Preference Between Precoital and Continuous Use of Duet® in Zimbabwe

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1. Background

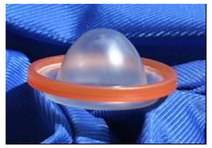
- Inadequate adherence to female-initiated methods has called into question the ability of several recent HIV prevention trials to evaluate product efficacy.[1,2]
- New coital-independent methods are being developed to simplify use, improve adherence, and better assess effectiveness.
- Duet® is a combination microbicide-delivery system and a cervical barrier that can be used continuously or precoitally.

This study explores factors associated with Zimbabwean women's preference of one use-regimen versus another.

2. Study Products

Duet Device

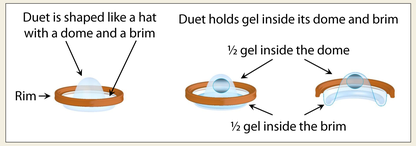
- Reusable microbicide delivery system
- Single size (70mm), polyurethane cervical barrier
- Gel is loaded into the dome and the brim



Gel

- BufferGel provided in single-use 10g sachets
- Applied on both the vaginal and cervical sides of Duet prior to insertion

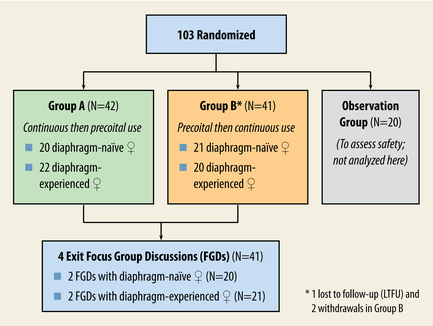
Duet Use Instructions



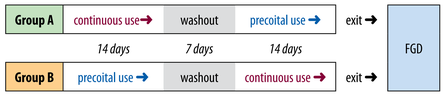
Brief Summary

- Load half the gel in the brim and half in the dome
- Squeeze the rim together
- Insert into the vagina

3. Study Design



4. Methods



- Crossover study: N=83 ♀ randomized
- Structured interviews at study entry and exit
- Multivariate logistic regression to identify factors associated with use-regimen preference at exit
- Exit FGDs conducted with subset (N=41) and analyzed thematically

Key Eligibility Criteria

Inclusion criteria

- Sexually active, healthy females aged 18–40
- Non-pregnant
- On highly effective contraception
- Demonstrated correct use of Duet at the clinic

Exclusion criteria

- Abnormal menstrual cycle
- Genital abnormalities or symptoms

5. Results

Duet Regimen Preference* (Study Exit)

- Precoital use preference: 51.2% (N=41)
  - Insert Duet (loaded with gel) within 1 hour prior to sex
  - Remove Duet 1–24 hours post coitus
  - Clean device and store in container until next use
- Continuous use preference: 38.8% (N=31)
  - Insert Duet loaded with gel
  - Remove daily to wash device, load with fresh gel, and reinsert immediately
- Likes both regimens: 10.0% (N=8)

* Missing data for 3 participants (withdrew or LTFU)

Characteristics by Regimen Preference

Baseline Variables	Preference for: Continuous Use (N=31)	Precoital Use (N=41)	*p*-value
Median age (range)	29 (23–39)	31 (18–39)	
Median years of education (range)	11 (7–13)	10 (3–13)	*
Married and monogamous	100%	100%	
Sex 3+ times/week	71%	78%	
Used condoms in past 3 months	32%	34%	
Diaphragm experienced	36%	59%	*
Randomized to Group A	45%	59%	
Follow-up Variables			
Duet worn for all sex acts:			
during continuous regimen	97%	83%	
during precoital regimen	94%	85%	

**$p<0.05$; *$p\leq0.1$ Fisher's exact test (categorical var.); Wilcoxon M-W test (continuous var.)

Multivariate Logistic Regression Modeling Preference for Precoital Use

	AOR	95% CI	*p*-value
Diaphragm experienced	2.8	1.01–7.8	**
Years of education	0.7	0.5–1.02	*
Age	1	0.9–1.08	

**$p<0.05$; *$p<0.1$ Wald Chi-square test

6. Reasons for Regimen Preference

Continuous Use

- Convenience
- Discreetness
- Feeling constant safety or protection
- Being prepared for sex-on-demand

Precoital Use

- Use only when needed (when having sex)
- Hygiene (Duet is cleaned after each sex act)
- Discomfort with the idea of wearing the device continuously
- Relationship with partner makes planned sex easy
- Part of foreplay

7. Focus Group Participant Comments

Continuous Use

- "…because when you wear [Duet] continuously and if you remove it, you will feel as if there is something missing or as if you don't have a pant."
  (Group A: Diaphragm-experienced participant)
- "I liked that even my partner wanted me to wear it continuously instead of saying 'wait, let me first insert' when he is ready [for sex]."
  (Group A: Diaphragm-naïve participant)

Precoital Use

- "It was no problem [precoital] because sometimes he is the one who reminded me that 'insert your thing' because today we are going to work [have sex]."
  (Group B: Diaphragm-naïve participant)
- "I didn't feel comfortable because of the thought that there is something inside [all the time]…it was not difficult to insert but if you have something inside [all the time], you don't feel comfortable."
  (Group A: Diaphragm-experienced participant)

Likes Both Regimens

- "I liked Duet and gel…I liked it; whether spending the whole day wearing it or wearing it when you are having sex because it is 'safe'. If it were that it is proven to prevent HIV, it will be 'safe' in that for those men who are not well behaved, the woman will be wearing it always [continuous use]…with men who are well behaved, you will wear it when you are about to have sex; this is what is good for me on Duet and gel."
  (Group B: Diaphragm-experienced participant)

8. Conclusions

- Product adherence not significantly associated with regimen preference
- Previous experience with using the diaphragm precoitally influenced current use-preference for Duet
- Varying personal and social circumstances impacted regimen preference
- Methods that accommodate both episodic and continuous use may provide more choice to future users

References

[1] Weiss et al., Emerging Themes in Epi (ETE) 2008.

[2] Masse et al., ETE 2009.

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