- Adolescent girls and young women (AGYW) are at substantial risk for HIV infection and gender-based violence (GBV)
- One-third of women globally experience physical and/or sexual violence by partner
- GBV increases the risk for HIV acquisition AND undermines the HIV treatment cascade



# Violence and harmful gender norms undermine HIV treatment



Limited data for prevention but emerging evidence for similar patterns

Source: Kouyoumdjian, 2013; Morfaw, 2013; Musheke, 2013; Musheke, 2014; Hatcher, 2015;

# Effects of violence and harmful gender norms on PrEP uptake and continuation



- Trials conducted in the context of high levels of violence
- Fear of rape or past IPV may motivate PrEP uptake
- Male partners play a critical role in decisions to continue product use
  - Fear of violence may lead to non-uptake, product concealment and low use
  - PrEP may exacerbate conflict in relationships
  - Violence is generally a rare event in trials 3-16%
- Strong association between reports of violence and sub-optimal adherence
  - > 2-fold higher risk of non-adherence to oral PrEP or vaginal ring
  - All forms of violence important, not just physical
  - Effects appear to be short-lived



# Prevention of violence against women and girls – the evidence



- Men and boys  
gender norms  
programming
- Economic  
empowerment
- One-stop crisis centres
- Women's police stations
- Perpetrator programmes
- Social marketing
- Alternative rights of  
passage
- Home visitation
- Infrastructure/transport
- ICT services

- Awareness raising  
campaigns
- Personnel training
- Justice and law  
enforcement  
responses

- Community  
mobilisation
- Empowerment  
training for women  
and girls
- Group training for  
women and men
- Microfinance/ cash  
transfers + gender  
training

# Research question

*Is it feasible, acceptable and safe to integrate responses to gender-based violence and harmful norms into an HIV prevention programme offering PrEP for AGYW aged 16-24 years?*

Will adherence clubs with a four-session empowerment curriculum enhance PrEP uptake and continuation?



Johannesburg, South Africa



Mwanza, Tanzania

# Study design and population

16-24 years,  
HIV negative, sexually active,  
non-pregnant, no renal or  
hepatic disease  
No immediate risk of harm\*

Randomised irrespective of PrEP uptake at baseline

Counselling & SMS reminders  
+ Empowerment clubs

Visits at M1 and M3, then quarterly up to M15

GBV screening, HIV testing, safety assessments, PrEP dispensing  
Youth friendly Comprehensive sexual and reproductive health package  
Qualitative interviews X 3 (n=25)

Counselling & SMS reminders

**Primary outcome: PrEP continuation at 6 months**

# PrEP support for all participants



- Participant-centred counselling
- SMS one way motivational messages and visit reminders
- Community dialogues
- PrEP demand creation materials



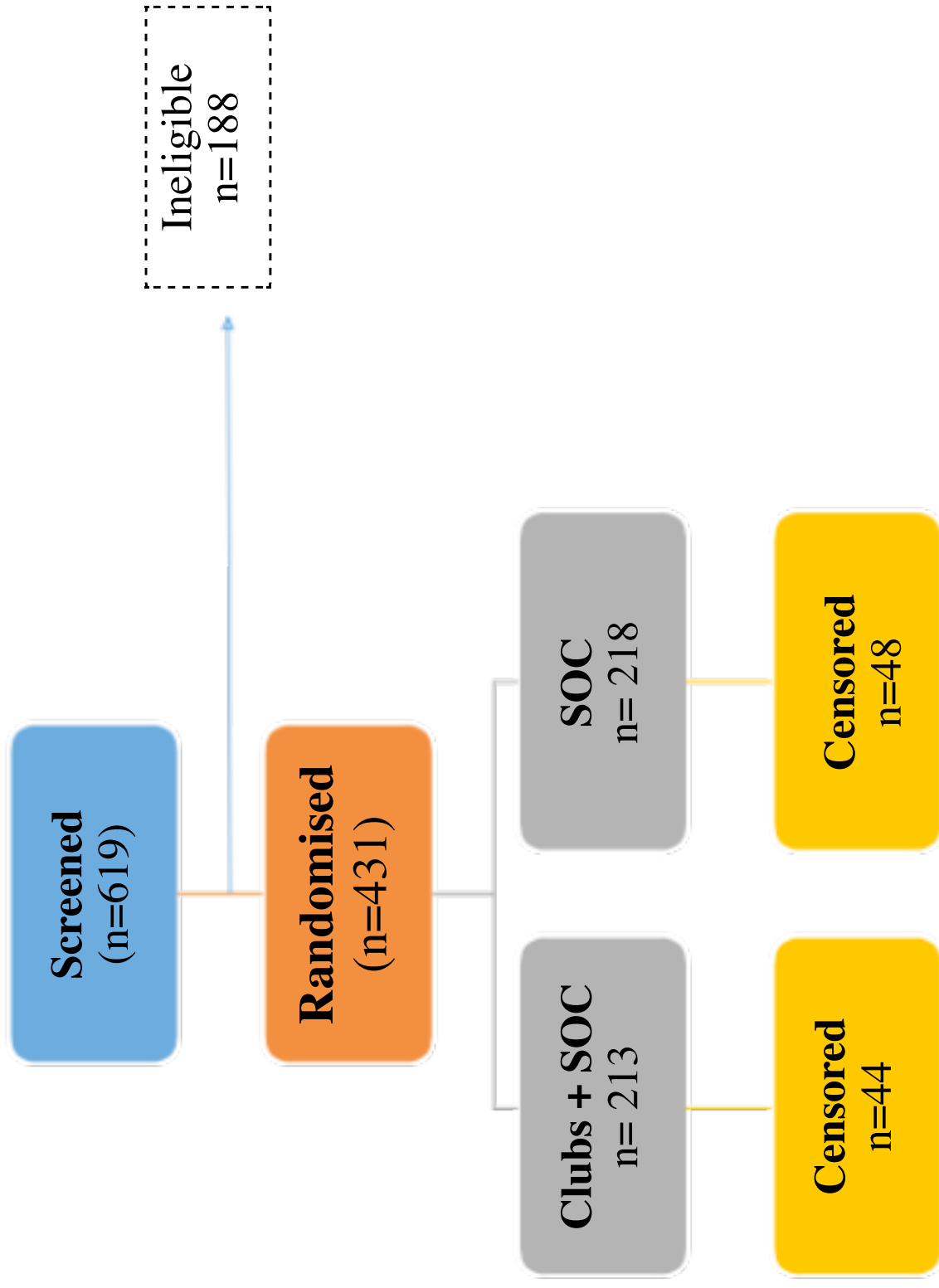
# Empowerment clubs

- Four session curriculum
  - Gender roles and social norms
  - Power and control
  - Sexual and reproductive health
  - Empowerment
- Modelled on experience of ART clubs
- Group-based participatory sessions
- Trained peer facilitator
- Non-clinic venue
- Monthly, 2-hour duration
- Planned 20 members per club



- PrEP continuation based on pharmacy refills
- Intent-to-treat analysis
  - Also included per protocol and pre-specified sub-group analysis
- Differences in PrEP continuation at M6 assessed using Kaplan-Meier survival analysis, by log-rank test.
- Assessment of differential efficacy in population sub-groups explored using stratified Cox regression analysis
- Associations between baseline characteristics and PrEP continuation or club attendance compared using chi square tests

# Results: screening & enrolment



*Censored at time of product discontinuation for medical reason or relocation*

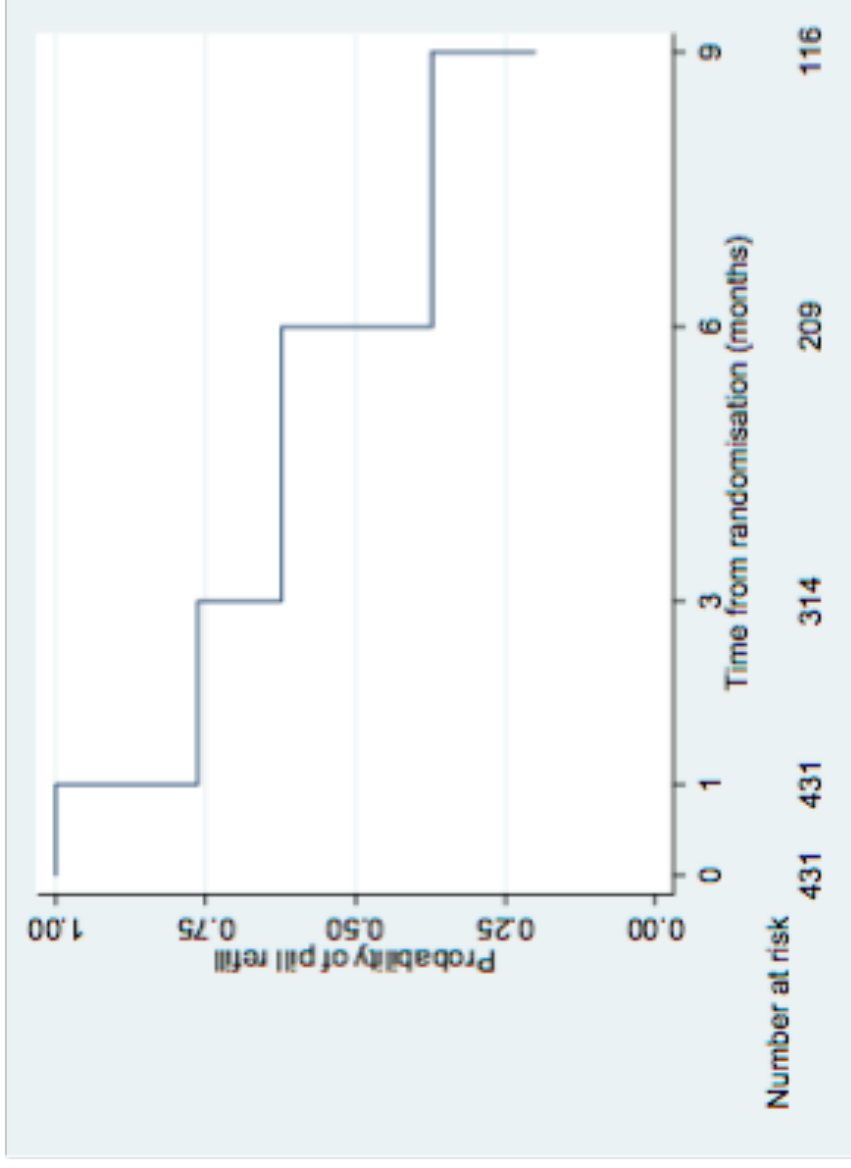
# Baseline characteristics

	Clubs N=213 % or Median (IQR)	No Clubs N=218 % or Median (IQR)
Site: South Africa	88%	81%
Age < 20 years	27%	23%
Unmarried	91.8 (190)	92.1 (187)
Ever experienced GBV	30.5 (65)	36.1 (79)
> 1 partner past 6 months	32.9 (68)	27.6 (56)
Condom use at last sex	41%	40%
Using Contraception	88%	89%
Nulliparous	62%	61%
Curable STI	33.8 (72)	33.5 (73)
VOICE risk score $\geq 5$	93.4 (199)	95.0 (207)
Believes PrEP prevents HIV	86.7 (182)	81.4 (175)



