

# Evaluation of a video to enhance the informed consent process in the Phase 3 Carraguard® trial

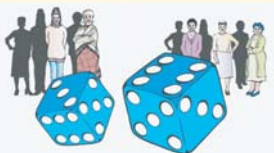
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## BACKGROUND

- Carraguard Phase 3 trial conducted among 6,202 women in South Africa (2004-2007)
- Evaluation of educational video conducted at 2 sites:
  - University of Cape Town (UCT) in Gugulethu
  - University of Limpopo, Medunsa Campus (Medunsa) in Soshanguve (Pretoria)

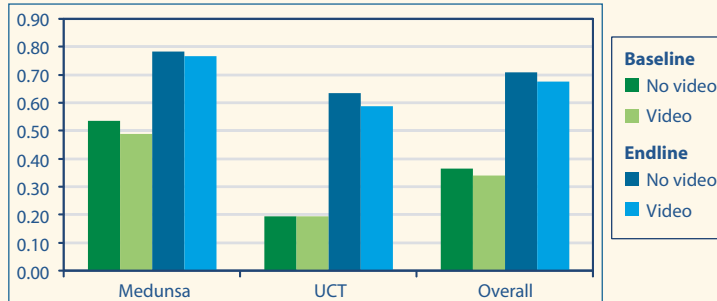
### Video part of holistic approach to informed consent (IC) process

- 20-minute video produced to enhance informed consent process (English, Setswana, Xhosa, Zulu)
- As complement to IC form, booklet and counseling
- Recommended by Phase 2 participants
- To explain difficult concepts and key themes (randomization, placebo, microbicide, HIV test, voluntary participation, pelvic exam)



- To facilitate recruitment/retention (> 9,500 screened) by ensuring consistent study introduction and reducing burden on recruiters

## Mean Comprehension Scores, by Site & Group



There was no significant difference between video groups in mean comprehension scores (baseline or endline), but there was a significant difference between sites ( $p = 0.00$ ).

## Multivariate Regression: Baseline Scores

Variable	Coefficient	p-value
UCT (vs. Medunsa)	-0.28	0.00
Level of education	0.05	0.00
Recruited by study staff (vs. not)	0.07	0.01
Recruited by stranger or media (vs. not)	-0.15	0.00

- Women who had more education or who were recruited by study staff had significantly **higher** baseline scores.
- Women who were from UCT or who were recruited by a stranger or media (vs. study staff, relative or friend) had significantly **lower** baseline scores.

## Multivariate Regression: Endline Scores

Variable	Coefficient	p-value
Video (vs. No Video)	-0.024	0.09
UCT (vs. Medunsa)	-0.06	0.00
Reads >1 language (vs. 1 language or less)	-0.06	0.00
Level of education	0.06	0.00
Housing density (>2 people/room vs. <2 people/room)	-0.03	0.03
Recruited by pamphlet (vs. not)	0.19	0.02
Baseline score	0.33	0.00

- Video group did not have a significant effect on endline scores; the strongest predictor of endline score was baseline score.
- Women had significantly **lower** endline scores if they were from UCT, read more than one language, or had a higher housing density.
- Women had significantly **higher** endline scores if they were from Medunsa, had more education, or were recruited by pamphlet.

## Willingness to Participate

- 96.5% of women at both sites said they would be interested in being in the trial, with no difference between video groups.

## STUDY OBJECTIVES

To assess if video plus information booklet improved comprehension of key trial concepts and willingness to participate compared to booklet alone

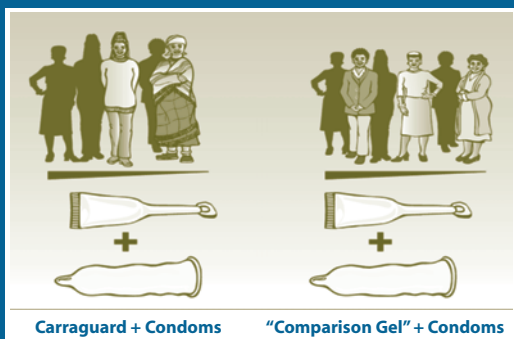
## DESIGN AND METHODS

- 400 women at UCT and Medunsa (200 per site) attending recruitment were randomized to Video + Booklet (Video) or Booklet Only (No Video) group
- Questionnaire administered before and after recruitment sessions by independent interviewers (Xhosa at UCT, Setswana at Medunsa)
- Data entered into EpiInfo and analyzed in SPSS
- Statistical analysis:
  - T-tests to compare mean comprehension scores, by group and site;
  - Multivariate regression: variables affecting baseline and endline scores

## Comprehension Questions

Assessed understanding of:

- Trial purpose: safety and efficacy of Carraguard**
- Study concepts: randomization, purpose of placebo, reason for condoms, meaning of informed consent and confidentiality, meaning of "safety"**
- Study procedures: Gel instructions, HIV test schedule**
- Risks and benefits of study participation**



Carraguard + Condoms

"Comparison Gel" + Condoms

## RESULTS Demographics

Characteristic (N, %)	Medunsa (N=190)	UCT (N=194)	Total (N=384)*
Average age in years (mean, range)	28.3 (16-58)	28.7 (15-59)	28.5 (15-59)
Education			
No formal education	6 ( 3%)	2 ( 1%)	8 ( 2%)
Grades R-9	39 (21%)	70 (37%)	109 (28%)
Grades 10-12	138 (73%)	121 (62%)	259 (67%)
Grades 13+	7 ( 4%)	1 ( 1%)	8 ( 2%)
Housing density (#people/#rooms)			
≤ 2 people/room	95 (50%)	111 (57%)	206 (54%)
> 2 people/room	95 (50%)	83 (43%)	178 (46%)
Home Language			
Xhosa	5 ( 3%)	188 (97%)	193 (50%)
Setswana	71 (37%)	0 ( 0%)	71 (18%)
Other	114 (60%)	6 ( 3%)	120 (31%)
Interview Language			
English	21 (11%)	0 ( 0%)	21 ( 5%)
Xhosa	0 ( 0%)	189 (97%)	189 (49%)
Setswana	168 (88%)	0 ( 0%)	168 (44%)
Read/write more than one language	168 (36%)	106 (55%)	274 (71%)
Interview language ≠ home language	123 (65%)	5 ( 3%)	128 (33%)
Recruitment method			
Study staff	62 (33%)	6 ( 3%)	68 (18%)
Relative	27 (14%)	55 (28%)	82 (21%)
NGO	4 ( 2%)	0 ( 0%)	4 ( 1%)
"Other" (stranger, media, etc.)	5 ( 3%)	18 (10%)	23 ( 6%)

\* 384 women were included in the final analysis

## DISCUSSION

- Mean scores improved significantly between baseline (35%) and endline (75%), but video group did not have a significant effect on scores.
- Scores were significantly higher at Medunsa, which could be due to:
  - Completing more than 10 years of education (77% at Medunsa vs. 63% UCT);
  - Being recruited by study staff (33% at Medunsa vs. 3% UCT);
  - Being interviewed in language other than their home language (65% Medunsa vs. 3% UCT) which might be an indication of greater language facility.

## Limitations

- Video intervention not implemented consistently:** Question & Answer segments of recruitment sessions were often shorter for the Video group (both sites) or did not occur (UCT site); therefore, participants at Video sessions often had less exposure to information than those at No Video sessions.
- Conduct of evaluation:** Some interviewers had no prior experience and training may not have been sufficient for full understanding of the Phase 3 trial protocol. In addition, the study instrument (open-ended questions with list of possible responses) may have been difficult to implement.

## CONCLUSIONS

- The video did not have a significant effect on improving comprehension, however, Video sessions were shorter (sometimes half the length) than No Video sessions, with less effort from study staff, while achieving the same results.
- Almost all women, regardless of site or video group, expressed interest in being in the trial which may mean they had already decided to join prior to attending recruitment sessions.
- The way participants first learn about a study can have a significant impact on baseline understanding, affecting ability to give truly informed consent.

## RECOMMENDATIONS

- Video can facilitate recruitment and should be integrated into future large-scale trials; video is a helpful tool for training study staff and community outreach.
- To enable videos to achieve their full potential, standardized procedures (such as training manuals) should be developed to ensure consistent use.
- This study also highlighted the importance of monitoring the informed consent process (not just checking signatures on IC forms) to ensure that tools and strategies are used properly within and across sites in multi-center trials.

## ACKNOWLEDGEMENTS

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