Mental Health and Medication Adherence Among MSM in South Africa

NCT06880172

June 26, 2024

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study title: **Addressing mental health and medication adherence among MSM in South Africa**

STUDY INFORMATION DOCUMENT

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Institution	Investigators
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Thank you for your interest in our study on mental health and medication adherence among MSM in South Africa.

My name is …… from The Aurum Institute.
We, researchers at The Aurum Institute in collaboration with researchers from Universities in and outside South Africa are doing research on how mental health wellbeing among MSM in South Africa can be improved. Research is a process used in seeking new knowledge. We would like to invite you to participate in this study.

The study aims to adapt a well-being coaching intervention for MSM. We are interested to discuss the social conditions of mental health and its relation to medication adherence with PrEP or ART taking MSM at the Aurum POP INN clinic in Ekurhuleni.

In a focus group discussion (FGD) with 7-10 MSM, we will discuss how social conditions of mental health will impact adherence to HIV prevention or treatment medication. We will also ask for suggestions how problem-solving counseling should include social conditions to improve medication adherence.

First, we will discuss who is **eligible for the study**.

All participants in this study will be 18 years or older, cis-gender male (assigned male at birth and identify as male), reside in the Johannesburg metropolitan area with no plans to relocate during the next 6 months, and be able to communicate in English. English speaking is a requirement as coaching done through virtual engagement is in English.

They should also take ART (HIV-positive participants) or daily oral PrEP (HIV-negative participants) and be registered at Aurum's POP INN clinic in Ekurhuleni.

Participants should also have self-reported challenges adhering to daily PrEP or ART. (

Exclusion Criteria –

All participants should be offered a copy of the Participant Information Document to keep for their records.

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- Presently engaged in mental health therapy.
- Participated as intervention participant in pilot mental health study (AUR6-8-403)
- Refuses audio recording of the focus group discussion.

Invitation to Participate: If you meet above enrolment criteria, and are interested in the study, we will ask you to give written consent that you are willing to participate in the study.

What is involved in the study?

1. You will be invited to one focus group discussion about social conditions of mental health and how addressing these may improve medication adherence for men who have sex with men (MSM).

2. Prior to the focus group discussion, we will ask you to complete some questions on your background (e.g. years of education) and nine questions related to how you have felt in the last two weeks (patient health questionnaire-9 (PHQ-9). If your PHQ-9 score indicates that you may benefit from further counselling, we will offer this at the POP Inn clinic.

3. We will record the year and month that you started to take PrEP or ART. If your virus load has been tested, we will record the last available virus load test result available for you in the POP Inn clinic.

2. The study will be done at the Aurum's POP INN clinic in Ekurhuleni.

3. There is no guarantee of confidentiality in the Focus Group Discussion.

Risks of being involved in the study: Answering question about social conditions of mental health may cause participants to feel lonely and may luxate feelings of isolation. Should this happen, we offer that participants debrief with a counsellor, or make an appointment for a follow up discussion with a counsellor. Our counsellors are trained to help participants reflect on any issue that may have come up during the FGD.

Benefits of being in the study: There are no individual benefits for you to participate in this study as you will be asked to contribute knowledge and experiences through the FGD. We anticipate that this study will provide much needed information on mental health improvements for MSM. Being part of such an effort may be considered beneficial to some MSM communities in South Africa.

Alternative procedures or courses of treatment: Aurum's POP INN clinics offer social support, including mental health support counselling to all participants in monthly group sessions.

Participation is voluntary: Participation in the study is entirely voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences. Your research participation or receiving care at POP INN clinic will not be affected by whether you decide to participate or not.

You will be given pertinent information on the study while involved in the project and after the results are available.

Reimbursements for "out of pocket" expenses: For the FGD, participants will be reimbursed up to R400 (US $21.14) for transportation costs.

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Confidentiality: Although POP INN clinic staff and researchers will make every effort to protect your privacy and confidentiality, in the focus group discussion you may be recognized by other participants. While the PI will request confidentiality, he is not in a position to enforce it. Therefore, anonymity cannot be guaranteed in a focus group discussion. Your data will be collected, processed, and stored according to the South African Protection of Personal Information (POPI) Act of 2013. The audio-recordings will be kept for 2 years after publication of results, or for 6 years if no publication.

Contact details of PI and Co-PI:

The PI of the study is [redacted] and phone number: +[redacted]

The Co-PI of the study is [redacted]. and phone number: [redacted]

Outputs
This study will produce a report on social conditions of mental health and how these conditions should be included in a problem-solving therapy intervention to improve medication adherence among MSM.

Contact details of HREC administrator and chair – for reporting of complaints / problems.
This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact [redacted], Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 717 2301 or via email: EthicsRegulatory@witshealth.co.za.

The study has been planned according to the Declaration of Helsinki (last updated: October 2013), which guides doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

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PARTICIPANT INFORMED CONSENT SIGNATURE PAGE

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- I have been given a Participant Information Sheet which explains the nature and processes involved in this study, which is attached hereto;
- I was given time to read it and was given time to ask any questions.
- I believe I fully understand why the study is being conducted and what the intended outcomes will be.
- If my PHQ-9 score indicates that I may benefit from further counselling, a counselling appointment at the POP Inn clinic will be offered to me.
- I understand that there will be no immediate benefit to me, should I agree to participate, nor will I receive any payment; conversely, participation will not cost me anything but my time.
- I understand that, even if I initially consent to take part in the study, I may subsequently withdraw at any time and would not be required to give any reasons; if that happened, any data collected about me for the purposes of the study would immediately be destroyed, unless I give consent for it to be retained.
- I have been given a range of contact details, listed below. If I require further information or become concerned about any aspect of this study I am free to speak to any of these contacts.
- I understand that there is no guarantee of confidentiality in the Focus Group Discussion.

Participant's name (print)	Participant's signature or mark	Date

Research staff (print)	Research staff signature	Date

All participants should be offered a copy of the Participant Information Document to keep for their records.

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INFORMED CONSENT FOR AUDIO RECORDING

I hereby confirm that I have been informed by, ... (NAME OF STAFF MEMBER), about the nature, conduct, benefits and risks of this study: **Addressing mental health and medication adherence among MSM in South Africa**

I have also received, read or had read to me, and understood the above written information (Participant Information Sheet and Informed Consent) regarding this study.

- By signing this consent form, I agree for the FGD to be audio-recorded.
- I may, at any stage, and with no prejudice, withdraw my consent to audio-recording the FGD.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to be audio-recorded.

Participant's name (print)	Participant's signature or mark	Date

Research staff (print)	Research staff signature	Date

All participants should be offered a copy of the Participant Information Document to keep for their records.