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The GOAL Trial: sport-based HIV prevention in South African schools

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ZACHARY A KAUFMAN

Thesis submitted in accordance with the requirements for the degree of Doctor of Philosophy of the

University of London

September 2014

Department of Infectious Disease Epidemiology

Faculty of Epidemiology and Population Health

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Funded by the Marshall Aid Commemoration Commission,

Comic Relief, and the MAC AIDS Fund.

Declaration

I, Zachary Kaufman, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed:



11 April 2014

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Abstract

Despite progress in increasing uptake of HIV testing and treatment, preventing new HIV infections remains a challenge for South Africa. Though in the last decade interest has grown in interventions using sport to promote health, rigorous evidence supporting the effectiveness of these interventions is limited. Also, although there is some evidence that SMS-based interventions can effectively promote healthy behaviour, few evaluations have been carried out.

In 2012, a three-year cluster-randomised trial was launched to assess the effectiveness of a sport-based HIV prevention (SBHP) intervention and associated SMS campaign. The trial enrolled 46 schools in informal settlements in Cape Town and Port Elizabeth. Schools were randomised to receive the SBHP intervention or standard life-orientation classes only, with intervention schools randomised to receive (or not receive) biweekly SMS's reinforcing the intervention. Self-administered questionnaires were completed on touchscreen mobile phones at baseline (n=4485) and midline (8-11 months post-intervention, n=3442) to assess the intervention's effectiveness in reducing reported sexual risk behaviour and improving HIV-related knowledge and reported attitudes. Random-effects logistic and linear regression was used to assess differences between study groups at midline, adjusting for age, site, school-level clustering and baseline prevalences.

Very strong evidence of a positive effect of the intervention was observed on HIV-related knowledge (β=0.39, 95%CI=0.25-0.53) among males and females and on reported HIV testing in the last year (OR=1.47, 95%CI=1.13-1.90) among males. There was, however, strong evidence of a negative effect on reported multiple partners in the last six months among males (OR=1.34, 95%CI=1.08-1.66) and on reported perpetration of intimate-partner violence by males (OR=1.27, 95%CI=1.00-1.60). There was strong evidence of that including SMS's in the intervention reduced reported multiple partners in the last six months (OR=0.75, 95%CI=0.58-0.96).

The midline results suggested the SBHP intervention was not effective in achieving its primary behavioural objectives but did improve HIV-related knowledge and HIV testing uptake among males. They provided further evidence that SMS's may be an effective sexual health promotion tool. Further qualitative research is investigating why the intervention may have led to an increase in certain risk behaviours.

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Rachel Jewkes from the Medical Research Council (MRC) of South Africa provided invaluable input into the trial's questionnaire. David, Sinead, Helen, Rachel and Cathy Matthews (of the University of Cape Town and also the MRC) served on the GOAL Trial Advisory Committee. Tim Clayton and Frances Cowan served on the GOAL Trial's Data Safety and Monitoring Board. Additional thanks to Tim and to Charlotte Watts for volunteering their time to serve on my MPhil-PhD upgrading committee.

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LIST OF ABBREVIATIONS

ACASI	Audio Computer Assisted Self-Interview
ADS	Age-Disparate Sex
AIDS	Acquired Immune Deficiency Syndrome
AIS	AIDS Indicator Survey
AOR	Adjusted Odds Ratio
ART	Antiretroviral Therapy
AUDIT	Alcohol Use Disorders Identification Test
CI	Confidence Interval
DBS	Dried Blood Spot
DoE	Department of Education
DHS	Demographic Health Survey
EMIMA	Education, Sport and Physical Activity
GBV	Gender-Based Violence
GEM	Gender Equitable Men Scale
GRS	Grassroot Soccer
HAU	Hazardous Alcohol Use
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
HoMBReS	Men Maintaining Wellbeing and Healthy Relationships
HSV-2	Herpes Simplex Virus 2
ID	Identification Code
IPV	Intimate Partner Violence
IQR	Interquartile Range
KAO	Kicking AIDS Out
LSHTM	London School of Hygiene and Tropical Medicine
LTFU	Loss-to-follow-up
MMC	Medical Male Circumcision
MP	Multiple partners (in the last year)
MYSA	Mathare Youth Soccer Association
NOS	Newcastle-Ottawa Scale

ODK	Open Data Kit
OR	Odds Ratio
RCT	Randomized Controlled Trial
RR	Risk Ratio
RTP	Right To Play
SBHP	Sport-Based HIV Prevention
SFD	Sport for Development
SMS	Short Message Service
STI	Sexually Transmitted Infection
UK	United Kingdom
UN	United Nations
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
WRHI	Wits Reproductive Health and HIV Institute

GENERAL INTRODUCTION

While South Africa has made remarkable progress in 'turning the tide' against its HIV epidemic, in particular in scaling up access to HIV testing and treatment, prevention remains a challenge.[1,2] The nation has more people living with HIV (6.4 million, 12.2% of the population) than any other nation in the world, with 469,000 new infections occurring in 2012.[2] HIV prevalence and incidence among 15-24 year-old young people in South Africa (7.1% prevalence, 1.5% incidence) are amongst the highest in the world, with females having a roughly four-times higher prevalence than males.[2] The epidemic is disproportionately concentrated in urban informal areas (19.9% prevalence), where prevalence is nearly twice as high as in urban formal (10.1%) and rural formal (10.4%) areas.[2] Though gains have been made in increasing coverage of anti-retroviral treatment (ART)—with more than 2 million South Africans now on ART—the most recent national health survey (2012) showed declines in reported condom use and HIV-related knowledge as well as increases in reported multiple partnerships and age-disparate relationships, compared to the 2008 survey.[2]

In its 2012-2016 strategic plan, the South African government identified reducing HIV infection in young people, particularly via comprehensive sexuality and life skills education in schools, as a key priority.[7] It stated that curricular and co-curricular sexuality education and life skills programs must be provided in all schools "to build skills, increase knowledge and shift attitudes, change harmful social norms and risky behaviour" (p41).[9] The Department of Education's Curriculum and Assessment Policy Statement identifies age-specific life orientation outcomes but does not provide detailed guidance to schools or teachers on how to achieve these outcomes.[21] A recent systematic review of youth HIV prevention in South Africa found that school-based interventions had the greatest impact by focusing on the causal pathways of HIV specific to southern Africa, including gender, sexual coercion, alcohol use, and economic risk.[9]

The last decade has seen a dramatic rise in Sport-for-Development programmes worldwide and particularly in sub-Saharan Africa, using sport as a vehicle to promote health, wellbeing, and peace.[3,4] A number of organisations within the Sport-for-Development sector have employed sport-based methodologies to deliver HIV prevention education and HIV testing and counselling.[5] The inspiration and support for these programmes may have come partly form the so-called 'Magic Johnson' effect observed in the 1990's, when the basketball star disclosed that he was HIV-positive and this had a short-term positive effect on adolescents' HIV-related knowledge and attitudes.[6-8] While there is strong evidence supporting the effect of well-designed school-based HIV prevention interventions on knowledge and self-reported behavioural outcomes,[10] little research has rigorously assessed the effectiveness of sport-based interventions delivered in schools.

Grassroot Soccer (GRS), a South Africa-based non-profit, has been delivering sport-based HIV prevention (SBHP) interventions in Southern Africa since 2003, when it began delivering interventions at schools in Bulawayo, Zimbabwe, led by local professional footballers. Promising early evaluations in Zimbabwe, Zambia, South Africa, Liberia, South Sudan, and the Dominican Republic led the organisation to scale its programmes, with support from USAID, the Bill and Melinda Gates Foundation, Nike, and others.[9-12] With a keen interest in assessing the effectiveness of its work, GRS sought and obtained support to run a randomised controlled trial of its Generation Skillz intervention in South African secondary schools.

The last decade has also seen a proliferation of interventions using SMS's to promote healthy behaviour, from smoking cessation interventions to sexual health promotion interventions to interventions aimed at increasing ART adherence.[13,14] While results have been promising, few evaluations have been published on the effectiveness of SMS-based sexual health interventions.[13] This thesis presents the basis, design, baseline results and midline results of a cluster-randomised trial assessing the behavioural effectiveness of Generation Skillz and an associated SMS campaign in reducing reported sexual risk behaviour and improving HIV-related knowledge and attitudes.

Definitions

Several definitions are drawn on throughout this thesis. "Sport-based HIV prevention" (SBHP) refers to the use of sport—activities, themes, metaphors, celebrities—in the design and delivery of interventions aiming to reduce HIV incidence and stigma and/or increase uptake of HIV-related services (e.g. HCT, ART, VMMC). The term "age-disparate sex" (ADS) refers to having a sexual partner who is five or more years older or younger. Though some studies and interventions have focused on inter-generational sex using an age-disparity threshold of ten years, Leclerc-Madlala argues—in a 2008 literature review on age-disparate sexual relationships in southern Africa—that greater attention must be paid to ADS (defined with 5-year threshold) among young women in the region.[15] And, indeed, South Africa's most recent national health survey used a five-year threshold to report nationally on the prevalence of age-disparate relationships among 15-19 year-old females.[1]

Aims

The GOAL Trial initially had three main aims. First, it set out to assess the biological and behavioural effectiveness of a sport-based HIV prevention intervention in South African schools. Secondly, it sought to assess whether sending biweekly SMS messages to participants enhanced the intervention's effect on knowledge, reported attitudes, and reported behaviour. Lastly, through a process evaluation, it sought to understand how and why the intervention was or was not effective in achieving its desired outcomes. The latter aim is the subject of Stefanie Dringus' doctoral work.

Three primary behavioural outcomes were chosen for the GOAL trial, based on the focus on Generation Skillz and the drivers of the HIV epidemic among young people in South Africa: age-disparate sex (ADS) in the last six months, multiple partnerships in the last six months, and reported rape perpetration ever. ADS partly explains why young women in South Africa and sub-Saharan Africa as a whole are more than twice as likely to be HIV-infected than their same-age male peers.[16] ADS is of interest as a behavioural outcome because it is common among young women in South Africa, is often tied to financial gain in relationships, has a significant and negative association

with the likelihood of safer sex, and because older partners are more likely than same-age partners to be HIV-positive.[15,17,18]

After the completion of the baseline survey round, the Trial Advisory Committee (TAC) decided to abandon the aim of assessing the intervention's biological effectiveness due to a much smaller-than-anticipated sample size. Whereas the trial had planned for a sample size of 64 schools and 9600 participants, its actual enrolment was much smaller due to (a) the lack of approval from the Gauteng Department of Education, which meant the largest study site—Soweto—could not be part of the trial and (b) smaller-than-anticipated cluster size, likely attributed to the requirement of written parental consent (instead of passive parental consent) insisted upon by the local ethics committee. Given the projected HIV and HSV incidence (1.5% and 5% per year, respectively),[1] the trial would need to be very large to be able to detect a reasonable effect. With only 4500 participants at baseline and the estimated 9% attrition per year, the trial would only be able to detect a 45% reduction in HIV incidence, which the TAC unanimously agreed the intervention was highly unlikely to achieve. Not having funding committed at the time for long-term biological follow-up, the TAC decided the trial would have to rely on behavioural outcomes to assess the intervention's effectiveness.

Research Questions, Hypotheses, and Methods

The primary research questions I have investigated in this work over the last three years are:

1. Globally, what is the evidence of effectiveness for sport-based HIV prevention interventions, particularly for young people?
2. What are the patterns of reported sexual risk behaviour among male and female adolescents in informal settlements in Cape Town and Port Elizabeth, South Africa?
3. Is social media use associated with reported multiple partnerships in the last year, age-disparate sex in the last year, and/or reported hazardous alcohol use among this population?

4. Over one year, does the Generation Skillz intervention reduce reported age-disparate sex, multiple partnerships, and/or rape perpetration among this population?
5. Does sending biweekly SMS messages to participants for one year enhance the effectiveness of Generation Skillz in improving HIV-related knowledge, reported attitudes, and/or reported behaviour over one year?

Table 1: Research questions, hypotheses and methodologies

Research Question	**Hypothesis (H_1)**	**Methodology used**
1. Globally, what is the evidence of effectiveness for sport-based HIV prevention interventions, particularly for young people?	Evidence is limited and primarily comes from observational studies.	Systematic review of published and grey literature
2. What are the prevalences of age-disparate sex, multiple partners in the last year, hazardous alcohol use, and reported rape perpetration among grade 9 male and female learners in informal settlement schools in Cape Town and Port Elizabeth, South Africa?	Prevalence of ADS is higher among females than among males; prevalence of multiple partners is higher among males than females; prevalence of HAU is higher among males than females.	Baseline questionnaire of GOAL trial.
3. Is social media use associated with reported multiple partnerships in the last year, age-disparate sex, and/or reported hazardous alcohol use among this population?	Participants who use social media have higher odds of reported multiple partnerships in the last year, age-disparate sex in the last year and hazardous alcohol use.	Baseline questionnaire of GOAL trial.
4. Over one year, does the Generation Skillz intervention reduce reported age-disparate sex, multiple partnerships, and/or rape perpetration among this population?	After 12 months, Generation Skillz participants have lower prevalence of reported age-disparate sex, multiple partnerships, and rape perpetration.	Midline questionnaire of GOAL trial, adjusted for baseline responses.
5. Does sending biweekly SMS messages to participants for one year enhance the effectiveness of Generation Skillz in improving HIV-related knowledge, reported	After 12 months, participants who receive SMS messages have better HIV-related knowledge and more	Midline questionnaire of GOAL trial, adjusted for baseline responses.

attitudes, and/or reported behaviour over one year?	favourable reported HIV-related attitudes.	

To answer Question 1, a Systematic Review was undertaken, assessing evidence of the effectiveness of SBHP interventions in published and grey literature. Details of the Systematic Review methods can be found in Paper 1 (p__). Question 2 was answered through cross-sectional analysis of baseline questionnaire data collected in 2012. Details of the data collection and analysis methods can be found in Paper 3 (p__). All questionnaires were self-administered and conducted using Open Data Kit (ODK) software on Android mobile phones, with data uploaded to and stored securely in a password-protected online database. Explanations of how and why ODK was selected, the process of developing the ODK questionnaire, and participants' reported acceptability of the ODK questionnaire can be found in the first Linking Section (pp_-__). Question 3 was assessed through multivariable random-effects logistic regression of data collected in the GOAL baseline questionnaire in 2012. Details of the data collection and analysis methods can be found in Paper 4 (p__). Questions 4 and 5 were assessed using random-effects logistic regression of data collected in the GOAL midline questionnaire in 2013, comparing the intervention and control groups and adjusting for school-level clustering as well as baseline prevalences. Details of the data collection and analysis methods can be found in Paper 5 (p__). Details of the participant tracing and follow-up process can be found in the second Linking Section (p__).

Partners, roles and funding

The GOAL Trial is a collaboration between the London School of Hygiene and Tropical Medicine (LSHTM), Grassroot Soccer, and the University of Witwatersrand's Reproductive Health and HIV Institute (WRHI). Intervention development and delivery was led by Grassroot Soccer, who also provided financial and operational oversight for the trial.

I served as Trial Director throughout the duration of the Trial. This role included: leading the study design (in consultation with my co-supervisors and advisors), co-writing the successful funding proposals to MAC AIDS and Comic Relief, drafting all

written material related to the trial (including the protocol, IRB submissions, consent forms, questionnaire, etc); developing the ODK questionnaire as well as the online trial participant database; working with Team Leaders to establish and handle the Trial's operations and logistics; and training, overseeing, and supporting/backstopping the survey teams.

The plan had been for WRHI to play a more significant role in providing local logistical support, but when the Gauteng Department of Education did not allow the trial to move ahead in Soweto schools, the trial's headquarters moved from Johannesburg to Cape Town.

The GOAL Trial was funded by Comic Relief and the MAC AIDS Fund. I received doctoral funding support from the Marshall Aid Commemoration Commission and the Harry S. Truman Foundation.

Thesis structure

This thesis is presented in a 'research paper' style, featuring five research papers. *Paper one* is a systematic review on the evidence of effectiveness of sport-based HIV prevention interventions. It was accepted by *AIDS and Behavior* in 2012 and published in 2013. *Paper two* details the Generation Skillz intervention development process and presents preliminary findings from pre/post questionnaires conducted during the intervention's pilot phase. It will shortly be submitted to the *African Journal of AIDS Research*. *Paper three* combines the GOAL Trial's study protocol with descriptive baseline results analysed by study group. The results were presented at the 2013 STI & AIDS World Congress in Vienna, with the abstract published in *Sexually Transmitted* Infections.[19] The full paper is currently under review at *Contemporary Clinical Trials*. *Paper four* presents an analytical cross-sectional study using data collected in the GOAL baseline, investigating associations between social media use, alcohol use, and reported sexual risk behaviour. It was published in *AIDS and Behavior* in July 2014*;* we have addressed and responded to the reviewers' first round of comments. *Paper five* presents recent findings from the trial's 2013 midline survey, assessing the Generation Skillz intervention's effect (as well as the effect of its related SMS campaign) in reducing age-disparate sex, multiple partners, and

reported rape perpetration. It has not yet been submitted to a journal for publication.

Two linking pieces are included in the thesis. One provides more details on the innovative technology—ODK for self-administered questionnaires, a Force.com database for trial management, and SMS-Magic for sending bulk SMS's—used in the trial. It presents descriptive data on non-response rates and the acceptability of ODK among trial participants. The second linking piece explains elements of the study protocol in more detail than *Paper three*, including the participant tracing process.

Six annexes are included in the thesis: (A) lists and maps of participating schools in Cape Town and Port Elizabeth, (B) the trial's consent and assent forms, (C) approval letters from Wits HREC, LSHTM Interventions Research Ethics Committee, and the Western Cape Department of Education, and the Pan-African Clinical Trial Registry, (D) the trial sponsor letter from LSHTM, (E) Good Clinical Practice certificate from NIDA Clinical Trials Network, (F) baseline GOAL questionnaire.

Fieldwork

Data collection took place in two rounds: 5 March to 30 September 2012 and 11 February to 30 August 2013. In all, the doctoral candidate made six trips to South Africa during the course of the study, spending a total of approximately 10 months in the field, between Cape Town, Port Elizabeth and Johannesburg. The largest portion of time spent in the field was from December 2011 to July 2012, which included survey team training, survey pilot-testing, randomisation of schools, and four months of direct survey team oversight. Trial Advisory Committee meetings were held in Cape Town in January 2012, November 2012, and October 2013.

Questionnaire development

The baseline questionnaire was developed through consultation with a range of stakeholders, including Grassroot Soccer curriculum development staff, the Trial Advisory Committee, domain experts from the Medical Research Council of South Africa, and staff at LSHTM. Numerous survey instruments were consulted, including the AIDS Indicator Survey (AIS), the UNGASS guidelines,[20] and the questionnaire used

in the Stepping Stones trial.[21] Standard and adapted scales used in the questionnaire, included the Alcohol Use Disorder Identification Test (AUDIT),[22] the Center for Epidemiological Studies Depression Scale (CES-D, for assessing depressive symptoms),[23] and an adapted Gender-Equitable-Men scale[24] (shortened version adapted for use with both sexes). Several indices were developed specifically for the questionnaire: a five-item asset index, a ten-item HIV-related knowledge index, a four-item HIV stigma index, and an eight-item HIV prevention self-efficacy index. Items for assessing reported sexual behaviour were defined with the aim of maximizing consistency with HSRC's most recent National Health Survey.

Survey team recruitment and training

The doctoral candidate initially recruited three survey team leaders—one per survey team—who then assisted in the recruitment of 12 local survey administrators for the baseline survey. Eight of the 12 survey administrators stayed on to continue their roles in the 2013 follow-up survey round.

Two trainings were held in February 2012—one in Cape Town and one in Port Elizabeth. Content of the training included:

- Background of the study and introduction to randomised controlled trials
- Administering the ODK survey
- Collecting dried blood spots
- The consent and assent process
- Important ethical considerations in research with adolescents
- How to respond to distress

Most training sessions were led by the doctoral candidate, with some sessions led by guest facilitators from the University of Cape Town, the Contract Lab Services, and Childline South Africa. All survey administrators and team leaders were certified by CLS in the collection of dried blood spots. One training for both 2013 survey teams was conducted in Port Elizabeth in January 2013.

Trial Advisory Committee and Data Safety and Monitoring Board

In November 2011, a Trial Advisory Committee was formed, consisting of local and international researchers and GRS senior leadership. The committee planned to meet annually and act as a steering committee for the trial, providing input into the design, protocol, intervention, survey team training methods, and trial management. A two-member Data Safety and Monitoring Board (DSMB) was formed at the same time, consisting of a statistician and a trialist with experience in adolescent-targeted HIV prevention. The DSMB's purpose was to sign off on the data analysis plan prior to starting analysis and to ensure the trial complied with good clinical practice. Since the risk of participation in the study was minimal, the DSMB did not actively monitor for safety issues in the trial. Because delivery of the Generation Skillz Utshintsho booster sessions (see Paper 2) occurred immediately after the midline (2013) follow-up questionnaires were completed at intervention schools, it was not possible for the DSMB to review follow-up data or results prior to booster session delivery. Thus, had the DSMB advised termination the trial as a result of the midline findings, this would not have prevented any additional interventions from being delivered.

Equipment

Data collection for the trial, especially during the baseline survey, depended on large amounts of locally sourced equipment. Four hatchback cars were purchased for the trial – one for each survey team and one for use in the process evaluation and for overall study coordination. Each team was outfitted with 50 Samsung Galaxy Gio Android mobile phones. The sim cards for these phones were removed to ensure that data collection took place offline and that participants could not be distracted by any web applications. DBS equipment (for baseline surveys) was obtained from BARC labs in Cape Town.

Translation and audio recordings

The questionnaire was translated into Xhosa and back-translated into English by staff at the University of Cape Town, under supervision from Dr. Cathy Mathews. The Xhosa translations were audio-recorded on one of the Android phones by Survey Administrator Nonzukiso Sixwaru under the supervision of the doctoral candidate.

The recordings were stored in AMR files, which were stored in a folder on each of the 150 study Android phones.

Survey pre-testing and piloting

The questionnaire was pre-tested with small groups of Grassroot Soccer local staff and coaches in Cape Town and Port Elizabeth in late 2011. Feedback was obtained on questionnaire content, Xhosa translations, and the user-friendliness of ODK. The baseline questionnaire was then piloted in three trial schools—one in each site. Grade 10 learners participated in the pilot to ensure no study participants (Grade 9 learners) were pre-exposed to the questionnaire content. This piloting offered the survey teams an opportunity to practice administering the survey protocol prior to initiating the Trial's baseline survey.

Prior to the Trial, Grassroot Soccer had piloted Generation Skillz in four sites across South Africa. Paper 2 describes the curriculum development process and the lessons learned during these pilots. The curriculum used in trial interventions was in its fourth iteration.

Ethics and approvals

Ethics approval

Ethics approval for the trial was obtained from the Wits University Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine's Interventions Research Ethics Committee. Written parental/guardian consent as well as written participant assent was obtained for all study participants, with the exception of participants over the age of 18 years at baseline (these participants were allowed to consent for themselves). The parental/guardian consent for and the participant assent form can be found in Annex A and B, respectively. The doctoral candidate completed training in Good Clinical Practice through the NIDA Clinical Trials Network (Annex E), and all survey staff were trained in ethical research conduct. Participation in the study entailed relatively minimal risk; there was a possibility that some participants might find some of the survey questions distressing. Participants were given the option of not answering any question(s) they

did not wish to answer and had the right to withdraw from the study at any time. Survey staff were trained in how to respond to distress should the case arise.

Department of Education Approval

Approval was obtained from school administrators in each trial school as well as from the provincial departments of education in the Western Cape and Eastern Cape provinces. We had planned to include schools in Soweto in the trial but were unable to obtain approval from the Gauteng Department of Education and thus had to focus the trial exclusively in the Cape.

Sensitive disclosures

Since participants might disclose to survey administrators sensitive information about their sexual behaviour, personal lives, or experiences with violence or abuse, a protocol was developed for handling distress and sensitive disclosure. The protocol focuses on comforting the participants upon disclosure and making referrals to either school social workers or to service organisations. In the event of disclosure, survey team staff would offer to reach out to service providers on participants' behalf and accompany them to their first visit.

South Africa's Criminal Law (Sexual Offenses and Related Matters) Amendment Act (No 32, 2007) requires the reporting to authorities of any cases of disclosed perpetration or experience of sexual violence or rape perpetration.[25] Since data collected via ODK are confidential and questionnaires are locked upon saving, survey administrators were not able to connect identifying information to participants' sensitive survey responses. By answering sensitive questions affirmatively, participants were not disclosing to our study staff that they had committed violence or engaged in risky behaviour – rather, they were honestly answering questions on a confidential questionnaire. Given the sensitive nature of the questionnaire, we set up our data system to ensure confidentiality is maintained at all times. Study staff did not know if participants disclosed any sensitive information—including perpetration of violence or rape—via the survey. Therefore, we were not required to report cases of violence perpetration to authorities. If participants had personally disclosed to survey administrators that they had perpetrated violence or rape

(including statutory rape), this would have been reported to the police, as required by law.

Minimizing and managing risks

Our study team was highly aware of the ethical issues involved in interviewing young people regarding risky behaviour and taking blood samples. Steps were implemented to protect research participants from any social harms or discomforts by ensuring that the study staff made every attempt to create a comfortable and secure environment in which to interact with participants. We anticipated that the use of cell phone-based self-interviews would help reduce this discomfort. No tests have yet been run on the DBS data, but if/when they are, all test results will be kept confidential.

Risks to subjects were minimized by: 1) training of staff in the ethical conduct of research; 2) strict protection of confidentiality through ODK and survey team monitoring; 3) monitoring of any adverse events and social harms; and 4) referral to appropriate referral services if/when necessary. If individuals were uncomfortable during the survey, they were reminded that they could terminate the questionnaire or withdraw from the study at any time.

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London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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   I carried out the systematic review, data analysis, and led manuscript preparation.

NAME IN FULL (Block Capitals) **ZACHARY A KAUFMAN**

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SUPERVISOR/SENIOR AUTHOR'S SIGNATURE (3 above) .....

Zachary A Kaufman, MSc
PhD Candidate, Faculty of Epidemiology and Population Health
London School of Hygiene & Tropical Medicine
Keppel St, London WC1E 7HT, UK
Tel: +27 71 590 0820
Email: zachary.kaufman@lshtm.ac.uk

18 February 2012

Dear Dr. Kalichman,
We are pleased to submit our manuscript "Effectiveness of sport-based HIV prevention interventions: a systematic review of the evidence" to AIDS and Behavior for consideration. The abstract has been submitted to the XIX International AIDS Conference for presentation in July 2012, but the manuscript has not been submitted for publication anywhere else.

We feel AIDS and Behavior would be an appropriate journal for publishing this systematic review, especially as the first published evaluation of a sport-based HIV prevention program (Clark et al. 2006) was published in your journal just over five years ago. With upcoming randomized controlled trials of sport-based HIV prevention interventions about to begin in South Africa and Washington DC, we feel this systematic review is an important and timely addition to the literature, synthesizing the existing evidence base in the growing field of sports-based HIV prevention.

Sincerely,



Zachary A. Kaufman, MSc
PhD Candidate, Faculty of Epidemiology and Population Health
London School of Hygiene & Tropical Medicine

Effectiveness of sport-based HIV prevention interventions: A systematic review of the evidence

Kaufman ZA[1,2], Spencer TS[3], Ross DA[1]

[1] London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health: London, UK

[2] Wits Reproductive Health and HIV Institute: Johannesburg, South Africa

[3] Grassroot Soccer, Inc: Cape Town, South Africa

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Abstract

Interest in sport as a tool for behavioral HIV prevention has grown substantially in the past decade. With dozens of organizations now using sport-based HIV prevention (SBHP) approaches and upcoming randomized controlled trials in South Africa and Washington DC, there is a pressing need to synthesize previous evaluation findings and identify gaps in existing research. A systematic review on the effectiveness of SBHP interventions was carried out, identifying both published and unpublished studies on SBHP interventions that measured effectiveness quantitatively. Study quality was scored using an adapted Newcastle-Ottawa Scale. Random-effects meta-analyses were carried out across studies for effects on six categories of HIV-related outcomes. The review identified 952 publications, 21 of which met inclusion criteria. No randomised controlled trials on SBHP interventions and no studies assessing biological outcomes were identified. Mean study quality score was 5.1 (SD 3.1) out of 20 points. Overall strong evidence was observed for positive effects on HIV-related knowledge (RR=1.26, 95% CI=1.15-1.37), stigma (RR=1.13, 95% CI=1.02-1.24), self-efficacy (RR=1.22, 95% CI=1.02-1.41), reported communication (RR=1.24, 95% CI=1.06-1.41), and reported recent condom use (RR=1.29, 95% CI=1.00-1.59). Generally, the review found encouraging evidence for at least short-term effects but relied predominantly on low-quality studies. More rigorous research on SBHP is needed to objectively assess effectiveness. Randomised controlled trials could play an important role in guiding policies, strategies, and funding related to SBHP.

Keywords: Systematic review, HIV prevention, sport, effectiveness, evidence

INTRODUCTION

With more than 34 million people living with HIV and more than 2.5 million new infections in 2010, the need for effective and scalable HIV prevention interventions remains an urgent public health priority.[1] While the UN set a target to ensure that 95% of the world's youth had accurate and comprehensive HIV prevention knowledge by 2010,[2] national health surveys reveal that only about 30% of young people today in low- and middle-income countries have comprehensive HIV prevention knowledge.[3]

Strong evidence exists supporting the impact of well-designed school-based HIV prevention interventions on knowledge, reported attitudes, and reported sexual risk behaviours.[4] To date, however, only three such interventions in sub-Saharan Africa have been evaluated via randomised controlled trials (RCT) with biologial outcomes. None of these interventions demonstrated an effect on HIV incidence and only one demonstrated an effect on HSV-2 incidence.[5-7] While none have shown negative effects on HIV or other sexually transmitted infections (STIs), debate remains on whether school-based interventions are contributing effectively to the fight against HIV, at least in the short to medium term.[8]

In the 1990's, several studies revealed the positive impact that basketball star Magic Johnson's public HIV status disclosure had on the attitudes of young Americans towards the infection.[9-11] Out of these powerful, yet short-lived, effects grew the concept of sport-based HIV prevention (SBHP): the idea that sports role models, activities, and metaphors could increase knowledge, improve attitudes, and change behaviours related to HIV.[12] Interest in this approach has grown internationally over the last decade, with support from prominent figures such as Michelle Obama, Michel Sidibé, and Peter Piot. Dr. Piot has said of the approach:

> *"Soccer offers an exciting platform for intensifying HIV prevention efforts across Africa helping promote self esteem and supporting the development of protective communication and life skills."*[13]

Today, more than a dozen nonprofit organisations are dedicated to SBHP, and numerous other organisations, sports teams, Olympic Committees and Ministries of Education have incorporated elements of SBHP into their work.[14,15] Numerous toolkits and curricula have been developed, most notably those used by Grassroot Soccer (GRS), Kicking AIDS Out (KAO), and Right To Play (RTP). Some SBHP interventions are explicitly theory-based. The Grassroot Soccer model, for instance, is rooted in Social Learning Theory,[16] using interactive

teaching methods and role models with an aim to increase knowledge, improve attitudes and self-efficacy, and ultimately change sexual behaviour to reduce HIV incidence. More details on the GRS model and on other SBHP interventions can be found in the articles referenced in this review. Despite growing support for SBHP interventions, little is known about their effectiveness.

The purpose of this systematic review was to synthesize findings from all published and grey literature on SBHP interventions in order to:

1. Determine whether current evidence supports the effectiveness of SBHP
2. Identify gaps, weaknesses and limitations of existing research in order to guide future research in this area.

METHODS

Inclusion criteria

In order to be included, studies had to evaluate an SBHP intervention, defined as an intervention that explicitly uses sports themes, activities, metaphors, and/or role models in an effort to reduce HIV transmission. This included educational interventions as well as interventions aiming to increase uptake of health services that contribute to reducing HIV transmission and/or acquisition—i.e., medical male circumcision (MMC), HIV counselling and testing (HCT), STI treatment, or antiretroviral treatment (ART). Studies that did not assess effectiveness quantitatively—either via an intervention/control or pre/post comparison—were excluded. Eligible study designs included randomised controlled trials, non-randomised intervention studies, and cross-sectional or case-control studies comparing intervention and control groups. In order to be included, studies needed to assess one or more of the following HIV-related outcomes: knowledge, stigma, self-efficacy, reported communication, reported sexual behaviour, service uptake, or HIV, STI, or pregnancy incidence or prevalence.

Search strategy

The review employed a two-pronged search strategy to identify published and unpublished studies. First, four electronic databases (MEDLINE, EMBASE, Global Health, and PsycInfo) were searched on August 2, 2011 to identify published articles on the topic, using search terms related to the problem/outcomes, intervention, and methods of interest (Annex 1). The search did not restrict on the basis of year published. The emerging studies were then deduplicated using the Ovid deduplication tool. Secondly, known researchers and staff at key organisations working in SBHP (including GRS, KAO, RTP, Moving the Goalposts, streetfootballworld Network, Beyond Sport, The Grassroot Project, Sport-and-Dev, UK Sport)

were contacted and asked for any relevant published or unpublished studies on SBHP effectiveness (see Annex 2).

Appraisal of studies

Studies were appraised using an adapted Newcastle-Ottawa Quality Assessment scale (NOS).[17] The adapted scale included all elements of good study design from the NOS (related to selection, comparability and outcome measurement) with additional elements accounting for random allocation, use and reporting of appropriate sample size calculations, sufficient study size, and appropriate statistical analysis. Each of ten elements of good study design was given a score between 0 and 2 (0 = No/Unclear; 1 = Partly; 2 = Yes). Scores were aggregated across elements to determine each included study's quality score (out of a possible 20 points). Table I describes the elements of good study design, along with criteria for assigning point values. Scores were tabulated across studies (to determine mean study quality) and across elements (to determine the most common strengths/weaknesses). Where multiple study reports were identified, the most complete report was used for appraisal.

[INSERT TABLE I HERE]

Study findings were analysed within outcome categories to determine the evidence of intervention effectiveness in improving knowledge, stigma, self-efficacy reported communication, reported sexual behaviour, service uptake and biological outcomes. Where one report or publication disaggregated results from multiple interventions or countries, these were treated as separate studies.

Meta-analysis

Random-effects meta-analyses were carried out for overall effects on knowledge, stigma, reported communication, reported uptake of HCT, and reported recent condom use (i.e. condom use at last sex or consistent condom use in last 30 days). It was not possible to conduct such a meta-analysis for other attitudes or behaviours due to the heterogeneity of indicators used across studies. If not reported explicitly, pre-post and/or intervention-control percents of favourable responses were calculated for each study by taking the mean percent of favourable responses across questions or by converting a numeric score to a percent out of the total points possible. Relative differences were then calculated for each study by comparing post to pre and/or intervention to control, and estimates of effect (RR) with 95% confidence intervals were then computed for use in random-effects meta-analysis.

Two levels of sensitivity analysis were carried out—first by excluding studies classified as 'poor quality' (Sensitivity Level 1) and second by excluding unpublished studies (Sensitivity Level 2).

RESULTS

Inclusion and exclusion of studies

[INSERT FIGURE 1 HERE]

The literature search identified 924 studies and the grey literature search yielded 28 additional studies. Of the 952 study titles reviewed, 869 were excluded for irrelevance or redundancy. Abstracts were then screened for 83 studies. Sixty-two of these studies were excluded, 54 after abstract review and eight more after full text review. The reasons for exclusion were: (a) the study did not quantitatively assess the effectiveness of an intervention (n=45), (b) the intervention was not sport-based (n=13), (c) the outcomes were not HIV-related (n=9), and/or (d) the study design did not meet review criteria (n=15). Some studies were excluded for more than one reason. The remaining 21 studies[18-35] were included in the review. Nine of these studies had been published in peer-reviewed journals, four had been presented at international conferences, and seven were unpublished reports or Masters theses.

Characteristics of included studies

[INSERT TABLE II HERE]

Seven of the included studies were quasi-experimental (i.e. non-randomized, prospective studies with intervention and comparison groups); four were cross-sectional, and ten utilized a pre/post (or time-series comparison) design. No randomised controlled trials of SBHP interventions were identified. Sixteen of the studies were conducted in sub-Saharan Africa, two in the Caribbean, and three in the United States. Most study participants were between 12 and 16 years old; only one study included participants over 30 years. Most of these studies assessed youth-targeted interventions delivered either with sports teams or school classes through curricula that used sports themes, activities and metaphors (note: 12 studies evaluated interventions either run by or adapted from GRS). Rhodes et al.[28], however, assessed an intervention–HoMBReS—that recruited adult male soccer players to be lay health advisors and trained them to deliver health promotion and education to their teammates. More details about the individual interventions can be found in the referenced studies. No identified studies were published or presented prior to 2006. Eighteen studies assessed HIV-related knowledge, fourteen assessed reported attitudes, five assessed

reported communication, six assessed reported behaviour, and four assessed uptake of HCT. No studies assessed biological outcomes and no studies assessed uptake of other HIV-related services.

Study appraisal

[INSERT TABLE III HERE]

Table III presents the results of study appraisal. Two studies were classified as Good-quality, eleven as OK-quality, and eight as poor-quality. None of the included studies were classified as having Very Good quality. The mean study quality score was 5.1 (SD 3.1) points out of 20 possible points. The most common limitations identified were lack of objective outcome measures (all studies relied on self-reported outcomes), lack of randomisation in both sampling and group allocation, and lack of extended follow-up. Only five studies adjusted analyses for confounding, only three reported that they had used sample size calculations to determine the study size, and only one followed participants for more than six months.

Knowledge

Of the 18 studies assessing HIV-related knowledge, 15 reported an overall positive effect, two found no effect, one found a negative effect. Of the 15 studies finding a positive effect, ten had very strong evidence of effect ($p<0.01$), one had strong evidence ($p<0.05$), and four did not present p values. Kim and colleagues (2011) reported very strong evidence of effect but only reported the mean change in knowledge rather than pre and post scores, making it impossible to include in the meta-analysis. Knowledge questions varied across studies, though common questions assessed knowledge of HIV transmission, HIV prevention methods, understanding of asymptomatic infection, rejection of myths related to HIV, and knowledge of the distinction between HIV and AIDS. The strongest knowledge effect was observed in Kaufman and colleagues' evaluation of Fútbol Para la Vida in the Dominican Republic,[24] which found a nearly 40% increase in knowledge from pre-to-post and very strong evidence of post-intervention difference between participants and controls, after adjusting for confounders and baseline responses (AOR=2.7, 95%CI=1.7-4.2). The knowledge meta-analysis (Figure 2) found strong evidence of positive effects across studies (RR=1.25, 95% CI=1.16-1.34).

Stigma

Eight of eleven studies assessing stigma reported a positive effect. The Mercy Corps studies[18] in Liberia and Sudan reported absolute increases in willingness to purchase from an HIV-

positive shopkeeper of 41% and 16%, respectively. Kaufman and colleagues[24] found very strong statistical evidence (p<0.003) of increased willingness to support an HIV-positive friend, while Clark and colleagues[19] found weak evidence of this (p=0.068). Both studies found that the high rates of reported support for friends living with HIV was sustained over 4- and 5-month follow-up. Harvey observed an increase from 70.6% to 79.4% in reported willingness to care for an HIV-infected relative, but this result was not statistically significant (p=0.31). Kaufman and colleagues[23] (2010) found strong evidence that graduates from GRS programmes in Zimbabwe and Botswana reported greater willingness to care for an HIV-positive family member 2-5 years later (p=0.01), but did not find an overall effect on HIV-related attitudes. The meta-analysis for stigma (Figure 3) found strong overall evidence of effect (RR=1.21, 95% CI=1.09-1.32).

Self-efficacy

Three out of five studies reported increases in self-efficacy. After adjusting for baseline scores, relationship status and clustering, Rhodes and colleagues[28] found strong evidence of an effect of the HoMBReS intervention on self-efficacy to use condoms (AOR=1.7, 95%CI=1.1-2.6). Rajan and colleagues[32] also reported an increase in self-efficacy to use condoms but did not report measures of effect or statistical probability. Kaufman and colleagues[24] found an increase from 56% to 97% in participants' perceived ability to protect themselves from HIV, whereas graduates and non-graduates reported the same level of self-efficacy to protect themselves (95%) in the Zimbabwe/Botswana long-term follow-up study.[23] Braunschweig and colleagues found strong evidence for a pre/post effect in participants' self-efficacy to resist peer pressure. The meta-analysis for self-efficacy (Figure 4) found strong evidence of an overall effect on self-efficacy (RR=1.22, 95% CI=1.02-1.41).

Other Attitudes

Five of eight studies reported an effect on other HIV-related attitudes and life skills. Peacock-Villada and colleagues[27] found an effect on reported decision-making skills in a study of the GRS Resiliency Programme in Zambia (p<0.05). Maro and colleagues[26] found evidence of positive effects of the KAO-based EMIMA intervention on attitudes towards condom use and having an exclusive partner (p<0.01). Rhodes and colleagues[28] found no effect on adherence to traditional masculine norms (AOR=1.2, 95% CI=0.6-2.0). No other studies reported measures of gender norms.

Reported Communication

Of the five studies assessing reported communication, four studies found a positive effect on reported HIV-related communication (two with strong evidence, one with unclear evidence) and one multi-country study found no effect. Clark and colleagues[19] found that the proportion of graduates who could name three people with whom they could talk about HIV increased from 48% to 64% after the intervention in Zimbabwe ($p<0.01$), though this effect diminished at 5-month follow-up. Kaufman and colleagues[24] found that the proportion of GRS program graduates in the Dominican Republic reporting having spoken to a parent or friend about HIV increased from 24% to 54% and from 34% to 56%, respectively ($p<0.003$). Harvey found weak statistical evidence of a pre/post increase in the proportion of Grassroot Project participants who reported talking to a friend about condoms ($p=0.054$). Kaufman and colleagues[23] found no differences between GRS graduates and non-graduates in Zimbabwe and Botswana at 3-5 year follow-up in terms of reported communication. The meta-analysis for communication (Figure 5) found strong evidence of effect (RR=1.24, 95% CI=1.06-1.41).

Reported Sexual Behaviour

Of the six studies that assessed an effect on reported sexual behaviour, five reported positive effects on at least one behaviour and one study found no effect. Four out of four studies found evidence of a positive effect on condom use, though one study's[26] unconventional analysis methods precluded its inclusion in the meta-analysis. At 18-months post-intervention, Rhodes and colleagues[28] found that participants in the HoMBReS intervention were roughly 2.3-times more likely to report consistent condom use in the last 30 days than non-participants (AOR=2.3, 95%CI=1.2-4.3). Delva and colleagues[20] found evidence of effect on reported condom use at first sex ($p=0.033$) and last sex ($p=0.04$) as well as reported frequency of condom use with current/last partner ($p=0.037$), though the strength of effect diminished after adjusting for media exposure. The meta-analysis found overall strong evidence of an effect on recent condom use (pooled RR= 1.29, 95% CI=1.00-1.59).

Two studies reported effects on reported sexual debut (both with very weak evidence). Two studies found very weak evidence of an effect on reported number of partners, while two found no effect. Rajan and colleagues[32] found evidence of an effect on reported transactional sex ($p=0.011$). No studies found evidence of a negative effect on reported behaviours.

Reported service uptake:

Three studies measured intervention effectiveness in increasing reported uptake of HIV counselling and testing. No evidence of an overall effect on HCT uptake was observed in the meta-analysis (RR=1.81, 95% CI=0.20-3.42), though two of the three studies found very strong evidence of effect. Rhodes and colleagues[28] found very strong evidence of an effect of the HoMBReS intervention on reported HIV testing among male soccer players (AOR=2.5, 95%CI=1.5-4.3, p=0.001). Kaufman and colleagues[23] meanwhile, found no significant effect on reported HIV testing in Botswana and Zimbabwe in cross-sectional follow-up surveys with GRS graduates 2-5 years post-intervention. No studies assessed the effectiveness of SBHP in increasing uptake of other HIV-related services.

Biological outcomes

None of the studies included biological outcome measures, such as HIV, HSV-2 or pregnancy incidence.

Results summary and sensitivity analysis

[INSERT TABLE IV HERE]

Table IV summarizes the main meta-analysis results as well as the results from the two levels of sensitivity analysis. The first level of sensitivity analysis, excluding poor-quality studies, found consistent effects with the main analysis, with strong evidence of effects on knowledge (RR=1.26, 95% CI=1.15-1.37), stigma (RR=1.13, 95% CI=1.02-1.24), self-efficacy (RR=1.22, 95% CI=1.02-1.41), reported communication (RR=1.24, 95% CI=1.06-1.41), and reported recent condom use (RR=1.29, 95% CI=1.00-1.59). The second level of sensitivity analysis, excluding unpublished studies, found larger effect estimates and wider confidence intervals across outcomes, with strong evidence of effects on knowledge (RR=1.37, 95% CI=1.22-1.52), self-efficacy (RR=1.68, 95% CI=1.22-2.14), reported communication (RR=1.40, 95% CI=1.14-1.65), and reported HCT uptake (RR=2.50, 95% CI=1.10-3.90) and no evidence of effect on stigma (RR=1.66, 95% CI=0.65-2.67) and reported recent condom use (RR=1.51, 95% CI=0.81-2.21).

DISCUSSION

Given the urgent need for effective HIV prevention efforts, it is crucial to ensure that policymakers and funders direct resources into interventions that maximize public health impact. School-based HIV prevention has proven promising in its scalability and potential, but disappointing in its inability to demonstrate biological effectiveness or sustained effects

on reported behaviors. SBHP has gained great traction in recent years as a way of making youth-targeted HIV prevention initiatives more engaging and, perhaps, more effective.[12]

This systematic review provides strong evidence that SBHP interventions have at least a short-term effect on HIV-related knowledge, stigma, self-efficacy, reported communication, and reported recent condom use. There is no evidence that these interventions increase uptake of HCT or other HIV-related services, as few studies assessed this. Limited follow-up data suggests that intervention effectiveness on knowledge, attitudes, and communication may diminish over time. More rigorous intervention studies are needed to determine whether these effects are consistent across multiple settings and whether SBHP interventions have an effect on biological outcomes, such as HIV incidence and STI incidence.

The majority of studies identified in this review only assessed knowledge and stigma and none assessed biological outcomes. This is a major limitation in assessing SBHP effectiveness. Since knowledge and reported attitudes are quite distal factors in influencing HIV risk, we are limited in what we can ultimately conclude about the true effectiveness and health impact (i.e., reduction in new HIV infections) of these interventions. Moreover, since reported attitudes, reported communication, and reported sexual behaviour are subject to desirability bias,[36] these intermediate variables may not be valid surrogates for HIV prevention.

The characteristics of the identified studies provide a useful picture of the current landscape of SBHP interventions and research. The geographical distribution suggests that SBHP interventions are most commonly implemented and/or evaluated in sub-Saharan Africa (15 of the 19 studies). Nearly all of the reviewed interventions targeted early adolescents (12-16 years), suggesting this is the primary target group for SBHP interventions. The fact that 12 of the 19 studies evaluated GRS interventions or interventions adapted from GRS either suggests that this is a predominant model that has been used in SBHP to date or that a disproportionate amount of research has been conducted on GRS, compared to other interventions. It is not possible, at this stage, to draw conclusions about the comparative effectiveness of different interventions (e.g., KAO vs. GRS) because studies used different indicators and methods to measure effectiveness and no head-to-head comparison has been

made. Future studies should compare the effectiveness of different SBHP interventions against each other and against conventional school-based HIV prevention interventions.

The long-term follow-up evaluations of GRS in Zimbabwe and Botswana[23] found less encouraging evidence than the shorter-term evaluations in Zimbabwe,[19] Zambia,[27] South Africa[34] and the Dominican Republic.[24] This could support Clark and colleagues'[19] hypothesis that differences between program graduates and non-participants may diminish over time due to diffusion, or it could be the result of limitations in the small, cross-sectional follow-up study.

The fact that only nine studies have been published in peer-reviewed journals either suggests that authors have not published their research or, more likely, that much of the research on SBHP interventions has not been of sufficient quality to merit peer-reviewed publication. Indeed, this review's study quality assessment revealed that only two of the 20 studies could be classified as 'Good quality' while seven were classified as 'Poor quality'. A commitment from researchers, funders and implementers to carry out more rigorous, objective epidemiological research on these interventions' effectiveness is paramount.

Apart from the clear limitations of the included studies, this review also had several important limitations. First, since studies used different indicators and since few studies reported epidemiological measures of effect, conducting a meta-analysis for certain outcomes was not possible. Secondly, the lack of standardized reporting methods resulted in our inability to include some studies in meta-analyses since some studies, and selective outcome reporting may have meant some negative effects or non-effects that were not published or reported. Publication bias may have led the review to overestimate effect estimates, though this would have likely only affected the sensitivity analysis, as the grey literature search yielded 28 studies and identified several studies reporting negative or no effects.

Overall, there is strong evidence that well-designed and implemented SBHP interventions can reduce stigma and increase HIV-related knowledge, reported communication and condom use by roughly 20-40%. There is no evidence either way, however, on whether they can reduce HIV, STI or unintended pregnancy rates. There is also no evidence to suggest that these interventions have had negative effects. Thus, public health practitioners designing

HIV prevention interventions may want to consider including sport-based components in their interventions or modelling interventions on existing SBHP models like GRS, but should ensure that these are evaluated rigorously. Further evidence of effectiveness, ideally from randomised controlled trials with biological outcomes, is needed for policymakers to be able to compare the relative effectiveness and cost-effectiveness of SBHP interventions to other HIV prevention interventions, such as teacher-led sexual and reproductive health education in schools, medical male circumcision, HCT, condom promotion, and vaginal microbicides.

Acknowledgments:

We wish to acknowledge the Marshall Aid Commemoration Commission and the Rhodes Trust for support of this review. We also wish to acknowledge organizations that shared grey literature sources for the review. In addition to the authors, Lucie Cluver at Oxford University provided input into the review's design and Helen Weiss provided input into the meta-analysis.

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Table I: Elements of good study design and appraisal criteria

Element	Description
Random Sampling	Were the participants or clusters representative of the population? (i.e. selected at random)*
Control Group	Did the study include an appropriate control or comparison group? (partly if controls group was too small or not comparable)*
Random Allocation	Were participants randomly allocated to groups? (Reportedly random but unclear method = partly; randomised via clusters but clustering not accounted for in analysis = partly; clear/appropriate randomisation process = Yes)
Extended Follow-up	Did the study follow participants beyond the intervention? (1-6 months follow-up = partly; 6+ months follow-up = Yes)*
Sample Size Calculations	Did the researchers use and report sample size calculations to establish or justify the size of the study? (Partly if reported but with inappropriate or unclear assumptions)
Sufficient Power	Did the study have sufficient power to detect a realistic size of effect? (<150 participants = No; 150-499 participants = Partly; 500+ participants = Yes)
Adjustment for confounding	Did the study adjust for the most important potential confounder(s)?*
Appropriate Statistical Analysis	Did the study report p values and/or confidence intervals? Or did the study only report crude % differences? (Partly if p values reported but unclear what tests were carried out)
Objective outcomes	Were outcomes self-reported (0 pts), measured biologically or via records (1 pt), assessed blindly (1 pt)?* Evidence of selective outcome reporting? (-1 pt)
Low Loss-to-follow-up	<15% LTFU = Yes; 15-30% LTFU = Partly; >30% LTFU = No* (Unclear if not explicitly following the same participants)

* Element from the NOS scale

Figure 1: Identification, screening and exclusion of studies

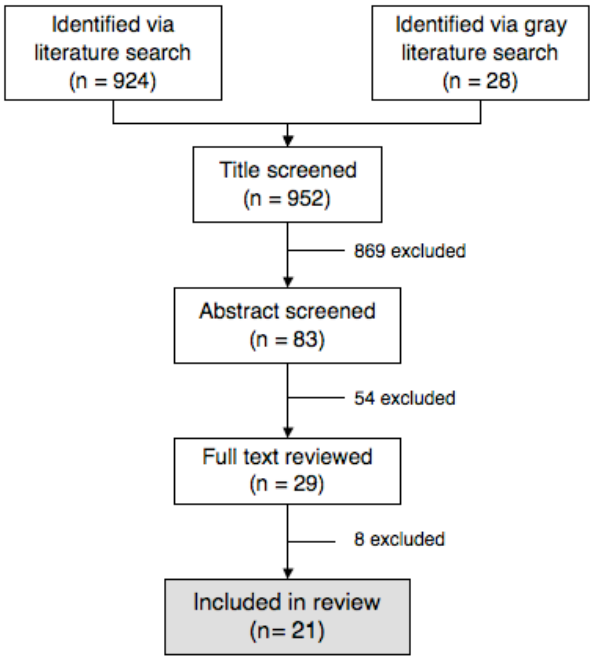


Table II: Characteristics of included studies (n=21)

		Study Details					*Intervention Details*				*Outcomes Reported**					
	Ref	**Authors**	**Year**	**Source**	**Study Design**	**N**	**Country**	**Age group**	**Intervention**	**Length**	**K**	**A**	**C**	**B**	**S**	**Bio**
Published	19	Clark et al.	2006	AIDS & Behavior	Quasi-experimental	304	Zimbabwe	12-14 years	GRS	4 sessions 8 hours	✓	✓	✓			
	27	Peacock-Villada et al.	2007	New Dir for Youth Development	Pre/Post	274	Zambia	10-18 years	GRS/Resiliency	6 weeks		✓				
	26	Maro et al.	2009	Scand J Med Sci Sports	Quasi-experimental	764	Tanzania	12-15 years	EMIMA/KAO	8 weeks	✓	✓		✓		
	28	Rhodes et al.	2009	AIDS Education and Prevention	Quasi-experimental	222	USA	mean age: 29 years	HoMBReS	18 months	✓	✓		✓	✓	
	21	Fuller et al.	2010	British Journal of Sports Medicine	Quasi-experimental	370	South Africa	11-15 years	Football-For-Health	11 sessions 16.5 hours	✓					
	20	Delva et al.	2010	AIDS Care	Cross-sectional	892	Kenya	12-24 years	MYSA	Varied	✓	✓				
	22	Fuller et al.	2011	British Journal of Sports Medicine	Pre/Post	389	Mauritius	12-15 years	11 For Health	11 sessions 16.5 hours	✓					
	22	Fuller et al.	2011	British Journal of Sports Medicine	Pre/Post	395	Zimbabwe	10-14 years	11 For Health	11 sessions 16.5 hours	✓					
	24	Kaufman et al.	2011	AIDS Care	Quasi-experimental	140	Dominican Rep.	10-20 years	Fútbol para la vida^	5 sessions 10 hours	✓	✓	✓			
Conferences	32	Rajan et al.	2008	136th APHA Annual Meeting	Pre/Post	2,197	Ethiopia	13-24 years	Sport for Life^ Youth Action Kit^	24-30 activities	✓	✓	✓	✓	✓	
	29	Gray et al.	2009	IV SA AIDS Conference	Quasi-experimental	478	South Africa	13-18 years	Extra Time Magazine^	Just magazine	✓					
	23	Kaufman et al.	2010	XVIII International AIDS Conference	Cross-sectional	246	Zimbabwe	15-19 years	GRS	10 hours	✓	✓	✓	✓	✓	
	23	Kaufman et al.	2010	XVIII International AIDS Conference	Cross-sectional	307	Botswana	15-19 years	GRS	10 hours				✓	✓	
Grey Literature	25	Kruse	2006	NORAD	Cross-sectional	80	Zambia	14-18 years	KAO	Unclear	✓	✓				
	18	Mercy Corps	2007	mercycorps.org	Pre/Post	280	Liberia	16-30 years	Yes to Soccer^	14 activities 6 weeks	✓	✓				
	18	Mercy Corps	2007	mercycorps.org	Pre/Post	360	Southern Sudan	14-25 years	Sports for Peace and Life^	15 activities 8 weeks	✓	✓				
	30	Wardell	2009	Author	Quasi-experimental	94	St. Lucia	10-16 years	Football For Lives^	Unclear	✓	✓				
	33	Kim	2010	Author	Pre/Post	69	USA	10-15 years	Grassroot Project^	8 weeks	✓	✓				
	31	Luppe	2010	Author	Pre/Post	61	South Africa	9-20 years	GRS	8 sessions 4 weeks	✓					
	35	Harvey	2011	Author	Pre/Post	102	USA	9-14 years	Grassroot Project^	8 weeks	✓	✓	✓			
	34	Braunschweig et al.	2011	Author	Pre/Post	612	South Africa	14-17 years	Generation Skillz^	11 sessions	✓	✓	✓			

*K=Knowledge; A=Reported attitudes; C=Reported communication; B=Reported behaviours; S=Service uptake; Bio=Biomarkers
^ Intervention adapted from GRS curriculum

Table III: Appraisal of studies against elements of good study design

	Study				Elements of good study design											
	Ref	Authors	Year	Country	Random Sampling	Control Group	Random Allocation	Extended Follow-up	Sample Size Calculations	Sufficient Power	Adj. for confounding	Appr. Stat. analysis	Objective Outcomes	Low Loss-to-follow-up	Quality Score (out of 20)	Quality Category*
Published	19	Clark et al.	2006	Zimbabwe	No	Yes	No	Partly	No	Partly	No	Yes	No	No	**6**	**OK**
	27	Peacock-Villada et al.	2007	Zambia	No	No	No	No	No	Partly	No	No	No	Unclear	**1**	**Poor**
	26	Maro et al.	2009	Tanzania	No	Yes	Unclear	No	No	Yes	No	Partly	No	Partly	**6**	**OK**
	28	Rhodes et al.	2009	USA	Yes	Yes	No	Yes	No	Partly	Yes	Yes	No	Unclear	**11**	**Good**
	21	Fuller et al.	2010	RSA	No	Yes	Partly	Partly	Yes	Yes	No	Yes	No	Yes	**12**	**Good**
	20	Delva et al.	2010	Kenya	No	Yes	No	N/A	No	Yes	Yes	Yes	No	N/A	**8**	**OK**
	22	Fuller et al.	2011	Mauritius	No	No	No	No	Yes	Partly	No	Yes	No	Partly	**6**	**OK**
	22	Fuller et al.	2011	Zimbabwe	No	No	No	No	Yes	Partly	No	Yes	No	Partly	**6**	**OK**
	24	Kaufman et al.	2011	Dom.Rep.	No	Partly	No	Partly	No	Partly	Yes	Yes	No	No	**7**	**OK**
Conferences	32	Rajan et al.	2008	Ethiopia	Yes	No	No	No	No	Yes	Unclear	Partly	No	No	**5**	**OK**
	29	Gray et al.	2009	RSA	No	Yes	Partly	No	No	Partly	No	Yes	No	No	**6**	**OK**
	23	Kaufman et al.	2010	Zimbabwe	No	Yes	No	N/A	No	Partly	Yes	Yes	No	N/A	**7**	**OK**
	23	Kaufman et al.	2010	Botswana	No	Yes	No	N/A	No	Partly	Yes	Yes	No	N/A	**7**	**OK**
Grey Literature	25	Kruse	2006	Zambia	No	Partly	No	No	No	No	No	Yes	No	N/A	**3**	**Poor**
	18	Mercy Corps	2007	Liberia	No	No	No	No	No	Partly	No	No	No	Unclear	**1**	**Poor**
	18	Mercy Corps	2007	S Sudan	No	No	No	No	No	Partly	No	No	No	Unclear	**1**	**Poor**
	30	Wardell	2009	St Lucia	No	Partly	No	Partly	No	No	No	Yes	No	Unclear	**4**	**Poor**
	33	Kim et al.	2010	USA	No	No	No	No	No	No	No	Partly	No	No	**1**	**Poor**
	31	Luppe	2010	RSA	No	Partly	No	No	No	No	No	Partly	No	Unclear	**2**	**Poor**
	35	Harvey	2011	USA	No	No	No	No	No	No	No	Yes	No	Unclear	**2**	**Poor**
	34	Braunschweig et al.	2011	RSA	Yes	No	No	No	No	Yes	No	Yes	No	Unclear	**6**	**OK**
	Total across studies (out of 42)				**6**	**20**	**2**	**6**	**6**	**21**	**10**	**32**	**0**	**5**	**Mean: 5.1**	

*Poor=0-4 points; OK=5-9 points; Good=10-14 points; Very Good=15-20 points

Table IV: Summary of meta-analyses (including sensitivity analyses) across outcomes

	Main Analysis		Sensitivity Level 1*		Sensitivity Level 2**	
Indicator	**Studies**	**RR (95%CI)**	**Studies**	**RR (95% CI)**	**Studies**	**RR (95%CI)**
Knowledge	17	1.25 (1.16-1.34)	11	1.26 (1.15-1.37)	7	1.37 (1.22-1.52)
Stigma	11	1.21 (1.09-1.32)	5	1.13 (1.02-1.24)	2	1.66 (0.65-2.67)
Self-efficacy	5	1.22 (1.02-1.41)	5	1.22 (1.02-1.41)	2	1.68 (1.22-2.14)
Communication	5	1.24 (1.06-1.41)	5	1.24 (1.06-1.41)	2	1.40 (1.14-1.65)
HCT uptake	3	1.81 (0.20-3.42)	3	1.81 (0.20-3.42)	1	2.50 (1.10-3.90)
Recent condom use	3	1.29 (1.00-1.59)	3	1.29 (1.00-1.59)	2	1.51 (0.81-2.21)

* Excluding poor quality studies, based on study quality appraisal

** Excluding unpublished studies

Grey shading indicates strong evidence of effect ($p<0.05$)

Figure 2: Random-effects meta-analysis for effects on knowledge (n=17 studies)

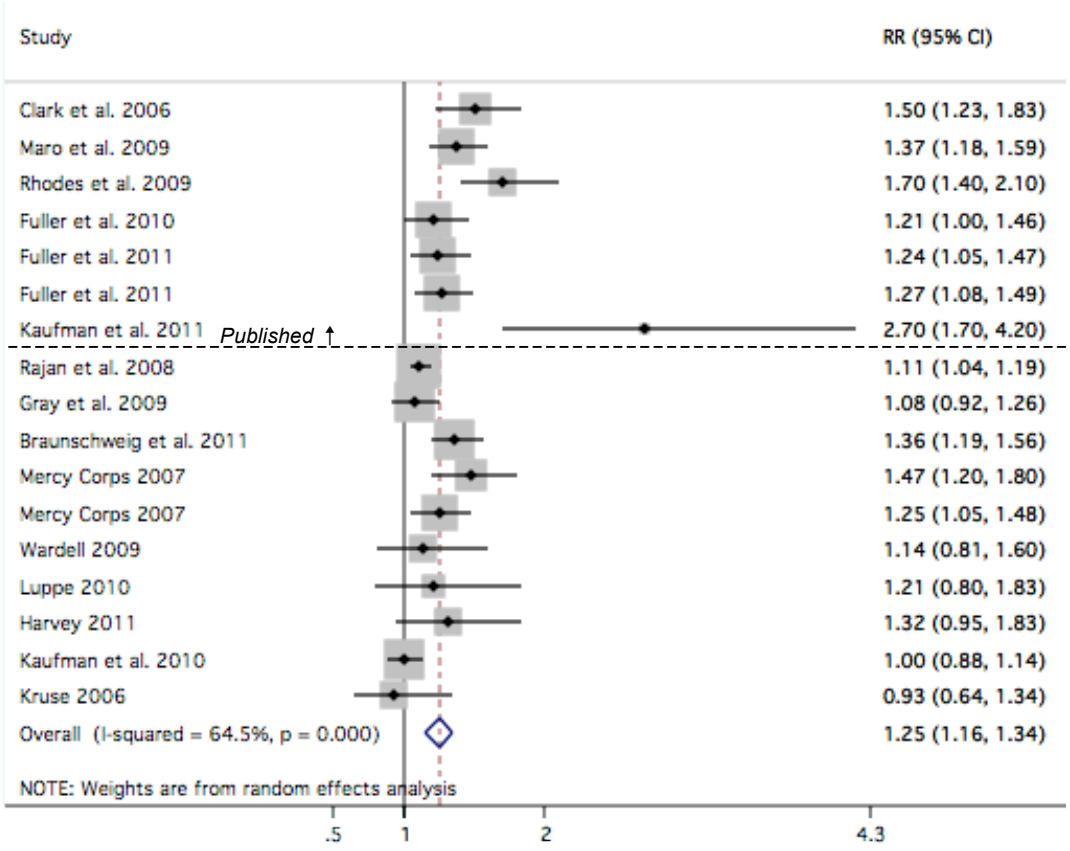


Figure 3: Random-effects meta-analysis for effects on stigma (n=11 studies)

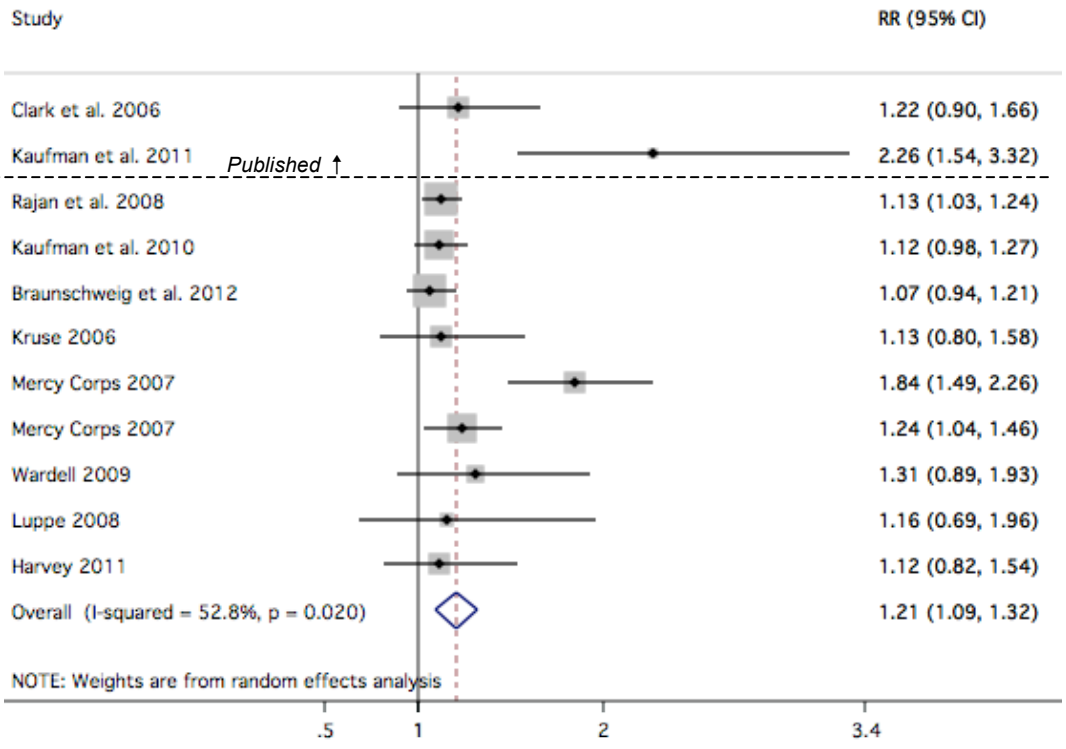


Figure 4: Random-effects meta-analysis for effects on self-efficacy (n=5 studies)

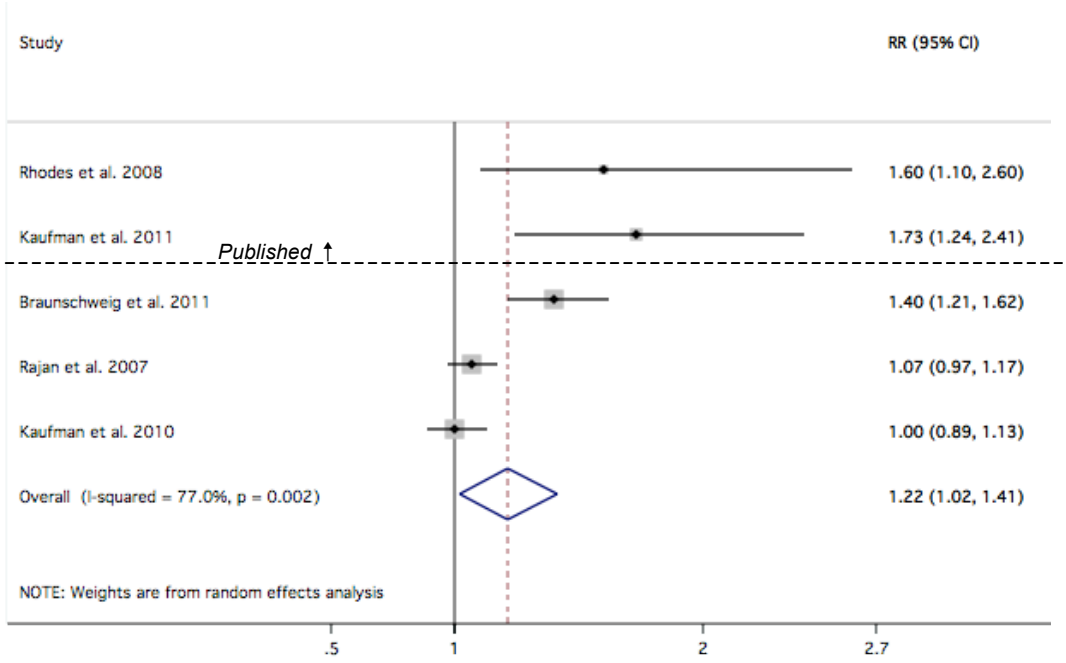


Figure 5: Random-effects meta-analysis for effects on communication (n=5 studies)

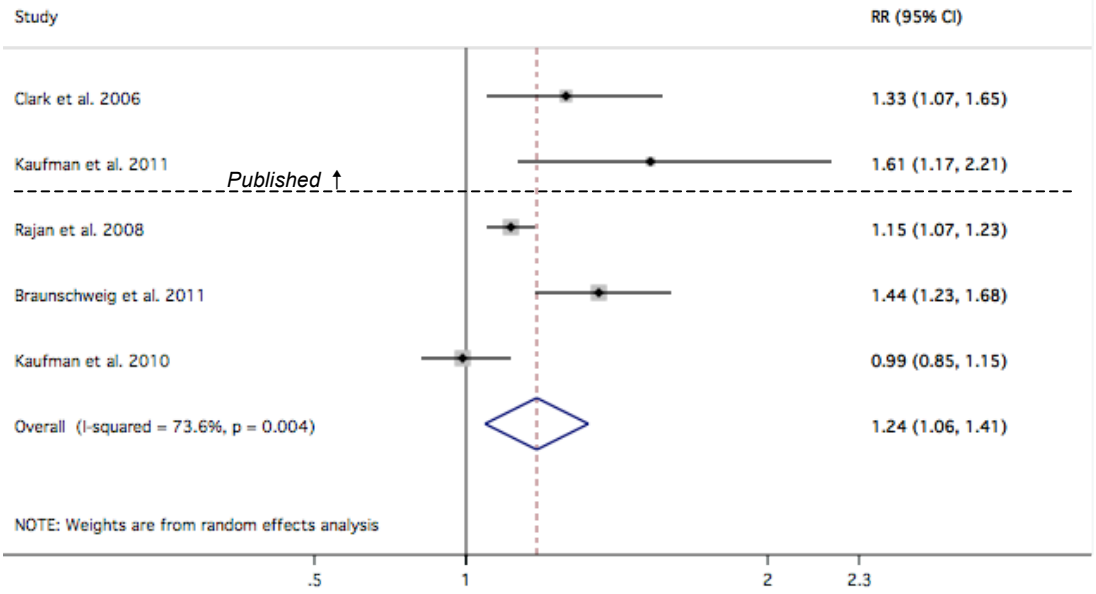


Table V: Systematic review search terms

Outcome (HIV-related)	Intervention (sports-based)		Study Design	
HIV	sport*	volleyball*	intervention*	clinical
AIDS	physical activity	cricket*	controlled	cross-sectional
STI	athlet*	tennis*	random*	case-control
STD	soccer*	hockey*	trial*	quasi-experimental
human immunodeficiency virus	football*	rugby*	compar*	pre and post
	basketball*	baseball*		
	wrestl*	golf*		

*Indicates wildcard search term, allowing any variations on the term following the asterisk

Table VI: Contacts and details of grey literature search

Last	Title	First	Email	Organisation	Location	Sent Date	Reply Date	Detail
Ahlgren	Mr.	Taylor	taylor.ahlgren@sbs.ox.ac.uk	Sports for Peace and Life	Sudan	31-Jan-11	02-Mar-11	Suggested contacting Zak Kaufman
Geddes	Mr.	Mike	Geddes@streetfootballworld.org	Kick4Life	Lesotho	20-Jan-11	16-Apr-11	Sent 2 citations
Oliver	Mr.	Ian	ian.oliver@verizon.net	Sports for Life	Africa	06-Oct-11	02-May-11	Recommended Lifshitz
Okoko	Mr.	Lungi	lungi.okoko@gmail.com	Africare	Africa	06-Oct-11	02-May-11	Sent 10 reports
Sanders	Ms.	Deidra	deidra.sanders@grassrootproject.org	Athletes United for Social Justice	USA	02-May-11	02-May-11	Sent 1 report (in press)
Bergholz	Mr.	Lou	lou@edgeworkconsulting.com	Edgework Consulting	Global	30-May-11	30-May-11	Sent Maro study
Dillingham	Dr.	Rebecca	rd8v@hscmail.mcc.virginia.edu	UVA School of Medicine/Global Health	Global	11-Jul-11	19-Jul-11	Referred Michael Sinclair
Sinclair	Mr.	Michael	MichaelS@kff.org	Director, Kaiser Family Foundation Program in South Africa	South Africa	19-Jul-11	19-Jul-11	Referred Frieda Subklew and suggested contacting Football for Hope
Lifshitz	Mr.	Wayne	wlifshitz@care.org	CARE	Global	20-Jul-11	20-Jul-11	Bounced
Generic			http://www.educo.org.za/contact/default.asp	Sisonke HIV/AIDS Project (EDUCOAFRICA)	South Africa	20-Jul-11	20-Jul-11	Alison Lee responded, sent 1 paper, suggested contacting Grassroot Soccer
Generic			info@umzingisi.org	Umzingisi Foundation (YDF Curriculum)	South Africa	20-Jul-11	20-Jul-11	Nick Mould responded, said it would be tough to find studies, but that Umzingisi is interested in final report. Said Umzingisi administers pre and post surveys with participants, but no control. Suggested contacting Grassroot Soccer
Phillips	Ms.	Anna	anna@gypafrica.org	Girls Kick It	Uganda	20-Jul-11	20-Jul-11	Out of contact until 5 Aug
Generic			pacifiquenday@yahoo.com	National University of Rwanda Anti HIV/AIDS Youth Club	Rwanda	20-Jul-11	20-Jul-11	Bounced
Cronin	Dr.	Orla	Orla@OrlaCronin.com	Orla Cronin Social Science Research and Strategic Consultancy	Global	20-Jul-11	20-Jul-11	Sent 12 citations
D'Souza		Tanya	tsouza@righttoplay.com	Right to Play	Global	20-Jul-11	20-Jul-11	Will Bennet responded, suggested contacting Grassroot Soccer
Subklew		Frieda	fsubklew@lovelife.org.za	Research Director at LoveLife	South Africa	19-Jul-11	20-Jul-11	LoveLife study will be complete in September
Chalat	Ms.	Alexandra	alex@benchmarksport.com	Beyond Sport Awards	Global	20-Jul-11	21-Jul-11	Referred Lou Bergholz (Edgework Consulting) and Brooke Wurst (Triad Trust)
Rosenbauer	Ms.	Brooke	brosenbauer@partners.net	A Ganar (Partners of the Americas)	Latin America	20-Jul-11	21-Jul-11	No contributions
Tuohey	Mr.	Brendan	btuohey@peaceplayersintl.org	PeacePlayers	Global	20-Jul-11	21-Jul-11	Tal Alter responded, suggested contacting Grassroot Soccer

Last	Title	First	Email	Organisation	Location	Sent Date	Reply Date	Detail
Nange		George	nange@kickingaidsout.net	Kicking AIDS Out	Africa	20-Jul-11	21-Jul-11	Sent 6 citations
Knight		Joanna	Joanna.Knight@uksport.gov.uk	UK Sport	Global	20-Jul-11	21-Jul-11	Asked for copy of review when finished. Sent 3 citations. Suggested contacting Davies Banda and Oscar Mwaanga
Barrell	Ms.	Clare	Clare.Barrell@uksport.gov.uk	UK Sport	Global	21-Jul-11	21-Jul-11	Fwd'ed email to colleagues, Melissa and Marizanne, and asked them to contact me directly. No response from them
Generic			info@sportanddev.org	International Platform for Sport and Development	Global	20-Jul-11	23-Jul-11	Chris Middleton responded, suggested sportanddev.org "Docs" section
Chawansky		Megan	m.e.chawansky@bath.ac.uk	Women Win	Global	20-Jul-11	23-Jul-11	Fwd'ed email to Cassie Clark at U Johannesburg
Wurst		Brooke	bwurst@triadtrust.org	CEO of Triad Trust	Africa	20-Jul-11	24-Jul-11	Will send info on new evaluation tool she is designing, but no papers now.
Rajan		Radha	rrajan@jhsph.edu	International Center for Research on Women (ICRW)	USA	03-Oct-11	03-Oct-11	Referred to Efua Orleans-Lindsay
Orleans-Lindsay		Efua	eorleans@fhi360.org	FHI 360	USA	04-Oct-11	04-Oct-11	Shared slides from APHA annual meeting (Rajan et al.)
Wardell	Mr.	Chris	wardell.chris@gmail.com	Football for Life	St Lucia, Belize	02-Jan-11		Bounced
Mwango	Mr.	Michael	edusport@coppernet.zm	EduSport	Zambia	19-Jul-11		No response
Forde Owuor	Ms.	Sara	http://www.mtgk.org/contact	Moving the Goalposts Kilifi	Kenya	19-Jul-11		No response
Tsoari	Mr.	George	geejox@yahoo.com	PlaySoccer	South Africa	20-Jul-11		No response
Generic			http://www.lovelife.org.za/contact/index.php	LoveLife	South Africa	20-Jul-11		No response
Generic			info@score.org.za	Sports Coaches' Outreach	Africa	20-Jul-11		No response
Peacock-Friedrich	Ms.	Paola	p.peacockfriedrich@gmail.com	Football for an HIV Free Generation	Africa	20-Jul-11		No response
Generic			http://www.laureus.com/contacts	Laureus Sport for Good	Global	20-Jul-11		No response
Cranmer	Ms.	Ziba	ziba.cranmer@nike.com	Nike/Ashoka Changemakers	Global	20-Jul-11		No response
Generic			http://sites.google.com/site/stpaulsanglicanchildrenproject/contact-us	St. Paul's Anglican Children Project	Zambia	20-Jul-11		No response
Mwamba Bukula	Mr.	David	mwambabukula@yahoo.com	Roan Youth Development	Zambia	20-Jul-11		No response
Generic			witabafo@witabafoundation.org	Witaba Foundation	Kenya	20-Jul-11		No response
Kaila	Ms.	Kelly	kellykaila@yahoo.co.uk	Kalim Sports Council	Zambia	20-Jul-11		No response
Generic			info@football4peace.eu	Football for Peace	Global	06-Apr-11		No response
Woodcock	Dr.	Alison	A.Woodcock@rhul.ac.uk	Royal Holloway University of London	Global	21-Jul-11		No response
Booth	Dr.	Mark	mark.booth@durham.ac.uk	Durham University	Global	20-Jul-11		No response
Pitchon	Mr.	Tom	tom.pitchon@laureus.com	Laureus Sport for Good	Global	20-Jul-11		No response
Evju		Bjorn	boe@nif.idrett.no	Norwegian Olympic and Paralympic Committee Confederation of Sports (NIF)	Global	20-Jul-11		No response
Hare		Darcy	darcy.hare@sportengland.org	Sport England	UK	20-Jul-11		No response
Hatton		Damian	hatton@streetfootballworld.org	Street Football World	Global	20-Jul-11		No response
Trotter		Lizzie	Lizzie.Trotter@footballfoundation	The Football Foundation	Global	20-Jul-11		No response
Mwaanga		Oscar	oscar.mwaanga@solent.ac.uk	Lecturer, Solent University	Africa	20-Jul-11		No response
Kay	Dr.	Tess	tess.kay@brunel.ac.uk	Professor of Sport and Social Sciences	Global	20-Jul-11		No response
Banda		Davies	d.banda@yorksj.ac.uk	Senior Lecturer, Sport Policy & Development	Africa	20-Jul-11		No response

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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.....

I led preliminary analysis and write-up of preliminary evaluation section. I worked with co-authors to outline the intervention design section and reviewed/edited that section.

NAME IN FULL (Block Capitals) ..... **ZACHARY A KAUFMAN**

STUDENT ID NO: **267998**

CANDIDATE'S SIGNATURE ..... Date ..... **11 April 2014**

SUPERVISOR/SENIOR AUTHOR'S SIGNATURE (3 above) .....

Generation Skillz: development process and preliminary results of a sport-based HIV prevention intervention in South African schools

Kaufman Z.A.[1,2], Braunschweig E.N.[1], DeCelles J.[3], Daniels D.[3], Ross D.A.[1]

Institutions:

[1] London School of Hygiene and Tropical Medicine, Epidemiology and Population Health: London, UK

[2] Wits Reproductive Health and HIV Institute: Johannesburg, South Africa

[3] Grassroot Soccer, Research and Development: Cape Town, South Africa

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ABSTRACT

Sport-based HIV prevention (SBHP) interventions are becoming increasingly common across Africa, though supporting evidence for these interventions is limited. Generation Skillz is a SBHP intervention targeting adolescents in South Africa, comprised of eighteen 45-minute sessions primarily focused on age-disparate sex, multiple partnerships, and gender-based violence. The curriculum was written and refined over three years, in a multi-faceted process that included careful review of the literature and other curricula, development of a logic model, extensive pilot testing, expert consultation and was grounded in almost a decade of GRS' experience designing SBHP activities for youth in Southern Africa. During pilot testing, a 20-item questionnaire assessing HIV-related knowledge, reported attitudes, and reported communication (KAC) was administered pre- and post-intervention to Generation Skillz participants (n=612, age 12-19 years) in Soweto, Mtubatuba, and Khayelitsha, South Africa. There was strong evidence of pre/post improvement in HIV-related knowledge ($t=27.2$, $p<0.001$), reported attitudes ($t=12.9$, $p<0.001$), and reported communication ($t=11.4$, $p<0.001$). After adjusting for age and site, there was strong evidence of dose-response between sessions attended and KAC change ($\beta=0.20$, 95%CI=0.08-0.33, $p=0.002$). This study provides encouraging evidence that Generation Skillz has short-term positive effects on participants' KAC related to HIV.

Keywords: HIV, Sport, South Africa, Adolescents, Curriculum Development

BACKGROUND

In spite of recent HIV prevention progress in many counties in sub-Saharan Africa, the need for effective adolescent-targeted HIV and sex education interventions remains critical. In South Africa, approximately 3.9% of males and 13.9% of females aged 15-24 years are living with HIV, and approximately 370,000 new infections occur annually across age groups.[1] The epidemic among young people is largely driven by age-disparate sex, multiple partnerships often concurrent in nature, male-dominant gender norms and gender-based violence (GBV) and lack of male circumcision.[2-6]

In its 2012-2016 Strategic Plan on HIV, STIs and TB, the South African government identified reducing HIV infection in young people, particularly via comprehensive sexuality and life skills education in schools, as a key priority.[7] Strong evidence exists supporting the impact of well-designed school-based HIV prevention interventions on knowledge, reported attitudes, and reported sexual risk behaviours.[8] A recent systematic review of youth HIV prevention in South Africa found that school-based interventions had the greatest impact by focusing on the causal pathways of HIV specific to southern Africa, including gender, sexual coercion, alcohol use, and economic risk.[9] To date, only three school-based interventions in sub-Saharan Africa have been evaluated via randomised controlled trials with biological outcomes. None of these interventions demonstrated an effect on HIV incidence, though one demonstrated an effect on HSV-2 incidence.[10-12] While none have shown negative effects on HIV or other sexually transmitted infections, debate remains on how much school-based interventions can contribute to the fight against HIV.

A growing number of organisations are employing sport-based HIV prevention (SBHP) methods in their interventions. They use sports role models, activities, and metaphors to increase knowledge, improve attitudes, and change behaviours related to HIV.[13] One such organisation, Grassroot Soccer (GRS), trains community role models to deliver SBHP interventions in schools across sub-Saharan Africa. Founded in Bulawayo, Zimbabwe in 2002, GRS has delivered interventions to more than 650,000 youth in 22 countries using a core curriculum, called “Skillz,” which is

regularly adapted to reflect the local context, epidemiology, and needs of the target population. Previous studies have shown strong evidence from Zimbabwe, Zambia and the Dominican Republic that local versions of the Skillz curriculum improve knowledge, reported attitudes and reported communication related to HIV.[14-16] GRS began developing the Generation Skillz intervention in 2009 with the aim of engaging an older adolescent population in activities and discussion tailored to their age-specific HIV prevention needs. Whereas most SBHP interventions designed by GRS have targeted 10-14 year-olds, Generation Skillz targets 15-19 year-old South African youth, focusing on reducing age-disparate sex, multiple partnerships, and GBV.

Launched in 2012, a three-year cluster-randomized trial (GOAL) is assessing Generation Skillz' effectiveness in improving knowledge, reported attitudes, and reported sexual risk behaviour among South African adolescents. The purpose of this paper is to (1) document the process by which the Generation Skillz intervention was developed and (2) to present findings from a preliminary evaluation of its short-term effectiveness in improving HIV-related knowledge, reported attitudes and reported communication. The paper is accordingly structured in two separate parts, with the first focusing on the intervention's development and the second on its preliminary evaluation.

PART 1: INTERVENTION DEVELOPMENT

Intervention Overview

The eighteen-session *Generation Skillz* curriculum was designed with the aim of reducing HIV incidence among South African adolescents, specifically by addressing three inter-related behavioural risk drivers of the South African epidemic: multiple partnerships, age-disparate sex, and GBV. Generation Skillz was developed in alignment with Kirby and colleagues' seventeen characteristics of effective sex and HIV education programmes [8], guided by the development of a logic model (Figure 1), grounded in GRS' experience of designing SBHP activities for youth in Southern Africa, and informed by extensive pilot testing and expert consultation.

[INSERT FIGURE 1 NEAR HERE]

Generation Skillz is a two-year intervention, consisting of eleven 45-minute sessions delivered once per week with Grade 9 students and another seven 45-minute booster sessions (called "Generation Skillz Utshintsho") delivered one year later with the same students in Grade 10. This programme marked the first time GRS had employed booster sessions. The decision to include booster sessions was made prior to the start of the GOAL Trial, drawing from previous evaluations' findings that the effectiveness of SBHP interventions may diminish over time.[13] Each interactive Generation Skillz session is facilitated by two "Generation Skillz Coaches" (see below on Coaches), one female and one male, who lead youth through an activity followed by a recap of key messages and a discussion of the topic addressed. Drawing on the language, metaphors, and themes of soccer—the world's most popular sport—the activities provide a platform for interactive learning, a safe space for questioning attitudes, values and norms, and an opportunity for critical reflection on high-risk behaviours. An example activity—Risk Field—is diagrammed and explained in Figure 2 and Table 1 shows a list of all the activities included in the curriculum.

[INSERT FIGURE 2 NEAR HERE]

Indeed, more young men than young women play competitive soccer in South Africa. Taking this into consideration, Generation Skillz avoids focusing on competition, instead leveraging its universal appreciation and utilizing a team-oriented educational approach that appeals equally to males and females. While the GRS core "Skillz" curriculum targeting younger adolescents focuses on building basic HIV prevention knowledge and life skills, Generation Skillz takes an intensified, gender-transformative approach, focusing on building self-efficacy to avoid high-risk behaviours such as age-disparate sex and multiple partners and transforming social norms through vital dialogue about gender equity, relationship power, and GBV.

Facilitators ("Coaches")

Generation Skillz Coaches are young adults aged 18-25 years, who are recruited from the communities in which GRS delivers interventions. Generation Skillz Coaches undergo a competitive selection process including a written application and group interview and are selected based on a number of criteria including completion of secondary school, leadership capacity, facilitation skills, passion for working with youth, and commitment to serving as role models for HIV prevention and healthy decision making. Generation Skillz Coaches participate in an initial five-day Training of Coaches workshop focused on HIV knowledge, facilitation skills, and curriculum delivery, and attend a series of regular development courses and refresher workshops, designed to build capacity and address areas for improvement. Coaches practice enriching their facilitation through the use of personal examples and refine a personal story of challenges faced and overcome—called a "Coach's Story"—to share with participants. Generation Skillz Coaches build relationships with participants during the intervention that are often sustained beyond the programme.

Curriculum activities

Table 1 provides a summary of curriculum activities and expected outcomes by school year. Generation Skillz supports the HIV prevention efforts of the South Africa Department of Basic Education (DBE), which grants GRS permission to deliver programmes directly in schools during the Life Orientation (LO) class period as well as after school. Generation Skillz was designed in alignment with the age-specific LO outcomes identified in the DBE's Curriculum and Assessment Policy Statement.[21] The curriculum is comprised of a combination of mixed-sex and single-sex activities, the format of which is determined by the goals of each activity and the needs of the target audience, in accordance with principles of gender transformative HIV and GBV prevention education.[17] Single-sex sessions are facilitated by a coach of the same sex, to enable discussion of sensitive topics such as violence and sexuality in an open and safe environment. In order to be considered a 'Graduate' of the first-year Generation Skillz intervention, a participant must attend at least seven of the eleven sessions. GRS uses similar 'graduation' thresholds in all its curricula, in order to ensure that beneficiaries reported internally and externally as 'reached' have received at least a minimum level of intervention dosage.

Drawing from lessons from a workshop with the International Centre for Research on Women (discussed later in this paper), Generation Skillz Utshintsho was developed with more single-sex sessions (five of seven) than the first-year Generation Skillz intervention (two of eleven). In the final session of Generation Skillz Utshintsho, during a graduation ceremony, participants make public commitments to practice healthy decision-making, challenge gender norms, and serve as agents of change in their communities. This ceremony is not restricted to Graduates, but is open to all participants.

[INSERT TABLE 1 NEAR HERE]

Theory of change

The GRS approach is guided by the principles of social learning theory, which suggest that learning occurs best within a social context through observation and modeling of peers' attitudes and behaviours.[18] Group participation in dynamic, activities-based sessions stimulates an environment of peer support and shared learning. Expanding on this notion, the GRS model draws further from Bandura's social cognitive theory, which asserts that individuals learn best from people with whom they can identify—role models—who are instrumental in generating self-efficacy in others.[19] This concept was central to the original GRS delivery model, which capitalized on the celebrity of professional soccer players trained to facilitate HIV prevention interventions.[14] GRS now trains influential community role models as intervention facilitators, in an effort to become both more sustainable and scalable. Elements of Generation Skillz that seek to challenge gender norms and address GBV rely on a holistic, ecological approach, recognizing the complexity of factors that influence norms and behaviours at the individual, relationship, community and societal levels.[20]

Intervention Development Process

Members of the GRS curriculum and training team developed Generation Skillz over the course of six distinct phases, with inputs from a wide range of sources, including consultation with external experts and key stakeholders. From October 2009 to November 2011, four versions of the curriculum were developed and rolled out

sequentially through an iterative process with evaluation conducted between each version. The phased process allowed for critical assessment and outcome-oriented improvement of the messages, activities and structure of the intervention as well as training content and monitoring tools. During this time, GRS also developed a mobile phone-based text messaging campaign to reinforce key messages and motivate participants to engage in healthy behaviours in the interim between years one and two of the programme. Generation Skillz Utshintsho was developed in late 2012 in response to lessons learned from Generation Skillz implementation as well as findings from the baseline survey of the GOAL Trial.

The section below describes the processes that were undertaken during the five phases of development of Generation Skillz (as shown in Figure 3), as well as key adaptations made in each phase.

[INSERT FIGURE 3 NERE HERE]

Phase 1: Initial Development of Generation Skillz, Version 1
(October 2009 to August 2010)

- **Literature review** - Relevant systematic reviews[8,22] and randomized controlled trials[10-12,23] provided insight into intervention design, while the most recent national health survey[3] revealed high prevalence of HIV risk behaviour amongst South African youth. Literature suggesting that the HIV epidemic in South Africa is driven largely by multiple sexual partnerships, age-disparate relationships, and GBV suggested that Generation Skillz should have a specific focus on these three behaviours, while retaining stigma, alcohol use, condom use, HIV testing and male circumcision as secondary emphases of the curriculum.[3-6]

- **Previous Curricula** - Previous curricula and activities developed by GRS from 2002-2010, including the Skillz core curriculum, were considered for inclusion in, or adaptation for, Generation Skillz. GRS also reviewed curricula from established programmes including Stepping Stones—South African edition,[25] One Man Can

Action Kit,[26] Men as Partners[27] and Rutanang[28] to identify existing approaches to addressing gender norms and GBV in the context of HIV prevention in South Africa. The review revealed the use of a mix of split- and combined-sex sessions to be a common practice in the field.

- **Previous Evaluations** – Pre and post-intervention questionnaires assessing HIV-related knowledge, attitudes and communication (KAC) with 989 graduates of GRS' existing Skillz curriculum in South Africa showed greater KAC improvement in participants under age 14 compared with those aged 14-18. This suggested that the Skillz curriculum successfully achieved at least short-term outcomes for Grades 6 and 7, but underlined the need to develop a new curriculum that better targeted those in grades 8 to 10.

  GRS reviewed previous evaluations of its programmes[13] as well as external reviews of the Skillz curriculum, which highlighted the importance of presenting new information about HIV in the context of relatively high existing knowledge derived from school LO classes, as well as the importance of engaging youth as expert reviewers in the curriculum development process.[24]

- **Logic model development** - Guided by the key drivers identified in the literature review, a logic model was developed to identify inputs, activities, outputs and outcomes for the Generation Skillz curriculum. Outcomes were categorized as short, medium or long-term and designed using SMART criteria (specific, measurable, attainable, relevant, and time-bound).[30] Each session was linked to the intended outcomes. The logic model was adapted iteratively to reflect curriculum changes.

- **Skillz Culture** - In 2008, curriculum consultants at Edgework Consulting carried out a thorough review of previous GRS curricula and interviewed key staff and stakeholders to identify the core elements of GRS methodologies. The report's main finding was that GRS interventions revolved around a unique culture (referred to as "Skillz Culture") with the following main components: interactive

curricula, soccer themes and metaphors, unique traditions and rhythms, imparting accurate HIV knowledge, creating safe space, building personal connections, sparking vital conversations, and sharing powerful praise.[29] Skillz culture was central to the development of Generation Skillz.

- **Pretesting new activities** – A draft curriculum consisting of ten 45-minute sessions was written by the GRS curriculum development team. Existing activities were adapted for youth aged 15-19 and new activities were developed to meet curriculum objectives. New activities, including *Take a Stand* (December 2009), *Red Card* (April 2010), and *Gender Stadium* and *Man/Woman Summit* (August 2010) were pre-tested at GRS sites in Cape Town and Port Elizabeth to assess their relevance and acceptability to local youth and identify adaptations required for inclusion in Version 1. Pre-testing revealed the suitability of the Red Card activity in providing participants with an opportunity to practice responding to realistic risk scenarios as well as the feasibility of addressing issues of gender norms and GBV within the target age group.

Phase 2: Generation Skillz, Version 1 to Version 2
(September to December 2010)

- **Training of Coaches and Observation** - A five-day Training of Coaches (ToC) workshop was designed by the GRS curriculum development and training team to prepare experienced community role models (called "Skillz Coaches") to deliver Generation Skillz Version 1 with youth. The training workshops focused on curriculum activities, facilitation skills, Skillz culture, and HIV knowledge and employed a participatory approach, which allowed Coaches to practice new skills and receive constructive feedback from full-time GRS Master Coaches who led the workshops at GRS sites in Cape Town and Port Elizabeth in September 2010. A range of GRS curriculum and programme management staff members were present to observe and comment on the workshops.

Observation of Coaches' responses to the curriculum provided the first indication of both the strengths and weaknesses of the first curriculum draft. Male and female coaches were highly engaged in the curriculum material, responding emotionally to discussions challenging widely held social norms and key risk behaviours. ToCs also revealed the need for ongoing training and development, to enhance Coaches' capacity to understand the linkage between HIV and GBV, internalize messages about gender equality, and to support their own gender transformation process.

- **Coach Support Visits** – Following training, Coaches delivered Generation Skillz Version 1 through in-school interventions and one-week holiday programmes in Cape Town and Port Elizabeth in December 2010. The concentrated, week-long curriculum delivery format enabled close observation by relevant GRS staff. Coach Support Visits (CSVs) were conducted by GRS Master Coaches to systematically assess coach performance in three key facilitation competencies: achievement of goals, fidelity to curriculum content and processes, and participant interaction and management. During a CSV, a Master Coach observes a Coach's delivery of a full session, taking notes on a CSV form, and debriefing afterwards with the Coach to discuss successes and areas for improvement.

- **Focus Group Discussions with Coaches and Participants** – GRS conducted 4 informal focus group discussions with Coaches (2 FGDs, n≈20 coaches) and participants (2 FGDs, n≈20 participants) following the Skillz Holiday programme to collect feedback on Generation Skillz activities, format, and acceptability. These FGDs were approximately 45 minutes long. Notes were taken but the discussions were not audio recorded; neither transcripts nor notes were available for review at the time of writing this paper. Staff members recall that feedback from participants was that participants and coaches both felt that the amount of movement and 'play' in Generation Skillz needed to be less than the Skillz Core curriculum targeting younger adolescents and that the intervention should give more time to discussion.

- **Pretesting (new circumcision activity)** – Due to perceived sensitivity around the topic, male circumcision had only been lightly addressed in the Fact/Nonsense activity. Input from experts and increasing openness to the topic in local communities motivated GRS to ensure youth were adequately informed about the health benefits of male circumcision. As a result, GRS created an activity called *Circumcise & Condomise to* address the topic in more depth. Male circumcision is a highly sensitive topic in the Eastern and Western Cape, where most Xhosa men go through traditional circumcision in late adolescence and many oppose medical male circumcision for cultural reasons.[31] Extensive formative research with male coaches and youth informed the creation of sensitive messaging that emphasized the health benefits of being circumcised while avoiding the explicit promotion of medical male circumcision. The activity was drafted and pre-tested with youth in Cape Town and Port Elizabeth in December 2010.

- **Curriculum Development Workshop** – GRS held an intensive three-day curriculum development workshop with 13 key internal stakeholders including Coaches, Master Coaches, Curriculum and Training team members, and Programme Managers. Participants proposed changes to Generation Skillz Version 1 based on a review of programmatic observations and experiences, qualitative feedback from Coaches and youth, and short-term effectiveness data collected throughout the initial implementation phase. The existing curriculum and proposed content and activity changes were assessed in terms of their compatibility with the health outcomes identified in the Generation Skillz Logic Model.

  It was determined that greater focus on age-disparate sex and GBV was needed to sufficiently address these key drivers. GRS designed a split-sex activity called *Man and Woman Summits*, in which participants pledge to make tangible changes to stop GBV in their communities. Male and female participants come together at the end of the activity to practice communication skills and share their commitments with one another. Additionally, based on positive preliminary

results with girls and the observed need to better address with boys the risk of age-disparate relationships, *HIV Limbo* was re-designed as a combined-sex session. The overall curriculum structure—now with eleven sessions—was also revised based on programme observation and feedback from FGDs with Coaches.

Phase 3: Generation Skillz, Version 2 to Version 3
(January to June 2011)

- **Training of Coaches and Observation -** GRS held three 5-day ToCs to train coaches in Soweto, Kimberley and Mtubatuba to deliver Generation Skillz Version 2. ToCs were led by GRS Master Coaches, and programme staff were present to observe curriculum uptake and acceptability with coaches. Observations were recorded and shared with the curriculum team for further revisions.

- **Coach Support Visits –** CSVs were routinely conducted by GRS Master Coaches to assess coach performance and observe intervention delivery in schools. During this period, approximately 30 CSVs were conducted on Generation Skillz sessions in Cape Town, Port Elizabeth, Soweto, and Mtubatuba.

- **Expert Review –** Through a structured technical review process, Generation Skillz was shared with international experts—including members of the GRS Research Advisory Council—in the fields of HIV prevention, gender-based violence and women's rights, and adolescent development. Experts received an overview of GRS and the Generation Skillz programme, the Generation Skillz Logic Model, and the Generation Skillz Curriculum and were asked to provide feedback either on the entire curriculum or content specific to their area of expertise.

  Experts were supportive of the curriculum's explicit focus on key HIV drivers, the activities-based approach, and structure/layout. Recommendations emphasized a number of gender considerations, including the importance of ensuring single-sex activities are facilitated only by coaches of the same sex and that discussions

of violence focus on action and responsibility rather than on the origins of violence against women, which may lead to victim blaming. GRS was encouraged to strengthen messaging on multiple partnerships, specifically focusing on the role of sexual networks and concurrency in driving new HIV infections. GRS created a short, focused activity called *Sexual Networks*, as well as a new activity called *Gates* highlighting strategies for partner reduction and healthy relationships rather than re-emphasizing the negative aspects of multiple partnerships. Expert feedback additionally influenced the language used in describing alcohol-related risks, focusing broadly on "sex and alcohol" rather than narrowly on "sex while drunk" in order to capture the breadth of the related risk environment.

Phase 4: Generation Skillz, Version 3 to Version 4
(June 2011 to November 2011)

- **Coach Support Visits -** Another round of approximately 30 CSVs were conducted to monitor coach performance and observe intervention delivery in schools.

- **Expert Review** - The Generation Skillz curriculum was shared with additional experts for feedback. GRS was encouraged to expand messaging regarding the benefits of condom use regardless of relationship status.

- **SMS Campaign Development** - A key finding of the curriculum development process was the presence and popularity of mobile phones among the target population. In light of a growing evidence base that suggests mobile technology may be effective in changing health behaviours,[32] GRS hypothesized that text messages (SMSs) sent to Generation Skillz participants at regular intervals following the intervention would prove an acceptable and low-cost means of extending contact time and reinforcing messages and social support with participants. Drawing on recommendations from other successful mobile technology interventions to balance educational and motivating messages, the GRS curriculum team drafted a series of messages which were reviewed by

experts and pre-tested with grade 9 youth in Cape Town, who provided feedback on the content, language and style of the messages as well as on preferred frequency and timing of delivery. GRS collected phone numbers from participants and integrated the SMS-Magic application into its existing online monitoring database to enable mass distribution of messages to participants.

Phase 5: Generation Skillz Utshintsho
(November 2012 to February 2013)

- **GOAL Trial Baseline Results –** The baseline findings from the GOAL Trial revealed high prevalence of key risk behaviours, including reported harmful alcohol use, number of sexual partners, and reported intimate partner violence among the target audience, particularly males.[33] This underlined the need for interventions to change risky behaviour as well as the extent to which sexual risk behaviour was already the norm amongst males in the target population.
- **Curriculum Development Workshop –** Representatives from the International Centre for Research on Women joined GRS in a curriculum development workshop to share lessons learned from *Parivartan,* a cricket-based programme which aims to reduce GBV in India and has been shown to improve gender-related attitudes and behaviours amongst men and boys.[34] The collaboration, sponsored by the DFID-supported STRIVE Research Project Consortium on the structural drivers of HIV, informed the design of five split-sex sessions as well as new messaging around masculinity, relationship power and harmful alcohol use. GRS adapted an activity called *Draw the Line* from a curriculum for middle school adolescents in the United States shown to improve knowledge and attitudes towards sexual risk behaviours,[35] in order to explore issues of abuse and personal boundaries with young women. Activities designed during the workshop were pre-tested with youth (see below), and Coaches were trained to the deliver the curriculum in February 2013. Attention was paid to avoid condemnation of male coaches or

participants as perpetrators, instead focusing on men's capacity to transform norms and champion healthy gender dynamics within their relationships and communities. In response to several disclosures of past experience of abuse prompted by discussions of violence against women during training workshops, GRS strengthened its referral system in each community by engaging more service providers, developing referral protocols, and providing additional referral training to Generation Skillz coaches.

- **Expert Review** – Given the strong link between GBV and HIV in South Africa[5,6] and the need to address gender based violence at the individual, relationship and community levels,[20] research advisors called for a more intensive intervention to increase dosage and address gaps in the Generation Skillz curriculum. While the need for a booster had already been discussed and decided before the GOAL Trial began, the experts at this stage gave feedback on the proposed content of Generation Skillz Utshintsho,
- **Pretesting –** GRS designed the 7-session Generation Skillz Utshintsho (meaning "change" in isiXhosa) curriculum to reinforce messaging about key drivers of the HIV epidemic, address the risks associated with alcohol use, challenge social norms of gender inequality and relationship power imbalance, and allow participants to practice assertive communication and conflict resolution techniques. After the Curriculum Development Workshop, the Generation Skilllz Utshintsho sessions were pre-tested by two pairs of coaches with youth in Khayelitsha, Cape Town during the December school holiday and observed by GRS staff. Key messages, timings, and other details of session content were refined based on observation and participant feedback during pretesting sessions.

PART 2: PRELIMINARY EVALUATION

Methods

Pre-post questionnaire

A 20-item questionnaire was developed to assess HIV-related knowledge, attitudes and communication targeted in the Generation Skillz curriculum. Items for this

questionnaire were selected on the basis of the intervention's intended outcomes and derived from United Nations General Assembly Special Session indicators,[36] demographic health surveys, the gender-equitable men scale[37] and previous questionnaires used in GRS evaluations.[14,15] Between February and September 2011, GRS Coaches trained in survey administration delivered the questionnaire with a sample of male and female Generation Skillz participants across three sites—Cape Town, Soweto, and Mtubatuba—immediately before and after the delivery of the curriculum. A 10 percent sample of Generation Skillz interventions was drawn using simple randomisation to select which groups would participate in the questionnaire. The questionnaire was not confidential but contained basic identifying information (name, sex, age).

Data analysis

Data analysis was restricted to only participants who completed both pre and post questionnaires. Evidence of change in favorable responses from pre- to post-intervention on each item in the questionnaire was assessed using McNemar's Chi-square, matching individuals' post-responses to their pre-responses. Overall pre-to-post score changes in HIV-related knowledge, attitudes and reported communication were assessed using paired-sample t-tests. Sub-group analyses were carried out for males and females. No tests were carried out to assess effect modification by sex. Multiple linear regression was used to assess evidence of an association between sessions attended and KAC change, adjusting for participants' age and site. Analyses were carried out using Stata version 12.1.

Results

Sample characteristics

In total, 612 participants completed both pre and post questionnaires. Of these, 329 (53.8%) were female and 283 (46.2%) were male. Participants' age ranged from 12 to 24 years, with 126 (20.6%) participants aged 12 to 14 years, 328 (53.6%) aged 15 to 16 years and 158 (26.8%) aged 17 or older. Only 19 participants (3.1%) were aged 20 years or older. The majority of participants (n=405, 67.8%) were from Soweto, while 178 (29.1%) were from Mtubatuba and 19 (3.1%) were from Cape Town. Five

hundred forty-seven (89.4%) participants graduated from Generation Skillz, while 65 (10.6%) participants had not met the graduation threshold of at least seven sessions attended (Table 2).

[INSERT TABLE 2 NEAR HERE]

Effects on knowledge, reported attitudes and reported communication (Tables 3 and 4)

Very strong evidence of positive change ($p<0.005$) was observed on 18 of 20 KAC indicators, with favorable response scores increasing, on average, from 11.46 to 15.08 ($t=28.3$, $p<0.001$). The strongest effects were observed on knowledge of older partners (RR=2.05, 95%=1.86-2.25), alcohol (RR=1.78, 95% CI=1.62-1.95) and acute transmission (RR=2.73, 95% CI=2.39-3.12) as HIV risk factors as well as male circumcision (RR=1.76, 95% CI=1.59-1.94) as an HIV prevention method. The percentage of participants who reported communicating with a parent/guardian about HIV in the past two months increased from 37% to 56% (RR=1.58, 95% CI=1.42-1.77), while the percentage who reported communicating with a friend about HIV in the last two months (outside of Generation Skillz) increased from 54% to 72% (RR=1.35, 95% CI=1.25-1.46).

[INSERT TABLE 3 NEAR HERE]

Overall, there was very strong evidence of change from pre-to-post on knowledge ($t=27.2$, $p<0.001$), reported attitudes ($t=12.9$, $p<0.001$) and reported communication ($t=11.4$, $p<0.001$). There was no evidence that effects on these were differential for males and females ($p=0.77$). On average, favorable response scores increased for males from 11.34 to 15.00 points ($t=19.4$, $p<0.001$) and for females from 11.57 to 15.15 ($t=20.6$, $p<0.001$).

[INSERT TABLE 4 NEAR HERE]

Table 5 shows mean pre/post changes in KAC by number of sessions attended. Mean KAC changes ranged from 0.91 (95% CI=-1.06-2.88) for participants who attended only one session to 3.93 (95% CI=3.63-4.23) for participants who attended all sessions. The mean KAC change for Generation Skillz graduates (n=547) was 3.81 (95% CI=3.55-4.08), while the mean KAC change for non-graduates (n=65) was 1.98 (95% CI=1.30-2.67). There was very strong evidence of a positive linear dose-response association between number of sessions attended and KAC change (β=0.25, 95% CI=0.16-0.36, p<0.001), which persisted after adjusting for participants' age and site (β=0.20, 95% CI=0.08-0.33, p=0.002) (Figure 4).

[INSERT TABLE 5 NEAR HERE]

[INSERT FIGURE 4 NEAR HERE]

DISCUSSION

Intervention Development

The lessons learned in the process of developing Generation Skillz and the positive preliminary evaluation results lend support to the value of the Kirby Characteristics for effective curriculum-based sex and HIV education programmes.[8] Importantly, the 17 characteristics guided the development process, curriculum content, and intervention delivery of Generation Skillz.

Feedback from experts, coaches and staff suggests that the participatory and iterative process used in designing Generation Skillz greatly strengthened the final curriculum and intervention. The wide cross-section of stakeholders—from youth and Coaches to staff and external experts—providing input into the curriculum was another strength in the development process. The use of various methods, including observation, focus group discussions, workshops, and expert reviews with structured questions, to gather feedback at different phases of development facilitated the honing of the intervention's content to best address the targeted risk behaviours. It also presented a challenge because of the need to re-train Coaches after each phase,

and required just over two years for the many iterations of development of the curriculum and the supporting SMS messages.

The development process and subsequent rollout of Generation Skillz revealed the suitability of the GRS approach in addressing issues of gender norms and GBV, as well as topics such as age-disparate sex and multiple partnerships. This new content area was well received by Coaches and youth, who have found GRS' methods to be effective at creating a safe, structured environment in which to begin to deconstruct gender norms and take steps to stop GBV in their communities.

Preliminary Evaluation

The preliminary evaluation found very strong evidence that the Generation Skillz intervention improves HIV-related knowledge, reported attitudes and reported communication, at least in the short-term. Basic HIV-related knowledge (e.g. on the risk of unprotected sex and multiple partners) was high at baseline. The intervention's strongest effects were observed on knowledge of HIV risk factors (alcohol, older partners, acute transmission) and male circumcision as a prevention method, likely because baseline knowledge on these indicators was relatively low.

There were important limitations to the evaluation. First, it lacked a control group and, as such, it is possible that some of the observed improvements in KAC were due to time or other interventions reaching the participants. The evidence of a dose-response effect, however, strengthens the likelihood that the improvements in KAC were due to participation in Generation Skillz. Secondly, the evaluation relied on self-reported outcomes, which may be prone to social desirability bias.[38] While this would not have affected the validity of findings related to knowledge improvements, it may be that the observed improvements in reported attitudes and communication partly reflected what participants perceived to be the 'desirable' answers to questions. This is a common limitation of studies assessing HIV-related attitudes and communication. Lastly, the evaluation follow-up period was too short to conclude whether improvements in KAC were sustained over time.

Overall, the evaluation provides encouraging evidence with regard to the short-term effectiveness of Generation Skillz. Questions remain as to the long-term effectiveness of the intervention and its ability to reduce sexual risk behaviour and GBV perpetration. The two-year GOAL Trial—which is being conducted in Cape Town and Port Elizabeth and will finish in 2014—will provide rigorous answers to these remaining questions and play an important role in informing policy and strategy related to sport-based HIV prevention.