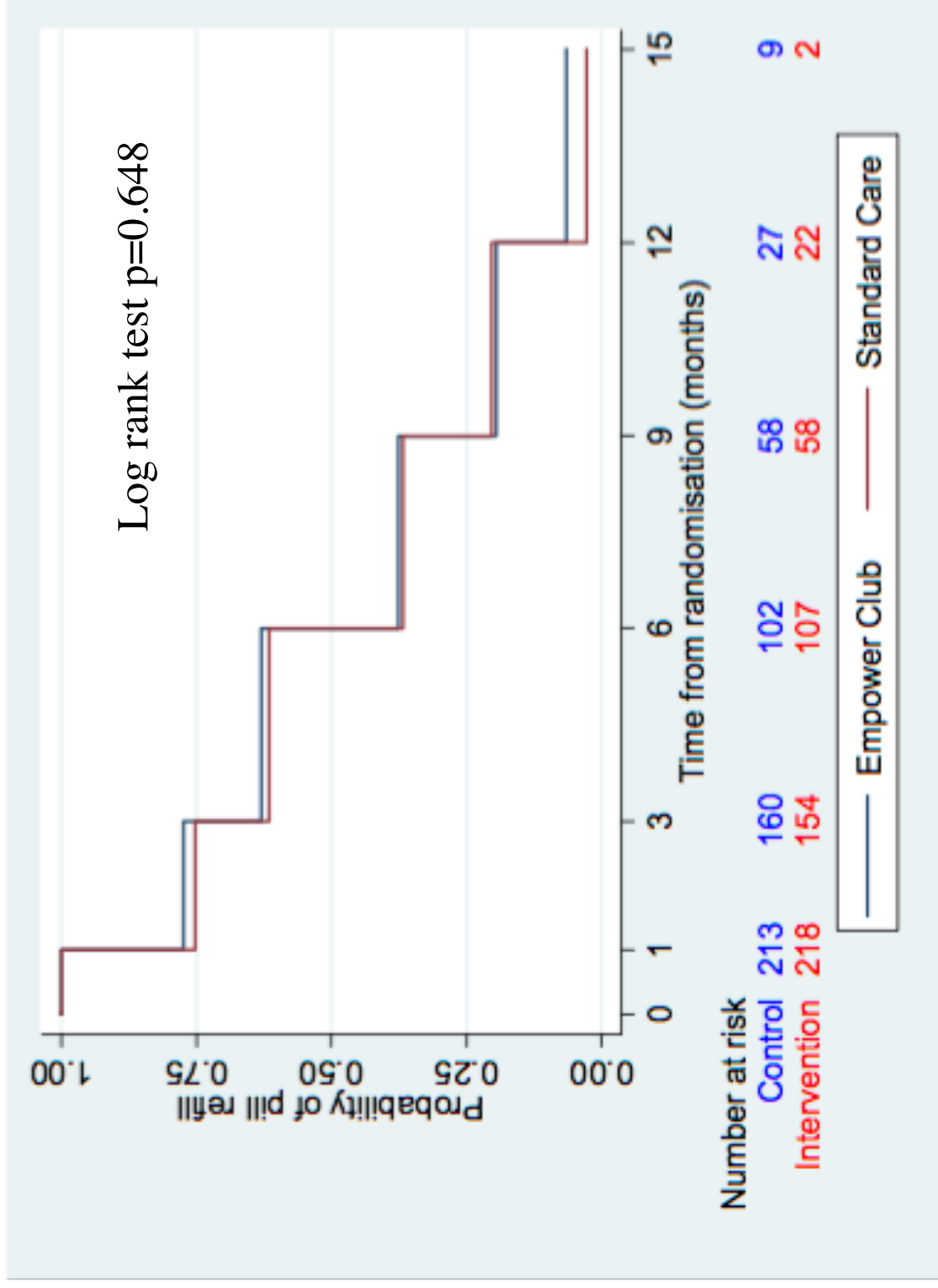
# PrEP uptake and continuation

PrEP uptake was high at 97% but continuation declined to 60% at M6



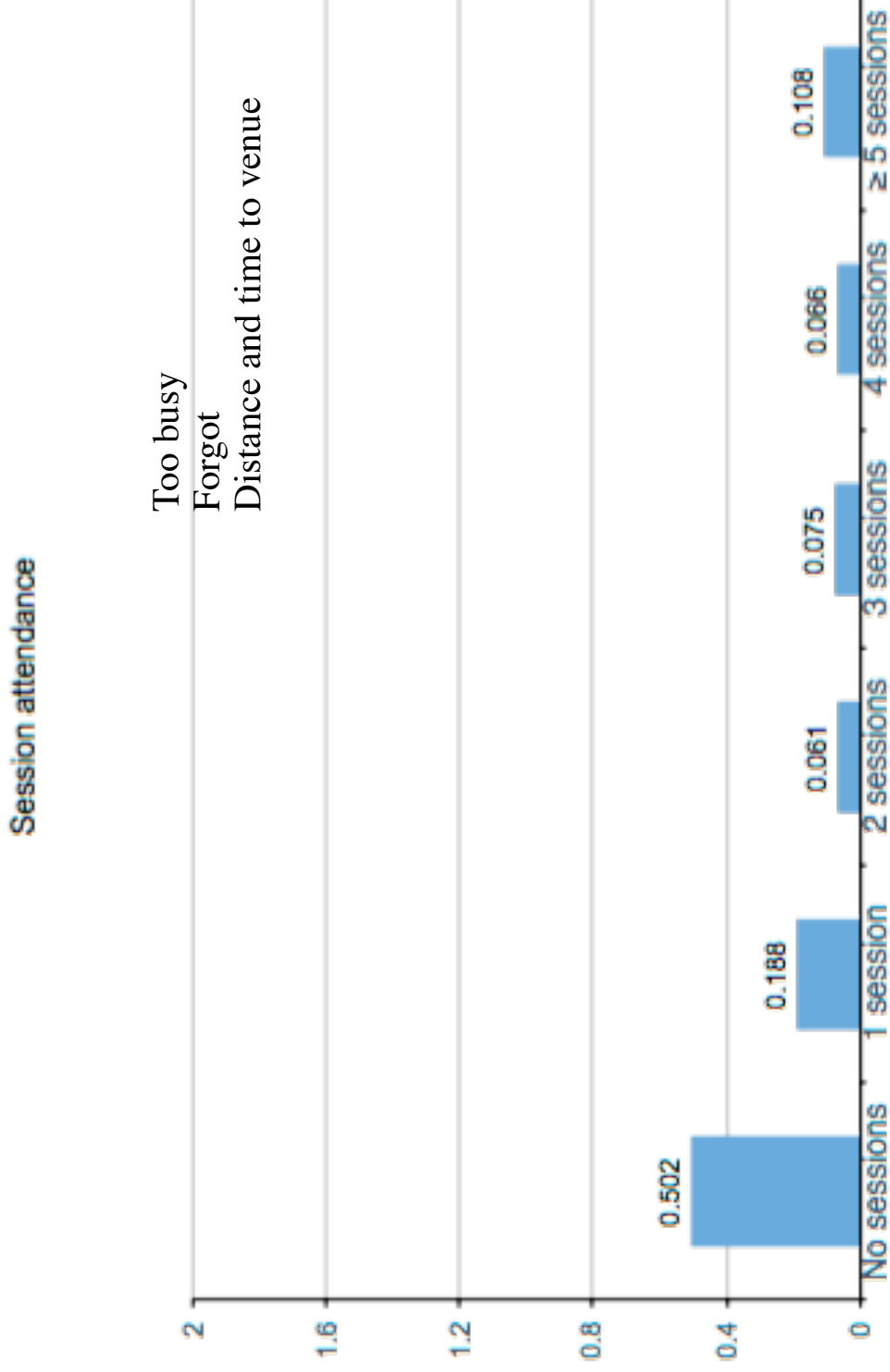
Participants significantly **LESS LIKELY** to continue if **married/living with partner**, partner was **source of income**, they had **2 or more children** or **did not think PrEP would prevent HIV infection**

# PrEP continuation, by arm



No difference in as-treated analysis, using retention in care or stratified by age group, risk score, GBV at baseline

# Club implementation



No significant differences in baseline characteristics between those that completed  $\geq 1$  sessions vs. those that did not

# Perceived benefits of attending clubs – qualitative data

“I have learned to be strong, to be a strong woman, to believe in myself... to know how to react in different scenarios”

(22 yr old student with **GBV** experience)

- Participants learnt new skills and knowledge
- Felt empowered in relationships
- Developed greater tolerance
- Were able to recognise violence in relationships and escape from it
- Found catharsis and self-expression in clubs



# DISCUSSION

- PrEP uptake in this population was high, but diminished with time and was not enhanced by empowerment club participation
- Empowerment club participation was low
  - Despite enthusiastic feedback from those that did participate
  - reflects the busy nature of young women's lives;
  - clubs may be more challenging to implement in large urban areas where social cohesion is lower;
  - Club cohesion may be more challenging to build in populations that are essentially healthy and not living with a stigmatised disease
- Need for ongoing development of strategies to support PrEP continuation and address high levels of violence and harmful gender norms experienced by young women

# Acknowledgements

Participants, CABs and communities  
Study teams in South Africa and Tanzania  
Partner organisations who provided violence referral services

This work was made possible by EHPSA

We acknowledge the contribution of the STRIVE consortium and the SA  
MRC to this work

