

# Goals for Girls: Evaluation of school-based sexual and reproductive health education programmes amongst adolescent female learners

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<b>Registration date</b> 02/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The Goals for Girls study will assess the impact of two school-based health empowerment programmes on sexual and reproductive health (SRH), namely the SKILLZ Health for Girls Programme and the national government sponsored life-skills program (Life Orientation), amongst 14-17 year old adolescent girls attending secondary schools.

Grassroot Soccer is a well-established adolescent health organisation that runs programmes in 23 countries, including South Africa, that use sport as a platform to engage and retain adolescents in health education. Its SKILLZ Health for Girls (SKILLZ) programme consists of a tailored and comprehensive SRH curriculum delivered in interactive, after-school sport sessions. Grassroot Soccer has reported success in HIV prevention education interventions, however, it is as yet unknown how feasible it would be to integrate the SKILLZ programme with other classroom-based, government-led SRH curricula in South Africa.

### Who can participate?

Females who are a registered learner in grade 8-10 (approximately aged 14-19 years) at a participating school.

### What does the study involve?

Goals for Girls will randomise forty schools 1:1 to receive the SKILLZ intervention or continue with the national curriculum alone. At baseline and post-intervention, learner attitudes and sexual risk behaviour, as well as key sexual and reproductive health indicators (pregnancy, sexually transmitted infections, HIV, and body mass index), will be measured. Sports activities consist predominantly of soccer-activities but include alternative physical exercises. Engaging, sport-based sexual health, HIV and life skills curriculum delivered in 10 sessions by trained "Caring Coaches" (age 20-30 years) over a 6 month period (2 school terms).

### What are the possible benefits and risks of participating?

Participants stand to benefit in the short and long term from the sexual health and related

information learnt in this study. All the health tests conducted in the study will be free and their time will be compensated with a R25 food voucher at each study visit (baseline and 8 months). While we do not think this study poses any threat to the participants physical or emotional wellbeing, it is possible that information they discuss during the SKILLZ sessions may not be kept confidential amongst their peers. For this reason, they could suffer loss of privacy or be stigmatised in some way due to their participation. The study team will provide support and referral where appropriate for any difficulties participants may incur whilst participating in the study. If medical care is required that we are unable to provide, we will refer participants to the appropriate services or organizations that can provide support. Some of the questions in the survey or health screening are of a sensitive nature and therefore have the potential cause distress. Support staff are aware of this potential and will be on hand to assist and refer to additional services if needed.

Where is the study run from?

Desmond Tutu HIV Foundation (South Africa)

When is the study starting and how long is it expected to run for?

May 2018 to December 2019

Who is funding the study?

ViiV Healthcare (USA)

Who is the main contact?

Carey Pike, Carey.Pike@hiv-research.org.za

Prof. Linda-Gail Bekker, Linda-Gail.Bekker@hiv-research.org.za

## Contact information

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

HREC 138/2018

## **Study information**

**Scientific Title**

Goals for Girls: A cluster randomized trial to evaluate the feasibility, acceptability and impact of integrating an in-school sexual and reproductive health (SRH) education programme with an after-school sports-based programme amongst adolescent female learners

**Study objectives**

1. The integrated SKILLZ programme will be more effective in achieving the project objectives than the national programme alone
2. The integrated model is predicated to be acceptable amongst adolescents in this setting and that those who participate in the integrated model will have lower rates of STI prevalence and pregnancy incidence
3. Those in the integrated model may show reduced school absenteeism
4. The incidence of HIV in this age group will be too low to demonstrate a significant reduction

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 20/04/2018, The Faculty of Health Science's Human Research Ethics Committee at the University of Cape Town (G50, Old Main Building, Groote Schuur Hospital, Observatory, 7925; +27 (0)21 650 1236; hrec-enquiries@uct.ac.za), ref: 138/2015

### **Study design**

Cluster randomized controlled 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 contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Adolescent sexual and reproductive health

### **Interventions**

The SKILLZ programme provides an enhanced sport-focused curriculum, framed as after-school sport lessons. Sports activities consist predominantly of soccer-activities but include alternative physical exercises. Engaging, sport-based sexual health, HIV and life skills curriculum delivered in 10 sessions by trained "Caring Coaches" (age 20-30 years) over a 6 month period (2 school terms). The sessions culminate in graduation, where participants who have attended seven or more sessions are considered to have received a sufficient "dose" to have an impact. The curriculum is integrated with the national curriculum because it was designed to complement that subject matter rather than duplicate it.

Participants in control schools will receive the national curriculum as normal.

The school was the unit of randomisation. A list of all eligible secondary schools in the study area (the Klipfontein/Mitchells Plain Health Sub-district) was constructed. School names were printed, sealed, and picked at random for allocation to the control and intervention arms. Schools were later allocated to cohort 1 (year 1) or cohort 2 (year 2) to conduct the study via geographical location: intervention and control schools in the Metro South district were allocated to cohort 1, while intervention and control schools in the Metro Central district were allocated to cohort 2.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Prevalence of sexually transmitted diseases (Chlamydia trachomatis and Neisseria gonorrhoea) testing was conducted at baseline and 8 months, with samples collected using a self-administered vaginal swab, and the test carried out using a GeneXpert machine (samples sent for laboratory testing)
2. Incidence of pregnancy at baseline and 8 months using a standard urine test
3. Incidence of HIV at baseline and 8 months (final study visit, post-intervention) using a nurse-administered HIV rapid test

### **Secondary outcome measures**

1. Body mass index was measured at baseline and 8 months using a BMI scale
2. A health screening questionnaire, which included questions related to sexual health history and sexual risk behaviour, was administered by a study nurse or counsellor at baseline and 8 months in conjunction with the biomedical tests
3. A sociobehavioural questionnaire, which included questions related to socioeconomic status, family support, and attitudinal questions related to gender, self-esteem, body perception, and sexual risk behaviour, was self-administered at baseline and 8 months
4. Attendance at intervention sessions was recorded per session
5. School attendance records for enrolled participants were collected from participating schools for a three-term (9 month) period
6. A post-intervention survey, which included questions on the quality of the session, the perception of the coach, session likes and dislikes, and ease of access to sessions, was self-administered at the final study visit to participants in the intervention arm
7. Participants and school staff who took place in the qualitative research took part in focus group discussions and in-depth interviews where the conversations were recorded, translated and transcribed
8. A registration form administered at baseline was completed by all participants. This form collects information related to basic demographics (date of birth, race, home address, contact details, next of kin) and permissions for contact (home visit, phone call, SMS).
9. The informed consent form was administered to all participants by a dedicated research staff member. Signed copies were retained by both parties

### **Overall study start date**

01/01/2018

### **Completion date**

31/12/2019

## **Eligibility**

### **Key inclusion criteria**

1. Female
2. A registered learner in grade 8-10 (approximately aged 14-19 years) at a participating school
3. Not pregnant at baseline

### **Participant type(s)**

Healthy volunteer

### **Age group**

Other

**Sex**

Female

**Target number of participants**

2800 participants across 40 schools (70 participants per school, 20 schools per arm)

**Total final enrolment**

2791

**Key exclusion criteria**

1. Not attending or having dropped out of the participating school
2. Grade 12 (final year) learners

Added 29/03/2021:

3. Pregnancy at baseline

**Date of first enrolment**

16/05/2018

**Date of final enrolment**

01/07/2019

**Locations****Countries of recruitment**

South Africa

**Study participating centre****Desmond Tutu Health Foundation**

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**Study participating centre****Grassroot Soccer**

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### Sponsor type

Research organisation

### Website

<https://desmondtutuhivfoundation.org.za/>

### ROR

<https://ror.org/01cc9yk21>

## Funder(s)

### Funder type

Industry

### Funder Name

ViiV Healthcare

### Alternative Name(s)

ViiV Healthcare Limited

### Funding Body Type

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

United Kingdom

## **Results and Publications**

### **Publication and dissemination plan**

The results of this evaluation will be shared with the relevant Ministries and used to guide South Africa's national strategic plan for improved uptake and retention of services by adolescents. We are working closely with the Western Cape Departments of health and education to pave the way for successful adolescent interventions. Our team will work closely with the Minister of Health (MOH) and Minister of Education (MOE) throughout study implementation to ensure that services are integrated, streamlined and sustainable. The National Department of Health and the Office of the President launched the "She Conquers" Campaign in 2016, as a pledge to reducing the impact of HIV among SA youth. As such, the national government is very keen to see evidence of successful interventions in this age group. Our study is a pragmatic trial with implementation and evaluation in a real-world setting. Hence, our results will have strong external validity and applicability to other sub-Saharan countries with a similar sociodemographic and epidemic profiles. Study results will in addition be disseminated to teachers, parents, and learners of participant schools through written reports and a dissemination event. Study results will be published in peer reviewed journals, including the primary paper, an implementation review paper, and paper detailing results from the participatory qualitative research.

### **Intention to publish date**

01/06/2023

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Data requests can be sent to: Carey Pike, Carey.Pike@hiv-research.org.za

Data type: Anonymised, delinked datasets pertaining to the sociobehavioural questionnaire responses and the health screening outcomes.

Data availability: Data will be made available to qualified investigators within 6 months of acceptance of the manuscripts describing major findings, for a 5 year period. Investigators who request to use the datasets will be required to have ethical approval (as necessary) and a data use agreement in place prior to any data being released to them. The team of investigators and partners involved in this study will discuss any data request and agree access prior to that being granted. Our collective aim is for data sharing and requests will not be unreasonably withheld. In the event that the investigator team disagree on whether to grant access, independent, external mediation will proceed in accordance with Desmond Tutu HIV Foundation and University of Cape Town guidance.

### **IPD sharing plan summary**

Available on request



Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		05/07/2023	09/07/2024	Yes	No
<a href="#">Results article</a>	lessons learned	22/12/2023	09/07/2024	Yes	No