



DESMOND TUTU
HIV FOUNDATION

MTN 017 Participant Selection

6 June 2013

Mr. Right...meet 'Simpfiwe'

- Simphiwe is **25** and has lived in Delft, a township just outside of Cape Town, his entire life. Simphiwe came out as gay to his parents 10 years ago and **they have always been supportive**. In fact, he still lives with his parents so that he can save money for school.
- Simphiwe is **studying** at the Cape Peninsula University of Technology (CPUT), just down the road from our site. He wants to become a software programmer and work for Google someday. Simphiwe **isn't employed full time** since he is studying, but he does work part time for Incredible Connection, a local computer business.
- Simphiwe has never been a participant in a clinical trial, but he is **actively involved** in his community and has participated in a number of DTHF community activities. He can't get enough of the netball tournaments
- Simphiwe first heard about MTN 017 from watching a microbicides video at one of the DTHF meetings in Delft. He has a lot questions but he's **motivated to take part** in the study because he sees how other gay men in his community are affected by HIV.



"Simphiwe", an ideal participant for MTN 017

Mr. Right...meet 'Simphiwe'

- He understands that by participating in MTN 017, **he is doing his part** to protect his community. Simphiwe is very involved in his community and **he's in touch regularly** with DTHF outreach staff.
- Also, Simphiwe's best friend was an iPrEX participant, so **he's heard about our research** and learned a lot about what clinical trials are from his friend.
- Simphiwe isn't real but he embodies the characteristics that we've found are the most important in a study participant.
- For 017, the "right" participant is someone who is motivated to take part in the study in order to contribute to the fight against HIV.
- They are someone who is actively involved in their community and who has engaged with the DTHF previously. Our right participant would also be someone who is easily reach and who doesn't drop communication with the site.



"Simphiwe", an ideal participant for MTN 017

Important Characteristics

- **Age.** The right participant for us is in his mid- to late-twenties. From previous studies, younger participants (18-22) have proven more challenging to retain and to sustain regular communication with. They also have the highest frequency of missed or late study visits.
- **Previous Experience.** Has considerable involvement with the DTHF through prior research experience or community activities.
- **Social Support.** Is out of the closet, has the support of family or friend support, or has a partner.
- **Employment.** There is no clear distinction between which type of employment is most beneficial for study participation. Full-time employment often creates stability over longer periods of time but can often restrict participants availability. Furthermore, it can lead to stress which is conducive to participants terminating their participation. Unemployment provides flexibility in scheduling appointment and offers participants time to fulfill study requirements but overall creates instability for retention. Participants may easily move to find employment elsewhere in the country.
- **Location.** Mobility is common so some connection to Cape Town is important. No plans to move, if studying, he is not graduating within the year, and ideally has stable accommodation within reach of the site

Pre-Screening

- Pre-screening activities are established at all levels of the site.
- Beginning with community-based work, all potential participants will or have already interacted with study staff, including outreach workers, recruiters, and counselors.
- Through these interactions, staff are able to gain a deeper understanding of participant lifestyles and personalities outside of a study setting.
- This allows us to rule out potentially complicated retention challenges in the future. This also offers ability to judge participants commitment and creates additional points of contact.
- On a site-level, participants will be required to attend an informational pre-screen visit during which they can meet study staff, and receive further in-depth information about the study.
- During this time the requirements for the study are clearly explained and discussions are held with participants to identify any potential barriers to their participation and retention. A formal pre-screen protocol is in development.



Outreach staff get to know MSM at a DTHF Netball Game



Counselors take part in outreach activities to discuss study participation

Lessons Learned

- From previous studies, we have learned a great deal about both recruitment and retention.
- It is critical to have multiple points of contact with a participant prior to enrollment. If not, its easy to enroll a participant who is not committed or otherwise challenging to retain.
- Points of contact include community meetings, social events, and clinic information sessions. It also includes points of contact with multiple types of staff including outreach and clinic staff.
- In terms of recruitment, in-person strategies have proven the most effective; however, multiple strategies must be implemented simultaneously, rigorously monitored, and adjusted as needed.
- A large team of outreach workers who are able to rotate their involvement with the study is essential. This also promotes a wider reach in terms of diversity in community and social networks. A commission-based system has been developed in order to invest resources into most successful recruiters.



The counseling team engage in multiple points of contacts with potential participants.



The recruitment team attends a monthly training meeting.

Lessons Learned

- Establishing a true relationship of partnership with the MSM community is absolutely necessary.
- Community activities are always focused on capacity building, education, and growth *not* on recruitment.
- Creating relationships and understanding between community members and the site is always the primary goal, recruitment is a byproduct.
- Staff Flexibility and scheduling is critical. In order to create strong relationships with community members and participants, staff must be willing to accommodate evening clinics, weekend events, and after-hour community activities.
- In doing so, participants who are unable to come during traditional hours are accommodated and staff are able to demonstrate to participants their commitment and motivation.



An outreach workers prepares warm Pap and Veg during a winter community meeting.

Recruitment: A Team Effort

- **Overall, its a team effort!** Recruiting the right participant is a team responsibility. Each study staff member will play an active role in the recruitment and retention of study participants for MTN 017. This is facilitated by clear roles and responsibilities as well as regular communication between all staff. All staff will: Promote comfort and openness environment to encourage trusted relationship. Ensure that the study site is a friendly, safe, and welcoming environment.
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Site Leadership.

- Will be responsible for designing, monitoring, and evaluating the recruitment and retention strategies in order to shift directions or change resources as needed.
 - Engages in daily check-ins among staff and facilitates weekly meetings with full clinic and community team to discuss updates, challenges and evaluations of pre-screening and screening attempts.
 - Works with site to develop solutions to challenges and barriers that are experienced.
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Counseling staff.

- Keep in touch with participants during pre-screen and after enrollment.
- Includes social networking, email, phone, and house visits at multiple intervals during pre-screen and after enrollment
- Orientation of potential participants to site and staff.
- Ensure participants needs are met during site visits.

Clinic Staff.

- Provide all relevant information to potential participants and answer questions to their satisfaction during pre-screening, screening, and throughout the study.
 - Study Coordinators are responsible for ensuring the smooth functioning of administrative aspects of the project and to facilitate regular trainings with all staff.
 - Over see the implementation of dry runs with team to ensure that visit flows provide the best experience for participants and maximum recruitment efforts.
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Outreach and Community Teams.

- Facilitate all community-based activities and responsible for disseminating information to potential study participants, with support of counseling staff.
- Conduct multiple activities to build rapport and trusting relationship which will aid regular visit attendance.

If all else fails...

We turn to “Three tons of Fun”, Cape Town’s infamous drag super stars...

