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Evaluation of a behavioural intervention to promote uptake of couples HIV testing in rural South Africa

Submission date
07/05/2022

Recruitment status
No longer recruiting

Registration date
26/05/2022

Overall study status
Completed

Last Edited
18/11/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and primary study aim
South Africa has experienced one of the most severe generalised HIV epidemics in the world, with 29 in every 100 adults aged 15–49 years in the province of KwaZulu-Natal living with HIV in 2011. HIV-testing remains the gateway for treatment and prevention pathways. South African HIV-testing campaigns have increased individual knowledge of HIV status but not overcome barriers to repeat HIV-testing and disclosure of HIV status to sexual partners. Couples HIV-testing and counselling (CHTC) refers to couples being counselled, tested and receiving their HIV results together. CHTC accomplishes two important goals. First, knowledge of each other's HIV status can facilitate risk-reduction behaviour within partnerships via effecting positive changes (e.g., condom use) in sexual behaviour with primary and any concurrent partners. Second, knowledge of HIV status can increase access to treatment and care for HIV-positive individuals, as well as reinforce behavioural choices (e.g., limiting concurrent partners) to stay HIV-negative.

Between 2012 and 2015, we tested the efficacy of a theory-based behavioural couples-focused intervention to increase participation in South Africa among couples who had never tested for HIV together or mutually disclosed their HIV status. 332 couples were randomised to the intervention arm (168 couples) or the control arm (164 couples). This trial known as the 'Uthando Lwethu Study' showed that the intervention was highly effective in increasing the proportion of couples that decided to learn their HIV status together within nine months after enrolment, (42% v. 12% [$p < 0.001$]) compared to the control group. However, success in 42% of couples choosing to test together in the intervention arm nonetheless means that the remaining 58% did not choose to test together, and the members of these partnerships did not learn their own and their partner's HIV status.

We have optimised the CHTC intervention used in the Uthando Lwethu study and in this study aim to evaluate the revised intervention success in promoting couples HIV-testing and counselling.

Who can participate?
The rural Sweetwaters community, part of the Greater Edendale Area of around 600,000 people,

lies just west of the capital of KwaZulu-Natal, Pietermaritzburg, South Africa, and it is representative of the many Zulu communities in the province.

Couples, where both partners are aged 18 years or older, in a relationship with a person of the opposite sex to whom they feel committed to above anyone else and with whom they have had sexual relations, and relationship length is 6 months or longer, and give their informed consent.

What does the study involve?
There are two types of visits in this study. There are visits where couples will receive counselling and support in looking after their health and relationship, and there are data collection interviews.
Counselling and support visits:
Visit 1: Participants will participate in a group session with their partner. This session will take approximately ½ day and will focus on couples health. For the second half of the session participants will be split into male and female groups to talk about topics such as HIV and family planning. This group session will be with up to 20 other couples.
Visit 2: Approximately a week after the first group session, couples will participate in a second group session in male groups and female groups with about 10 other participants. Group leaders will encourage discussions about relationship issues, such as commitment and trust. Training will also be provided about how to communicate about issues such as sex and HIV. This workshop will take approximately 1/2 day.
Visits 3-6: Couples will participate in up to four couples' counselling sessions with a trained couples' counsellor. There will be specific topics for each session, and the couple will be provided with some skills training, and an opportunity to discuss their health-related relationship goals with the counsellor. Each session will be approximately 90 minutes to two hours.
Data collection interviews will be conducted at baseline, 4 weeks and 4 months after enrolment. Partners will be interviewed separately. Follow-up for each couple ends after the 4 month interview.

What is the outcome of interest?
During the study couples will be offered the opportunity to take up a couples health screening visit at any time as a couple. This couples health screening visit offers screening for blood pressure and diabetes, and measurement of BMI, alongside HIV-testing and STI-testing, any of which the couple can opt out from. However, the primary outcome measure for this study remains the proportion of couples that take up CHTC.

What are the possible benefits and risks of participating?
Some of the topics in the questionnaire interview are personal and participants may feel embarrassed or uncomfortable. However, participants may skip any question at any time, and stop an interview at any time. Participants may decline to participate in any part of the group discussions, and may leave the group discussions at any time.
It is possible that a participant may ask their partner how they responded to certain questions or issues that come up in the interview. This may cause some discomfort or distress between partners. Participants who feel any discomfort or distress can consult one of the study counsellors. In addition, all participants will receive a list of community-based resources, including mental health counselling, general health services, and other issues.
Couples will receive counselling that may improve communication between partners and have other positive impacts on their relationship. They may also learn some information about general health issues and HIV and about resources in their community. In addition, the

information gained from the study may provide information that is very important for community organizations, researchers at HSRC, and health workers in this area to provide better services for couples.

Where is the study run from?
Human Sciences Research Council (HSRC), Sweetwaters office, KwaZulu-Natal, South Africa.

When is the study starting and how long is it expected to run for?
November 2019 to December 2022

Who is funding the study?
National Institute for Health and Care Research (UK)

Who are the main contacts?
1. Prof, Nuala McGrath, n.mcgrath@soton.ac.uk
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of a couples-focused behavioural intervention to increase health status testing including HIV and sexually transmitted infections among heterosexual couples in rural KwaZulu-Natal, South Africa

Acronym
The Igugu Lethu Study

Study objectives
We hypothesize that our optimised theory-based and culturally appropriate couples-focused intervention will increase the uptake of HIV-testing as a couple compared to the results of the intervention arm in the Uthando Lwethu study previously conducted in the same population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 04/09/2020, Human Sciences Research Council (HSRC) Research Ethics Committee, (c/o Khutso Sithole, Ethics Committee Secretariat, Private Bag X41, Pretoria, 0001, South Africa; +27 (0)12 302 2012; ksithole@hsrc.ac.za), REC 2/19/10/11c
2. Approved 05/11/2020, Faculty of Medicine Research Ethics Committee, (Southampton General Hospital, Mailpoint 801, South Academic Block, Tremona Road, Southampton SO16 6YD UK; +44 (0)2381 20 6316; medethic@soton.ac.uk), ref: ERGO 53709
3. Approved 06/11/2020, Health Research Committee of the KwaZulu-Natal Provincial Department of Health (330 Langalibalele Street, Pietermaritzburg, 3201, South Africa; +27 (0)33 395 2805; hrkm@kznhealth.gov.za), ref: KZ_202009_041

Study design
Prospective interventional cohort, single-center, with historical controls

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Uptake of couples HIV testing among couples who have never previously tested together nor mutually disclosed their HIV status.

Interventions
This behavioural intervention is comprised of up to 6 sessions (2 group sessions and 4 couple counselling sessions). The first group session will initially be mixed gender, to discuss couple's health and give information about specific health conditions. Mid-session, the group will be split into single gender discussion groups run simultaneously focusing on sexual health and barriers and benefits of the couple's HIV testing. Overall, the first group session will be a half-day event. The second group session will cover couple dynamics, communication skills and reproductive health (i.e. family planning, HIV etc) in a half-day workshop. This session will also be single gender, and the male and female sessions will run simultaneously. The 4 couple counselling sessions will include communication skills training, exercises to improve relationship dynamics (e. g., intimacy, satisfaction), and exploration of barriers to couples HIV testing to try and help couples feel ready to test together.

Couple's health screening visit: Enrolled couples may schedule a couple's health screening appointment with a study counsellor at any time during follow-up, once they feel ready to participate in HIV testing and counselling together. The health screening visit will only proceed if, on the appointment date, both partners consent to HIV testing together. During the health screening visit, the couple has the opportunity to also undertake random blood glucose (RBG) tests, blood pressure and body mass index (BMI) measurements, and self-sampling for sexually transmitted infection testing.

Height and weight will be measured, and BMI will be calculated. Blood pressure will be measured by a study counsellor using Brand Axcess BP 1359 devices while the participant is seated and three consecutive readings will be averaged, in line with recommendations by the American Heart Association.

After pre-test couples counselling for HIV, the counsellor will use a push button lancet safety needle to draw blood from the finger for simultaneous HIV testing, RBG using One Call Plus test strips: one Call Plus 50, and a dry blood spot card will be made to conduct an initial screener test for syphilis (Treponema pallidum particle agglutination assay).

A serial testing algorithm for rapid HIV testing will be used, following South African national guidelines. All participants who consent to HIV testing shall be first tested with an Advanced one step anti-HIV test and specimens that are non-reactive will be considered HIV negative. Any specimens that are reactive on the first test shall be tested again using a diagnostic kit for HIV antibody (colloidal gold) v2 test (KHB). For specimens that are reactive on both the first and the

second assays, results will be reported as HIV-positive. Specimens that are reactive on the first assay but non-reactive on the second assay will receive an ELISA laboratory test and be recorded as discordant.

The counsellor will use the BMI-based cardiovascular risk Framingham Heart Study tool to calculate participants 10 year risk of a fatal or non-fatal cardiovascular event (myocardial infarction or stroke), according to age, sex, blood pressure, presence or absence of diabetes, and smoking status, and will use this score when counselling about lifestyle changes. In addition to lifestyle counselling, active referral to the clinic will be made for individuals who have systolic blood pressure (SBP) ≥ 180 mm Hg or diastolic blood pressure (DBP) ≥ 110 mm Hg, and a letter of referral (passive referral) will be given to those with moderate hypertension (SBP: 160-179 mm Hg, DBP 100-109 mmHg), suggesting they have a repeat blood measure in two weeks. For individuals with an RBG result of > 11.0 mmol/L, questions will be asked to determine if the participant has symptoms indicating diabetes. If the participant's answers indicate symptoms of diabetes, they will be actively referred to clinic. If they do not report indicative symptoms, the participant will be given a letter of referral (passive referral) suggesting they request a fasting blood glucose test at the clinic. The local clinics are ready to receive such referred cases.

The counsellor will explain the need for self-collected samples to test for chlamydia, gonorrhoea, and trichomoniasis. The counsellor will explain and demonstrate the procedure for obtaining the self-collected vaginal swabs to the female member of the couple and will ask her to self-collect two sequential vaginal swabs, behind a medical curtain for privacy. A nurse will be on call if assistance is needed. For men, the counsellor will explain and demonstrate the procedure for obtaining one self-collected penile swab and a urine sample will be requested for testing Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis infections. After the sample collection, samples will be put in cool boxes for transport to Global Labs in Durban, a commercial accredited laboratory. The couple's health screening questionnaire includes questions on the acceptability of self-sampling.

Samples showing a reactive treponemal (TPPA) test could be reacting to a past/treated syphilis or active syphilis. Thus, any positive DBS TPPA results will be actively referred to the PHC for venous blood testing for syphilis. Urine from men will be tested for N gonorrhoeae, C trachomatis and T vaginalis using DNA amplification methods.

A date for the return (STI results) visit will be scheduled before the couple leave the health screening visit. For all couples who have at least one test ‘out of range’ between the two partners during the health screening visit, the STI results visit provides an opportunity for the study team to document whether the couple has followed up on any referral made for their condition, and if not, to counsel them again regarding the benefits of linking to care. Couples will also receive their STI results together at this visit.

To explore the acceptability of the intervention and participation in the study, a sub-sample of participants will be invited to take part in semi-structured process interviews at various time points during and after the intervention. Participants will be sampled purposively based on gender, age, engagement with the intervention, and engagement with the couples health screening visit offered. Topics explored will include experiences of the intervention and perceptions about attending couples testing. It is anticipated that a sample of 20-30 participants will be recruited, ideally including partners from within the same couple, until saturation is reached.

Intervention Type
Behavioural

Primary outcome(s)
The proportion of couples that take up couples HIV testing as part of a health screening visit during study follow-up i.e. within 4 months from the date of the first group session

Key secondary outcome(s))
1. Concordance of HIV test results among couples who take up couple's HIV testing during the couple's health screening visit
2. Uptake of blood pressure (BP) measurement as a couple during the couple's health screening visit
3. Concordance of hypertension diagnosis (defined as >140/90 mmHg) within couples who take up couple's BP measurements during the couple's health screening visit
4. Uptake of sexually transmitted infection (STI) testing as a couple during the couple's health screening visit
5. Acceptability of self-sampling for STI testing, measured using Likert scales asked as part of the questionnaire administered during the couple's health screening visit
6. DNA yield of the penile swab samples self-collected by men for STI testing during the couple's health screening visit, measured using DNA amplification methods
7. Concordance of STI test results (Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis, and Treponema pallidum) within couples who take up couple's STI testing
8. Uptake of random blood glucose (RBG) finger-prick test for diabetes as a couple during the couples health screening visit
9. Concordance of diabetes diagnosis (defined as RBG >11.0 mmol/L) within couples who take up the couple's RBG testing during the couple's health screening visit
10. Uptake of height and weight measurement for the calculation of body mass index (BMI), using an electronic scale (Scale Digital BMI 1110H (SOAMAA)), as a couple during the couple's health screening visit
11. Obesity (BMI≥30 kg/m2) concordance within the couple during the couple's health screening visit
12. Acceptability of the intervention and participation using individual, semi-structured process interviews at various time points during and after the intervention of a purposive sample of participating couples
13. Whether relationship dynamics are factors in achieving the outcome of couples' uptake of HIV-testing together within the Igugu Lethu study follow-up, using relationship scale variables collected at baseline, week 4, and 4 months
14. Penile microbiome characteristics among male partners using stored penile swabs collected by men during the couples health screening visit, assessed using metaproteomics analyses
15. Vaginal microbiome characteristics among female partners using stored vaginal swabs self-collected during the couples health screening visit, assessed using metaproteomics analyses
16. Concordance of results from metaproteomics analyses of penile and vaginal swabs within couples

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Couples will be considered eligible for baseline screening if :
1. Both partners aged 18 and older
2. In a primary relationship with opposite sex partner. [Defined as: "Are you currently in a

relationship with a person of the opposite sex to whom you feel committed above anyone else and with whom you have had sexual relations"]
3. Both partners report the relationship length has lasted at least 6 months
4. Both partners willing and able to provide informed consent

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Couples will be considered ineligible for baseline screening if :
1. Both partners report participating in couples-focused testing for HIV with their current partner [Defined as: Both partners tested for HIV at the same time and disclosed the results].
2. Either partner reports their current marital status as polygamous.
3. Either partner reports participating in the previous Uthando Lwethu study
4. Either partner fails to answer exploratory relationship-focused questions about their partner.

Date of first enrolment
03/12/2020

Date of final enrolment
15/08/2022

Locations

Countries of recruitment
South Africa

Study participating centre
Centre for Community Based Research, Human Sciences Research Council
Old Bus Depot, Mbubu Road, Sweetwaters.
Pietermaritzburg
South Africa
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be stored in a publicly available repository. At the time of publication, we will make the anonymised datasets freely available on the University of Southampton data repository, eprints.soton.ac.uk. In accordance with the University of Southampton's data policy, the data will be archived from a minimum of ten years after publication or last access, whichever is longer. DOIs will be issued for the dataset and data subsets as per the University's DOI policy.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/08/2022	22/08/2022	Yes	No

Participant information sheet			09/07/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes