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Engaging adolescent boys in a gender-transformative programme to prevent unintended pregnancy and promote sexual health: Trialing the 'If I Were Thabo' intervention in South Africa and Lesotho

Submission date
10/03/2022

Recruitment status
No longer recruiting

Registration date
20/04/2022

Overall study status
Completed

Last Edited
01/06/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
'If I Were Thabo' is a gender-transformative sexual and reproductive health intervention for young adolescents that aims to promote safe sexual behaviour and prevent and unsafe sex, unplanned pregnancy, and STI/STD transmission. 'If I Were Thabo' uses a gender transformative approach that challenges harmful masculinities, gender norms, and power relations. It consists of group-based sessions (interactive video and other activities), materials for intervention facilitators to implement the sessions, and educational materials for parents/caregivers, which aim to support caregivers to engage in conversations about sexual and reproductive health with their children.

Who can participate?
Students will be recruited from a select group of schools in Khayelitsha, South Africa, and schools and community groups for out-of-school adolescents in Maseru, Lesotho.

What does the study involve?
Schools and community groups will be randomized to intervention or control conditions after baseline data collection. Follow-up data collection will occur postintervention and 9 months after the end of the intervention in both sites (counted from the last day of intervention delivery).

If I Were Thabo is a gender-transformative sexuality and relationships (SRE) intervention, adapted from a Queens University Belfast-developed programme called If I Were Jack. The If I Were Thabo programme is delivered over four sessions at schools or community groups with adolescents in the first year of high school (or of the same age, approximately 13-14 years old). The intervention is based around an interactive video drama which tells the story of Thabo, a teenager who has just found out that his girlfriend is unexpectedly pregnant. It also includes

classroom materials to assist teachers in facilitating discussions around the issues raised in the interactive video drama, classroom-based activities for adolescents, homework activities for adolescents, and educational materials for parents.

What are the possible benefits and risks of participating?
Benefits may include reduced engagement in unprotected sex among intervention participants, and contribution to ongoing research about pregnancy prevention and gender-transformative approaches for adolescents in low- and middle-income country settings. There are minimal risks to participating in this intervention.

Where is the study run from?
Institute for Life Course Health Research (South Africa)

When is the study starting and how long is it expected to run for?
February 2021 to December 2023

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof Sarah Skeen, Stellenbosch University, skeen@sun.ac.za
Dr Áine Aventin, Queens University Belfast, a.aventin@qub.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N20/09/101

Study information

Scientific Title
Feasibility trial of the 'If I Were Thabo' intervention in South Africa and Lesotho: Engaging adolescent boys in a gender-transformative programme to prevent unintended pregnancy and promote sexual health

Acronym
THABO

Study objectives
Research questions:
1. Is the 'If I Were Thabo' intervention feasible to implement in i) secondary schools in SA, and ii) secondary schools and community groups in LE, and what refinements are suggested?
2. Is the 'If I Were Thabo' intervention acceptable to young adolescents, school staff, community facilitators and parents involved in implementation in i) secondary schools in SA, and ii) secondary schools and community groups in LE, and what refinements are suggested?
3. What are the optimal systems for delivering the intervention in educational and community settings, including selection, training, supervision and support for teachers/facilitators
4. What are the intervention participation rates?
5. What is the fidelity of intervention implementation?
6. What do qualitative data suggest in terms of intervention mechanisms and refinements to and the programme theory of change?
7. How do contextual factors appear to influence implementation of the intervention ?
8. What are the trial recruitment and retention rates?
9. Are the outcome and covariate measures understandable for and acceptable to young adolescents, and what refinements are suggested?
10. Are the outcome and covariate measures reliable and what refinements are suggested?
11. Are methods for economic evaluation in a definitive trial feasible?
12. Are any potential harms evident and how might these be reduced?
13. Based on the pilot RCT across eight schools and two community groups, is progression to a definitive trial justified in terms of pre-specified criteria? GREEN: process evaluation indicates that the intervention is acceptable to a majority of young adolescents, school and community facilitators involved in implementation, the intervention is implemented with fidelity in four out of five intervention sites, participant recruitment rate is >75%, participant retention rate is >80%, randomisation occurs and at least 5 of 6 schools accept randomization and continue within the study. AMBER: the intervention is acceptable to at least half of participants, participant recruitment rate is 50% to 75% OR follow-up data rate 60% to 79%. RED: not acceptable to participants, recruit <50% OR follow-up rate <60%.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 03/02/2021, Health Research Ethics Committee, Stellenbosch University (Education Building, Tygerberg Campus, Faculty of Medicine and Health Sciences, Francie van Zijl Drive, Tygerberg 7505, South Africa; +27 21 938 9819; afortuin@sun.ac.za), ref: N20/09/101
2. Approved 16/04/2021, Faculty of Medicine, Health and Life Sciences Research Ethics Committee (Queen's University Belfast, Medical Biology Centre, 97 Lisburn Road, Belfast BT9 7BL, Northern Ireland, UK; no telephone number provided; facultyrecmhls@qub.ac.uk), ref: MHLS_20_151
3. Approved 27/04/2021, Ministry of Health, Research Ethics Committee (O Box 514, Maseru 100, South Africa; no telephone number provided;
rcumoh@gmail.com), ref: ID215-2019

Study design
Feasibility cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Unprotected sex, unplanned pregnancy, STIs (including HIV)

Interventions
The trial will be implemented in Khayelitsha, South Africa (SA), and Maseru, Lesotho (LE). In SA the trial will take place in six schools, and in LE and the trial will take place in two schools and two community groups. Schools/community groups will be randomized to intervention or control groups and follow-up will occur postintervention and 9 months after the end of the intervention in both sites (counted from the last day of intervention delivery).

In each country, a random-number generator will be used to randomize schools (SA), and 1 school and 1 community group (LE) to the intervention condition, and 3 schools (SA) and 1 school and 1 community group (LE) to control condition, after evaluating equivalency across a number of domains. Intervention group recipients in eligible classes/groups will receive the 'If I Were Thabo' intervention: a group-based gender-transformative sexual health intervention.

The intervention targets adolescent boys (but includes girls) and addresses a gap relating to the successful engagement of boys in SRH initiatives in the region. It uses a gender transformative approach that challenges harmful masculinities, gender norms, and power relations, with the aim of promoting the SRH of boys and girls, and preventing unprotected sex, unintended adolescent pregnancy, and HIV and other sexually transmitted infections (STIs). It includes a)

group-based sessions for adolescents during which an interactive video drama is played and other materials are delivered, b) materials for intervention facilitators to implement the sessions, and c) materials for parents/caregivers to support and encourage caregivers to engage in conversations about safe sex with their children. 'If I Were Thabo' will be delivered to students in Grade 8 in SA and Form A (or youth of the grade-corresponding age for community group members) in LE. The number of sessions over which the intervention will be delivered (either 4 or 6) will be subject to testing during the preparatory phase and finalized before baseline. Control group schools (SA) and schools and community groups (LE) will receive an abbreviated version of the intervention after the nine-month follow-up interviews are complete (waitlist control).

There is one intervention arm, and one control arm. Randomization will happen at the level of clusters (schools and community groups), and will be done using an online random number generator.

The intervention schools and community group will receive the If I Were Thabo intervention, which is a four-session relationships and sexuality education (RSE) programme. The intervention includes a video, class activities, homework assignments, and materials for parents and for teachers. Each of the four sessions is about fifty minutes long, but the exact length varies depending on specific school or community group constraints. Follow up will occur immediately (within 1 month) after the completion of the final intervention session, and again at 9 months after completion of the final intervention session.

Control schools will follow care as usual, which is the South African and Lesotho government-mandated in-school SRE curriculum, or the community group equivalent. After the completion of the 9-month follow up data collection, control schools and the control community group will be given the If I Were Thabo materials, which they may then use in their classrooms and deliver to their students.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome measures:
1. Process evaluation indicates that the intervention is acceptable to a majority of young adolescents, school and community facilitators involved in implementation
2. Process evaluation intervention is implemented with fidelity in four out of five intervention sites
3. Participant recruitment rate is >75%
4. Participant retention rate is >80% at 9 months post-intervention
5. Randomisation occurs and at least 5 of 6 schools accept randomization and continue within the study

Secondary outcome measures
All secondary outcome measures will be assessed at baseline, at post-intervention follow-up and at the 9-month follow-up. Post-intervention follow-up will occur immediately (within 1 month) after the completion of the final intervention session, and the 9-month follow-up at 9 months after completion of the final intervention session.
1. Knowledge and attitudes, as measured by participant-report study questionnaire at 9 months:
1.1. Knowledge about preventing unintended pregnancy
1.2. Gender equitable attitudes about responsibilities to prevent unintended pregnancy

1.3. Equitable attitudes about gender (Gender Equitable Men Scale)
1.4. Self-efficacy to prevent unintended pregnancy
2. Behaviours, as measured by participant-report questionnaire at 9 months :
2.1. Delayed initiation of sex
2.2. Use of contraception at first and/or last sex
2.3. Consistent correct use of contraception
2.4. Pregnancy
2.5. Incidence of STIs
2.6. Number of sexual partners
2.7. 'Sexual competence' at first sex (willingness, timing, use of contraception)

Overall study start date
03/02/2021

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Young adolescents in South Africa and Lesotho (Grade 8 in SA, Form A in LE)

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
240-360 in each country, subject to variability based on class size

Key exclusion criteria
Unable or unwilling to assent and/or participate

Date of first enrolment
01/02/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Lesotho

South Africa

Study participating centre
Institute for Life Course Health Research
4009 Education Building
Faculty of Medicine and Health Sciences
Stellenbosch University
Cape Town
South Africa
7505

Study participating centre
Institute for Life Course Health Research Satellite Office
75 Constitution Rd
Care4Basotho Office Building
Maseru
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Sponsor information

Organisation
Stellenbosch University

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University/education

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ROR
https://ror.org/05bk57929

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications include a protocol paper, as well as description of the results of the feasibility trial in high-impact peer-reviewed journals; further ongoing dissemination efforts with partners (Stellenbosch University, Queens University Belfast, Ministries of Education in SA and LE) and their networks are also envisioned.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication