

Project Brief: South African Male User Research on Acceptability of Implants and Injections

Full Title of Study/Programme	South African Male User Research on Acceptability of Implants and Injections Short Title: SAMURAI
Technical Focus Area/Key Words	Injections, implants, PrEP, MSM, heterosexual men
Rationale	<p>Heterosexual men and MSM contribute to the spread of HIV, but they are often overlooked or under-represented in HIV prevention efforts. Unlike women of childbearing age, many men do not have regular interaction with the health care system, and are less likely to engage in HIV prevention or care. In South Africa, HIV prevalence among men is high and increases with age, with one-quarter (23.7%) of men aged 35 to 39 years HIV positive. Men who have sex with men (MSM), a diverse population including a broad range of identities, have historically been substantially under-served by HIV prevention and care programmes in sub-Saharan Africa. Studies among MSM have estimated an HIV prevalence of 49.5% in greater Johannesburg, 25.5% in Cape Town, and 27.5% in Durban. HIV incidence in these urban settings is also high. The identification of innovative strategies to increase involvement of both heterosexual and MSM in HIV prevention services in SSA is a critical priority. The current landscape for HIV prevention consists primarily of condoms and oral PrEP; both are highly effective tools for HIV prevention when used as prescribed. These methods have been associated with widespread adherence challenges for many reasons, including sociocultural factors and dosing burden. Injectable and implantable contraceptive products are well-accepted delivery forms among women, and their use is increasing in SSA. LA-PrEP may overcome many of the barriers to existing HIV prevention strategies. Implants and LA injectable are comparatively discreet, require less frequent clinic visits, and are less burdensome. Investigating the acceptability of LA-PrEP delivery platforms among men is a critical step toward designing products that will be adopted successfully. Early involvement of men in product development is an important opportunity to measure and address product acceptability and factors that may influence adherence, and to foster male ownership of novel HIV prevention delivery modalities</p>
Primary Objectives	Formative research: To conduct formative qualitative research of factors influential to acceptability of implant and injectable delivery forms for HIV prevention (including knowledge, attitudes and perceptions) among heterosexual men and MSM in South Africa

	<p>Cross over study: To conduct a crossover clinical study to assess acceptability of placebo Implants and Injections as HIV prevention methods for men</p>
Secondary Objectives	<p>Formative research: Not applicable</p> <p>Cross over study: In development</p>
Tertiary Objectives	<p>Formative research: Not applicable</p> <p>Cross over study: In development</p>
Primary Endpoints/Outcomes	<p>Formative Research:</p> <ul style="list-style-type: none"> • Explore heterosexual men and MSM’s knowledge, attitudes, and perceptions of implants and injectable and their use for HIV prevention • Examine anticipated benefits and challenges to clinical delivery of these products to men, study implementation concerns <p>Cross over study: In development</p>
Secondary Endpoints/Outcomes	<p>Formative research: Not applicable</p> <p>Cross over study: In development</p>
Tertiary Endpoints/Outcomes	<p>Formative research: Not applicable</p> <p>Cross over study: In development</p>
Study Design	<p>Formative research: Qualitative research that will be used to inform the development and refinement of materials, messages, and strategies for successful implementation of a clinical research study</p> <p>Cross over study: 200 men join the clinical component of the study. First 6 months 100 men will have the implant inserted while the other 100 men will receive injections every 2 months to assess acceptability of the proposed HIV prevention products. The second 6 months period the participants will do a crossover, those who were on the implant will then use injections every 2 months and participants who were on injection will use implants for the remainder of the 6 months period</p>
Study arms	<p>Formative research: Not applicable</p> <p>Cross over study: Placebo implant and injection arms</p>
Study population	<p>Formative research: Heterosexual men (n=~20) and MSM (n=~20) aged 18–35 who reside in one of the two clinic catchment areas in Johannesburg and Cape Town. Men who are HIV negative (by self-report) report current sexual activity (vaginal or anal sex at least 4 times in the past 3 months).</p> <p>Cross over study: Heterosexual men (n=~100) and MSM (n=~100) aged 18–35 who reside in one of the two clinic catchment areas in Johannesburg and Cape Town. Men who are HIV negative (by self-</p>

	report) report current sexual activity (vaginal or anal sex at least 4 times in the past 3 months
Study sample size	Formative research: 40 Heterosexual men and MSM Cross over study: 200 heterosexual men and MSM
Follow up/duration	Formative research: Not applicable Cross over study: 12 months
Study/Programme sites	Hillbrow, Johannesburg
Study/Programme duration	Formative research: 3 months Cross over study: 12 months
Intervention	Formative research: Not applicable Cross over study: Placebo implant and injection
Operations	The study team, in coordination with the funders will define key metrics
Investigators	Wits RHI Dr. Thesla Palanee-Phillips, Principal Investigator Ms Krishnaveni Reddy, Investigator Dr. Millicent Atujuna, Principal Investigator Dr. Elizabeth Montgomery, Principal Investigator Dr. Alexandra Minnis, Co-Principal Investigator
Other Partners & Collaborators	<ul style="list-style-type: none"> • Women’s Global Health Imperative, RTI International, Berkeley, CA, USA • Desmond Tutu HIV Research Foundation, Cape Town, South Africa • Wits Reproductive Health and HIV Institute, University of Witwatersrand, Faculty of Health Sciences, Johannesburg, South Africa
Sponsors/Donors	National Institutes of Mental Health; Grant No.: R01 MH121148-01A1
Linked Sub Studies and post grad projects	Not applicable at this time
Publications/key presentations to date	Not applicable
Progress Update as at 21 Oct 20	Formative research: Formative research protocol, informed consent forms and interview guides developed and submitted to Wits RHI Research Review Committee (RRC). Cross over study: In development
Frequency of donor narrative report	Every 3-6 months (To be decided)
Overall Study/Project Contact	Dr. Thesla Palanee-Phillips (tpalanee@wrhi.ac.za)
Briefing owner and date	Sibusisiwe Gumede, 23 October 2020