TRIO Study: Key Insights from Research with Female End-Users of MPT and HIV Prevention Products

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TRIO: Three Multi-purpose Prevention (MPT) Placebo Products

TRIO = Tablet, Ring, and Injectable as Options for women

Daily oral tablet

Monthly silicone ring

Monthly saline injections (2x 2ml)
Objectives and Approach

1. Inform early-stage development of three potential HIV prevention/MPT approaches among young women end-users:
   • Placebo products to focus on delivery form
   • Assess relative preference among products
   • Changes in preferences with increased exposure to products
     • Baseline: pre and post baseline video
     • After 1 month of use
   • Salient product attributes

2. Mixed-methods design intended to engage participants as co-designers

3. Stakeholder engagement & feedback
   • Male partners
   • Health providers

Kisumu, Kenya: N=137
Soshanguve, South Africa: N=140

Eligibility:
• HIV-negative
• Sexually active
• Non-pregnant
• Aged 18-30 years
• Microbicide and PrEP naïve
PrEP/Microbicide Acceptability Framework

Influencing factors

Social and structural context
- Organizations
- Partner
- Individual characteristics

Product acceptability

Product-associated norms
- Partner’s attitude
- Effects of product use on sex
- Use attributes

Product characteristics
- Delivery mechanism
- Efficacy (if known)
- Dosing regimen

Preference & choice
- Product alternatives
- Nothing

Adherence
- Initiation
- Execution/implementation
- Persistence
- Discontinuation

From Mensch, et al C.O.H 2012
TRIO Study Design and Timeline

5-Month Clinical study

EXPOSURE TO PRODUCTS

Rating, ranking and preference assessed

Chosen product

Qualitative data collection

Male Partners interviews

DCE with participants and community members

Video

Randomized Cross-Over Period

Choice

Usage Period

Health providers interviews
4 minutes Educational Video at Enrollment
1. Rating – product satisfaction - Effect of educational video
2. Ranking and preferences – among study products
3. Choice – (revealed preference) after trying each product for one month
4. Adherence – self-report, directly observed dosing in the clinic + Wisepill electronic monitoring
5. MPT interest
6. Product attributes - Discrete choice experiment (DCE)

### TRIO Participant Characteristics in clinical study (N=277)

<table>
<thead>
<tr>
<th></th>
<th>Soshanguve, South Africa (N=140)</th>
<th>Kisumu, Kenya (N=137)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (IQR)</td>
<td>23 (21-26)</td>
<td>24 (21-26)</td>
</tr>
<tr>
<td>Currently have a primary partner</td>
<td>96</td>
<td>92</td>
</tr>
<tr>
<td>Married or cohabiting*</td>
<td>9</td>
<td>48</td>
</tr>
<tr>
<td>Parity &gt;0</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Completed secondary school*</td>
<td>61</td>
<td>42</td>
</tr>
<tr>
<td>Earns an income*</td>
<td>13</td>
<td>50</td>
</tr>
</tbody>
</table>

*p<0.05

- 89% Completed the 5-month clinical study
1. Product rating changed with exposure: CO Period (N=249)

- All rating were significantly higher post 1-mo use vs. before video (p<0.001)
- Higher rating post-video (vs. pre-) only for the most unfamiliar product: ring
Please rank the three study products in order of your preference for using them for both pregnancy and HIV prevention.

2. TRIO Product Preference: Rankings after CO period (N=249)

<table>
<thead>
<tr>
<th>Product</th>
<th>Ranking Score</th>
<th>Percentage (%) of Study Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ring</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Women changed their mind re: preferred product (rank #1)

- Overall, **50%** of women changed their mind about their most preferred product after crossover.
- Those who chose the ring had biggest change in opinion
3. Choice by site for usage period (N=249)

<table>
<thead>
<tr>
<th></th>
<th>South Africa</th>
<th>Kenya</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>15%</td>
<td>27%</td>
<td>21%</td>
</tr>
<tr>
<td>Ring</td>
<td>13%</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td>Injections</td>
<td>71%</td>
<td>57%</td>
<td>64%</td>
</tr>
</tbody>
</table>

* Significantly different, p<0.05
3. Barriers shaped TRIO product choice (n=87 qualitative component)

- Overall, women described the same pros and cons of each product
- However, the “cons” weighed more heavily in decision **NOT to choose**
4. We assessed **All** components of adherence in TRIO

<table>
<thead>
<tr>
<th>Adherence components</th>
<th>Tablets</th>
<th>Ring</th>
<th>Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initiation</strong></td>
<td>Direct observation (DO) of first ingested tablet</td>
<td>Pelvic exam after vaginal ring insertion</td>
<td>2x 1ml saline injected in glutei</td>
</tr>
<tr>
<td>at clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>97</td>
<td>97</td>
<td>100</td>
</tr>
<tr>
<td><strong>Completion</strong></td>
<td>DO of last ingested dose</td>
<td>Ring in situ at return</td>
<td>NA</td>
</tr>
<tr>
<td>at clinic</td>
<td>97</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td><strong>Execution</strong></td>
<td>WISEPILL: (EM)</td>
<td>Self report</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td><strong>10%</strong></td>
<td>70</td>
<td></td>
</tr>
<tr>
<td><strong>Persistence</strong></td>
<td>At M-4 visit, continue or switch to another product</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>96</td>
<td>96</td>
<td>89</td>
</tr>
</tbody>
</table>
At the end of TRIO, most participants indicated **preference for a 2-in-1 product over using two separate products.**

South Africa  

![South Africa flag]  

98%

Kenya  

![Kenya flag]  

86%

This was strongly corroborated by qualitative findings with participants.
6. Discrete Choice Experiment (N=536)

- ½ Clinic sample and ½ community sample.
- Each participant answered 8 HIV prevention product choice questions.
- Participants randomized to one of 6 sets of choice questions.
6. Attributes Influential to Product Choice

- **Product efficacy** most important attribute.
  - More influential to choice among Kenyan than South African women.

- Other attributes influential to choice:
  - **Pregnancy prevention (MPT feature)**
  - **Product delivery form** more influential to choice in South Africa than in Kenya.
    - Injections favored; daily tablets disliked.

- Side effects played minor role in choice.
• **Scenario #1**: Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.

![Bar chart showing estimated % who would have chosen product]

- Tablets: 11%
- Ring: 35%
- Injections: 54%
6. Predicting product choice based on DCE preferences- SOUTH AFRICA

- Scenario #1: Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.
- Scenario #2: same as #1 except one product is no longer an MPT.

Estimated % who would have chosen product:

- **Tablets**: 14
- **Ring**: 15
- **Injections**: 71

 Mitarb. 22
6. Predicting product choice based on DCE preferences- SOUTH AFRICA

- Scenario #1: Assume TRIO products available with most favorable attributes: high HIV prevention efficacy, prevents pregnancy, no side effects and dosing frequency as implemented in TRIO.

- Scenario #2: same as #1 except one product is no longer an MPT.

Estimated % who would have chosen product

<table>
<thead>
<tr>
<th>Product</th>
<th>TRIO Products</th>
<th>TRIO Product no longer an MPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td>17</td>
<td>29</td>
</tr>
<tr>
<td>Ring</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Injections</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Lessons learned from TRIO

1. **Young women are interested in a MPT product**
   - Users recognize they are different and desired multiple options
     - Familiarity, simplicity, discretion favored injections
     - **Key + attributes were not product specific:** Low burden, stress-free, lifestyle congruent

2. **DCE:**
   - Efficacy is necessary but not sufficient.
   - Suggests higher preference for ring compared to tablets as MPT - Actual choice in clinical study showed no difference with tablets

3. **Experience with product use (and familiarity) informed choice**
   - Video and education material critical (mostly for the unfamiliar product)
   - For individuals, opinion changed with product experience
   - Residual reluctance with most unfamiliar product (ring);
   - Choice of tablet may have been driven by disinterest to use;

4. **Downside of products are real and must be discussed** - keep them as inconvenience vs. no becoming barriers

5. **Placebo use studies:**
   - Feasible and acceptable
   - Allow to measure the full product “lifecycle” from awareness to persistence
   - Valued by participants and helped to get insights by gaining their engagement as “co-designers”
Acknowledgements

Thank you!
All our study participants

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IPM
GILEAD