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Figure 1: Generation Skillz logic model (2012)

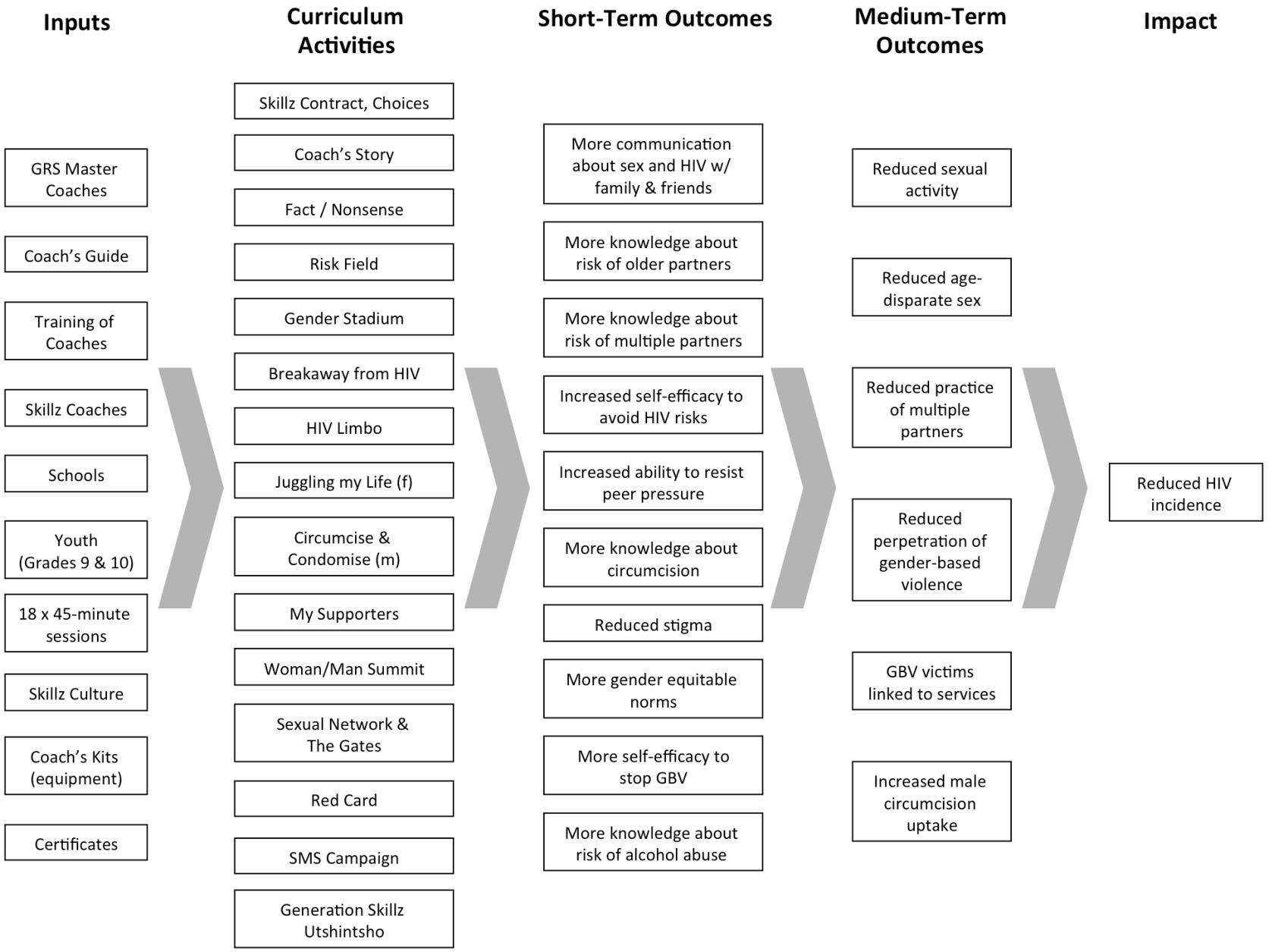
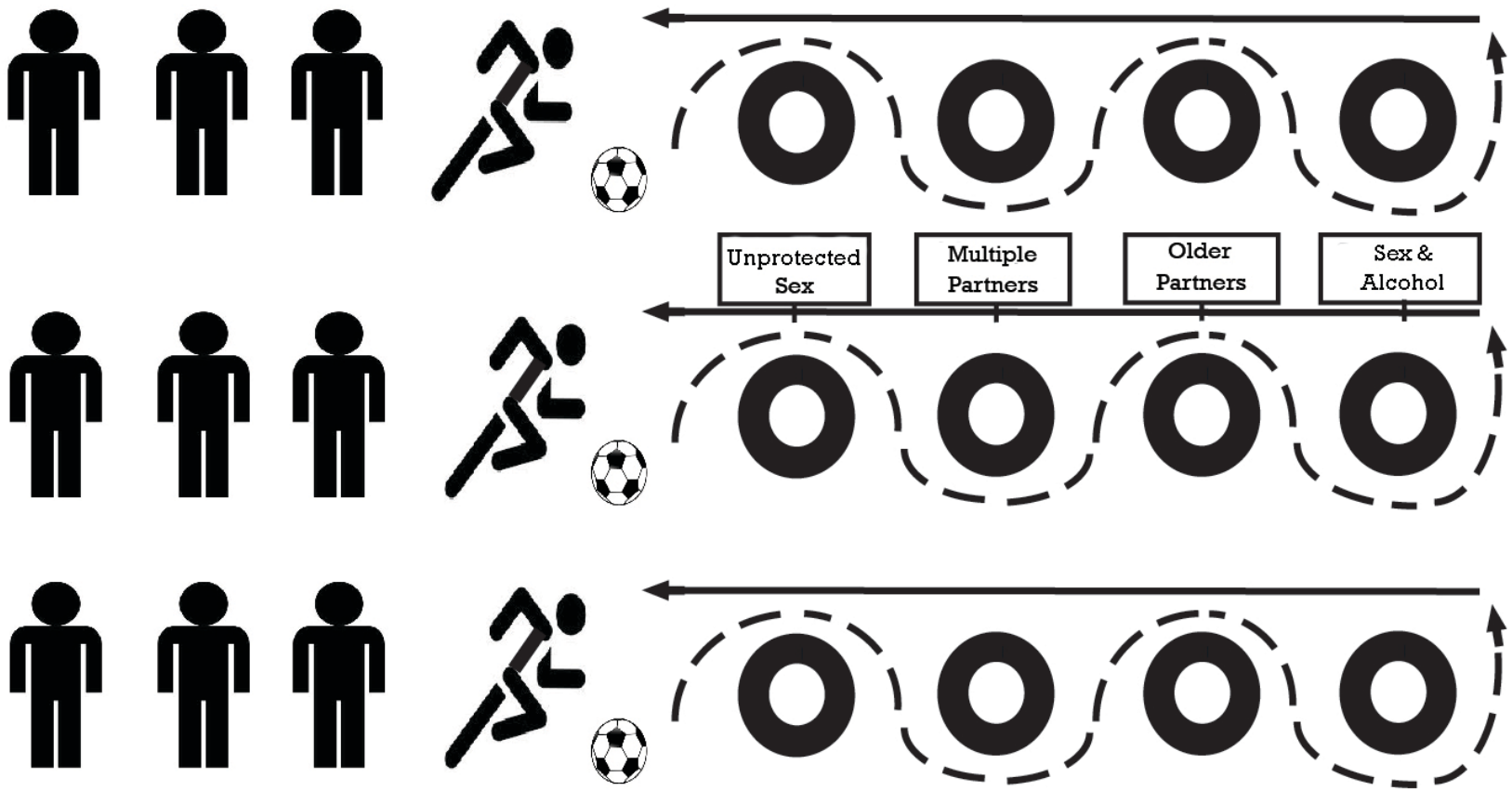


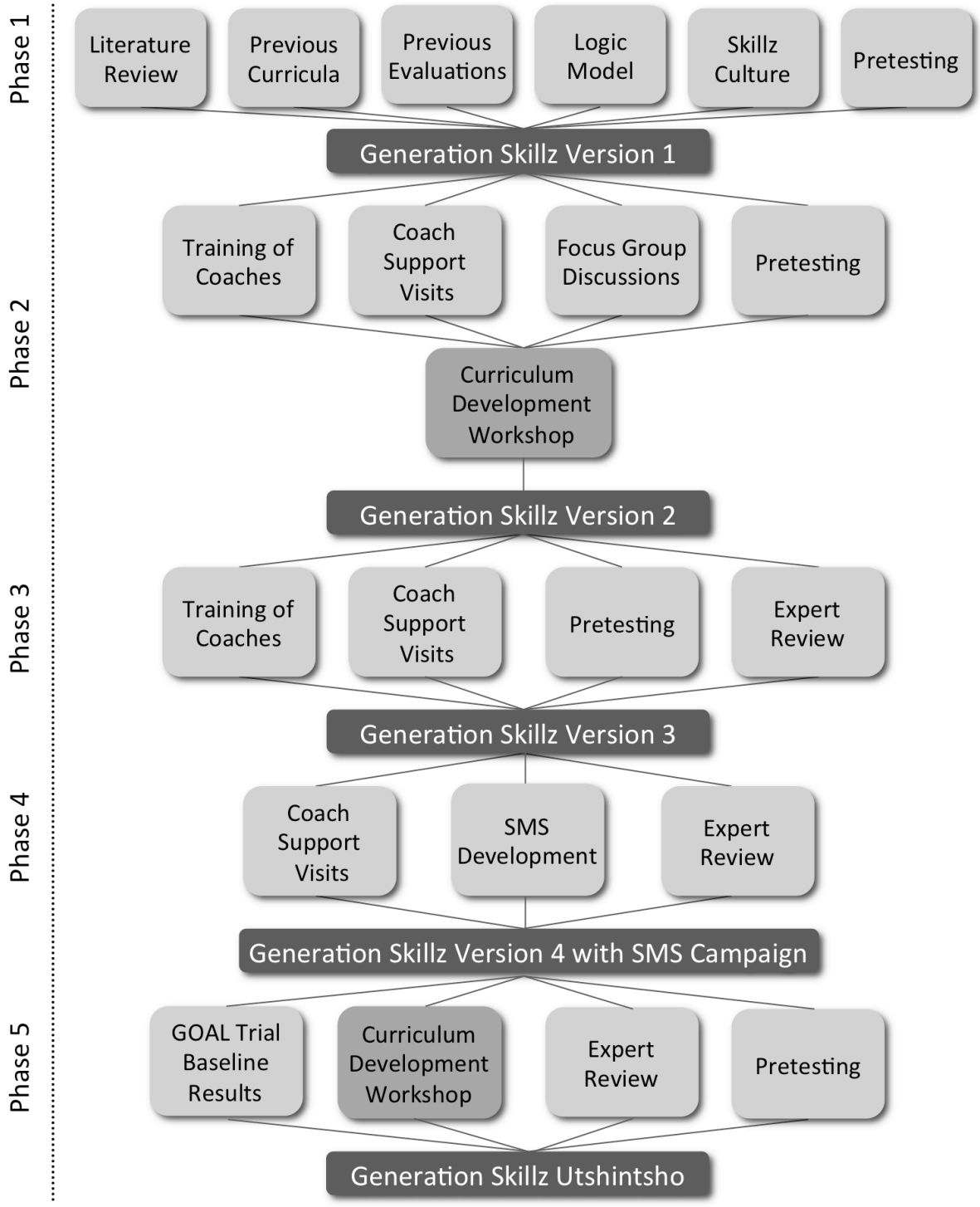
Figure 2: Risk Field (example Generation Skillz activity) diagram



Source: *Generation Skillz Curriculum*, Version 4

Caption: *In Risk Field, participants dribble a soccer ball in between cones representing HIV-related risks—multiple partners, sex and alcohol, older partners, etc. In the first round, if a player hits a cone, s/he must complete three push-ups or star jumps, representing the consequences of the risk s/he took. In the next round, if one player hits a cone, s/he must complete the task along with her/his teammates, showing how the consequences of one person's risk can affect her/his friends and family. In the final round, if one player hits a cone, everyone has to complete the task (including the other teams and the coaches), showing how one person's risks can have consequences for the entire community. Facilitated discussion follows each round, clarifying key messages, ensuring the lessons are understood and internalized by participants, and identifying risk avoidance strategies.*

Figure 3: Generation Skillz intervention development process



Caption: *Generation Skillz was developed in five phases from October 2009 to February 2013. Input for various sources fed into each version of the curriculum.*

Figure 4: Mean change in number of favorable responses by sessions attended

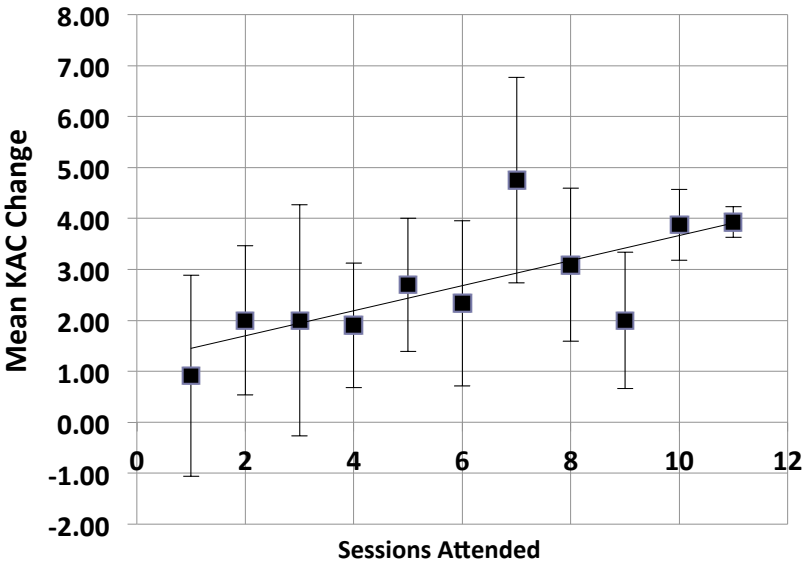


Table 1: Final Generation Skillz curriculum activities

Generation Skillz			Outcomes Addressed*				
Session	**Format**	**Curriculum Activity**	**ADS**	**MP**	**GBV**	**Other**	**Focus**
1	Mixed	Skillz Contract, Coach's Story				x	Establish ground rules, build teamwork, healthy decision making, resiliency
2	Mixed	Fact/Nonsense	x	x	x	x	Knowledge of HIV transmission and key HIV drivers, dispel common HIV-related myths
3	Mixed	Risk Field	x	x	x		Knowledge of HIV risks, consequences of risky behavior, peer support
4	Mixed	Gender Stadium			x		Gender norms, gender equality, listening to the other sex, communication
5	Mixed	Breakaway from HIV		x			Abstinence, concurrency vs. serial monogamy, sexual networks
6	Mixed	HIV Limbo	x		x		Risks of older partners, relationship power imbalance, and transactional sex
7	Females	Juggling My Life				x	Decision to have sex, pregnancy, prevention of mother to child transmission of HIV
	Males	Condomise & Circumcise				x	Benefits of medical male circumcision, consistent condom use
8	Mixed	My Supporters				x	Stigma and discrimination against PLHIV, building a strong support system
9	Females	Woman Summit			x		Violence against women, stopping violence in the community, alcohol abuse
	Males	Man Summit			x		Violence against women, stopping violence in the community, alcohol abuse
10	Mixed	Sexual Network and The Gates		x		x	Partner reduction, serial monogamy, condom use, HIV testing, window period
11	Mixed	Red Card	x	x	x		Key HIV drivers, build assertive communication skills, practice risk avoidance
Ongoing	Mixed	SMSs: 3x/month	x	x	x		Reinforce key messages, motivate participants to make healthy decisions
Generation Skillz Utshintsho			**Outcomes Addressed***				
	Format	**Curriculum Activity**	**ADS**	**MP**	**GBV**	**Other**	**Focus**
1	Mixed	Contract and Play On	x	x	x		Create and sign Skillz contract, build teamwork, review key HIV drivers, personalization
2	Females	Defining YOU			x		Gender roles, masculinity and femininity, positive deviance
	Males	Wear the Armband			x		Gender roles, masculinity and femininity, positive deviance
3	Females	Healthy Relationships	x	x	x		Characteristics of healthy and unhealthy relationships, relationship power imbalance
	Males	Power in Relationships	x	x	x		Gender equality, relationship power imbalance
4	Females	Draw the Line			x		Emotional, physical and sexual abuse; healthy boundaries; relationship termination
	Males	Nonviolent Communication			x		Understand personal triggers, practice conflict resolution strategies
5	Females	Red Card	x	x	x	x	Evaluate personal alcohol usage, consequences of alcohol abuse, practice avoidance
	Males	Juggling My Life			x	x	Evaluate personal alcohol usage, consequences of alcohol abuse, avoidance strategies
6	Females	Saying No			x		Practice relationship communication skills, assertive sexual decision making
	Males	Respecting No			x		Practice relationship communication skills, respecting partner's sexual decisions
7	Mixed	Graduation	x	x	x		Share learning from split-sex sessions, pledge to be community change agents
Ongoing	Mixed	SMSs: 3x/month	x	x	x		Reinforce key messages, motivate participants to make healthy decisions

*ADS: age-disparate sex, MP: multiple partnerships, GBV: gender-based violence, Other: described in table

Table 2: Sample characteristics (n=612)

Characteristic	N	%
All participants	612	100
Sex		
Male	283	46.2
Female	329	53.8
Age Group		
12-14	126	20.6
15-16	328	54.6
17+	158	26.8
Site		
Cape Town	19	3.1
Mtubatuba	178	29.1
Soweto	415	67.8
% sessions attended		
9-49%	50	8.2
50-99%	157	25.7
100%	405	66.2
GRS Graduate*		
Yes	547	89.4
No	65	10.6

**Attended at least 7 of the 11 Generation Skillz sessions*

Table 3: Changes in knowledge, attitudes, and communication from pre to post (n=612)

Item	Overall				Males				Females			
Attitudes	**Pre**	**Post**	**RR**	**95% CI**	**Pre**	**Post**	**RR**	**95% CI**	**Pre**	**Post**	**RR**	**95% CI**
It is the woman's responsibility to avoid getting pregnant. †	25%	41%	1.65	1.41-1.93	27%	45%	1.68	1.36-2.08	23%	37%	1.62	1.29-2.02
I can resist peer pressure.	50%	70%	1.41	1.30-1.53	54%	71%	1.31	1.16-1.47	47%	71%	1.51	1.35-1.70
I would stay away from a classmate with HIV.†	74%	79%	1.07	1.02-1.13	74%	77%	1.04	0.96-1.11	75%	83%	1.11	1.04-1.18
It is my responsibility to protect myself and others from HIV.	83%	87%	1.05	1.01-1.09	84%	86%	1.02	0.97-1.08	84%	90%	1.07	1.02-1.12
I would be willing to take an HIV test.	78%	87%	1.11	1.06-1.17	77%	89%	1.15	1.07-1.24	79%	86%	1.08	1.02-1.15
It is the man's responsibility to make decisions in a relationship. †	61%	75%	1.25	1.16-1.33	52%	70%	1.34	1.20-1.51	68%	80%	1.18	1.09-1.28
There are times when it is ok for a man to hit his girlfriend. †	64%	74%	1.16	1.09-1.23	62%	72%	1.16	1.06-1.27	66%	76%	1.15	1.06-1.25
Communication												
I have talked about HIV with a parent or guardian in the past 2 months.	37%	58%	1.58	1.42-1.77	33%	55%	1.67	2.06-5.05	40%	61%	1.53	1.32-1.73
I have talked about HIV with a friend in the past 2 months.	54%	72%	1.35	1.25-1.46	54%	75%	1.39	2.25-6.00	54%	70%	1.30	1.17-1.45
Knowledge												
Unprotected sex is the most common way HIV is spread.	85%	90%	1.06	1.02-1.10	85%	91%	1.08	1.03-1.14	86%	89%	1.04	0.99-1.10
Having more than one sexual partner increases your risk of getting HIV.	79%	92%	1.17	1.12-1.22	80%	94%	1.18	1.11-1.25	78%	91%	1.16	1.09-1.23
Having sex with an older partner increases your risk of getting HIV.	44%	90%	2.05	1.86-2.25	41%	92%	2.26	1.95-2.61	46%	87%	1.89	1.67-2.14
If a pregnant mother has HIV her baby will always be born with HIV. †	58%	76%	1.31	1.22-1.41	54%	73%	1.35	1.22-1.50	61%	78%	1.28	1.17-1.40
Circumcision can reduce a man's risk of getting HIV.	42%	73%	1.76	1.59-1.94	47%	79%	1.69	1.49-1.92	37%	68%	1.83	1.57-2.13
Drinking alcohol and using drugs can increase your risk of getting HIV.	46%	81%	1.78	1.62-1.95	43%	81%	1.88	1.64-2.16	48%	82%	1.70	1.51-1.92
You are more likely to spread HIV in the first 6 wks after infection.	29%	78%	2.73	2.39-3.12	35%	79%	2.24	1.89-2.65	24%	79%	3.35	2.73-4.11
Which of the following are HIV prevention methods:												
Having only one faithful partner	56%	70%	1.26	1.17-1.36	58%	70%	1.20	1.08-1.34	53%	70%	1.32	1.20-1.45
Washing after sex †	91%	92%	1.01	0.98-1.04	85%	87%	1.03	0.97-1.09	97%	97%	1.00	0.97-1.03
Using condoms during sex	72%	79%	1.09	1.03-1.15	78%	83%	1.06	0.99-1.14	66%	74%	1.12	1.03-1.22
Not having sex	50%	62%	1.24	1.14-1.35	46%	56%	1.23	1.07-1.42	53%	66%	1.25	1.13-1.38

Percentages in the table represent percentages of favorable responses. For items marked † the favorable response was 'disagree'.

Table 4: Pre/post changes in favorable response scores by sex (n=612)

Outcome	Questions	Mean Pre	SD	Mean Post	SD	t score	p value*
Knowledge	**11**	**6.34**	**1.93**	**8.73**	**2.02**	**27.2**	**<0.001**
Males		6.31	1.91	8.72	1.98	18.9	<0.001
Females		6.37	1.96	8.74	2.06	19.6	<0.001
Attitudes	**7**	**4.23**	**1.67**	**5.06**	**1.64**	**12.9**	**<0.001**
Males		4.17	1.72	4.99	1.72	8.6	<0.001
Females		4.29	1.63	5.13	1.57	9.63	<0.001
Communication	**2**	**0.88**	**0.71**	**1.29**	**0.73**	**11.4**	**<0.001**
Males		0.85	0.71	1.29	0.73	8.1	<0.001
Females		0.91	0.71	1.29	0.73	8.1	<0.001
Overall	**20**	**11.46**	**3.18**	**15.08**	**3.51**	**28.3**	**<0.001**
Males		11.34	3.24	15.00	3.50	19.4	<0.001
Females		11.57	3.14	15.15	3.53	20.6	<0.001

*Based on paired-sample t test

Table 5: Mean change in favorable responses by sessions attended

Sessions Attended	N	%	Mean Change	95% CI
1	11	1.8	0.91	-1.06-2.88
2	16	2.6	2.00	0.53-3.47
3	3	0.5	2.00	-0.27-4.27
4	10	1.6	1.90	0.68-3.12
5	10	1.6	2.70	1.39-4.01
6	15	2.5	2.33	0.71-3.96
7	12	2.0	4.75	2.73-6.77
8	23	3.8	3.09	1.59-4.59
9	26	4.3	2.00	0.66-3.34
10	81	13.2	3.88	3.18-4.57
11	405	66.2	3.93	3.63-4.23
All	**612**	**100.0**	**3.62**	**3.37-3.87**

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

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Zachary A Kaufman, MSc
PhD Candidate, Faculty of Epidemiology and Population Health
London School of Hygiene & Tropical Medicine
Keppel St, London WC1E 7HT, UK
Tel: +27 71 590 0820
Email: zachary.kaufman@lshtm.ac.uk

23 February 2014

Dear Editors,
Please consider our manuscript entitled, The GOAL Trial to assess the behavioural effectiveness of a sport-based HIV prevention intervention in South African informal settlement schools: study design and baseline results of a cluster-randomised trial, for publication in C*ontemporary Clinical Trials*. The paper presents the trial design of an ongoing cluster-randomised trial assessing the effectiveness of a sport-based HIV prevention intervention in Cape Town and Port Elizabeth, South Africa.

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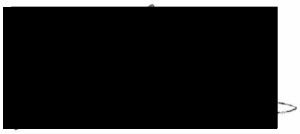
The corresponding author for this manuscript is:

Zachary A Kaufman
London School of Hygiene and Tropical Medicine
Keppel Street London WC1E 7HT
+447506998037
zachary.kaufman@lshtm.ac.uk

All authors have reviewed and approved the manuscript, as well as contributed to its content.

Thank you for your consideration.

Sincerely,



Zachary A Kaufman (for all contributing authors)
London School of Hygiene and Tropical Medicine
Keppel Street London WC1E 7HT
+447506998037
zachary.kaufman@lshtm.ac.uk

The GOAL Trial to assess the behavioural effectiveness of a sport-based HIV prevention intervention in South African informal settlement schools: study design and baseline results of a cluster-randomised trial

Kaufman Z.A.[1,2], Kaufman E.B.[1], DeCelles J.[3], Weiss H.A.[1], Dringus S.[1], Delany-Moretlwe S.[2], Ross D.A.[1]

[1] London School of Hygiene and Tropical Medicine, Epidemiology and Population Health, London, UK

[2] Wits Reproductive Health and HIV Institute: Johannesburg, South Africa

[3] Grassroot Soccer, Research and Development: Cape Town, South Africa

Target journal: *Contemporary Clinical Trials*

Abstract

Introduction: The need for effective and scalable HIV prevention interventions for young people in South Africa remains an urgent public health priority. The potential for using sports-based HIV interventions is of increasing interest globally, but few studies have evaluated the effectiveness of these interventions.

Methods/Design: The GOAL Trial is a three-year cluster-randomised trial being conducted in Cape Town and Port Elizabeth, South Africa. The trial assesses the effectiveness of Generation Skillz, a sport-based HIV prevention intervention, in reducing reported sexual risk behaviour and perpetration of gender-based violence. In 2012, immediately prior to intervention implementation, 4485 Grade 9 learners (median age 15 years) in 46 schools completed a 146-item baseline questionnaire. Follow-up surveys are taking place in 2013 and 2014. The primary analysis will be by intention-to-treat, comparing three primary outcomes—age-disparate sex in the last year, multiple partners in the last year, and reported rape perpetration in the last year—between intervention and control participants, adjusted for school-level clustering. A process evaluation being conducted alongside the trial will assess how and why Generation Skillz either leads or does not lead to the desired outcomes.

Discussion: This is the first randomised controlled trial to assess the effectiveness of a sport-based HIV prevention intervention and one of the first trials in the growing field of sport-for-development. The results will inform HIV prevention efforts for young people in South Africa.

Trial Registration: Pan African Clinical Trials Registry PACTR201402000767141

Keywords: South Africa; HIV/AIDS; HIV education; sport; cluster-randomized trial

Introduction

The need for effective and scalable HIV prevention interventions for young people remains an urgent public health priority, particularly in sub-Saharan Africa. South Africa is enduring the world's most severe HIV epidemic, with more than 6.4 million infected and approximately 469,000 new infections per year.[1] The epidemic among young people in South Africa is driven in large part by age-disparate sex,[2] multiple partnerships (often concurrent in nature),[3] male-dominant gender norms and gender-based violence (GBV),[4,5] and lack of male circumcision.[6]

Interest is growing internationally in the use for sport in interventions to change behaviour and improve health, with numerous sport-based HIV prevention (SBHP) interventions currently being delivered across Sub-Saharan Africa.[7] A recent systematic review showed that while results of observational and quasi-experimental studies of SBHP interventions have been promising, no RCTs have been conducted to date and there is limited evidence of effectiveness from high-quality research.[8]

In its 2012-2016 strategic plan, the South African government identified young women and people living in informal settlements as key target populations for HIV prevention, also stating that curricular and co-curricular sexuality education and life skills programs must be provided in all schools "to build skills, increase knowledge and shift attitudes, change harmful social norms and risky behaviour" (p41).[9] While there is strong evidence supporting the effect of well-designed school-based HIV prevention interventions on knowledge and self-reported behavioural outcomes,[10] little research has rigorously assessed the effectiveness of sport-based interventions delivered in schools.

Developed by Grassroot Soccer (GRS) and rooted in social learning theory,[11] the Generation Skillz intervention consists of 17 interactive sessions that focus on reducing age-disparate sex (ADS), multiple partners and intimate partner violence (IPV). Generation Skillz is delivered in secondary schools over two years (Grade 9 and 10) by GRS "coaches," 18-25 year-old local female and male role models. A preliminary before-after evaluation of the intervention showed strong, positive effects on HIV-related knowledge, reported attitudes, and reported communication

about HIV with family and friends.[12] In 2012, a cluster-randomised trial (the GOAL Trial) was initiated in Cape Town and Port Elizabeth, South Africa to assess the long-term effectiveness of Generation Skillz delivered by GRS "coaches" in addition to standard, teacher-delivered life skills orientation classes, compared to the teacher-delivered life skills orientation classes on their own in secondary schools in informal-settlements.

Mobile technology presents promising opportunities to create and enhance health promotion interventions for young people, particularly in South Africa, which has the highest mobile phone penetration in Africa.[13] Evidence of the potential health effects of electronic Short Message Service (SMS) messages has come from a trial of smoking cessation SMSs in the UK[14] and two trials of ART-adherence SMSs in Kenya.[15,16] SMSs have been used in a variety of contexts that have aimed to improve sexual health (as well as other aspects of health behaviour change), but have rarely been evaluated.[17]

The GOAL trial seeks to (I) assess the effectiveness of the Generation Skillz intervention in reducing reported sexual risk behaviour and/or reported rape perpetration over two years, (II) assess whether biweekly SMS messages reinforcing Generation Skillz enhance the intervention's effectiveness, and (III) understand how and why the intervention either leads to or does not lead to its desired outcomes.

Methods/Design

Study Participants and Setting

The study enrolled male and female Grade 9 learners at 46 public secondary schools in informal settlements in Cape Town (n=16 school) and Port Elizabeth (n=30 schools). Port Elizabeth was divided into two sites: Port Elizabeth 1 (urban townships in the city – Zwide, New Brighton, Kwazakhele, n=15 schools) and Port Elizabeth 2 (peri-urban townships to the east of city – Motherwell and Uitenhage, n=15 schools). Participating schools in Cape Town (n=16) were located in the communities of Khayelitsha, Gugulethu, and Langa. A youth advisory committee was formed with adolescents from participating schools, advising on questionnaire content,

recruitment procedures, and ways to make the trial's data collection as youth friendly as possible.

Trial Design

The study employed a cluster-randomised design, with schools randomly allocated to either receive the Generation Skillz intervention during the trial period (Intervention Group) or be offered the intervention after the trial (Control Group). Ethical approval for the trial was obtained from the University of the Witswatersrand Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine Interventions Research Ethics Committee.

Sampling and Recruitment

The 46 enrolled schools represented 56% of the 87 open public secondary schools in the participating communities. The schools were selected purposively, excluding those that had been exposed to the trial intervention during pilot testing of the intervention (n=10), and enrolling those that were most receptive to participating in the trial. In schools with five or fewer classes of Grade 9 learners, all Grade 9 classes and learners were invited to participate. To yield an optimum cluster size, in schools with six or more Grade 9 classes, five classes were selected using simple random sampling. Only participants providing both written parental/guardian consent and assent were enrolled in the study.

Class registers were collected for participating grade 9 classes. These were manually entered into an online database and participants were assigned 6-digit study identification code (ID) numbers. To determine the number of potential participants for study enrolment, the database of all learners in the selected classes in school registers was first de-duplicated on the basis of first name, last name, and school and then this and the numbers enrolled in the trial were cross-tabulated by trial arm and site in Table 1.

Study Outcomes

The primary behavioural outcomes of interest in the GOAL Trial are:

- Reported age-disparate sex in the last six months: defined as reporting having had sex in the six months with a partner who is 5 or more years older or younger (consistent with the definition used in the most recent national health survey)[18];

- Reported recent multiple partnerships: defined as reporting more than one sexual partner in the last six months at follow-up (consistent with the national health survey[18], though it uses a 12-month period. This was not possible for the GOAL trial, as some schools had less than 12 months between intervention and follow-up surveys); and

- Reported perpetration of rape: defined as reporting having forced sex with a partner or non-partner who did not want to have sex (consistent with a recent study investigating rape perpetration among adult South African men).[19]

Secondary outcomes for the trial include:

- Reported hazardous alcohol use (measured via the AUDIT scale[20]; a score of 8 or higher is considered hazardous. This cut-off also includes those who screen positive for harmful drinking);

- Belief in male-dominant gender norms (measured via an adapted 10-item GEM scale[21], divided into three equal score ranges: low, medium, and high);

- HIV-related stigma (adapted from the Measure DHS AIDS Indicator Survey (AIS)[22], divided into three equal score ranges: low, medium, and high); and

- HIV-related knowledge (measured on a 10-item scale, including items from AIS[22] and UNGASS[23] as well as others related to circumcision, prevention of mother to child transmission, and ADS; divided into three equal score ranges: low, medium, and high).

Sample Size Calculations

Using the Hayes and Bennett[24] method for assessing sample size for cluster randomised trials, we determined that a sample size of 46 schools and 4600 participants would be sufficient. The trial design assumed an average of 100 learners per school, 9% attrition per year (source similar trials in Tanzania and South

Africa[25,26]) 15% end-line period prevalence of ADS in the control group, and a k of 0.25. Under these assumptions, the calculated sample size would enable the trial to detect a 27% effect of the Generation Skillz intervention on the period prevalence of ADS with 80% power and 5% significance. With the same parameters and an assumed 25% endline prevalence of recent multiple partners in the control group, the trial would be able to detect at least a 24% effect on multiple partners in the last 6 months.

Randomisation

Stratified randomisation was used to determine each school's group allocation. Schools were stratified first by site, then by size (large vs. small, based on whether they fell into the upper or lower 50% of schools based on enrolment numbers) and then by estimated attrition (based on the expected percentage of school dropouts between Grade 9 and Grade 12, approximated using 2012 cross-sectional enrolment numbers provided by schools). Thus, a total of 12 strata were utilized in randomisation. This method was used in an effort to ensure groups were balanced by site and so groups would have comparable numbers of participants at both baseline and follow-up. To ensure transparency, public randomisation events were held in each site approximately 3-4 weeks prior to the start of data collection, with life-orientation teachers, school administrators, and GRS staff and volunteers in attendance. After the main allocation, intervention schools were re-randomised using the same stratified approach to determine which schools would receive the SMS booster. All schools had agreed to participate in the trial before the randomisation events were held. Due to the logistical need to disclose whether a school would receive the intervention (after randomisation), it was not possible to mask a school's allocation from school administrators, teachers, study participants, or survey administrators.

Intervention

The Generation Skillz core curriculum for Grade 9 learners was specially developed by GRS in 2009 for use in South African secondary schools, building on the organisation's experience delivering similar interventions with more than 30,000 Grade 6-8 learners across the country. The Generation Skillz core curriculum consists

of eleven 45-minute activity- and discussion-based sessions, delivered during life-orientation school periods by trained "Coaches". The curriculum is primarily focused on reducing multiple partnerships, age-disparate sex, and gender-based violence, but also addresses male circumcision, condom use, and HIV counselling and testing. In the GOAL Trial, the core curriculum was delivered between March and October 2012 in the 23 intervention schools. In addition, approximately 10-12 months after the core intervention, Generation Skillz Coaches delivered a further seven 'booster' sessions (known as Generation Skillz Utshintsho) between March and September 2013, by which time most learners were in Grade 10. The intervention is further described elsewhere.[12] Intervention schools also receive the standard Department of Education life orientation curriculum (see Control Group). At the time of implementation within the GOAL Trial, the 97-page Generation Skillz curriculum[27] was in its fourth version.[12]

Generation Skillz 'Coaches' are young community role models from the informal settlements where the interventions are delivered. They are typically between 18 and 25 years-old and have at least completed secondary school. Coaches receive a 5-day pre-service training, additional on-the-job training and support from certified Master Coaches with at least one visit per month per coach, and weekly development sessions led by Master Coaches where they discuss challenges and sharpen their skills. In addition to curriculum content, Coach training courses teach facilitation skills, local HIV and AIDS epidemiology, attendance monitoring, and referrals. Coaches monitor participant attendance for all Generation Skillz interventions. Attendance data are uploaded into GRS' online monitoring database on a monthly basis.

Between May 2012 and March 2013, all youth in a randomly selected 12 of the 23 intervention schools were sent biweekly SMS messages. The SMS messages were developed from key messages in the Generation Skillz curriculum and encourage participants to share their knowledge and start meaningful conversations with their peers. For example, one SMS reads: "WOW! In SA, 20% of people 20-34 years old have HIV! Only 5% of people your age have HIV. Which partner puts you more at risk?" This nested trial will assess the effectiveness of these SMSs in "boosting"

adolescents' knowledge, attitudes, behaviours, and biological outcomes related to HIV.

Control Group

Control schools receive standard, teacher-led Department of Education (DoE) life orientation classes, which vary in nature site-to-site and school-to-school. The DoE's National Policy on HIV and AIDS states:

> *"Learners and students must receive education about HIV/AIDS and abstinence in the context of life-skills education on an ongoing basis…Life-skills and HIV/AIDS education should not be presented as isolated learning content, but should be integrated in the whole curriculum".*[28]

The DoE further states within its curriculum statement that, following life orientation (LO) education, Grade 9 learners should be able to "Critically evaluate resources on health information, health services and a range of treatment options, including [for] HIV/AIDS".[29] Of relevance to Generation Skillz, the statement states that Grade 9 learners should spend four hours learning about 'sexual behaviour and sexual health' and an additional four hours learning about 'goal-setting: personal lifestyle choices'. Following completion of the trial, control schools will be offered the Generation Skillz intervention, if it has been found to be effective.

Data Collection

A 146-item questionnaire was developed to assess participants' demographic status, HIV-related knowledge, reported attitudes, reported gender norms, reported alcohol use, reported experience or perpetration of IPV, and reported sexual behaviour. The questionnaire was pre-tested on Grade 10 learners (rather than Grade 9 learners, to avoid pre-exposing study participants to survey questions) in selected trial schools in Cape Town and Port Elizabeth.

The baseline survey was carried out using Open Data Kit (ODK) Collect (version 1.2) on Android mobile phones provided temporarily by the study to the respondents for questionnaire completion.[30] ODK has been pilot tested successfully in numerous resource-limited settings in Africa and Latin America.[31] We have observed high

participant acceptability for a similar ODK-based sexual behaviour survey in Zimbabwe.[32] Similar, more expensive technologies—such as Audio Computer Assisted Self-Interview (ACASI)—for collection of data on sexual behaviour have been shown to be more valid in cross-sectional surveys than self-administered questionnaires on pen and paper or face-to-face interviews [33]. Questionnaires took participants, on average, approximately 25-30 minutes to complete. When completing a questionnaire, participants have the option to read and select options written in English or isiXhosa, with optional audio assistance also available in isiXhosa. All GOAL surveys are confidential; participants were identified only with a six-digit study ID, and no personal identifying information is entered into the mobile phones. Questionnaire responses can only be linked to individuals in the password-protected study enrolment database via the six-digit study ID. Data are transmitted daily through a secure Wi-Fi connection to an online database. Most demographic questions were removed from follow-up questionnaires, shortening them to 109 items plus an additional 12 questions assessing the intervention group's perceptions of the Generation Skillz intervention. Participants had the option to select "I don't want to answer" on each question.

Process Evaluation

A mixed-methods process evaluation is being conducted alongside the delivery of the Generation Skillz intervention in an effort to investigate how and why the intervention either leads to or does not lead to its desired outcomes, thus affording a more rigorous interpretation of the main findings of the trial. The evaluation will assess the quality, fidelity, and coverage of implementation, the participant-perceived relevance of the intervention, and the larger social context in which the intervention is delivered. This will include the collection and analysis of: (i) routine data on intervention delivery; (ii) pre-/post-training questionnaires administered to GRS coaches and to a sample of learners; (iii) structured observations of both the training of GRS coaches and of the in-school intervention sessions they deliver; and (iv) focus group discussions and in-depth interviews with GRS coaches and learners. Results of the process evaluation will be presented separately.

Results

Recruitment

Based on school registers, the 46 participating schools had 8226 enrolled grade 9 learners. Observation of recruitment at schools in all three sites suggested that the actual number of attendees on days when consent forms were distributed was, on average, 20-30 percent less than the number of participants on a class register. Classes were visited 2 to 3 times for consent form distribution and collection in order to allow the maximum number of learners to participate. In all, 4485 participants (54.5% of those listed on registers) completed baseline surveys: 2173 participants (52.3%) at intervention schools and 2312 participants (56.8%) at control schools. Estimated study enrolment rates varied widely by school, particularly in Port Elizabeth 2, ranging from 23% of those listed on registers (note: one intervention school closed temporarily due to gang violence during the baseline period and had even lower study enrolment) to 90%. Enrolment was highest in Port Elizabeth 1 (61% intervention, 68% control) and lowest in Port Elizabeth 2 (44% intervention, 56% control). In Cape Town, enrolment was slightly higher in the intervention group (52%) than the control group (49%). Table 1 details participant enrolment numbers by study group and site. Figure 1 shows the flow of participants thus far.

[INSERT TABLE 1 NEAR HERE]

[INSERT FIGURE 1 NEAR HERE]

Sample Characteristics

Table 2 summarizes the sample characteristics by study group and by sex. The intervention group had a slightly lower proportion of females (n=1234, 54.5%) than the control group (n=1260, 56.8%) as well as a slightly higher proportion of participants in Cape Town (n=822, 37.8%) than the control group (n=762, 33.0%) and a slightly lower proportion of participants in Port Elizabeth 2 (n=566, 26.1%) than the control group (n=758, 32.8%). The groups were well balanced in terms of self-identified race (approximately 92.1% black) and language spoken at home (approximately 95.8% isiXhosa). In both groups, nearly 1 in 3 participants (28.9% overall) was a single or double orphan, and a minority lived with both of their

parents (35.9% intervention group, 32.2% control group). Intervention participants had slightly more highly educated mothers than the control group (47.1% vs. 44.1% matric or higher education) and slightly more highly educated fathers (51.6% vs. 47.0% matric or higher education). The control group (median age: 16 years, interquartile range (IQR)=15-17 years) was slightly older on average than the intervention group (median age: 15 years, IQR=14-16 years). In both groups, male participants (median age: 16 years) were slightly older on average than females (median age: 15 years). Females in the control group were slightly older on average (IQR=15-16) than females in the intervention group (IQR=14-16). The groups were similar in household size (median size: 5 people, IQR: 4-6 people) and asset index score (median score: 0.7, IQR=0.7-0.8).

[**INSERT TABLE 2 NEAR HERE]**

HIV-related knowledge, reported attitudes, and reported behaviour by group

Table 3 summarizes HIV-related knowledge, reported attitudes and reported behaviour by group and by sex. The groups were comparable in terms of HIV-related knowledge, with approximately 1 in 3 participants scoring in the high range. Males in the control group had slightly less favourable attitudes towards people living with HIV (31.2% control vs. 25.7% intervention scored in the low range for stigma). HIV-related self-efficacy was higher among intervention group males than control group males (38.0% vs. 32.1% in high range).

Almost twice as many males in the intervention group (14.0%) reported being circumcised at baseline than in the control group (7.7%). Fewer males in the intervention group (25.0%) than the control group (31.4%) screened positive for depression, while depression among females was similar in the two groups (26.7% vs. 26.4%). Slightly fewer males in the intervention group (22.5%) than the control group (24.4%) screened positive for hazardous alcohol use, while females in the control group were comparable (12.1% vs. 12.9%). Slightly fewer males in the intervention group (28.2%) than the control group (32.2%) reported having ever taken an HIV test. Slightly fewer females and males in the intervention group (40.9% and 68.2%, respectively) than the control group (45.1% and 70.0%, respectively) reported having ever had sex. Among participants reporting having ever had sex, in

both groups more females than males reported having ever used a condom (68.9% vs. 62.0% in the intervention group; 70.7% vs. 60.1% in the control group). Males in both groups reported similar numbers of lifetime partners (53.3% vs. 56.7% reporting 3 or more lifetime partners) and recent partners (29.2% vs. 31.0% reporting 3 or more partners in the last year). Slightly fewer males in the intervention group (33.4%) than the control group (37.6%) reported having ever perpetrated physical IPV. The same pattern was observed for reported rape perpetration (23.7% vs. 29.1%). Little difference was observed between groups among females in having ever experienced physical IPV (29.8% intervention vs. 30.6% control).

[**INSERT TABLE 3 NEAR HERE]**

Discussion

The GOAL Trial is the first randomised controlled trial to assess the effectiveness of a sport-based HIV prevention intervention and one of the first trials in the growing field of sport-for-development. The cluster randomised design with schools as clusters was essential, given group-level intervention delivery and to minimize risk of contamination between study groups.

The study's large size has yielded a rich baseline data set that provides the basis for subsequent evaluation of the intervention's effectiveness, but also on the prevalence of, and risk factors for, important HIV outcomes in this study population. In other cross-sectional papers we have used these data to investigate prevalence and risk factors for hazardous alcohol use,[34] reported rape perpetration,[35] and reported intimate-partner violence experience and perpetration.[36] The baseline findings were considered in the design and development of Generation Skillz Utshintsho.

A small number of baseline differences—due to chance as a result of the randomisation and thus it is not appropriate to test them statistically—were observed between study groups. A larger proportion of males in the intervention group reported being circumcized at baseline (14.0% vs. 7.7%), while a smaller

proportion reported age-disparate sex in the last year (12.0% vs. 15.7%), screened positive for depressive symptoms (25.0% vs. 31.5%), and reported rape perpetration ever (23.7% vs. 29.1%). No noteworthy differences were observed between groups among females. The differences among males may be related to the age difference between groups, with the control group being slightly older on average than the intervention group (though this would not explain the difference in reported circumcision status). It will be important to adjust our final analyses for age and potentially site. Given the markedly different patterns of reported risk behaviour between males and females, we will analyse results separately by sex and only combine if the results show the intervention impact to be similar in the two sexes.

The trial has several anticipated limitations. First, selection bias may occur due to the requirement of written parental/guardian consent for participants under 18 years. It is plausible that would-be participants with less involved parents and difficulty obtaining a parental signature were less likely to participate in this study. Considering previously observed associations between parent/child relations and reported risk behaviour among adolescents in South Africa[37] and Sub-Saharan Africa [38] as well as associations between parental supervision and sexually transmitted infection (STI) risk among low-income, urban African-American adolescents,[39] this may result in underestimates of reported risk behaviour. We do not have reason to believe this selection bias would be differential between study groups or between males and females, though we lack pre-enrolment data that could confirm whether or not any bias is differential.

Secondly, our trial lacks biological outcomes such as HIV and HSV-2 incidence, which would be optimal measures of the intervention's effectiveness. We originally designed the trial to use these measures as primary outcomes and received ethical approval to do so. However, due primarily to the local ethics committee's insistence on written parental consent[1] and the unwillingness of the Gauteng provincial Department of Education to endorse the study,[2] we were unable to achieve a sample size that would have been sufficient to detect a reasonable biological effect. Whereas we had designed the trial to be able to detect a 30% reduction in HIV incidence, we reran sample size calculations after completing the baseline surveys and determined that the trial would only be able to detect, at best, a 48% reduction

in HIV incidence. The Trial Advisory Committee thus decided in November 2012 that it would be impractical to continue biomarker collection beyond baseline.

The validity of data on self-reported sexual behaviour has been extensively questioned and debated.[40,41] Social desirability bias may lead male participants to over-report their sexual experience, number of sexual partners and/or alcohol consumption and female participants to under-report their sexual experience and number of partners. Our confidential, mobile-assisted self-interview approach likely minimizes such reporting bias, however, as all answers appear to remain private to the individual. Indeed, both the survey method and the results mirror that of Beauclair and colleagues' recent ACASI sexual behaviour survey in similar communities in Cape Town, from which they concluded that the self-interview method "may considerably reduce social desirability bias in sexual behaviour surveys".[42]

On the other hand, the trial has several key strengths. It is the first randomised controlled trial to assess the effectiveness of a sport-based HIV prevention intervention. Its cluster randomised design and detailed baseline survey will give confidence that any observed differences in the adjusted comparisons between intervention and control schools at follow-up are unlikely to have been due to selection bias. Also, the trial has good power to detect differences of public health importance in the three primary trial outcomes. Its results will help to better understand the effectiveness of sport-based HIV prevention, answer questions about sexual behaviour patterns among informal settlement youth in Cape Town and Port Elizabeth, and help inform HIV prevention efforts for young people in South Africa.

Endnotes

[1] Consistent with other school-based HIV prevention trials, we originally designed the study to use a written participant assent procedure coupled with a passive parental consent procedure for participants under 18 years, whereby parents would receive written information as well as SMSs about the trial and have the opportunity to opt their child(ren) out of the study. However, the local ethics committee decided that this approach contradicted national law and insisted that the study would only be approved if it employed a written parental/guardian consent process for minors under 18 years. We anticipate that this requirement accounted for the vast majority of non-participation among the 3740 learners (see Figure 1) who were listed on registers but did not enroll in the trial.

[2] Twenty-two schools in Soweto had agreed to participate in the trial and we anticipated being able to recruit at least 30 schools (with at least 3000 more participants) between Soweto and Alexandra. The Gauteng provincial Department of Education did not approve the study, however, stating that after a recent lawsuit, the department was not allowing any research to take place in schools until further notice.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

DR and SDM are co-Principal Investigators, responsible for overall design and implementation of the study; both contributed to the intellectual content and writing of the paper. ZK conceived of and manages the study, conducted the analysis and drafted the manuscript. EK and JD participated in study design, developed the intervention, and support study implementation. HW advised on the design of the study as well as the statistical analysis plan. SD supervised baseline data collection and leads the process evaluation. All authors have contributed to and offered edits on the original draft, and all have read and approved the final manuscript.

Role of the funding source

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Figure 1: GOAL Trial participant flow diagram

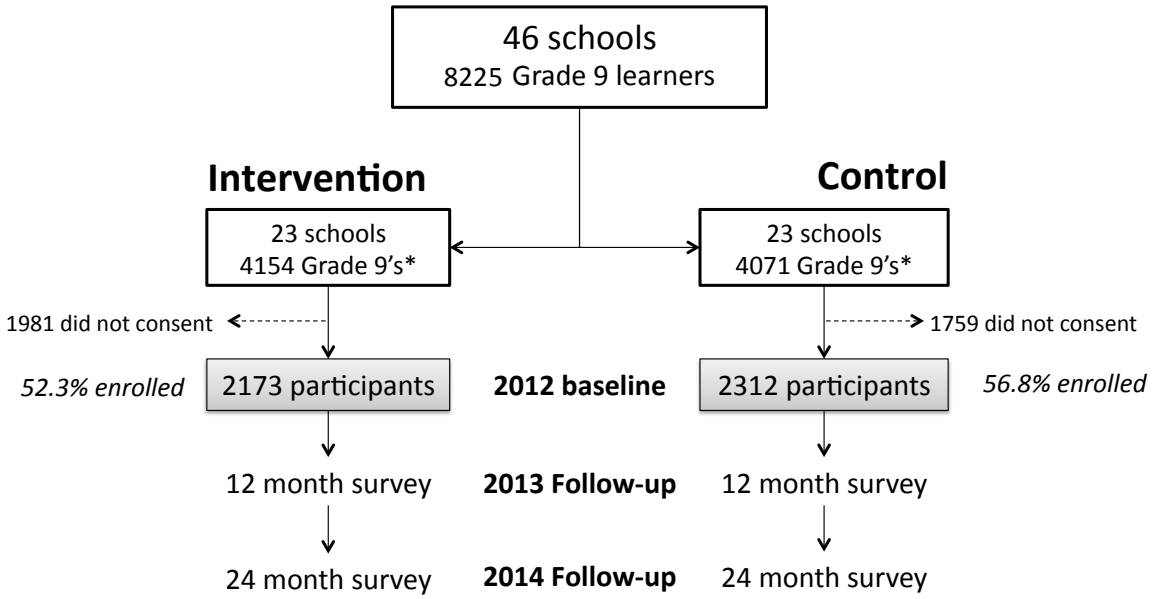


Table 1: Enrolment by group and by site

Group	Cape Town	Port Elizabeth 1	Port Elizabeth 2
Intervention			
Schools	8	8	7
Estimated learners*	1584	1286	1284
GOAL Participants	822	785	566
Percent Enrolled	52%	61%	44%
Control			
Schools	8	7	8
Estimated learners*	1547	1173	1351
GOAL Participants	762	792	758
Percent Enrolled	49%	68%	56%

*Estimates based on the number of students listed on school registers in January 2012

Table 2: Sample characteristics by group and by sex (n=4485)

	All				Males				Females			
	Intervention		Control		Intervention		Control		Intervention		Control	
Characteristic	**N**	**%**	N	%	N	%	N	%	N	%	N	%
All participants	2173	48.5	2312	51.6	939	43.2	1052	45.5	1234	56.8	1260	54.5
Site												
Cape Town	822	37.8	762	33.0	306	32.6	306	29.1	516	41.8	456	36.2
Port Elizabeth 1	785	36.1	792	34.3	378	40.3	382	36.3	407	33.0	410	32.5
Port Elizabeth 2	566	26.0	758	32.8	255	27.2	364	34.6	311	25.2	394	31.3
Race (self-identified)												
Black	1946	92.4	2066	91.8	826	91.4	943	92.0	1120	93.2	1123	91.6
Coloured	62	2.9	57	2.5	34	3.8	19	1.9	28	2.3	38	3.1
White	78	3.7	98	4.4	33	3.7	51	5.0	45	3.7	47	3.8
Indian	9	0.4	15	0.7	6	0.7	6	0.6	3	0.2	9	0.7
Other or N/A	11	0.5	15	0.7	5	0.6	6	0.6	6	0.5	9	0.7
Language spoken at home												
Xhosa	2092	96.3	2204	95.3	905	96.4	998	94.9	1187	96.2	1206	95.7
English	35	1.6	51	2.2	14	1.5	28	2.7	21	1.7	23	1.8
Sesotho	19	0.9	29	1.3	4	0.4	13	1.2	15	1.2	16	1.3
Other	27	1.2	28	1.2	16	1.7	13	1.2	11	0.9	15	1.2
Orphan status												
Both parents living	1557	71.7	1631	70.5	692	73.7	744	70.7	865	70.1	887	70.4
Single orphan	501	23.1	537	23.2	200	21.3	249	23.7	301	24.4	288	22.9
Double orphan	115	5.3	144	6.2	47	5.0	59	5.6	68	5.5	85	6.7
Parents in Household												
Live w/both parents	773	35.9	737	32.2	342	36.8	352	34.0	431	35.3	385	30.8
Live w/mother only	849	39.5	929	40.6	367	39.5	409	39.6	482	39.4	520	41.5
Live w/father only	110	5.1	142	6.2	59	6.4	85	8.2	51	4.2	57	4.6
Live w/neither parent	419	19.5	478	20.9	161	17.3	188	18.2	258	21.1	290	23.2
Mother's education												
None	152	8.1	205	10.0	72	8.9	108	11.9	80	7.4	97	8.5
Primary	292	15.5	354	17.3	125	15.4	165	18.1	167	15.5	189	16.6
Some secondary	553	29.3	587	28.6	222	27.3	241	26.5	331	30.8	346	30.3
Completed Secondary	626	33.2	632	30.8	282	34.7	265	29.1	343	31.9	367	32.2
Higher	264	14.0	273	13.3	111	13.7	131	14.4	153	14.2	142	12.4
Father's education												
None	172	9.8	226	11.9	61	8.1	109	12.7	111	11.1	117	11.3
Primary	274	15.7	305	16.1	125	16.7	134	15.7	149	14.9	171	16.4
Some secondary	402	23.0	475	25.1	162	21.6	207	24.2	240	24.0	268	25.8
Completed Secondary	607	34.7	560	29.6	271	36.2	244	28.5	336	33.6	316	30.4
Higher	295	16.9	329	17.4	130	17.4	161	18.8	165	16.5	168	16.2
Characteristic	**Med.**	**IQR**	**Med.**	**IQR**	**Med.**	**IQR**	**Med.**	**IQR**	**Med.**	**IQR**	**Med.**	**IQR**
Age	15	15 - 16	16	15 - 17	16	15 - 17	16	15 - 17	15	14 - 16	15	15 - 16
Household size	5	4 - 6	5	4 - 6	5	4-6	5	4-6	5	4 - 6	5	4 - 6
Asset Score	0.7	0.7-0.8	0.7	0.7-0.8	0.8	0.7-0.8	0.8	0.7-0.8	0.7	0.6-0.8	0.7	0.6-0.8
Media Connectedness Score	0.4	0.2-0.6	0.4	0.2-0.6	0.4	0.2-0.6	0.4	0.2-0.6	0.4	0.2-0.6	0.4	0.2-0.6

Med = Median ; IQR = Inter-quartile range

Table 3: Knowledge, reported attitudes, and reported behaviour by group and by sex (n=4485)

	Males (n=1991)				Females (n=2494)			
Item	Intervention		Control		Intervention		Control	
Knowledge & Attitudes	mean	SD	mean	SD	mean	SD	mean	SD
HIV Knowledge (out of 10)	5.60	1.98	5.62	1.95	5.58	2.00	5.50	2.07
HIV Stigma (out of 3)	2.05	0.54	1.98	0.56	2.10	0.55	2.09	0.56
HIV Self-efficacy (out of 3)	1.89	0.52	1.85	0.54	1.89	0.52	1.85	0.54
GEM Scale (out of 3)	1.59	0.31	1.57	0.29	1.64	0.33	1.66	0.32
Health and Behaviour	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Circumcised (males)								
Yes	147	14.0	72	7.7				
No	741	70.4	677	72.3				
Don't want to answer	164	15.6	188	20.1				
Depressive Symptoms	235	25.0	331	31.5	324	26.7	333	26.4
Harmful alcohol use	211	22.5	257	24.4	149	12.1	163	12.9
Ever tested for HIV	264	28.2	339	32.2	430	34.9	455	36.1
Ever had sex	603	68.2	684	70.0	482	40.9	543	45.1
Ever used a condom*	374	62.0	411	60.1	332	68.9	384	70.7
Used condom at first sex*	264	45.2	283	43.3	279	67.2	309	66.3
Used condom at last sex*	317	52.6	347	50.7	257	53.3	298	54.9
Lifetime partners								
0, or don't want to answer	298	33.7	349	35.2	753	63.9	728	60.5
1	125	14.1	142	14.3	214	18.2	221	18.4
2	149	16.9	136	13.7	116	9.8	136	11.3
3 or 4	148	16.7	188	19.0	61	5.2	93	7.7
5 or more	164	18.6	177	17.8	35	3.0	26	2.2
Partners in last 12 months								
0, or don't want to answer	295	33.4	338	34.1	742	62.9	725	60.2
1	252	28.5	261	26.3	314	26.6	334	27.7
2	165	18.7	190	19.2	83	7.0	104	8.6
3 or 4	116	13.1	129	13.0	30	2.5	30	2.5
5 or more	56	6.3	74	7.5	10	0.8	11	0.9
Intimate-partner Violence (IPV)	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Ever perpetrated IPV (males)	314	33.4	396	37.6				
Ever perpetrated rape (males)*	143	23.7	199	29.1				
Ever a victim of IPV (females)					368	29.8	385	30.6

*Restricted to participants who reported having ever had sex



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Linking section 1: Innovative uses of web and mobile technology in the GOAL Trial

While the GOAL Trial adhered to standard best practices in the design and conduct of cluster-randomised trials, it also presented the opportunity to drive innovation in data collection and management. Web and mobile technologies—many of which are free or cheap for non-profits and institutions of higher education—offer many benefits to researchers over traditional pen/paper/spreadsheet approaches, including reducing costs of data collection and storage, providing more confidential survey methods, enhancing data security, and simplifying the jobs of survey staff. This section describes the use of (i) Open Data Kit (ODK) as a mobile phone-based, audio-assisted, self-administered sexual behaviour questionnaire tool, (ii) Force.com as an online database for storage of participation and identifying information, and (iii) SMS-Magic as a Force.com plugin used for composing and sending mass SMS messages.

Selecting a survey tool for the GOAL Trial

Prior to starting the trial, many colleagues and advisors had suggested we use an Audio-Computer-Assisted-Self-Interview (ACASI) method[1] with QDS software to carry out surveys. This recommendation came on the basis of strong evidence from 26 studies that ACASI can reduce reporting bias when used to assess self-reported sexual behaviours.[2] Indeed, the technology has numerous advantages over face-to-face interviews or paper-based self-administered questionnaires, namely that it reduces opportunities for survey administrators to influence participants' responses, it provides greater confidentiality, it negates the need for printing long paper-based questionnaires, it can handle skip patterns (simplifying the survey process), and it improves data quality by reducing the risk of human error by the survey administrator or the participant (i.e., accidentally skipping a question or marking the wrong response).[2,3] ACASI's main disadvantages are the complexity of developing a questionnaire (typically done via Nova Research's proprietary QDS™ software) and its cost (USD 295 for the survey-building software, USD 495 for the warehouse

manager and USD 236-495 per data collection unit). In the context of a clinic-based study where only one survey is conducted at a time, this cost could be manageable, as only one or two data collection units are required. In the context of a study like the GOAL Trial (i.e. collecting up to 50 questionnaires at once in three different sites), however, the costs quickly add up to more than USD 50,000. In this context, we researched alternative technologies that could provide the same advantages as ACASI but where we could afford to collect data on 150 devices.

Four strong alternatives to ACASI were identified, and the costs of carrying out the study via pen-and-paper were also estimated for comparison. iFormsBuilder is an app built for Mac OSx devices. The tool provides a simple user experience and has a user-friendly web-based tool for building surveys. However, it does not allow audio-assistance and, at the time of investigation in 2012, it had a per-device unit cost of USD 360, making it more expensive than ACASI. Mobile Researcher (now called Mobenzi Researcher) was built by a South African company with medical and epidemiological research in mind. Mobile Researcher's primary advantage is that it works on simple, non-smart phones and transmits data via the phone network. Its primary disadvantages are lack of an audio-assistance option and a unit cost based on pieces of data collected (i.e., individual survey questions; roughly USD 0.01 per item), making it a relatively expensive option for long surveys (more than USD 20,000 for three rounds of 4600 surveys with 146 items).[4] Episurveyor (now called Magpi) is similar to Mobile Researcher but requires WAP-enabled phones and does not have a per-question unit cost (rather costing USD 5,000 per year for up to 10,000 surveys and unlimited online storage).[5] It has an easy-to-learn online interface for designing surveys and managing data. Like Mobile Researcher, it does not have an option for audio-assistance, excluding it as an option for the GOAL Trial (though it would be a viable option for studies not needing audio-assistance). Lastly, ODK provides all of ACASI's features (audio assistance, displaying images, skip patterns, multiple languages, etc) plus a few additional benefits such as the ability to collect GPS coordinates, audio, photos, or videos. Surveys for ODK can be built either online via a user-friendly drag-and-drop form builder (ODK Build) or through a more powerful tool called XLSform, which converts a survey designed in Microsoft Excel®

into XML that can be used in ODK. Completed ODK surveys can be transmitted securely into an online database (hosted locally or on Google Appspot) via either Wi-Fi or the phone network. ODK is open-source, so there is no cost for downloading or using the survey-building, data management or data collection software. Table 1 compares the features and costs between the six data collection options we considered for the GOAL Trial (ACASI, ODK, EpiSurveyor, iFormsBuilder, Mobile Researcher, and pen-and-paper).

Table 1: Comparing features and costs of six data collection tools

Characteristic	ACASI (QDS)	iformsbuilder	Open Data Kit (ODK)	Mobile Researcher	EpiSurveyor	Pen-and-paper (SAQ)
Audio assistance	Yes	No	Yes	No	No	No
Display images & videos	Yes	Unclear	Yes	No	No	No
Skip patterns	Yes	Yes	Yes	Yes	Yes	Not automated
Easy to setup	No	Yes	Yes	Yes	Yes	Yes
Multiple languages	Not easy	Easy	Easy	Easy	Easy	Yes
Data transfer	Manual	Wifi	Wifi or network	Phone network	Wifi or network	Manual entry
Support	$$	$$	Online group	30 hrs included	Included	N/A
Costs						
Mgmt software	$ 1,200	0	0	0	0	N/A
Collection unit cost	$ 295	360	0	$ 20,148	$ 5,000	$ 3.00
Unit	per device	per device	N/A	per piece of data	up to 10,000 submissions	per survey (printing + data entry)
Handheld	PDA	ipod touch	Android	Any phone	WAP phone	N/A
HH unit cost	$ 100	$ 150	$ 130	$ 50	$ 50	N/A
Total Cost	**$ 60,450**	**$ 76,500**	**$ 19,500**	**$ 27,648**	**$ 12,500**	**$ 36,000**
Website	novaresearch.com/products/qds/index.cfm	iformbuilder.com	opendatakit.org	mobileresearcher.org	episurveyor.org	N/A
Overall Conclusion	Too expensive. Not as user-friendly as alternatives.	Very user-friendly but no audio and expensive.	Best value for audio-assisted survey. Much easier to setup than ACASI, no software costs. No ongoing costs.	Good option for non-audio-assisted survey. Cheaper than iforms and more appropriate. Each survey round would cost about $7,000 in "credits".	'dumb' phones if audio is not needed. Especially good option if relatively small numbers of surveys are conducted.	Lacks the features of new technology options, more expensive when considering data entry time

Note: Cost calculations assume 150 data collection units, 12,000 submissions, and 120 items

Key features of ODK for self-administered sexual behaviour questionnaires

The key features of ODK that made it stand out as the optimal tool for mobile data collection in the GOAL Trial (in addition to its cost advantages) were (i) skip patterns, (ii) validation, (iii) multi-language support, (iv) optional audio assistance, (v) the ability to send data through Wi-Fi or the phone network, and (vi) the ease of setup. Screenshots, explanations, and examples are provided below for each of these features.

Skip patterns and validation

One key feature of ODK is that simple and complex skip patterns can be easily configured. Of the 146-items in the baseline survey, 70 had skip-pattern logic built-in. The way skip patterns are configured into ODK is through the '*relevant*' XML attribute of a bind call. For example, the XML code below shows how the question 'Have you ever used a condom?' is only asked to participants who answer Yes to 'Have you ever had sex?'. The *relevant* attribute for the second question is shown in bold.

<bind nodeset="/GOAL-baseline/sex_ever" required="true()" type="select1"/>

<bind nodeset="/GOAL-baseline/condom_ever" ***relevant=" /GOAL-baseline/sex_ever = 1****" required="true()" type="select1"/>*

Multiple conditions can be used for the same item with appropriate AND / OR logic. On the surface, the logic for configuring an ODK skip pattern is backwards from building a skip pattern into a paper-based questionnaire. In the latter, one would put "If No, skip to Item 74" next to the question causing the skip, whereas in ODK the logic is coded into the item being skipped, essentially telling the device 'only show this item if Item 72 is Yes'. Validation is also a key element for self-administered questionnaires, to ensure that participants provide answers that are consistent. For example, we built in validation to ensure that the number of sexual partners reported in the last year was equal-to or less-than the number of sexual partners reported ever. The XML code below shows how this is accomplished using the '*constraint'* attribute and a period in reference to the given answer.

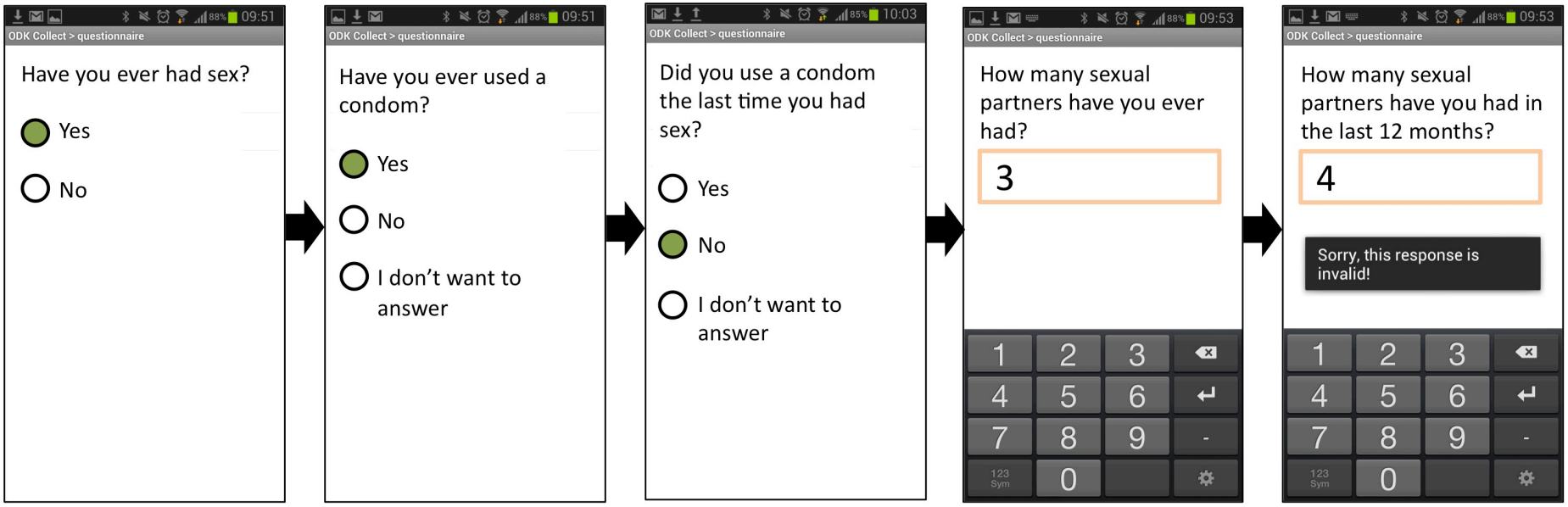
<bind nodeset="/GOAL-baseline/partners_ever" relevant=" /GOAL-baseline /sex_ever = 1" required="true()" type="select1"/>

<bind ***constraint=". <= /GOAL-baseline/partners_ever or . = 99" constraintMsg="Your answer must be less than or the same as your number of lifetime partners."*** *nodeset="/GOAL-baseline/partners_12" relevant=" /GOAL-baseline/sex_ever = 1" required="true()" type="select1"/>*

The three figures below illustrate how this plays out on a mobile device.

Figure 1: Illustrative ODK screenshots showing skip patterns for three participants

Participant A (has had sex and used a condom):



Multiple choice response option selected via touch screen, and entered by swiping the screen to see the next question

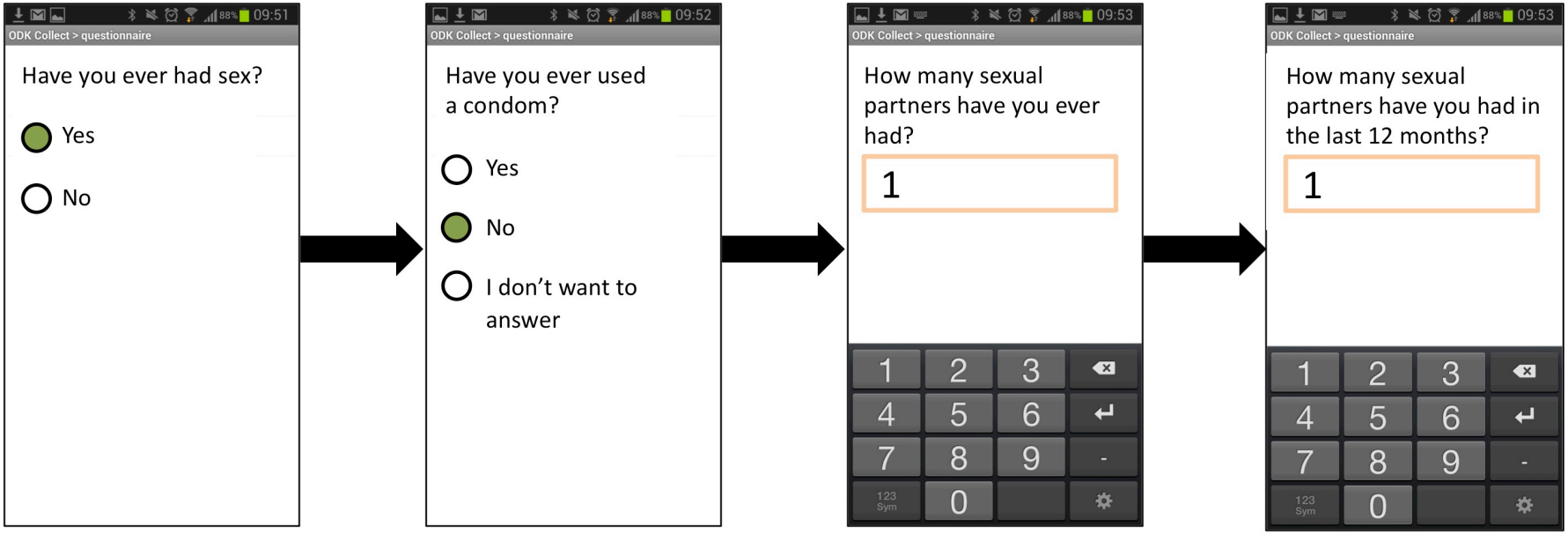
Participants can be given the option to refuse to answer a question

One question appears on the screen; previous answers are saved so that they can either be revisited or not

Numbers (or letters) can be entered

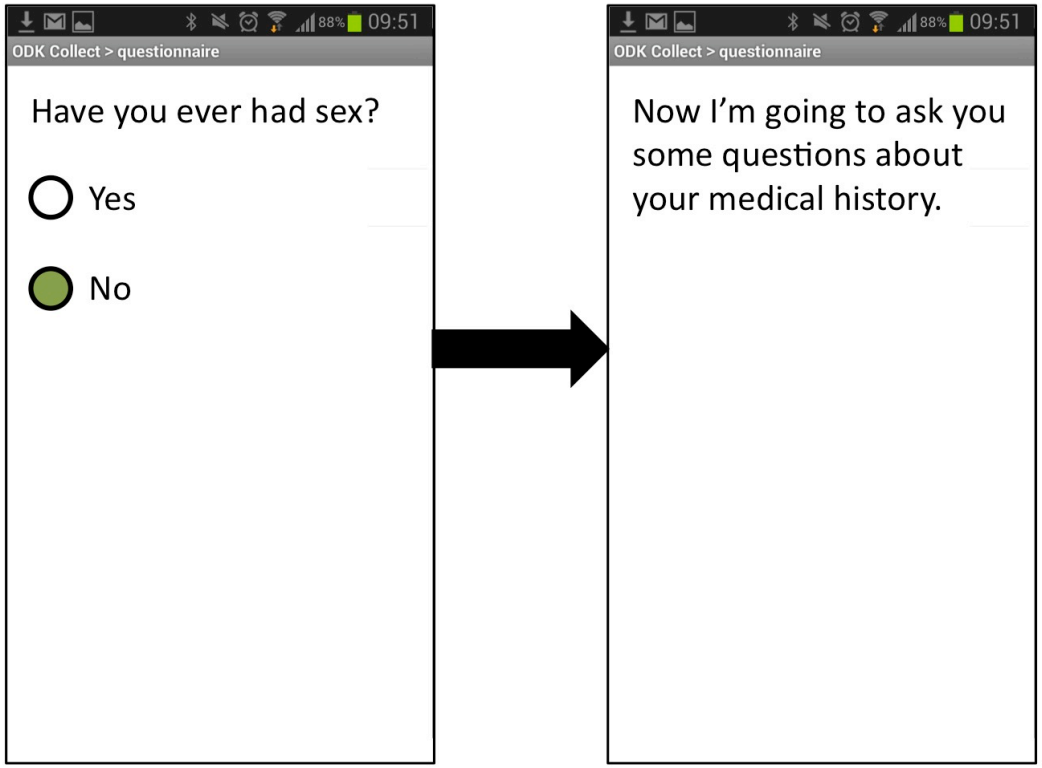
Data can be checked for range or consistency as they are entered

Participant B (has had sex but never used a condom):



Based on the "No" response to the "Have you ever used a condom?" question, the form was pre-programmed to skip the question "Did you use a condom the last time you had sex?"

Participant C (has never had sex):

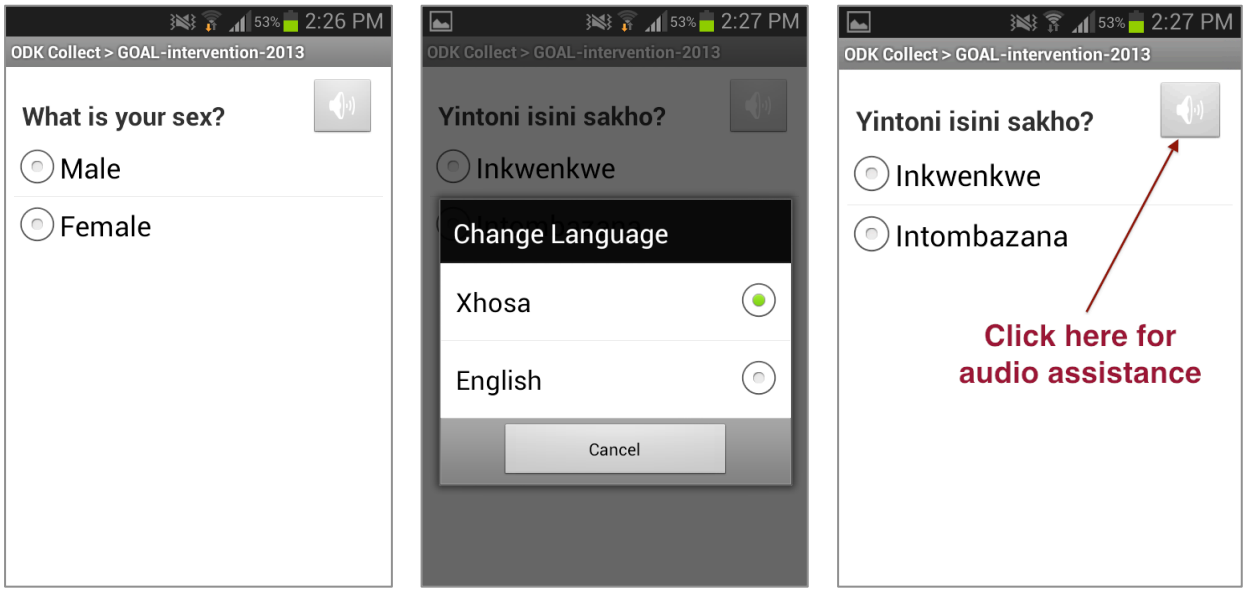


Based on the "No" response to the "Have you ever had sex?" question, the form was pre-programmed to skip to the end of the series of questions about condom use and sexual partners

Multi-language support and audio assistance

A critical element of any self-administered questionnaire is ensuring it is completed in a language that the participant understands. In the GOAL Trial, though nearly all participants were comfortable reading and writing in English, more than 95 percent were native Xhosa speakers, so it was important to have the option for participants to complete the questionnaire in Xhosa. Figure 2 shows how users can change from English to Xhosa as well as the button available to get audio assistance.

Figure 2: Illustrative ODK screenshots showing multi-language support and audio assistance



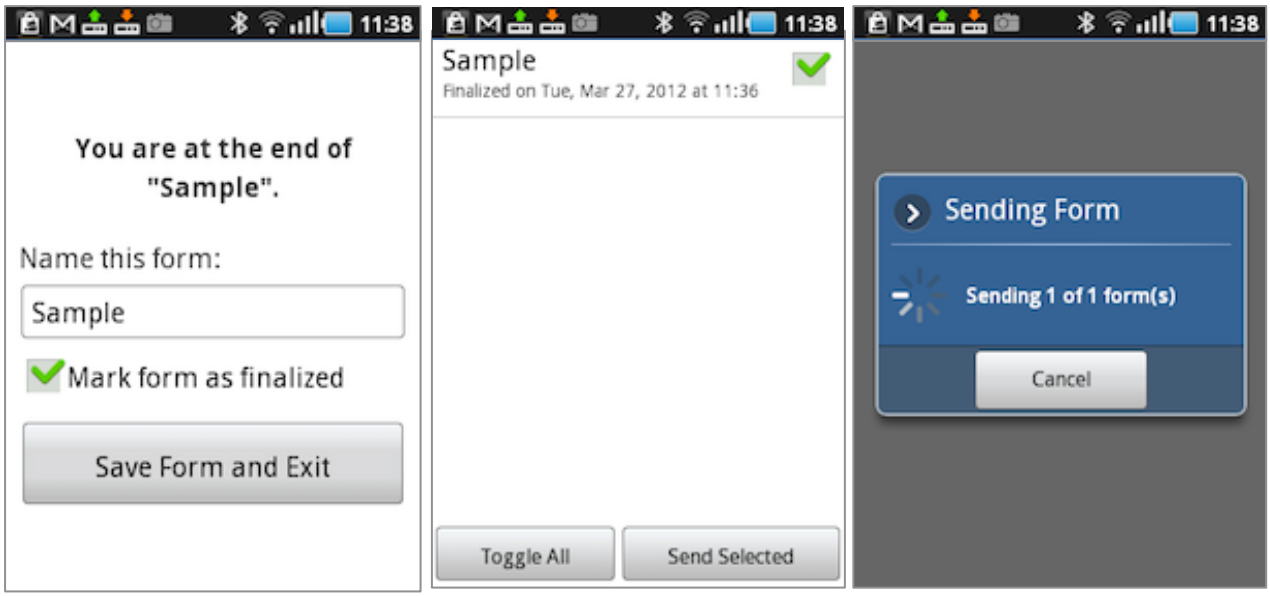
User can change the language by pushing the menu button. This brings up the middle screen where they can select which language they would like to use. More than two languages can be configured.

Submitting surveys through Wi-Fi or the phone network

Whereas computer-based ACASI tools either require storing completed survey files locally or transferring them manually from the collection device to a storage device, data collected using ODK Collect are stored in a secure ODK Aggregate database, which can either be stored online or locally. Unfinished ODK surveys can be saved on the device—not marked as finalized—and finished at a later time. When a survey is saved and marked as finalized (the default setting when reaching the end of the survey), the survey file is locked on the phone, making it impossible for anyone to review or modify the data. Data can then be transmitted to ODK aggregate either by transferring the file(s) to a computer (as with ACASI) and uploading them using ODK

Briefcase,[1] through a Wi-Fi connection or through the phone network. Figure 3 shows how this is done on a mobile phone after a survey has been completed.

Figure 3: Illustrative ODK screenshots showing how data are saved and sent to the online database

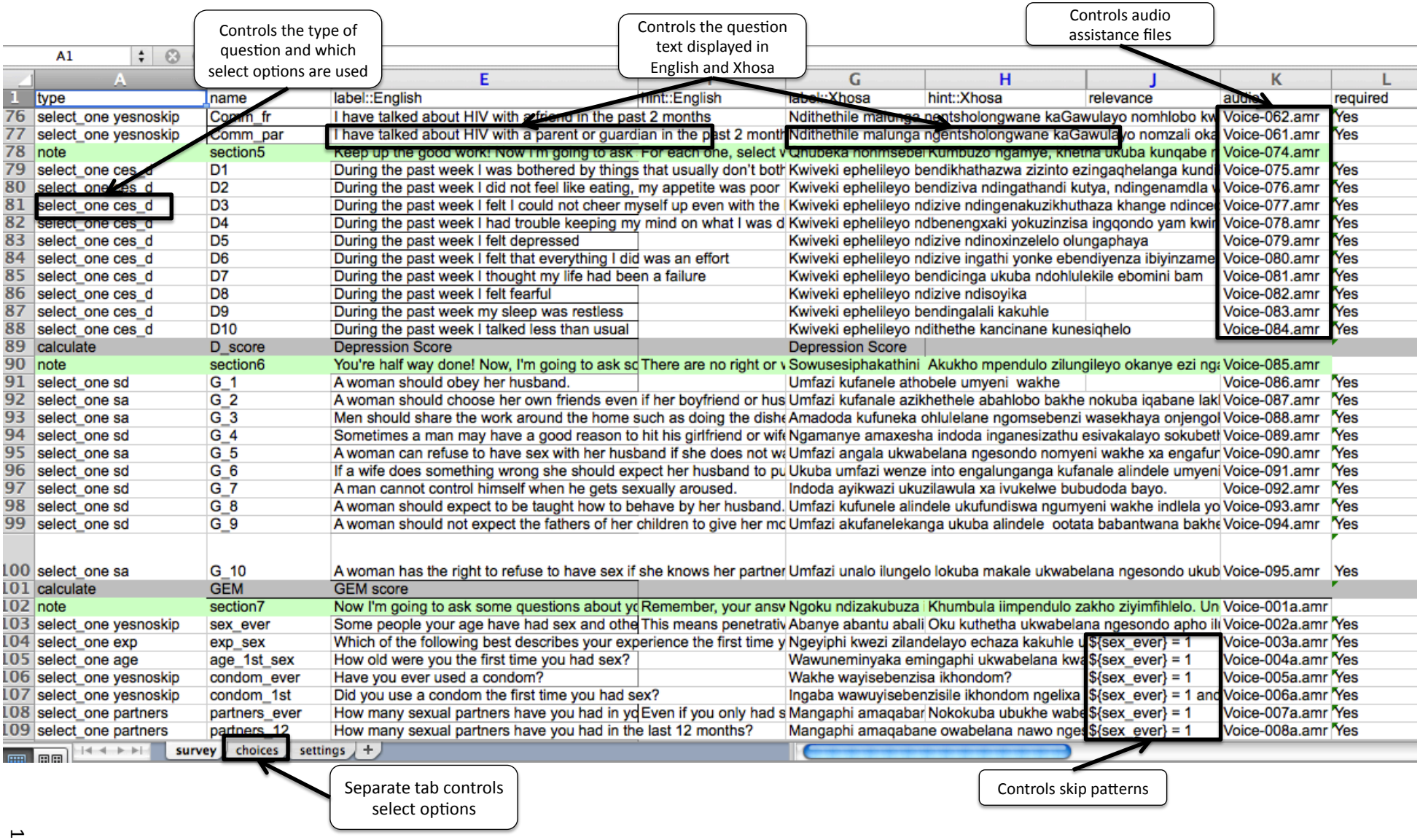


Ease of ODK setup

Another key advantage of ODK over QDS™ is the ease of setting up devices, surveys and the ODK Aggregate database. Setting up devices with the ODK Collect application is the simplest step, as the application is freely available with two clicks from the Google Play store. Once installed, the app can be opened directly on the device without further setup. ODK Aggregate is installed via a PC or Mac computer through a five-step process documented online.[2] Surveys then need to be configured and sent to both ODK Aggregate and the mobile devices. For the GOAL Trial, we configured the surveys in Microsoft Excel® and then converted the XLSX files into XML files (which are used by ODK) using ODK's XLSform conversion tool.[3] This approach is more efficient and less error-prone than writing XML code directly and more powerful than using ODK Build,[4] ODK's drag-and-drop online tool for survey-building that, at the time of GOAL survey building, did not allow for audio assistance, complex skip patterns or calculations. Figure 4 illustrates how the GOAL surveys were configured in Excel®. After the XLSX file was converted into XML, this file was uploaded to ODK Aggregate and then downloaded onto each mobile device (note: the files can be downloaded from ODK Aggregate or transferred directly from a

computer to a mobile device via USB or Bluetooth). Finally, the settings of ODK Collect need to be configured with the server address (e.g., https://goaltrial.appspot.com) and a username and password with data collection permissions on the relevant ODK Aggregate account.

Figure 4: Annotated screenshot of how the GOAL Trial survey was designed in Excel® before conversion to XML



	A	B	E	F	G	H	J	K	L
1	type	name	label::English	hint::English	label::Xhosa	hint::Xhosa	relevance	audio	required
76	select_one yesnoskip	Comm_fr	I have talked about HIV with a friend in the past 2 months		Ndithethile malunga ngentsholongwane kaGawulayo nomhlobo kw			Voice-062.amr	Yes
77	select_one yesnoskip	Comm_par	I have talked about HIV with a parent or guardian in the past 2 month		Ndithethile malunga ngentsholongwane kaGawulayo nomzali oka			Voice-061.amr	Yes
78	note	section5	Keep up the good work! Now I'm going to ask For each one, select v		Qhubeka nomnsebel	Kumbuzo ngamye, khetha ukuba kunqabe r		Voice-074.amr	
79	select_one ces_d	D1	During the past week I was bothered by things that usually don't both		Kwiveki ephelileyo bendikhathazwa zizinto ezingaqhelanga kund			Voice-075.amr	Yes
80	select_one ces_d	D2	During the past week I did not feel like eating, my appetite was poor		Kwiveki ephelileyo bendiziva ndingathandi kutya, ndingenamdla v			Voice-076.amr	Yes
81	select_one ces_d	D3	During the past week I felt I could not cheer myself up even with the		Kwiveki ephelileyo ndizive ndingenakuzikhuthaza khange ndince			Voice-077.amr	Yes
82	select_one ces_d	D4	During the past week I had trouble keeping my mind on what I was d		Kwiveki ephelileyo ndbenengxaki yokuzinzisa ingqondo yam kwi			Voice-078.amr	Yes
83	select_one ces_d	D5	During the past week I felt depressed		Kwiveki ephelileyo ndizive ndinoxinzelelo olungaphaya			Voice-079.amr	Yes
84	select_one ces_d	D6	During the past week I felt that everything I did was an effort		Kwiveki ephelileyo ndizive ingathi yonke ebendiyenza ibiyinzame			Voice-080.amr	Yes
85	select_one ces_d	D7	During the past week I thought my life had been a failure		Kwiveki ephelileyo bendicinga ukuba ndohlulekile ebomini bam			Voice-081.amr	Yes
86	select_one ces_d	D8	During the past week I felt fearful		Kwiveki ephelileyo ndizive ndisoyika			Voice-082.amr	Yes
87	select_one ces_d	D9	During the past week my sleep was restless		Kwiveki ephelileyo bendingalali kakuhle			Voice-083.amr	Yes
88	select_one ces_d	D10	During the past week I talked less than usual		Kwiveki ephelileyo ndithethe kancinane kunesiqhelo			Voice-084.amr	Yes
89	calculate	D_score	Depression Score		Depression Score				
90	note	section6	You're half way done! Now, I'm going to ask sc	There are no right or v	Sowusesiphakathini	Akukho mpendulo zilungileyo okanye ezi ng		Voice-085.amr	
91	select_one sd	G_1	A woman should obey her husband.		Umfazi kufanele athobele umyeni wakhe			Voice-086.amr	Yes
92	select_one sa	G_2	A woman should choose her own friends even if her boyfriend or hus		Umfazi kufanale azikhethele abahlobo bakhe nokuba iqabane lak			Voice-087.amr	Yes
93	select_one sa	G_3	Men should share the work around the home such as doing the dishe		Amadoda kufuneka ohlulelane ngomsebenzi wasekhaya onjengol			Voice-088.amr	Yes
94	select_one sd	G_4	Sometimes a man may have a good reason to hit his girlfriend or wife		Ngamanye amaxesha indoda inganesizathu esivakalayo sokubetl			Voice-089.amr	Yes
95	select_one sa	G_5	A woman can refuse to have sex with her husband if she does not wa		Umfazi angala ukwabelana ngesondo nomyeni wakhe xa engafur			Voice-090.amr	Yes
96	select_one sd	G_6	If a wife does something wrong she should expect her husband to pu		Ukuba umfazi wenze into engalunganga kufanale alindele umyeni			Voice-091.amr	Yes
97	select_one sd	G_7	A man cannot control himself when he gets sexually aroused.		Indoda ayikwazi ukuzilawula xa ivukelwe bududoda bayo.			Voice-092.amr	Yes
98	select_one sd	G_8	A woman should expect to be taught how to behave by her husband.		Umfazi kufunele alindele ukufundiswa ngumyeni wakhe indlela yo			Voice-093.amr	Yes
99	select_one sd	G_9	A woman should not expect the fathers of her children to give her mc		Umfazi akufanelekanga ukuba alindele ootata babantwana bakhe			Voice-094.amr	Yes
100	select_one sa	G_10	A woman has the right to refuse to have sex if she knows her partner		Umfazi unalo ilungelo lokuba makale ukwabelana ngesondo ukub			Voice-095.amr	Yes
101	calculate	GEM	GEM score						
102	note	section7	Now I'm going to ask some questions about yc	Remember, your answ	Ngoku ndizakubuza	Khumbula iimpendulo zakho ziyimfihlelo. Un		Voice-001a.amr	
103	select_one yesnoskip	sex_ever	Some people your age have had sex and othe	This means penetrativ	Abanye abantu abali	Oku kuthetha ukwabelana ngesondo apho il		Voice-002a.amr	Yes
104	select_one exp	exp_sex	Which of the following best describes your experience the first time y		Ngeyiphi kwezi zilandelayo echaza kakuhle u		${sex_ever} = 1	Voice-003a.amr	Yes
105	select_one age	age_1st_sex	How old were you the first time you had sex?		Wawuneminyaka emingaphi ukwabelana kwa		${sex_ever} = 1	Voice-004a.amr	Yes
106	select_one yesnoskip	condom_ever	Have you ever used a condom?		Wakhe wayisebenzisa ikhondom?		${sex_ever} = 1	Voice-005a.amr	Yes
107	select_one yesnoskip	condom_1st	Did you use a condom the first time you had sex?		Ingaba wawuyisebenzisile ikhondom ngelixa		${sex_ever} = 1 and	Voice-006a.amr	Yes
108	select_one partners	partners_ever	How many sexual partners have you had in yo	Even if you only had s	Mangaphi amaqabar	Nokokuba ubukhe wabe	${sex_ever} = 1	Voice-007a.amr	Yes
109	select_one partners	partners_12	How many sexual partners have you had in the last 12 months?		Mangaphi amaqabane owabelana nawo nge		${sex_ever} = 1	Voice-008a.amr	Yes

Acceptability of ODK among GOAL Trial participants

A mixed methods approach was used to assess participants' acceptability of ODK. The methods used were three-fold. These data were presented in 2013 at the STI & AIDS World Forum in Vienna.[5] First, four questions were included at the end of the questionnaire to ascertain participants' reported understanding, comfort, honesty, and survey method preference (phone-based vs. pen-and-paper). The questions were analysed descriptively and also using random-effects logistic and linear regression to assess sex differences in acceptability. Secondly, five focus group discussions (FGDs) were carried out with a total of 20 participants and survey administrators in Cape Town, Port Elizabeth and Soweto (the latter during a survey pre-test). These FGDs were transcribed and analysed for themes, with quotes pulled out to illustrate commonly reported feelings. Lastly, non-response rates were analysed for selected sensitive questions. Participants had been given the option to select "I don't want to answer" – the proportion of participants who selected this answer was analysed descriptively.

Focus group discussions

FGDs found that the participants reported being comfortable and engaged when using the mobile phones to complete the self-administered questionnaire. Overall reported satisfaction with the phones and the tool was quite high among focus group participants, with both males and females unanimously endorsing the touchscreen phones as 'cool', 'fun' and 'new'.

> **"This is the *coolest!* If every exam was like this, we would do so much better [in school]."** – Male pre-testing participant, Soweto

There was a strong reported feeling that using the mobile phone provided increased privacy and confidentiality when answering sensitive questions, compared to self-administered paper-based sexual behavior surveys.

> **"I was honest with all the questions because I know no one will read my answer and I get privacy."** – Male participant; Port Elizabeth
>
> **"I felt comfortable and I was happy. It was like talking to someone that I trust."** – Female participant; Port Elizabeth
>
> **"It was like I was talking to myself...it felt like it was my diary."** – Female pre-testing participant; Soweto

These quotes illustrate sentiments that were echoed by other focus group participants, suggesting that the ODK approach created a suitable environment for collecting sensitive data. A more detailed analysis of the data collected from focus groups will be presented in a forthcoming paper.

Structured items on reported acceptability

Table 2 presents data on reported ODK acceptability and non-response rates from selected sensitive items from the GOAL baseline survey. In all, 4015 (78.1%) participants reported preferring the mobile-phone-based survey to pen-and-paper survey, while 716 (13.9%) reported preferring pen-and-paper. After adjusting for school and age, males had lower odds of reporting preferring the phone-based survey than females (p=0.048), reporting that the questionnaire was easy (p=0.001), reporting that they understood most or all of the questions on the questionnaire (p=0.03), reporting that they answered most or all of the questions honestly (p<0.001), and reporting that they felt comfortable taking the questionnaire (p=0.03).

Table 2: Reported acceptability, ease, understanding, and comfort of ODK survey (n=4482)

	Males (n=1989)		Females (n=2491)		Diff*
Questionnaire Item (answer)	**n**	**%**	**n**	**%**	**P value**
Do you prefer this type of questionnaire (on a phone) or a pen-and-paper questionnaire?					
Phone	1489	74.9	1952	78.4	
Pen-and-paper	177	8.9	197	7.9	0.05
No preference	323	16.2	342	13.7	
How easy or difficult was it to use this phone for the questionnaire? (Very easy or pretty easy)	1398	70.3	1931	77.5	0.001
How well do you feel you understood the questions on this questionnaire? (Most or all questions)	1086	54.6	1515	60.8	0.03
How well were you able to answer questions on the questionnaire honestly? (Most or all questions)	1079	54.3	1619	65.0	<0.001
How comfortable did you feel taking this questionnaire? (Very comfortable or pretty comfortable)	1191	59.9	1638	65.8	0.03

*Via random-effects logistic or linear regression, adjusting for age group and school-level clustering

Non-response rates

Table 3 presents descriptive data by sex on non-response rates for selected sensitive questionnaire items. After adjusting for age group and school-level clustering, more males (n=72, 3.6%) than females (n=48, 1.9%) selected "I don't want to answer" for HIV testing (OR=1.73, 95%CI=1.18-2.53). Non-response on reported condom use ever was higher and differed by sex, with fewer males (n=53, 4.1%) than females (n=147, 14.3%) refusing to answer (OR=0.26, 95%CI=0.18-0.36). A similar pattern was observed for reported number of sexual partners in the last year, with fewer males (n=44, 3.4%) than females (n=109, 10.6%) choosing not to respond (OR=0.31, 95%CI=0.21-0.45). Non-response was slightly lower when asking participants about their frequency of alcohol consumption, with 111 males (5.6%) and 130 females (5.2%) choosing not to respond (OR=1.05, 95%CI=0.81-1.38). The item with the highest non-response was "Are you circumcised?" (only asked to males: 17.7% refused to answer).

Table 3: Non-responses on selected sensitive questions at baseline of the GOAL Trial (n=4485)

	Males		Females		Diff	
Questionnaire Item	**n/N**	**%**	**n/N**	**%**	**OR**	**95% CI**
Have you ever been tested for HIV?	72/1989	3.6	48/2491	1.9	**1.73**	**1.18-2.53**
Have you ever used a condom?	53/1287	4.1	147/1025	14.3	**0.26**	**0.18-0.36**
Have you ever had a sexually transmitted infection? (such as herpes, syphillis or gonorrhea)	116/1287	9.0	73/1025	7.1	1.26	0.93-1.73
How many sexual partners have you had in the last 12 months?	44/1287	3.4	109/1025	10.6	**0.31**	**0.21-0.45**
How often do you have a drink with alcohol?	111/1989	5.6	130/2491	5.2	1.05	0.81-1.38
Are you circumcised?	352/1989	17.7			N/A	

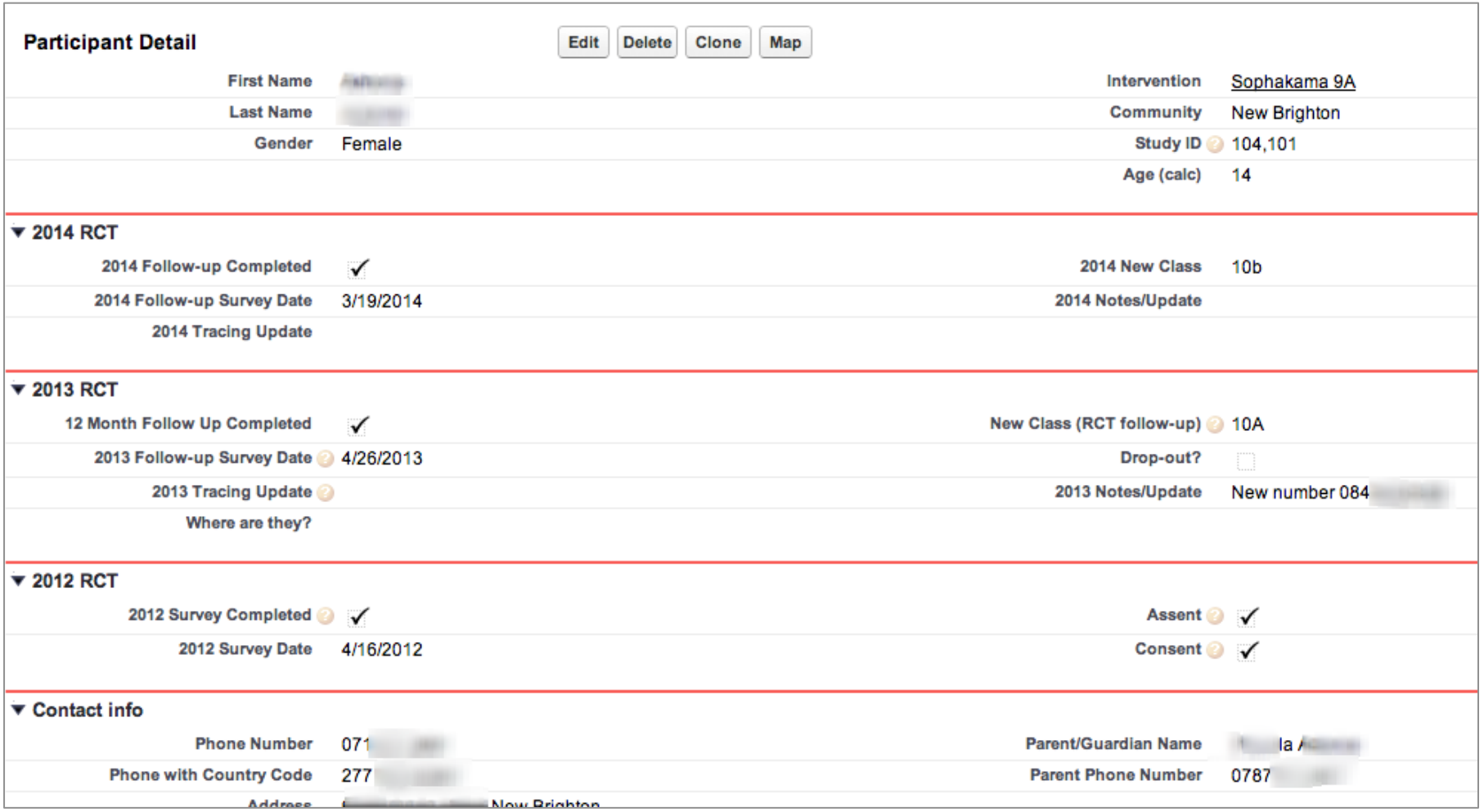
Using Force.com as a trial management database

The Force.com platform, provided as a service by Salesforce.com, is a cloud-computing platform used by more than 100,000 companies and 20,000 non-profits around the world.[6] The platform combines a highly powerful and flexible relational database core with a sophisticated and customizable security model and numerous other features, including workflow automation and user-friendly reporting and analytics. Non-profit

organisations and higher education institutions receive ten free licenses through the Salesforce.com Foundation's Power Of Us Programme and enjoy an 80 percent discount on corporate rates for further licenses.[7] In 2009, GRS transitioned its Excel®-based monitoring and evaluation system over to Force.com and has since used the platform to track the programme participation of more than 500,000 adolescents.[8] Given the success of the Force.com system at GRS and the local staff's familiarity with it, the decision was taken to build the trial participant database on the platform.

The platform was customized to track elements of RCT participation, including study ID, contact information, completion of baseline and follow-up surveys, completion of dried blood spots (DBS), and baseline and follow-up survey dates. A designated member of each survey team was responsible for capturing data (from consent forms and school registers) in Force.com daily. Each survey team only had access to its participants and was not able to see or edit participant records from the other sites. Figure 5 shows an anonymised detailed page of an example participant in New Brighton, Port Elizabeth

Figure 5: Example record detail page of an anonymised GOAL Trial participant



Participant Detail Edit Delete Clone Map

First Name	[redacted]	Intervention	Sophakama 9A
Last Name	[redacted]	Community	New Brighton
Gender	Female	Study ID	104,101
		Age (calc)	14

2014 RCT

2014 Follow-up Completed	✓	2014 New Class	10b
2014 Follow-up Survey Date	3/19/2014	2014 Notes/Update	
2014 Tracing Update			

2013 RCT

12 Month Follow Up Completed	✓	New Class (RCT follow-up)	10A
2013 Follow-up Survey Date	4/26/2013	Drop-out?	☐
2013 Tracing Update		2013 Notes/Update	New number 084 [redacted]
Where are they?			

2012 RCT

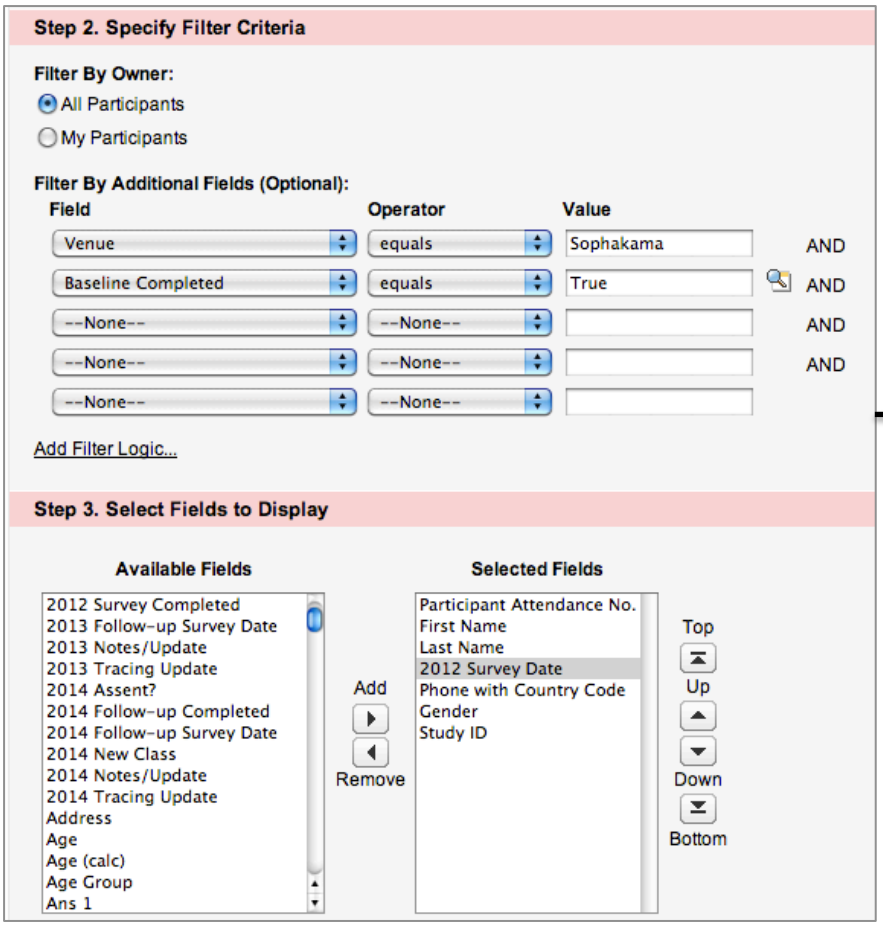
2012 Survey Completed	✓	Assent	✓
2012 Survey Date	4/16/2012	Consent	✓

Contact info

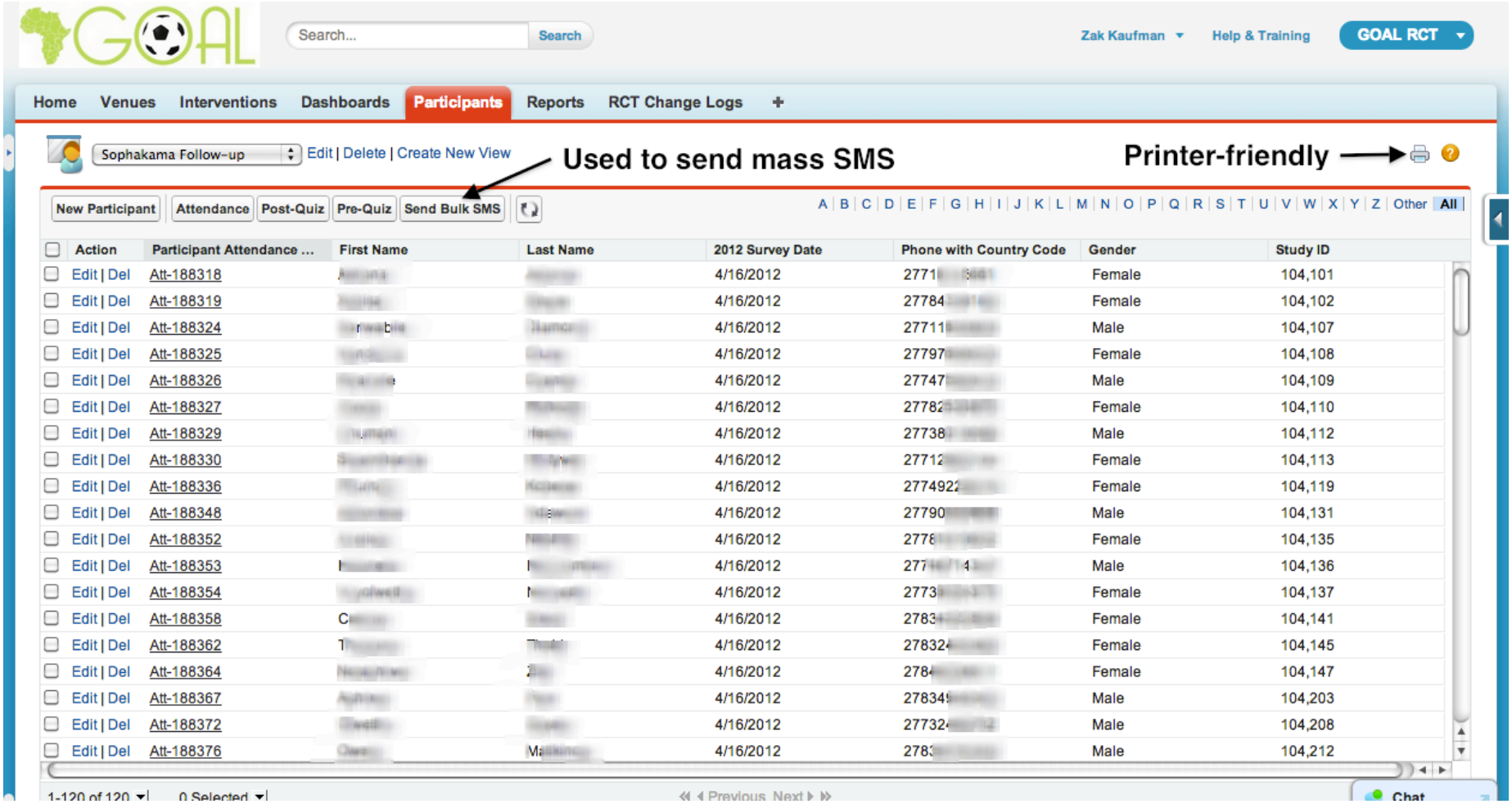
Phone Number	071 [redacted]	Parent/Guardian Name	[redacted]
Phone with Country Code	277 [redacted]	Parent Phone Number	0787 [redacted]
Address	[redacted] New Brighton		

Force.com's list view feature enables users to easily filter based on any number of criteria and to generate a simple table of data. This was used to prepare class lists before visiting a school during a survey day. Figure 6 shows an example list view filter used at follow-up to filter to participants at Sophakama high school who completed the baseline survey. The list view feature was also used in conjunction with a Force.com-based application called SMS-Magic to send mass SMS's for the Generation Skillz SMS campaign.

Figure 6: Screenshot of list view feature, including filter criteria

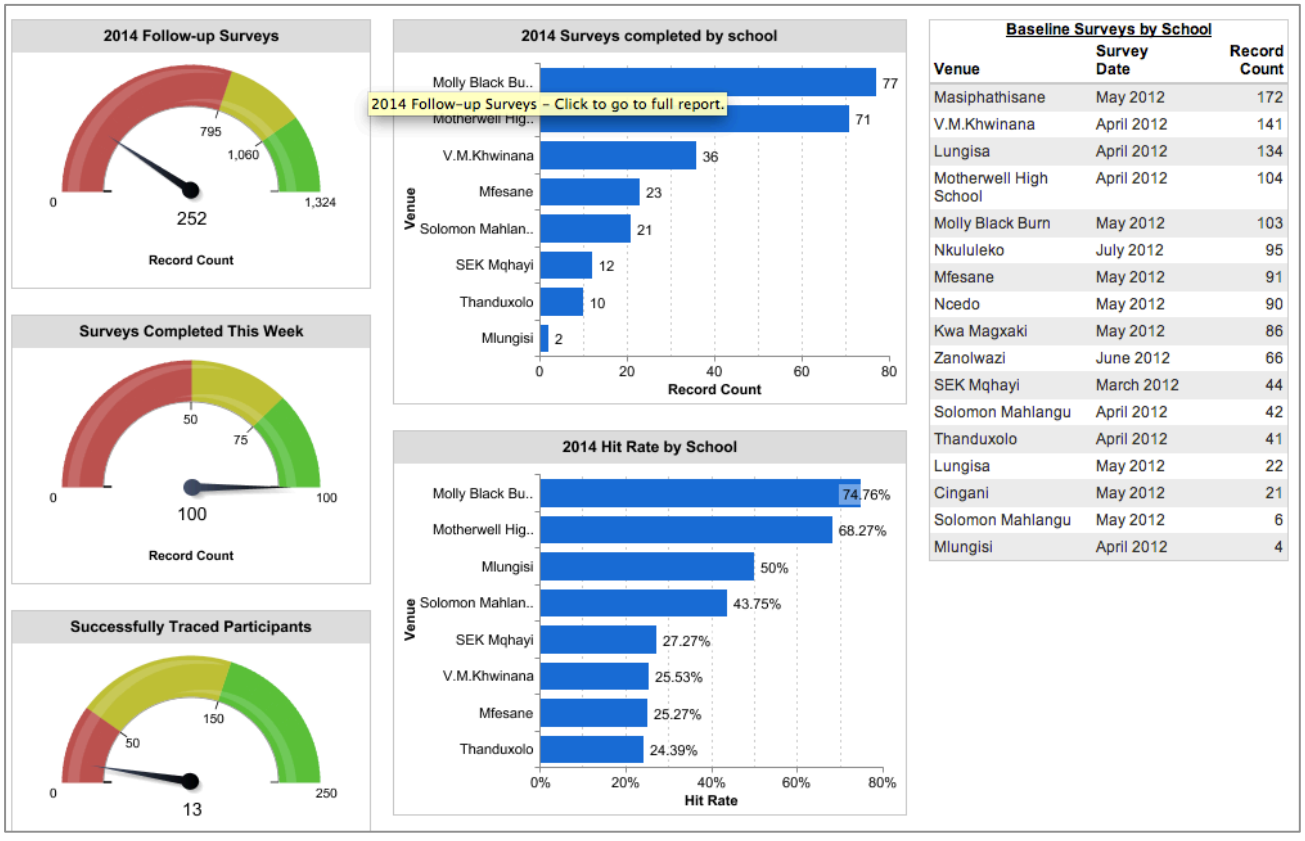


See list view on next page


Search...
Search
Zak Kaufman
Help & Training
GOAL RCT
Home
Venues
Interventions
Dashboards
Participants
Reports
RCT Change Logs
Sophakama Follow-up
Edit | Delete | Create New View
Used to send mass SMS
Printer-friendly
New Participant
Attendance
Post-Quiz
Pre-Quiz
Send Bulk SMS
A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | Other | All
Action
Participant Attendance ...
First Name
Last Name
2012 Survey Date
Phone with Country Code
Gender
Study ID
Edit | Del Att-188318 4/16/2012 Female 104,101
Edit | Del Att-188319 4/16/2012 Female 104,102
Edit | Del Att-188324 4/16/2012 Male 104,107
Edit | Del Att-188325 4/16/2012 Female 104,108
Edit | Del Att-188326 4/16/2012 Male 104,109
Edit | Del Att-188327 4/16/2012 Female 104,110
Edit | Del Att-188329 4/16/2012 Male 104,112
Edit | Del Att-188330 4/16/2012 Female 104,113
Edit | Del Att-188336 4/16/2012 Female 104,119
Edit | Del Att-188348 4/16/2012 Male 104,131
Edit | Del Att-188352 4/16/2012 Female 104,135
Edit | Del Att-188353 4/16/2012 Male 104,136
Edit | Del Att-188354 4/16/2012 Female 104,137
Edit | Del Att-188358 4/16/2012 Female 104,141
Edit | Del Att-188362 4/16/2012 Female 104,145
Edit | Del Att-188364 4/16/2012 Female 104,147
Edit | Del Att-188367 4/16/2012 Male 104,203
Edit | Del Att-188372 4/16/2012 Male 104,208
Edit | Del Att-188376 4/16/2012 Male 104,212
1-120 of 120
0 Selected
Previous Next
Chat

The system provided weekly analytics to survey teams and trial management staff on progress throughout the trial. Figure 7 shows Port Elizabeth 2's 2014 dashboard as of 21 March 2014; the dashboard updates weekly and emails out to the Team Leader and other trial staff. Each survey team has a dashboard that updates at the end of each week. The dashboards allow survey staff to see how they have done against their weekly survey target, how many surveys they have completed so far, and their follow-up rate school-by-school. Teams have reported that feeding these data back to them regularly helps to motivate them, increase mutual accountability, and give them a sense of ownership over and the data being collected.

Figure 7: GOAL Trial 2014 dashboard for Port Elizabeth 2 site, as of 21 March 2014

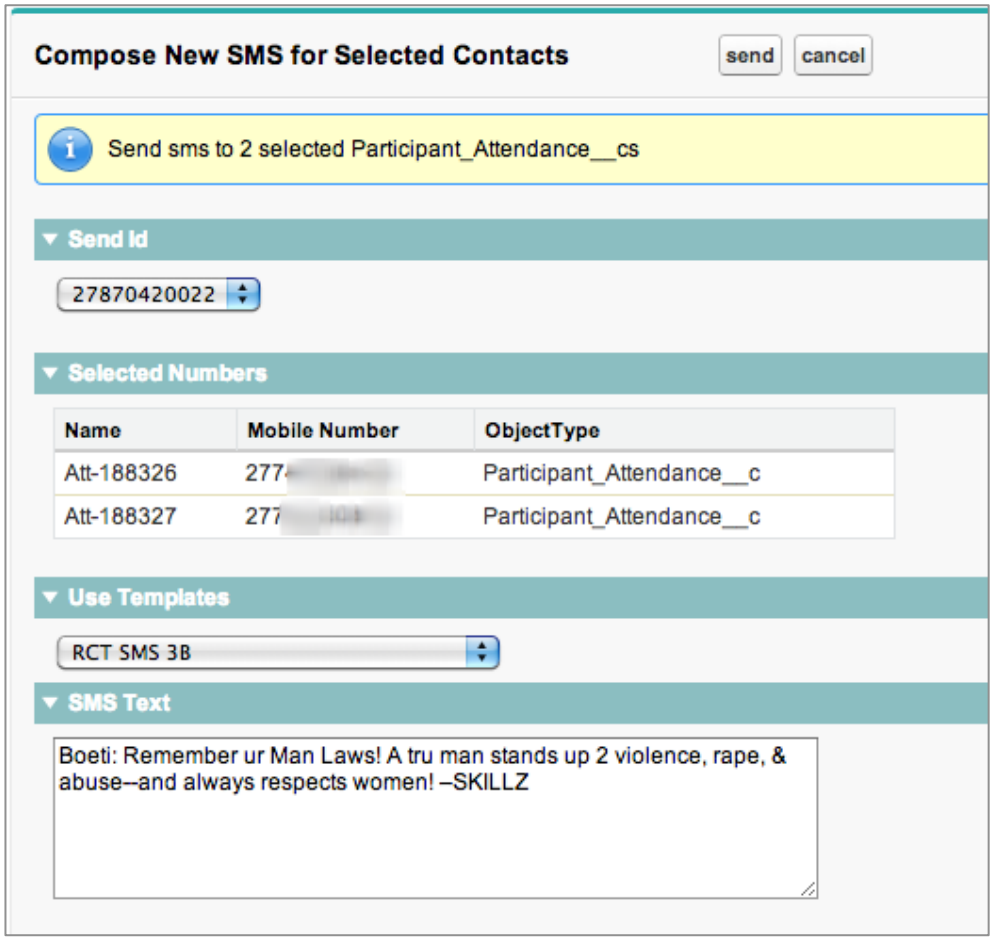


Using SMS-Magic for delivering bulk SMS's to GOAL Trial participants

Numerous web-based tools are available for sending bulk SMS's in South Africa. We chose to use SMS-Magic because it was a native Force.com plug-in. Rather than having to export data from the trial database, we could send SMS's from the same tool used to track schools, participants, and their phone numbers. Because SMS-

Magic requires that phone numbers be stored with their country code, a validation rule was configured into Force.com at baseline to ensure that all phone numbers entered began with 27 and had exactly 11 digits. Each of the SMS's for the campaign was configured and saved as an SMS Template, some using merge fields to personalize SMS's and some separating out different messages to deliver to males and females. Every two weeks, all participants in schools that had been randomised to receive SMS's were selected via a list view (see Figure 6). Figure 8 shows the screen used to select the template, review the content and send the SMS to the selected participants.

Figure 8: Sending a bulk SMS via SMS-Magic



Conclusion

In sum, the web and mobile technology tools utilized in the GOAL Trial—ODK, Force.com, and SMS-Magic—provided state-of-the-art yet low-cost mechanisms for streamlining and improving data collection and trial operations. As an open-source

application, ODK was selected as the mobile data collection tool over several other options, given its better value-for-money, ease of use and setup, and arsenal of features (including optional audio-assistance). ODK acceptability was quite high, with more than 75 percent of participants reporting they prefer the phone-based survey over pen-and-paper (this is consistent with previous research on computer-assisted self-interviews,[2] though participants in this study had not taken a pen-and-paper survey so they did not have a clear basis for comparison). Focus group discussions suggested that ODK provided a comfortable, safe environment for survey completion, though reported understanding, honesty and comfort levels on the questionnaire were slightly lower than expected. This may have been due to the sheer length of the baseline questionnaire, which took most participants over 30 minutes to complete (note: the ODK acceptability questions were at the very end of the questionnaire). Females generally reported greater questionnaire acceptability than males. These differences may indeed reflect differences in experiences of ODK by sex or may rather just reflect differences in the number of sensitive questions asked (e.g., males were asked questions about circumcision, rape perpetration and having sex with other men, whereas females were not asked these questions). Additionally, these differences may have been related to the higher proportion of males who reported ever having had sex, as participants who reported having had sex were asked 15 to 20 more questions than participants who reported having never had sex, and we hypothesize that there was an inverse relationship between questionnaire length and questionnaire acceptability.

Non-response rates on ODK were generally low (less than 10 percent on most sensitive questions), with high non-response among males on questions of circumcision status and STI experience and among females on questions about condom use and number of sexual partners. Some notable differences in non-response were observed between males and females, after adjusting for age and school-level clustering. Force.com provided a powerful, central online platform for storing participant information, with automated analytics that helped to keep trial staff informed of progress, and SMS-Magic plugged into this database to provide a simple mechanism for delivering bulk SMS's to participants.

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London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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SUPERVISOR/SENIOR AUTHOR'S SIGNATURE (3 above) ……

Sexual risk behavior, alcohol use, and social media use among secondary school students in informal settlements in Cape Town and Port Elizabeth, South Africa

Abstract

South Africa's HIV prevalence among young people remains among the highest in the world. A cross-sectional study was carried out in 2012 to estimate prevalences of sexual risk behavior and hazardous alcohol use (via the AUDIT) as well as to investigate potential associations between these outcomes and social media use. In all, 4485 students (mean age 15.66 years, SD 1.39) at 46 secondary schools in informal settlements in Cape Town and Port Elizabeth completed mobile-phone-assisted, self-administered baseline questionnaires within a cluster-randomized trial. In all, 312 females (12.5%) and 468 males (23.5%) screened positive for hazardous alcohol use (AOR=1.98, 95%CI=1.69-2.34). 730 males (39.9%) and 268 females (11.8%) reported having had two or more partners in the last year (AOR=3.46, 95%CI=2.87-4.16). Among females, having a Facebook account was associated with reported multiple partnerships in the last year (AOR=1.81, 95%CI=1.19-2.74), age-disparate sex in the last year (AOR=1.96, 95%CI=1.16-3.32) and hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74). Using Mxit—a popular mobile instant messaging application—was associated with higher odds of reported multiple partnerships in the last year among both males (AOR=1.70, 95%CI=1.35-2.14) and females (AOR=1.45, 95%CI=1.07-1.96) and with hazardous alcohol use among both males (AOR=1.47, 95%CI=1.14-1.90) and females (AOR=1.50, 95%CI=1.18-1.90). Further longitudinal and qualitative research should explore in more depth the observed links between social media and risk behavior.

Keywords: HIV, South Africa, Adolescents, Alcohol, Social Media

INTRODUCTION

South Africa is enduring the world's most severe HIV epidemic, with approximately 6.4 million people living with HIV and approximately 370,000 new infections per year.[1,2] The last two national health surveys have shown declining HIV prevalence among 15-24 year-olds, though it still remains among the highest in the world, with prevalence among 15-19 year-old females (5.2%) more than four-times higher than among males of the same age (1.2%).[2,3] While South Africa has seen tremendous success in scaling up access to HIV testing and treatment, with more than 2 million South Africans now on anti-retroviral treatment,[4] behavior change for HIV prevention remains a critical challenge and many barriers to ART adherence exist[5], underscoring the importance of adolescents remaining HIV-negative.

Numerous behavioral factors influence HIV risk among adolescents in South Africa. Multiple partnerships present a key risk factor for young men, with nearly one in three males aged 15-24 reporting having more than one partner in the last year.[3] Hazardous and harmful alcohol use, which is associated with increased HIV risk and with increased sexual risk behavior among young people, is also very common in South Africa, with 40-50% of adult men screening positive for risky drinking in urban settings.[6-8] Orphan status has also been found to be associated with sexual risk behavior among South African adolescents.[9] Since HIV prevalence increases with age, age-disparate sex (ADS) with older partners is an important risk factor, especially for young women.[10-13] More than 1 in 4 South African girls aged 15-19 report having ever had a male sexual partner who was five or more years older than

themselves.[3] Intimate-partner violence (IPV), which is also associated with HIV prevalence, presents another key risk factor for HIV in South Africa, with more than one in four men reporting having ever perpetrated rape and the vast majority of them starting before the age of 20.[14] Complex gender norms and the social constructions of manhood in post-Apartheid South Africa underlie many of these risk factors and fuel the HIV epidemic.[15,16] Few studies have provided estimates for the prevalence of these risk factors among youth in informal urban settlements, where HIV prevalence is highest (25.8% among 15-49 year-olds), compared to formal urban and rural settings.[17]

In the last decade, mobile phone access and ownership has greatly increased in South Africa, with over 50 million subscribers – the third highest number in Africa, behind Nigeria and Egypt.[18] Surveys estimate that roughly 84% of South African adults own or have access to a mobile phone, with 72% of young people aged 15-24 reporting owning a phone in a 2007 national survey.[18,19] A 2009 survey of low-income adolescents in Cape Town found that 96 percent reported using a mobile phone on a typical day, with many using phones for a popular social messaging application called Mxit, which enables instant messaging between users and is available and affordable on nearly every mobile phone model in SA.[20]

Social media platforms increase adolescents' connectedness with their peers and may facilitate their pursuit of sexual relationships.[21] A 2011 UNICEF study conducted with Mxit users across South Africa (85 percent 15-24 year-olds) found that the most commonly reported topic of conversation was "love life and dating" (46%).[22] Several

studies have identified the Internet as an STI risk environment among those seeking sexual partners online.[23,24] Concerns have been raised that social media use may create opportunities for sexual experimentation[25] and expose adolescents to sexually explicit material.[22] Little research, however, has examined the association between use of modern social networking applications and sexual risk behavior, though one study among homeless youth in USA found that social media may be associated with an increase or decrease in sexual risk behavior, depending on the nature of use.[26]

Research suggests that exposure to alcohol consumption in media is associated with increased alcohol use among adolescents.[27] This association may extend to social media, where users are exposed to alcohol-related advertising content[28] as well as user-generated content depicting alcohol consumption and overuse.[29] Since adolescents are heavily influenced by their perceptions of peer behavior,[30] we hypothesized that the aforementioned exposures in the context of online peer interactions might fuel sexual risk behavior and/or hazardous alcohol use among South African adolescents using social media. Figure 1 presents a hierarchical conceptual framework[31] that may explain these hypothesized associations, considering the potential role of upstream socio-demographic factors and telecommunications access.

[INSERT FIGURE 1 HERE]

Using baseline cross-sectional survey results of a two-year cluster-randomized trial among grade 9 secondary school students aged 12-20 years in informal settlements

of two South African cities, this paper (i) presents descriptive findings on reported sexual risk behavior and alcohol use, (ii) assesses differences in these outcomes by sex, and (iii) assesses associations between self-reported social media use and reported risk behaviors.

METHODS

Study Design

This study draws on baseline data from a two-year cluster-randomized trial to assess the behavioral effectiveness of an HIV prevention intervention delivered in informal settlement schools in Port Elizabeth and Cape Town. Ethics approval for the cluster-randomized trial was obtained from the Wits University Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine Ethics Committee. A cross-sectional analysis was carried out on the trial's baseline data to better understand the risk profile of the study population.

Study Participants and Setting

Between March and September 2012, the study enrolled male and female Grade 9 learners (n=4485) at 46 public secondary schools in Cape Town (n=16 school) and Port Elizabeth (n=30 schools). Port Elizabeth was divided into two sites: Port Elizabeth 1 (urban townships in the city – Zwide, New Brighton, Kwazakhele) and Port Elizabeth 2 (peri-urban townships to the east of the city – Motherwell and Uitenhage). Participating schools in Cape Town were located in the communities of Khayelitsha, Gugulethu, and Langa.

Sampling and Recruitment

The 46 schools represented 56% of the 87 open public secondary schools in the participating communities. The schools were selected purposively, excluding those that had been exposed to the trial intervention during pilot testing of the intervention (n=10), and enrolling those that were most receptive to participating in the trial. In order to yield a reasonable cluster size for the trial, in schools with five or fewer classes of Grade 9 learners, all Grade 9 classes were invited to participate. In schools with six or more Grade 9 classes, five classes were selected using simple random sampling. All learners in the selected classes were invited to participate in the study. Only participants providing both written parental/guardian consent and assent were enrolled in the study.

Data Collection

A 146-item questionnaire was used to assess the individual learner's demographic status, social media use, reported alcohol use, reported IPV, and reported sexual behavior. The prevalence of IPV and its associations with other baseline variables will be the subject of a separate publication. Surveys were carried out using the Open Data Kit (ODK) application suite on Android mobile phones provided temporarily by the study for questionnaire completion.[32] ODK has been pilot-tested successfully in numerous resource-limited settings in Africa and Latin America,[33] with high participant acceptability in sexual behavior surveys in South Africa and Zimbabwe.[34] Similar, more expensive technologies—such as Audio Computer Assisted Self-Interview (ACASI)—for collection of data on sexual behavior have been shown to be more valid in cross-sectional surveys than self-administered questionnaires or face-

to-face interviews.[35] The questionnaire was translated into Xhosa and back-translated to English. Participants had the option to read and answer the survey in English or Xhosa and also had optional audio-assistance in Xhosa, but not English. The questionnaire was pilot-tested with grade 10 learners in Cape Town and Port Elizabeth. Surveys were confidential – participants were identified only with six-digit study ID's, and no personal identifying information was entered into the mobile phones. Data were transmitted daily through a secure wifi connection to an online database.

Measurement of outcomes and other factors

The primary behavioral outcomes of interest in this cross-sectional study were:

- Reported multiple partners in the last year: defined as reporting more than one sexual partner in the last 12 months. This is a self-reported measure commonly used on national health surveys.
- Reported age-disparate sex (ADS) in the last year: defined as reporting having had sex in the last 12 months with a partner who was 5 or more years older or younger. Participants who reported having ever had sex were asked the age of their oldest and youngest sexual partner in the last 12 months. Age disparities were calculated; those with a disparity of five or more years were considered to have had ADS.
- Reported hazardous alcohol use (HAU), measured via the 10-item Alcohol Use Disorder Identification Test (AUDIT); scores of 8 and above were classified as hazardous alcohol use)[36]. The AUDIT was developed by the World Health Organization as a screening tool for identifying problem

drinking, has been shown to be reliable and valid (especially when embedded into a questionnaire assessing other health-related behaviors), and has been used widely in South Africa.[37-39]

Secondary outcomes for the study include:

- Reported have ever had sex (defining sex as 'penetrative sex where the penis enters the vagina, anus or mouth');
- Reported condom use ever, at first sex, and at last sex (only asked to participants reporting having ever had sex);
- Reported current concurrent partners. Participants who reported having ever had sex were asked whether they currently have no sexual partners, one sexual partner, or more than one sexual partner.

Socio-demographic variables measured included:

- Socioeconomic status (SES): measured via a 5-item asset index (whether participants had in their household a TV, radio, piped water, car, or flush toilet)
- Language spoken at home (grouped into Xhosa and other for analysis)
- Self-identified race (grouped into Black and other for analysis)
- Living situation: number of people living in the household and whether participants were living with either, both or neither parent
- Level of mother's and father's education (none, primary, some secondary, completed secondary, higher)
- Orphan status: whether one or both parents were no longer living

Telecommunications access was measured in terms of whether participants reported that they owned a sim card, owned a mobile phone, and/or had an email address. Social media use was measured by asking participants whether they had a Mxit account and/or Facebook account and their reported frequency of social media use ('How often do you use Facebook, Mxit, or other social networks?' – Every day, Every 2-3 days, Once a week, Once every 2-3 weeks, Never or almost never).

Statistical Methods

Descriptive statistics were tabulated for all outcomes and variables of interest. Random-effects logistic regression was used to assess differences by sex. Further multivariable random-effects logistic regressions were conducted to assess differences in behavioral outcomes of interest by sex, adjusting for age group, site, and school-level clustering.

Multivariable random-effects logistic regression was used to assess the associations between social media exposure and the three primary behavioral outcomes, adjusting for age, site, school-level clustering, sim card ownership (included as a priori confounder in order to isolate the effect of social media use from the effect of telecommunications access) and other identified confounders. Given the stark differences in patterns of reported sexual behavior, alcohol use, and social media use, an *a priori* decision was made to assess these associations independently for males and females. A *post-hoc* decision was made to assess for effect modification by sex using likelihood ratio tests. Variables were considered potential confounders

and included in the multivariable analysis if found to have strong evidence ($p<0.05$) of a crude association with both the exposure and the outcome of interest. Statistical analysis was carried out using Stata Version 10.

RESULTS

Recruitment and sample characteristics

Based on school registers collected in January/February 2012, the 46 participating schools had 8226 enrolled grade 9 learners. Observation of recruitment at selected schools in all three sites suggested that the actual number of learners attending school on days when consent forms were distributed was 20-30 percent less than the number of participants on class registers, though the exact number of consent forms distributed was not recorded. Data on sex and age was not available from registers and was therefore only obtained for participants enrolling in the study. In all, 4485 participants (54.5% of those listed on registers) completed baseline surveys: 2494 (55.7%) females and 1991 (44.3%) males. Table 1 details the participants' characteristics. Almost all participants (95.8%) spoke Xhosa at home, and 89.5% self-identified as being 'black'. 1297 participants (28.9%) reported that at least one of their parents was no longer living. Significant sex differences were observed in whether participants were living with their parents, with males having higher odds of reporting living with their father only (OR=1.70, 95%CI=1.31-2.20) and lower odds of reporting living with neither parent (OR=0.75, 95%CI=0.65-0.87). More than half of participants (56.3%) reported personally knowing someone who has HIV or who died of HIV or AIDS. Males scored higher on the SES asset index (AOR=1.24, 95%CI=1.13-1.37).

[INSERT TABLE I HERE]

Details of telecommunications and social media use are presented in Table 2. Nearly two-thirds of participants reported that they owned a sim card (62.3%) and more than half reported they owned their own phone (55.5%), with no evidence of difference by sex (Table 2). Reported Mxit use was high—with more than half of participants reporting having an account (52.8%)—and was higher among males (54.5%) than females (51.5%). Additionally, more males (13.7%) than females (10.7%) reported having a Facebook account. After adjusting for age, site and school, reported frequency of social media use (AOR=1.17, 95%CI=1.02-1.34) and internet use for purposes other than social media (AOR=1.54, 95%CI=1.35-1.77) was higher among males than females (Table II).

[INSERT TABLE II HERE]

Reported sexual behavior

Selected reported sexual risk behaviors are presented in Table III, by sex. Among all participants, 1025 females (43.0%) and 1287 males (68.6%) reported having ever had sex. After adjusting for age, site and school, males had roughly 2-times higher odds than females of reporting having ever had sex (AOR=1.98, 95%CI=1.69-2.34).

Among participants who reported having ever had sex, 109 females (11.8%) and 170 males (13.7%) reported having ever had an age-disparate partner (5 or more years older or younger) (Table 4). Females had roughly 2.8-times higher odds of reporting having had a partner in the last year who was 5 or more years older (AOR=2.79, 95%CI=1.92-4.05), while they had roughly 2.5-times lower odds of reporting having had a partner in the last year who was five or more years younger (AOR=0.40,

95%CI=0.26-0.63). Only 31 males (2.4%) reported having had an age-disparate older partner in the last year, while 142 (11.0%) reported having had an age-disparate younger partner in the last year.

The number of reported lifetime partners and partners in the last year differed greatly by sex. Among participants who had ever had sex, 435 females (48.2%) and 267 males (21.7%) reported having only ever had one partner, with 648 females (70.7%) and 513 males (41.3%) reporting having only had one partner in the last 12 months. Meanwhile, 81 females (8.8%) and 276 males (30.2%) reported having had three or more partners in the last 12 months. After adjusting for age, site and school, males had 9-times higher odds than females of reporting five or more lifetime partners (AOR=9.11, 95%CI=6.42-12.9), more than 4-times higher odds of reporting three or more partners in the last year (AOR=4.50, 95%CI=3.46-5.86), and more than 3-times lower odds of reporting having only had one partner in the last year (AOR=0.29, 95%CI=0.24-0.35). Males (n=276, 22.5%) had more than 4-times higher odds than females (n=62, 6.0%) of reporting having more than one current sexual partner (AOR=4.15, 95%CI=3.09-5.57).

716 females (69.9% of those who reported having ever had sex) and 785 males (63.6% of those reporting having ever had sex) reported having ever used a condom. After adjusting for age, site and school, males who had ever had sex had roughly 2.5-times higher odds of reporting having never used a condom (AOR=2.53, 95%CI=2.06-3.11) than females who had ever had sex. Compared to females who reported having ever used a condom (n=716), males who reported have ever used a condom

(n=785) had roughly 2.3-times higher odds of reporting not having used a condom at first sex (AOR=2.29, 95%CI=1.78-2.95), but slightly lower odds of reporting not having used a condom at last sex (AOR=0.72, 95%CI=0.55-0.95). Fewer males (n=603, 31.5%) than females (n=885, 36.2%) reported having ever taken an HIV test (AOR=0.73, 95%CI=0.64-0.84). Only 327 males (16.6%) and 464 females (18.8%) reported having been tested for HIV in the past year.

[INSERT TABLE III HERE]

Reported alcohol use

Table IV presents self-reported alcohol use by sex. More females (63.2%) than males (51.1%) reported never drinking alcohol (AOR=0.76, 95%CI=0.66-0.87). After adjusting for age, site, and school, males reported greater frequency of alcohol use ($p<0.001$) and higher alcohol consumption per day ($p<0.001$). Overall, males (23.5%) had roughly 2-times higher odds than females (12.5%) of screening positive for hazardous alcohol use (AOR=1.98, 95%CI=1.69-2.34) and more than 2.5-times higher odds of screening positive for high-risk alcohol use (11.1% vs 4.2%, AOR=2.55, 95%CI=1.99-3.27).

[INSERT TABLE IV HERE]

Associations between hazardous alcohol use and reported sexual risk behavior

Table V details sex-specific univariable and multivariable analyses assessing differences in reported sexual risk behavior by whether or not participants screened positive for HAU. After adjusting for age, site and school, compared to those not screening positive for HAU, males screening positive for HAU had roughly 2.3-times higher odds of reporting having ever had sex (AOR=2.32, 95%CI=1.77-3.04), roughly 2.1-times higher odds of reporting having not used a condom at last sex (AOR=2.14,

95%CI=1.43-3.21), roughly 1.5-times higher odds of reporting having not used a condom at first sex (AOR=1.54, 95%CI=1.11-2.12), roughly 2.8-times higher odds of reporting having two or more partners in the last year (AOR=2.77, 95%CI=2.22-3.47), nearly 3.9-times higher odds of reporting currently having more than one sexual partner (AOR=3.93, 95%CI=2.91-5.33), and nearly 2.8-times higher odds of reporting having had an age-disparate sexual partner in the last year (AOR-=2.76, 95%CI=1.98-3.84). Females screening positive for HAU had nearly twice the odds of reporting having ever had sex (AOR=1.97, 95%CI=1.53-2.54), nearly 3.6-times higher odds of reporting having two or more partners in the last year (AOR=3.59, 95%CI=2.66-4.85), and roughly 3.6-times higher odds of reporting currently having more than one sexual partner (AOR=3.62, 95%CI=2.01-6.54). There was also weak evidence that females screening positive for HAU had higher odds of reporting not using a condom use at last sex (AOR=1.46, 95%CI=0.95-2.24). Very strong associations were observed for both sexes ($p<0.001$) between screening positive for HAU and a greater number of reported lifetime sexual partners.

[INSERT TABLE V HERE]

Association of telecommunications access and *social media use with multiple partnerships*

Table VI shows the associations for telecommunications access and social media use with reported multiple partners in the last year. After adjusting for age group, site, and sim card ownership, females with a Facebook account had roughly 2.1-times higher odds of reporting multiple partners in the last year (AOR=2.11, 95%CI=1.41-3.16). Females with a Mxit account had nearly 1.5-times higher odds of reporting multiple partners in the last year than those without (AOR=1.45, 95%CI=1.07-1.96).

Females reporting using social media every day had approximately 1.7-times higher odds of reporting multiple partners in the last year (AOR=1.70, 95%CI=1.23-2.35).

After adjusting for age, site, SES, household language, and sim card ownership, males who had Mxit accounts had roughly 1.7-times higher odds of reporting multiple partners in the last year than those without (AOR=1.72, 95%CI=1.39-2.13), while there was no significant multivariable evidence of association between Facebook and multiple partnerships among males. Males reporting using social media every day had nearly 1.9-times higher odds of reporting multiple partners in the last year (AOR=1.86, 95%CI=1.48-2.35).

There was strong evidence of effect modification by sex for the association between having a Mxit account and reporting multiple partners in the last year (p=0.04), with the association being stronger in males than in females. There was very weak evidence of effect modification by sex for the association between having a Facebook account and reporting multiple partners in the last year (p=0.12), with the association being stronger in females than in males. There was no evidence of effect modification by sex for the association between using social media every day and reported multiple partners in the last year (p=0.17).

[INSERT TABLE VI HERE]

Associations of telecommunications access and social media use with age-disparate sex

Table VII displays the associations for reported telecommunications access and social media use with self-reported ADS in the last 12 months. There was strong evidence that females owning a sim card had higher odds of reporting ADS in the last 12 months (AOR=1.71, 95%CI=1.07-2.72). After adjusting for age, site, sim-card ownership and school-level clustering, females with a Facebook account had nearly twice the odds of reporting ADS in the last 12 months than those without (AOR=1.96, 95%CI=1.16-3.32). There was very strong evidence that reporting using social media every day was associated with higher odds of reported ADS in the last 12 months for females (AOR=1.87, 95%CI=1.20-2.92) but no evidence of this association for males (AOR= etc). No associations were observed for males between telecommunications access or social media use and reported ADS in the last 12 months. There was no evidence of effect modification by sex for associations between having a Facebook account and reported ADS in the last 12 months (p=0.47) or having a Mxit account and reported ADS in the last 12 months (p=0.48). There was strong evidence, however, for effect modification by sex for the association between using social media every day and reported ADS in the last 12 months (p=0.02), with the association being stronger in females than in males.

[INSERT TABLE VII HERE]

Associations of telecommunications access and *social media use with hazardous alcohol use*

Table VIII displays the associations for reported telecommunications access and social media use with self-reported hazardous alcohol use. After adjusting for age, site, orphan status, sim-card ownership and school-level clustering, females with a

Facebook account had nearly 2-times higher odds of screening positive for hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74), while those with a Mxit account had roughly 41 percent higher odds (AOR=1.41, 95%CI=1.14-1.90). Females reporting using social media every day had roughly 61 percent higher odds of screening positive for hazardous alcohol use (AOR=1.61, 95%CI=1.23-2.10).

After adjusting for age, site, SES, household language, race, sim-card ownership and school-level clustering, males with a Mxit account had roughly 1.4-times higher odds of screening positive for hazardous alcohol use (AOR=1.40, 95%CI=1.12-1.77). Males reporting using social media every day had nearly 1.5-times higher odds of screening positive for hazardous alcohol use (AOR=1.48, 95%CI=1.15-1.90). No evidence of association was observed between hazardous alcohol use and having a Facebook account for males. There was weak evidence of effect modification by sex for the association between having a Facebook account and screening positive for hazardous alcohol use (p=0.07), with the association being stronger in females than in males. There was no evidence of effect modification by sex for associations between having a Mxit account (p=0.83) or using social media every day (p=0.49) and hazardous alcohol use.

[INSERT TABLE VII HERE]

DISCUSSION

Important differences were observed between males and females in reported sexual behavior and alcohol use. After adjusting for age and site, males had roughly 2.5-times higher odds of reporting having ever had sex, roughly 4.5-times higher odds of reporting having three or more sexual partners in the last 12 months, roughly 4-

times higher odds of reporting currently having multiple sexual partners, and 2-times higher odds of screening positive for hazardous alcohol use. Females, however, had 2-times higher odds of reporting having an age-disparate older partner – an important HIV risk factor.[10-12] These findings were generally consistent previous literature on differences by sex in reported sexual behavior among adolescents in South Africa,[40] including the 2008 South African national health survey, which also found that young men reported more partners than young women, while young women were more likely to have older partners.[3]

Our findings support previous literature from sub-Saharan Africa in the observed associations between hazardous alcohol use and sexual risk behavior.[6-8] For both sexes, very strong associations were observed between HAU and higher reported numbers of partners, and in males very strong associations were observed with increased age-disparate sex and reduced condom use at last sex. This supports previous findings that risky drinking is an important HIV risk factor,[6-8] and underlines the importance of designing and scaling up effective interventions that reduce hazardous alcohol use among adolescents in South Africa.

Though not the primary focus of the study, two interesting findings emerged with respect to reported condom use. Firstly, 36.4 percent of males and 18.4 percent of females reporting ever having had sex reported never having used a condom, with only 51.6 percent of males and 54.2 percent of females who reported having ever had sex reporting using a condom at last sex. These proportions are substantially lower than those observed in the 2008 national health survey among 15-24 year-olds

(87.4 percent among males; 73.1 percent among females)[3] and support the observation that reported condom use appears to have declined between 2008 and 2012.[2] In a 2010 cross-sectional study of 474 grade 8 learners in Cape Town, Gevers and colleagues' had observed a similar proportion of males reporting condom use at last sex (50.0%) but a much higher proportion of girls reporting condom use at last sex (73.9%). The difference in girls might be due to differences in sampling, study populations or their small sample. Secondly, after adjusting for age group, site and school, males had 2.5-times higher odds of reporting having never used a condom than females. This discrepancy also differs from the national health survey and from a 2012 cross-sectional survey of 3123 18-24 year-old men and women in four South African provinces,[41] both of which found higher reported condom use among males.

Our findings related to social media use and risk behavior provide interesting avenues for further research and potential intervention. That females using Facebook had nearly 2-times higher odds of reporting multiple partnerships in the last year, age-disparate sex in the last year, and hazardous alcohol use invites questions of causality—are adolescent girls who engage in riskier behavior more likely to use Facebook or does using Facebook fuel risky drinking and sexual behavior among adolescent girls? A previous study of low-income American MySpace users aged 18-20 found the majority (56%) made references to sexual activity and the vast majority (85%) made reference to substance use on their profiles, supporting the notion that using social media may reinforce risk behavior.[42] However, our finding may also be a result of residual confounding (e.g., girls who use Facebook may have different social networks than girls who do not, and these network differences may

explain the observed differences in reported risk behavior). The fact that Facebook use was not associated with riskier behavior among males, meanwhile, suggests that the associations may be unique to girls in this population. Indeed, evidence of effect modification by sex was observed for the associations between having a Facebook account and reported multiple partners in the last year and hazardous alcohol use. The tests for effect modification also revealed that the link between using social media every day and reported ADS in the last year was much stronger among females than males.

That males using Mxit had 1.5-times higher odds of reporting multiple partners in the last year and that both males and females using Mxit had roughly 1.5-times higher odds of screening positive for hazardous alcohol use merits further investigation. If the observed associations are indeed causal to a certain extent, then Mxit's role in increasing risk behavior would be of greater public health importance than Facebook's, due to Mxit's greater popularity and widespread accessibility (more than half of participants reported using Mxit, whereas only 1 in 8 participants reported using Facebook). Irrespective of whether these associations are causal—and, if so, the directions of causality—our findings suggest that these social media platforms—particularly Mxit—may provide an important avenue for targeting at-risk adolescents with interventions aimed at reducing sexual risk behavior and hazardous alcohol use.

The study had several important limitations. First, selection bias may have occurred due to the requirement of written parental/guardian consent for participants under

18 years, such that young participants who were less likely to obtain a parental/guardian signature—who may have had less involved parents—may have also been less likely to participate in this study. Considering previously observed associations between parent/child relations and reported risk behavior among adolescents in South Africa[43] and Sub-Saharan Africa[44] as well as associations between parental supervision and STI risk among low-income, urban African-American adolescents,[45] this may have resulted in underestimates of reported risk behavior. We do not have any reason to believe that this potential selection bias would have been differential for males and females. We also note that the sampling method may have resulted in slightly over-sampling small schools with fewer than five classes, thus potentially affecting generalizability. Secondly, social desirability bias (SDB) may have led male participants to over-report their sexual experience, number of sexual partners and/or alcohol consumption and female participants to under-report their sexual experience and number of partners. However, the confidential, mobile-assisted self-interview approach likely minimized SDB, as all answers remained private to the individual. Indeed, both the survey method and the results mirrored that of Beauclair and colleagues' recent ACASI sexual behavior survey in similar communities in Cape Town, from which they concluded that the method "may considerably reduce social desirability bias in sexual behavior surveys".[46] Thirdly, the purposive sampling of schools—a necessity to ensure the trial's validity—may have affected the study's generalizability. On the other hand, while the results should not be generalized to South Africa as a whole or to the entire Cape, they do likely provide an accurate profile of reported risk behavior

among grade nine learners in informal settlement secondary schools in Cape Town and Port Elizabeth.

Overall, this study provides useful insight into designing interventions aimed at reducing HIV and STI transmission and acquisition among adolescents in this setting. The findings suggest that interventions targeting this population should include a focus on reducing multiple and concurrent partners (especially among males), hazardous alcohol use (especially among males), and age-disparate partnerships as well as increasing condom use. Future qualitative and longitudinal studies should further examine the observed links between social media use and reported risk behavior among South African adolescents and other populations at-risk for HIV.

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Table I: Demographic characteristics of the participants, by sex (N=4485)

	All		Female		Male		p value[a]
Characteristic	N	%	N	%	N	%	
All participants	4485	100.0	2494	55.7	1991	44.3	
Age Group							
12-14	902	20.1	614	24.6	288	14.5	
15	1391	31.0	869	34.8	522	26.2	
16	1051	23.4	522	20.9	529	26.6	
17	627	14.0	281	11.3	346	17.4	
18-20	514	11.5	208	8.3	306	15.4	<0.001
Site							
Cape Town	1584	35.3	972	39.0	612	30.7	
Port Elizabeth 1	1577	35.2	817	32.8	760	38.2	
Port Elizabeth 2	1324	29.5	705	28.3	619	31.1	0.002
Self-identified race							
Black	4012	92.1	2243	92.4	1769	91.7	
Coloured	119	2.7	66	2.7	53	2.7	
White	176	4.0	92	3.8	84	4.4	
Indian	50	1.1	27	1.1	23	1.2	0.80
Language spoken at home							
Xhosa	4296	95.8	2393	96.0	1903	95.6	
English	86	1.9	44	1.8	42	2.1	
Sesotho	48	1.1	31	1.2	17	0.9	
Other	55	1.2	26	1.0	29	1.5	0.16
Orphan status							
Both parents living	3188	71.1	1752	70.2	1436	72.1	
Single orphan	1038	23.1	589	23.6	449	22.6	
Double orphan	259	5.8	153	6.1	106	5.3	0.22
Parents in Household							
Live w/neither parents	897	20.2	548	22.2	349	17.8	
Live w/mother only	1778	40.1	1002	40.5	776	39.5	
Live w/father only	252	3.6	108	4.4	144	7.3	
Live w/both parents	1510	16.9	816	33.0	694	35.4	<0.001
Mother's education							
None	357	9.1	177	8.0	180	10.5	
Primary	646	14.4	356	16.1	290	16.8	
Some secondary	1140	25.4	677	27.7	463	24.5	
Completed secondary	1257	28.0	710	25.7	547	25.4	
Higher	537	12.0	295	9.0	242	9.6	0.16
Father's education							
None	398	10.9	228	11.2	170	10.6	
Primary	579	15.9	320	15.7	259	16.2	
Some secondary	877	24.1	508	24.9	369	23.0	
Completed secondary	1167	32.0	652	32.0	515	32.1	
Higher	624	17.1	333	16.3	291	18.1	0.32
Household Size							
1 to 3	969	21.6	511	20.5	458	23.0	
4 to 6	2547	56.8	1463	58.7	1084	54.4	
7+	969	21.6	520	20.9	449	22.6	0.59
Asset Index							
Low	436	9.7	263	10.5	173	8.7	
Medium	1931	43.1	1122	45.0	809	40.6	
High	2118	47.2	1109	44.5	1009	50.7	0.001

[a] Difference by sex assessed via random-effects logistic regression, adjusting for clustering

Note: missing values not presented in the table. Percentages use available data as denominator.

Table II: Self-reported telecommunications access and social media use by sex

	All		Females		Males		Comparing males vs females			
Characteristic	**N**	**%**	**N**	**%**	**N**	**%**	**OR[a]**	**95% CI**	**AOR[b]**	**95% CI**
Own a sim card	2795	62.3	1562	62.6	1233	61.9	1.01	0.89-1.14	1.00	0.88-1.14
Own a cell phone	2488	55.5	1366	54.8	1122	56.4	1.09	0.96-1.23	1.08	0.95-1.23
Have a Mxit account	2369	52.8	1284	51.5	1085	54.5	1.16	1.03-1.32	1.19	1.05-1.35
Have an email address	1211	27.0	648	26.0	563	28.3	1.15	1.00-1.32	1.07	0.93-1.23
Have a facebook account	538	12.0	266	10.7	272	13.7	1.38	1.15-1.66	1.05	0.98-1.14
Frequency of social media use										
Never or almost never	1483	33.1	860	34.5	623	31.3				
Once every 2-3 weeks	370	8.2	186	7.5	184	9.2				
Once a week	686	15.3	380	15.2	306	15.4	1.18	1.04-1.35	1.17	1.02-1.34
Every 2-3 days	416	9.3	218	8.7	198	9.9				
Every day	1146	25.6	634	25.4	512	25.7				
Frequency of other internet use										
Never or almost never	1707	38.1	1035	41.5	672	33.8				
Once every 2-3 weeks	462	10.3	236	9.5	226	11.4				
Once a week	958	21.4	514	20.6	444	22.3	1.55	1.36-1.77	1.54	1.35-1.77
Every 2-3 days	328	7.3	161	6.5	167	8.4				
Every day	454	10.1	209	8.4	245	12.3				

[a]Random-effects logistic regression adjusted for school-level clustering

[b]Random-effects logistic regression adjusted for age group, site and school-level clustering

Table III: Self-reported sexual behavior by sex (N=4485)

	Female		Male		Males vs Females		
Reported Sexual Behavior	N	%	N	%	AOR [a]	95% CI	p value
Ever had sex	1025	43.0	1287	68.6	2.56	2.24-2.93	<0.001
Never used a condom [b]	162	18.5	449	36.4	2.53	2.06-3.11	<0.001
No condom at first sex [b]	277	31.4	678	54.8	2.88	2.38-3.48	<0.001
No condom at last sex [b]	453	44.2	603	46.9	0.72	0.55-0.95	0.020
Lifetime partners							
None or declined to answer	1481	62.1	647	34.5			
One	435	18.3	267	14.2	1.00		
Two	252	10.6	285	15.2	1.84	1.46-2.32	
3 or 4	154	6.5	336	17.9	3.55	2.75-4.59	
5 or more	61	2.6	341	18.2	9.11	6.42-12.9	<0.001
Partners last 12 mo							
None or declined to answer	1467	59.5	633	28.1			
One	648	26.3	513	22.8	0.29	0.24-0.35	<0.001
Two or more	268	10.9	730	32.4	3.46	2.87-4.16	<0.001
3 or more	81	3.3	375	16.7	4.50	3.46-5.86	<0.001
Current sexual partners							
None	1609	69.2	857	47.2	1.00		
One	655	28.2	681	37.5	2.00	1.74-2.30	
More than one	62	2.7	276	15.2	8.55	6.38-11.45	<0.001
Age-disparate partner ever [b]	109	11.8	170	13.7	1.29	0.99-1.69	0.06
5+ year older partner	68	7.9	31	2.6	0.40	0.26-0.63	<0.001
5+ year younger partner	41	4.5	142	11.6	2.79	1.92-4.05	<0.001
Ever tested for HIV	885	36.2	603	31.5	0.73	0.64-0.84	<0.001
Tested in last 12 mo	464	18.8	327	16.6	1.12	0.90-1.38	0.32

[a] Assessed via random-effects logistic regression, adjusted for age group, site, and school-level clustering

[b] As percent of those who report having ever had sex

Note: Percentages do not include missing values in the denominator

Table IV: Self-reported alcohol use by sex (N=4485)

	Female		Male		Males vs Females univariable		Males vs Females multivariable	
Reported Alcohol Use	N	%	N	%	OR	95% CI	AOR[a]	95% CI
Frequency of alcohol use								
Never	1492	63.2	960	51.1	0.76	0.66-0.87	0.81	0.70-0.93
Once a month or less	665	28.2	558	29.7	1.00		1.00	
2-4 times a month	118	5.0	208	11.1	2.10	1.63-2.71	1.92	1.48-2.49
2-3 times a week	44	1.9	73	3.9	1.98	1.34-2.93	1.95	1.30-2.92
4 or more times a week	42	1.8	79	4.2	2.24	1.51-3.32	2.30	1.53-3.45
Number of drinks per day when drinking [b]								
1 or 2	507	59.7	413	46.7	1.00			
3 or 4	187	22.0	197	22.3	1.29	1.02-1.64	1.33	1.03-1.70
5 or 6	85	10.0	74	8.4	1.07	0.76-1.50	1.02	0.72-1.46
7 to 9	46	5.4	68	7.7	1.81	1.22-2.70	1.90	1.26-2.87
10+	24	2.8	133	15.0	6.80	4.24-10.9	7.50	4.70-2.87
Hazardous Alcohol Use [c]	312	12.5	468	23.5	2.16	1.84-2.54	1.98	1.69-2.34
High-Risk Alcohol Use [d]	105	4.2	220	11.1	2.85	2.23-3.63	2.55	1.99-3.27

[a] Assessed via random-effects logistic regression, adjusted for age group, site and school-level clustering

[b] As percent of those who report drinking alcohol at least once a month

[c] Defined as scoring 8 or higher on the AUDIT

[d] Defined as scoring 15 or higher on the AUDIT

Table V: Self-reported hazardous alcohol use (HAU) and reported sexual risk behaviors, by sex

	Females				Males			
	HAU vs No HAU: Univariable [a]		HAU vs No HAU: Multivariable [b]		HAU vs No HAU: Univariable [a]		HAU vs No HAU: Multivariable [b]	
Reported Sexual Behaviour	OR	95% CI	AOR	95% CI	OR	95% CI	AOR	95% CI
Ever had sex	1.97	1.53-2.54	1.83	1.40-2.37	2.63	2.01-3.44	2.32	1.77-3.04
Never used a condom [c]	0.87	0.56-1.35	0.86	0.55-1.34	0.92	0.71-1.19	0.99	0.76-1.28
No condom at first sex [c]	0.87	0.52-1.44	0.87	0.52-1.43	1.54	1.11-2.14	1.54	1.11-2.12
No condom at last sex [c]	1.46	0.95-2.24	1.44	0.94-2.20	2.13	1.42-3.20	2.14	1.43-3.21
Lifetime partners								
None	1.00		1.00		1.00		1.00	
One	1.37	0.97-1.93	1.28	0.90-1.82	1.00	1.46-3.53	0.91	0.59-1.40
Two	2.36	1.64-3.41	2.16	1.48-3.16	2.27	1.58-3.24	2.05	1.43-2.94
3 or 4	4.71	3.19-6.96	4.26	2.85-6.37	3.65	2.63-5.07	3.22	2.31-4.49
5 or more	3.76	2.07-6.82	3.37	1.84-6.17	4.22	3.06-5.84	3.65	2.63-5.07
Partners last 12 mo								
None	1.00		1.00		1.00		1.00	
One	1.09	0.83-1.42	0.98	0.74-1.29	0.66	0.51-0.84	0.65	0.50-0.84
Two or more	3.59	2.66-4.85	3.25	2.38-4.43	3.07	2.46-3.83	2.77	2.22-3.47
Three or more	3.70	2.28-6.01	3.23	1.98-5.27	2.74	2.15-3.50	2.49	1.95-3.19
Current sexual partners								
None	1.00		1.00		1.00		1.00	
One	2.46	1.90-3.18	2.25	1.72-2.94	1.74	1.36-2.24	1.52	1.17-1.96
More than one	3.62	2.01-6.54	3.26	1.79-5.91	4.34	3.21-5.86	3.93	2.91-5.33
Age-disparate partner last 12 mo	2.27	1.43-3.59	1.92	1.21-3.05	3.24	2.34-4.49	2.76	1.98-3.84
5+ year older partner	1.58	0.88-2.83	1.51	0.84-2.71	3.57	1.72-7.41	3.74	1.79-7.81
5+ year younger partner	1.75	0.85-3.61	1.67	0.80-3.49	2.28	1.59-3.26	2.08	1.45-3.00

[a] Assessed via random-effects logistic regression, adjusted for school-level clustering

[b] Assessed via random-effects logistic regression, adjusted for age group, site, and school-level clustering

[c] Restricted to those reporting having ever had sex

HAU = Hazardous alcohol use, defined as scoring 8 points or higher on the AUDIT scale

Table VI: Associations of reported telecommunications access and social media use with reported multiple partners (MP) in the last year, by sex

	Females				Males			
	MP vs No MP: Univariable [a]		MP vs No MP: Multivariable [b]		MP vs No MP: Univariable [a]		MP vs No MP: Multivariable [c]	
Characteristic	**OR**	**95% CI**	**AOR**	**95% CI**	**OR**	**95% CI**	**AOR**	**95% CI**
Socio-Demographic factors								
Age Group	1.61	1.45-1.79 [d]			1.36	1.26-1.47 [d]		
Socioeconomic status (Asset Index)	1.03	0.85-1.25			1.19	1.03-1.39 [d]		
Xhosa Speaker	1.38	0.68-2.82			0.61	0.40-0.95 [d]		
Self-identify as Black	0.78	0.50-1.24			0.95	0.62-1.46		
Father's Education	0.90	0.80-1.00			1.08	0.99-1.17		
Mother's Education	0.97	0.86-1.09			1.07	0.99-1.17		
Orphan (single or double)	1.13	0.85-1.49			0.92	0.74-1.14		
Household > 5 people	0.94	0.69-1.28			1.00	0.78-1.28		
Live with both parents	0.76	0.57-1.02			1.06	0.83-1.34		
Site								
Cape Town	1.00	[d]			1.00			
Port Elizabeth	0.44	0.29-0.68			0.95	0.72-1.25		
Uitenhage/Motherwell	0.77	0.52-1.15			0.88	0.66-1.17		
Telecommunications Access								
Own a sim card	1.18	0.89-1.56	1.02	0.74-1.42	1.09	0.85-1.38	1.07	0.85-1.34
Own a cell phone	1.15	0.88-1.50	1.01	0.72-1.44	1.10	0.87-1.39	0.90	0.67-1.23
Have an email address	1.51	1.14-2.00	1.32	0.97-1.80	1.06	0.83-1.36	1.06	0.86-1.32
Social Media Use								
Have a facebook account	1.66	1.12-2.47	**2.11**	**1.41-3.16**	1.45	1.05-2.00	1.26	0.96-1.67
Have a Mxit account	0.98	0.73-1.31	**1.45**	**1.07-1.96**	1.52	1.21-1.92	**1.72**	**1.39-2.13**
Use social media every day	1.45	1.08-1.93	**1.70**	**1.23-2.35**	1.86	1.50-2.31	**1.86**	**1.48-2.35**

[a] Random-effects logistic regression adjusted for school-level clustering

[b] Random-effects logistic regression adjusted for age group, site, and owning a sim card

[c] Random-effects logistic regression adjusted for age group, site, asset index, household language, and owning a sim card

[d] $p<0.05$, variable included in multivariable model as potential confounder

MP = Multiple partners (more than one sexual partner reported in the last 12 months)

Table VII: Associations of reported telecommunications access and social media use with age-disparate sex (ADS) in the last year

	Females				Males			
	ADS vs No ADS Univariable [a]		ADS vs No ADS Multivariable [b]		ADS vs No ADS Univariable [a]		ADS vs No ADS Multivariable [c]	
Characteristic	**OR**	**95% CI**	**AOR**	**95% CI**	**OR**	**95% CI**	**AOR**	**95% CI**
Demographic/structural factors								
Age Group	1.55	1.33-1.82 [d]			1.59	1.39-1.82 [d]		
Socioeconomic status (Asset Index)	0.96	0.71-1.28			1.32	1.01-1.72 [d]		
Xhosa Speaker	1.33	0.47-3.78			0.92	0.45-1.88		
Self-identify as Black	0.99	0.48-2.05			0.77	0.45-1.30		
Father's Education	0.88	0.74-1.04			0.86	0.76-1.01		
Mother's Education	0.92	0.77-1.10			0.87	0.75-1.00 [d]		
Orphan (single or double)	1.13	0.74-1.73			0.79	0.54-1.14		
Household > 5 people	0.79	0.51-1.23			0.74	0.52-1.06		
Live with both parents	0.71	0.46-1.11			1.39	1.00-1.92 [d]		
Site								
Cape Town	1.00	[d]			1.00			
Port Elizabeth	0.34	0.16-0.70			0.74	0.46-1.19		
Uitenhage/Motherwell	0.43	0.21-0.89			1.04	0.65-1.66		
Telecommunications Access								
Own a sim card	1.81	1.14-2.87	**1.71**	**1.07-2.72**	1.11	0.79-1.56	0.75	0.50-1.12
Own a cell phone	1.65	1.08-2.52	1.33	0.76-2.31	1.22	0.88-1.71	0.99	0.57-1.73
Have an email address	1.54	1.02-2.34	1.31	0.85-2.01	1.30	0.92-1.84	1.14	0.78-1.67
Social Media Use								
Have a facebook account	2.21	1.33-3.67	**1.96**	**1.16-3.32**	1.68	1.12-2.52	1.36	0.86-2.15
Have a Mxit account	1.03	0.69-1.53	1.05	0.70-1.60	1.34	0.96-1.88	1.41	0.96-2.08
Use social media every day	1.93	1.26-2.95	**1.87**	**1.20-2.92**	1.13	0.79-1.63	1.14	0.76-1.71

[a] Random-effects logistic regression adjusted for school-level clustering

[b] Random-effects logistic regression adjusted for age group, site, and owning a sim card

[c] Random-effects logistic regression adjusted for age group, site, SES, mother's education,living with both parents, and owning a sim card

[d] $p<0.05$, variable included in multivariate model as potential confounder

ADS = Age-disparate sex (sexual partner 5+ years older or younger) in the last 12 months

Table VIII: Associations of self-reported telecommunications access and social media use with reported hazardous alcohol use (HAU) by sex

	Females				Males			
	HAU vs No HAU Univariable [a]		HAU vs No HAU Multivariable [b]		HAU vs No HAU Univariable [a]		HAU vs No HAU Multivariable [c]	
Characteristic	**OR**	**95% CI**	**AOR**	**95% CI**	**OR**	**95% CI**	**AOR**	**95% CI**
Demographic/structural factors								
Age Group	1.20	1.09-1.32 [d]			1.34	1.23-1.45 [d]		
Socioeconomic status (Asset Index)	1.07	0.89-1.28			1.15	0.97-1.36		
Xhosa Speaker	0.68	0.40-1.16			0.61	0.38-0.97 [d]		
Self-identify as Black	0.98	0.62-1.53			0.69	0.49-0.99 [d]		
Father's Education	0.98	0.88-1.09			1.05	0.95-1.15		
Mother's Education	0.98	0.88-1.10			1.02	0.93-1.12		
Orphan (single or double)	1.34	1.04-1.72 [d]			0.95	0.75-1.20		
Household > 5 people	1.10	0.85-1.42			1.03	0.82-1.28		
Live with both parents	0.81	0.62-1.05			0.97	0.78-1.21		
Site								
Cape Town	1.00	[d]			1.00			
Port Elizabeth	0.63	0.45-0.90			0.79	0.58-1.08		
Uitenhage/Motherwell	0.63	0.44-0.90			0.83	0.60-1.14		
Telecommunications Access								
Own a sim card	1.40	1.08-1.82 [d]	**1.38**	**1.06-1.79**	1.07	0.86-1.34	0.89	0.69-1.14
Own a cell phone	1.36	1.06-1.75 [d]	**1.36**	**1.06-1.75**	1.18	0.95-1.47	1.03	0.78-1.36
Have an email address	1.21	0.93-1.58	1.16	0.88-1.52	1.30	1.04-1.64	1.23	0.97-1.38
Social Media Use								
Have a facebook account	1.97	1.42-2.74	**1.79**	**1.27-2.53**	1.30	0.97-1.75	1.18	0.87-1.60
Have a Mxit account	1.45	1.13-1.85	**1.46**	**1.12-1.89**	1.46	1.17-1.81	**1.40**	**1.12-1.77**
Use social media every day	1.63	1.25-2.11	**1.61**	**1.23-2.10**	1.48	1.17-1.88	**1.48**	**1.15-1.90**

[a] Random-effects logistic regression adjusted for school-level clustering

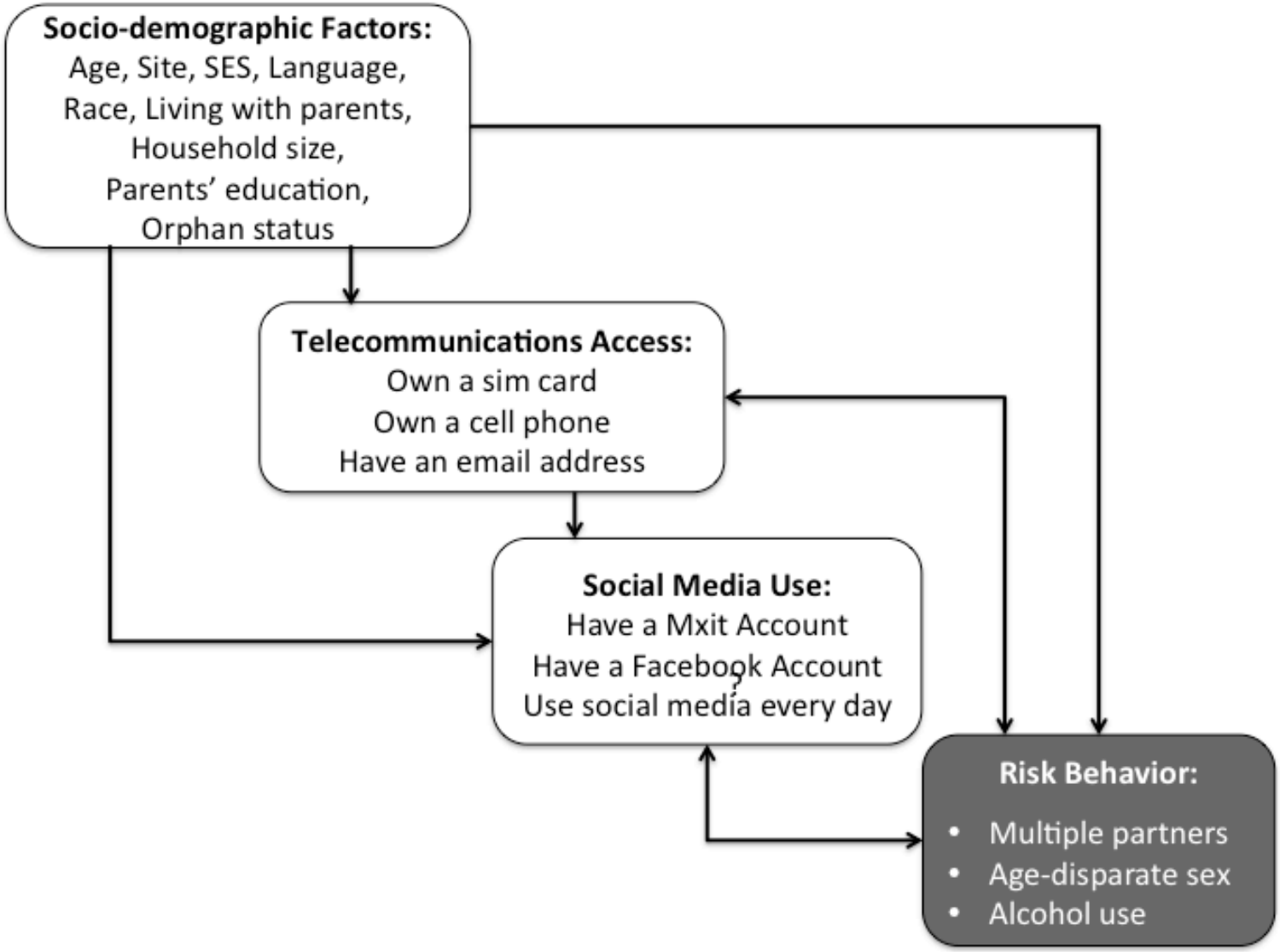
[b] Random-effects logistic regression adjusted for age group, site, orphan status, sim card ownership and cell ownership

[c] Random-effects logistic regression adjusted for age group, site, SES, household language, race and owning a sim card

[d] $p<0.05$, variable included in multivariate model as potential confounder

HAU = Hazardous Alcohol Use, defined as AUDIT score ≥ 8

Figure 1: Hierarchical conceptual framework for hypothesized associations between social media use and risk behavior



Linking section 2: Approach to follow-up in the GOAL Trial

Attrition in South African secondary schools

Entering the follow-up survey, we anticipated significant challenges with attrition. South Africa's dropout rate increases dramatically between Grade 9 (6.5%) and Grade 10 (11.5%).[1] This indeed is one of the reasons that Grade 9 is an optimal age group to target with school-based HIV prevention interventions; the majority of students are soon-to-become sexually active if not starting to engage in sexual intercourse, and many dropout of school - grade repetition is also high in South African secondary schools, with approximately 12.3% of male and 9.0% of female learners nation-wide repeating Grade 9.[1] This is especially problematic in the Eastern Cape, which consistently has the lowest matriculation pass-rate of any province in the country (64.9% compared to the national average of 78.2%) as well as one of the lowest secondary school gross-enrolment ratios.[2,3]

Follow-up Data Collection Methods

Changes to the follow-up questionnaire

While the vast majority of the baseline questionnaire was repeated for follow-up, a number of noteworthy changes were made to the questionnaire prior to beginning follow-up surveys.

- In order to shorten the questionnaire and make it less burdensome, the 20-item depression section was removed.
- Reported sexual behaviour questions asking about the last 12 months were modified to ask about the last 6 months, since some schools had only 8-10 months in between completion of the Generation Skillz intervention and the follow-up survey.
- 10 items were added to the questionnaire completed by intervention participants, asking about their experience and perceptions of the intervention (if they remembered it) and the SMS's (if they received and remembered them).

- The Asset Index and questions about the participants' households were removed, as it was assumed that answers to these questions were unlikely to have changed notably between 2012 and 2013.
- As a result of these changes (and perhaps also because participants had familiarity with the phones), survey completion time at follow-up was substantially shorter (approximately 15-25 minutes) than at baseline (approximately 25-35 minutes).

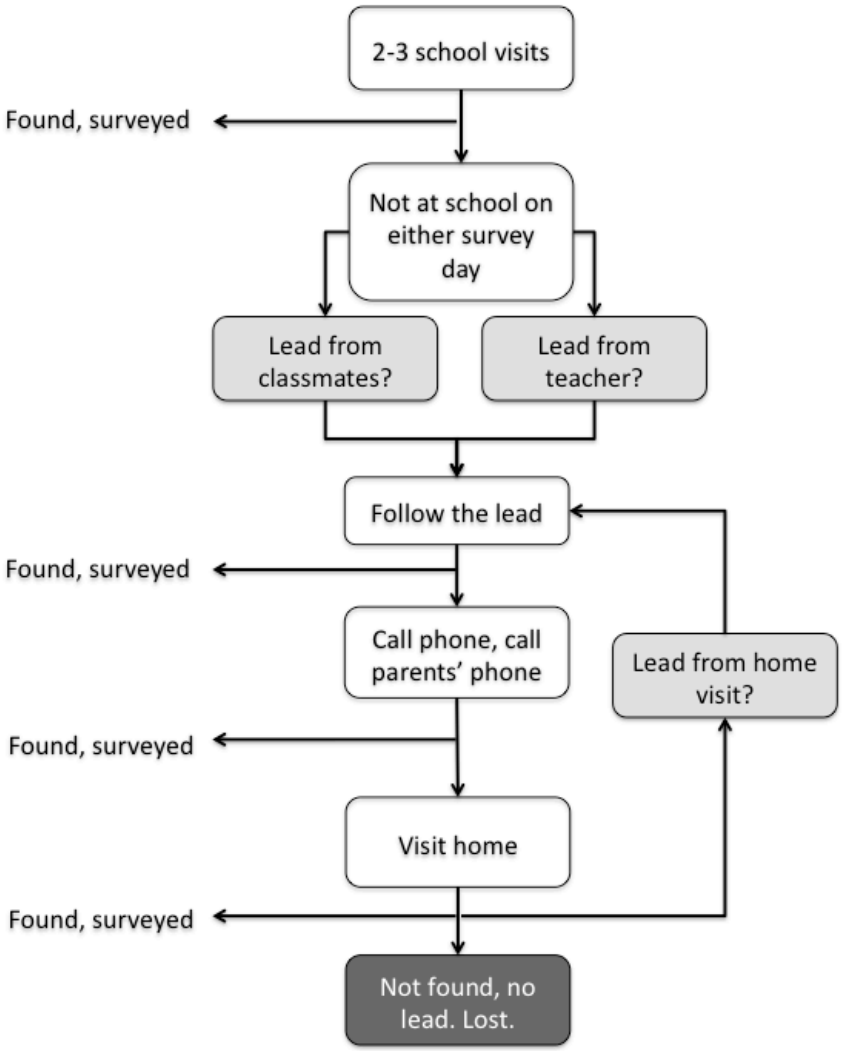
Follow-up strategy and tracing

In order to minimize loss-to-follow-up and reach as many participants as possible at 12-month follow-up, the study adopted a multi-pronged follow-up strategy. Figure 1 presents a flowchart of the GOAL follow-up tracing process.

First, repeat visits were made to each school to conduct follow-up questionnaires with participants now in Grade 10 as well as those repeating Grade 9. The survey teams liaised with Life Orientation teachers to identify which students were in Grade 10, still in Grade 9 or had dropped out. Efforts then were made to trace participants who could not be located at their trial school (i.e. those who had dropped out, moved to another school, etc). Each survey team had at least 1 survey administrator who served as point person for tracing, with the entire team helping with tracing during school holidays.

If information had been obtained about a participant, the survey teams would first follow that lead. For instance, in Khayelitsha, the team learned that a number of trial participants had left their high school and enrolled in False Bay College, so they visited the college several times and found roughly a dozen participants there. If no information

Figure 1: Diagram showing GOAL Trial tracing process



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London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

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.....
I led all analysis and write-up (and designed and directed the trial).
.....

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STUDENT ID NO: ..... **267998** .....

CANDIDATE'S SIGNATURE .....  Date ..... **11 April 2014** .....

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Midline results of the GOAL Trial: a cluster-randomised trial of a sport-based HIV prevention intervention and associated SMS campaign in South African schools

Kaufman Z.A.[1,2], Kaufman E.B.[1], Hershow R.[3], DeCelles J.[3], Dringus S.[1], Weiss H.A.[1], Free C.[1], Delany-Moretlwe S.[2], Ross D.A.[1]

[1] London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health: London, UK

[2] Wits Reproductive Health and HIV Institute: Johannesburg, South Africa

[3] Grassroot Soccer, Inc: Cape Town, South Africa

Target journal: *To be decided*

Abstract

Purpose: The need for effective interventions to reduce sexual risk behaviour among adolescents remains critical. Previous evaluations of sport-based HIV prevention (SBHP) interventions have shown promise but lacked rigour, and a growing body of research suggests SMS messaging may be an effective tool for promoting sexual health.

Methods: A cluster-randomised trial was carried out in forty-six schools in informal settlements in Cape Town and Port Elizabeth, South Africa to assess the effectiveness of an eleven-session SBHP intervention and an associated 12-month, biweekly SMS campaign in reducing reported age-disparate sex, multiple partnerships, and rape perpetration. The primary trial results will be based on a 2014 endline survey, but in 2013, midline questionnaires were completed by 3442 participants 8-11 months post-intervention delivery (median age: 16 years). Random-effects logistic and linear regressions were used to assess differences between study groups, adjusting for age group, site, school-level clustering, and baseline outcomes.

Results: There was very strong evidence that the SBHP intervention increased HIV-related knowledge for both males and females (β=0.39, 95%CI=0.25-0.53), reported ever testing for HIV among males (OR=1.38, 95%CI=1.11-1.72), and reported testing for HIV in the last year among males (OR=1.47, 95%CI=1.13-1.90). On the other hand, there was strong evidence that the intervention increased reported multiple partnerships in the last six months among males (OR=1.34, 95%CI=1.08-1.66). Within the intervention arm, there was strong evidence that the SMS campaign reduced reported multiple partnerships in the last six months among males and females combined (OR=0.75, 95%CI=0.58-0.96), but no evidence that it improved knowledge or attitudes.

Conclusions: The trial's midline results suggest the SBHP intervention was not effective in achieving its primary behavioural objectives in the first year, despite increases in knowledge and self-reported HIV testing. Our findings provide further evidence that targeted SMS's may be an effective tool for sexual health promotion.

Keywords: HIV, sexual behaviour, sport, SMS, adolescents

Introduction

The need for effective adolescent-targeted interventions to reduce sexual risk behaviour remains critical. South Africa is enduring the world's most severe HIV epidemic, with more than 6.4 million people living with HIV and approximately 469,000 new infections per year.[1,2] Roughly 30% of these new infections occur among 15-24 year-old youth, corresponding to approximately 1.5% HIV incidence per year.[1]

Interest is growing internationally in the use of sport in interventions to change behaviour and improve health, with numerous sport-based HIV prevention (SBHP) interventions currently being delivered across Sub-Saharan Africa, for example[3]. A recent systematic review showed that while results of observational and quasi-experimental studies of SBHP interventions have been promising, no RCTs had been reported.[4]

In its 2012-2016 strategic plan, the South African government identified young women and people living in informal settlements as key target populations for HIV prevention, also stating that curricular and co-curricular sexuality education and life skills programs must be provided in all schools "to build skills, increase knowledge and shift attitudes, change harmful social norms and risky behaviour" (p41).[5] While there is strong evidence supporting the effect of well-designed school-based HIV prevention interventions on knowledge and self-reported behavioural outcomes,[6] no trials have yet compared sport-based interventions with traditional teacher-led interventions in schools.

The use of short messaging service (SMS) messages is becoming increasingly common in health promotion programmes—including sexual health—around the world, including in sub-Saharan Africa.[7,8] This is particularly relevant in South Africa, which has the highest mobile phone penetration in Africa.[9] Evidence of the potential positive health effects of SMS-based interventions has come from a trial of smoking cessation SMS's in the UK [10] and two trials of ART-adherence SMS's in Kenya.[11,12] Reviewing the literature on the use of SMS's specifically for sexual health, Lim and

Colleagues[8] highlighted the growing use of SMS's by clinics for partner notification, contact tracing, and sexual health education, finding some evidence of effectiveness but an overall need for further evaluation of these interventions. Outside of an intervention context, however, use of instant-message-based social media may increase sexual risk-taking, as suggested by a cross-sectional study among South African adolescents.[13]

This paper presents midline results from the GOAL Trial, assessing the effect on reported sexual behaviour, HIV-related knowledge and HIV-related attitudes of (i) the first year of the Generation Skillz intervention, and (ii) the additional effect of sending biweekly SMS messages.

Methods

Trial Design

Schools were the unit of randomisation in this cluster-randomised trial. Detailed aspects of the trial design have been documented previously.[14] Ethics approval for the trial was obtained from the University of the Witwatersrand's Human Research Ethics Committee and the London School of Hygiene and Tropical Medicine Ethics Committee. The trial is registered with the Pan-African Clinical Trials Registry (ID number: PACTR201402000767141).

Participants

The study enrolled male and female Grade 9 learners at 46 public secondary schools in informal settlements in Cape Town (n=16 school) and Port Elizabeth (n=30 schools). Port Elizabeth was divided into two sites: Port Elizabeth 1 (urban townships in the city – Zwide, New Brighton, Kwazakhele, n=15 schools) and Port Elizabeth 2 (peri-urban townships to the east of the city – Motherwell and Uitenhage, n=15 schools). Participating schools in Cape Town (n=16) were located in the communities of Khayelitsha, Gugulethu, and Langa. A youth advisory committee was formed with adolescents from participating schools, advising on questionnaire content, recruitment procedures, and ways to make the trial's data collection as youth-friendly as possible.

The trial's baseline results[15] showed that the vast majority of trial participants spoke Xhosa at home (96%) and self-identified as black (92%). It also showed that groups were well matched in terms of socio-economic status (as measured via a five-item asset index), telecommunications access, and baseline knowledge and reported attitudes, though control group males were slightly older at baseline and a slightly higher proportion of females in the control group reported having ever had sex.

Interventions

The Generation Skillz core curriculum was designed and delivered by Grassroot Soccer (GRS), an international NGO with its headquarters in Cape Town, South Africa. Generation Skillz consists of eleven 45-minute activity- and discussion-based sessions, delivered during life-orientation school periods by trained "Coaches" (see below). The curriculum is primarily focused on reducing multiple partnerships, age-disparate sex, and gender-based violence, but also addresses male circumcision, condom use, and HIV counselling and testing. The core curriculum was delivered between March and October 2012 in the 23 intervention schools. In addition, approximately 10-12 months after the core intervention, Generation Skillz Coaches delivered a further seven 'booster' sessions (known as Generation Skillz Utshintsho) between March and September 2013 (the midline survey was conducted prior to delivery of Generation Skillz Utshintsho interventions). The intervention and its development process are described in detail elsewhere.[16] Both intervention and control schools also received standard Department of Education life orientation classes related to HIV. At the time of implementation within the GOAL Trial, the 97-page Generation Skillz curriculum [17] was in its fourth version. [16]

Generation Skillz 'Coaches' are young community role models from the informal settlements where the interventions are delivered. Most are between 18 and 25 years and have completed secondary school. Coaches receive a 5-day pre-service training, additional on-the-job training and support from certified "Master Coaches" with at least one visit per month per coach, and weekly development sessions led by Master Coaches. In addition to curriculum content, Coach training courses teach facilitation skills, HIV and AIDS epidemiology, and how to make referrals.

Between May 2012 and March 2013, biweekly SMS messages were sent to all youth in 12 (of the 23) randomly chosen intervention schools. The SMS messages were developed to reinforce key messages in the Generation Skillz curriculum and encourage participants to share their knowledge with their peers. For example, one SMS reads: "WOW! In SA, 20% of people 20-34 years old have HIV! Only 5% of people your age have HIV. Which partner puts you more at risk?" A total of 35 different SMS messages sent out over 12 months. SMS's were sent from the online trial database to participants' phone numbers that had been collected at the beginning of the study on assent forms.

Control schools received standard, teacher-led Department of Education (DoE) life orientation classes, which vary in nature site-to-site and school-to-school. Of relevance to Generation Skillz, the DoE's curriculum statement states that Grade 9 learners should spend a total of four hours learning about 'sexual behaviour and sexual health' during the year, and an additional four hours learning about 'goal-setting: personal lifestyle choices'.[18]

Outcomes

The trial had three primary, predefined behavioural outcomes:

- Age-disparate sex (defined as reporting having had a sexual partner who was five or more years older or younger) in the last six months. Participants were asked "How old was the oldest sexual partner you had sex with in the last 6 months?" and "How old was the youngest sexual partner you had sex with in the last 6 months?"
- Multiple partners (defined as reporting two or more sexual partners) in the last six months
- Reported rape perpetration ever among males (defined as responding affirmatively to a question about having forced unwanted sex with a partner/girlfriend and/or a question about having forced unwanted sex with a non-partner)

Secondary outcomes for the trial include:

- Reported hazardous alcohol use (measured via the AUDIT scale[19]; a score of 8 or higher is considered hazardous. This cut-off also includes those who screen positive for harmful drinking);

- Belief in male-dominant gender norms (measured via an adapted 10-item GEM scale[20], divided into three equal score ranges: low, medium, and high);

- HIV-related stigma (adapted from the Measure DHS AIDS Indicator Survey (AIS)[21], divided into three equal score ranges: low, medium, and high); and

- HIV-related knowledge (measured on a 10-item scale, including items from AIS[21] and UNGASS[22] as well as others related to circumcision, prevention of mother to child transmission, and ADS; divided into three equal score ranges: low, medium, and high).

Originally, we had planned to use a recall period of the last twelve months for these outcomes. However, since some schools had only 9 to 11 months in between the end of intervention delivery and the follow-up survey, the outcome period was shortened to six months for all participants.

Sample Size

The trial design assumed an average of 100 learners per school, 9% attrition per year, 15% end-line period prevalence of ADS, 25% end-line period prevalence of recent multiple partners, and 15% end-line period prevalence of reported rape perpetration in the control group, and a k of 0.25. Using the Hayes and Bennett [23] method for assessing sample size for cluster randomised trials, we determined that a sample size of 46 schools and 4600 participants would give the trial an 80% chance of detecting a true 27% effect of the Generation Skillz intervention on the period prevalence of ADS (p=0.05), a true 24% effect on multiple partners in the last 6 months, and a true 29.5% effect on reported rape perpetration.

Randomisation

Stratified randomisation was used to determine each school's group allocation. Schools were stratified first by site, then by size (large vs. small, based on whether they fell into the upper or lower 50% of schools based on enrolment numbers) and then by estimated attrition (high or low, based on the expected percentage of school dropouts between Grade 9 and Grade 12, approximated using 2012 cross-sectional enrolment numbers provided by schools). This gave a total of 12 strata. To ensure transparency, public randomisation events were held in each site approximately 3-4 weeks prior to the start of data collection, with life-orientation teachers, school administrators, and GRS staff and volunteers in attendance. After the main allocation, intervention schools were re-randomised using the same stratified approach to determine which schools would receive the SMS booster. All schools had agreed to participate in the trial before the randomisation events were held. Due to the logistical need to disclose whether a school would receive the intervention (after randomisation), it was not possible to mask a school's allocation from school administrators, teachers, study participants, or survey administrators.

Data Collection

A 146-item questionnaire was developed to assess participants' demographic status, HIV-related knowledge, reported attitudes, reported gender norms, reported alcohol use, reported experience or perpetration of IPV, and reported sexual behavior at baseline. Most demographic questions were removed from follow-up questionnaires, shortening them to 109 items plus an additional 12 questions assessing the intervention group's perceptions of the Generation Skillz intervention. Participants had the option to select "I don't want to answer" on each question.

Baseline and midline surveys was carried out using Open Data Kit (ODK) Collect (version 1.2) on Android mobile phones provided temporarily by the study to the respondents for questionnaire completion.[24] ODK has been pilot tested successfully in numerous resource-limited settings in Africa and Latin America.[25] We have observed high participant acceptability for a similar ODK-based sexual behaviour survey in Zimbabwe.[26] Similar, more expensive technologies—such as Audio Computer Assisted Self-Interview (ACASI)—for collection of data on sexual behaviour

have been shown to be more valid in cross-sectional surveys than self-administered questionnaires on pen and paper or face-to-face interviews [27]. Questionnaires took participants, on average, approximately 25-30 minutes to complete. When completing a questionnaire, participants had the option to read and select options written in English or isiXhosa, with optional audio assistance also available in isiXhosa. All GOAL surveys were confidential; participants were identified only with a six-digit study ID, and no personal identifying information is entered into the mobile phones. Data were transmitted daily through a secure wifi connection to an online database.

Statistical methods

A pre-hoc analysis plan was developed and approved by the trial's Data Safety and Monitoring Board prior to data analysis being carried out. Cluster-level summary statistics for primary and secondary outcomes from baseline surveys were computed by sex for each school. For the primary trial results presented here, an intention-to-treat analysis was conducted. Random-effects logistic regression was used to assess differences between groups on behavioural outcomes, adjusting for age group, school-level clustering and cluster-level baseline summaries of each outcome. Differences between groups in continuous outcomes (knowledge, reported self-efficacy, reported stigma, reported gender-equitable norms) were assessed using random-effects linear regression, adjusting for age group, school-level clustering, and cluster-level baseline summaries of each outcome. For example, the assessment of knowledge differences at follow-up between males receiving Generation Skillz and those in the control group was adjusted for age group, school-level clustering and school-level mean baseline knowledge scores among males. This approach was favoured over a cohort-style analysis based on imperfections in study ID linkage between baseline and follow-up surveys.

Results

Recruitment

At baseline, 4485 participants were enrolled and completed questionnaires (2173 interventions; 2312 control). The results of the baseline survey, including sample characteristics and descriptive statistics for the trial's primary and secondary outcomes have been documented in a separate paper.[14] In the 2013 midline follow-up, 3442 surveys were completed (1607 intervention, 74.0% follow-up; 1835 control, 79.4% follow-up) for an overall follow-up rate of 76.7%. The follow-up rate for females (77.8%) was slightly higher than the follow-up rate for males (75.4%). Figure 1 shows the flow of participants in the trial by group.

[INSERT FIGURE 1 NEAR HERE]

Table 1 presents sample characteristics by group and by sex. The median age at follow-up was 16 years for female participants (IQR: 15-17 years) and 17 years for male participants (IQR: 16-18 years). Control males (mean age=16.9 years, SD=1.4 years) were slightly older, on average, than intervention males (mean age=16.6 years, SD=1.3 years). Across sexes, the intervention group had a slightly lower proportion of participants from Port Elizabeth 1 (25.3% vs 29.1%) and a slightly higher proportion of participants from Port Elizabeth 2 (33.1% vs 30.8%). A slightly higher proportion of intervention participants reported living with both parents (33.0% vs 29.2%) and a slightly lower proportion reported living with neither of their parents (21.8% vs 24.4%).

[INSERT TABLE 1 NEAR HERE]

Effects of Generation Skillz on reported sexual behaviour

Table 2 presents differences between groups by sex in reported sexual behaviour. After adjusting for age group, site, school-level clustering and baseline prevalence, males in the intervention group had 34% higher odds of reporting more than one partner in the last six months than males in the control group (OR=1.34, 95%CI=1.08-1.66). Females in the intervention group had higher odds of reporting an age-disparate partner in the last six months than females in the control group (5.2% vs 3.4%, OR=1.65, 95%CI=1.03-2.63) and there was a similar, but non-significant tendency for them to report age-disparate older partners (4.1% vs 2.9%, OR=1.65, 95%CI=0.90-3.01, p=0.10). Relative to males in the control group, males in the intervention group had higher odds of reporting having ever tested for HIV

(OR=1.38, 95%CI=1.11-1.72) and of having tested for HIV in the last 12 months (OR=1.47, 95%CI=1.13-1.90). On the other hand, males in the intervention group also had higher odds of reporting having ever perpetrated physical intimate-partner violence (OR=1.27, 95%CI=1.00-1.60).

[**INSERT TABLE 2 NEAR HERE]**

Effects of Generation Skillz on HIV-related knowledge and reported attitudes

Table 3 presents differences overall and by sex between groups in HIV-related knowledge, reported attitudes, and reported gender norms. After adjusting for age group, site, school-level clustering and baseline knowledge scores, there was very strong evidence at midline that participants in intervention schools (μ=6.40, SD=2.04) had higher HIV-related knowledge than participants in control schools (μ=5.96, SD=2.12) (β=0.39, 95%CI=0.25-0.53. This effect was consistent for both males (β=0.44, 95%CI=0.22-0.66, p<0.001) and females (β=0.35, 95%CI=0.17-0.53). No evidence of effect was observed on HIV stigma, self-efficacy to prevent HIV, or gender-equitable norms.

[INSERT TABLE 3 NEAR HERE]

Table 4 presents knowledge differences between groups question-by-question. Specifically, the intervention group scored higher than the control group on knowledge of older partners as a risk factor (OR=1.87, 95%CI=1.46-2.41), having other STIs as a risk factor (OR=1.30, 95%CI=1.07-1.56), alcohol as a risk factor (OR=1.47, 95%CI=1.19-1.80), and the increased risk of HIV transmission during the first 6-8 weeks of infection (OR=1.25, 95%CI=1.07-1.46).

[INSERT TABLE 4 NEAR HERE]

Effects of Generation Skillz SMS campaign

Table 5 presents differences in reported behavioural outcomes between the intervention sub-groups (SMS and non-SMS). Across sexes, after adjusting for age group, site, sim card ownership, school-level clustering and baseline prevalence, there was strong evidence that participants at schools receiving the SMS campaign had roughly 25% lower odds of reporting multiple partners in the last six months, compared to participants at schools receiving only Generation Skillz without the SMS

campaign (OR=0.75, 95%CI=0.58-0.96). There was strong evidence that girls at the SMS schools had nearly 2-times lower odds of reporting having had sex while drunk in the last six months (OR=0.54, 95%CI=0.32-0.92) and weak evidence that they had nearly twice the odds of reporting having ever used a condom (OR=1.94, 95%CI=0.99-3.78). On the other hand, males at SMS schools had roughly 1.6-times higher odds of reporting more than two lifetime partners (OR=1.59, 95%CI=1.07-2.37), but there was no significant difference in their odds of reporting recent or current multiple partnerships. No evidence of an effect of the SMS campaign on age-disparate sex in the last six months was observed, though responses trended towards lower odds for both sexes (Combined OR=0.72, 95%CI=0.42-1.22). Similarly, there was no significant effect of the SMS campaign on reported rape perpetration but a trend towards lower odds in the group receiving SMS's (OR=0.65, 95%CI=0.33-1.29).

[INSERT TABLE 5 NEAR HERE]

Table 6 presents differences in knowledge, reported attitudes and reported gender norms between participants from intervention schools receiving SMS's and those from schools not receiving SMS's. After adjusting for age group, site, sim card ownership, school-level clustering, and baseline scores, there was no evidence that the SMS campaign had an effect on HIV-related knowledge, stigma, self-efficacy or gender-equitable norms. Sex-specific analyses did not reveal evidence of any differences in this lack of an effect for males or females.

[INSERT TABLE 6 NEAR HERE]

Table 7 presents differences in the three primary behavioural outcomes between schools receiving Generation Skillz and the SMS campaign (n=12) and control schools (n=23). No evidence of difference was observed on reported age-disparate sex in the last six months (OR=1.04, 95%CI=0.64-1.71), multiple partners in the last six months (OR=0.98, 95%CI=0.74-1.29) or rape perpetration (OR=0.74, 95%CI=0.47-1.15).

[INSERT TABLE 7 NEAR HERE]

Loss-to-follow-up analysis

The loss-to-follow-up (LTFU) analysis revealed 1309 participants (29.5% of the baseline sample) who were surveyed at baseline and did not have midline surveys

matching their study ID. Of these, 677 were intervention participants (31.6% LTFU) and 632 were control participants (27.6% LTFU). There was no evidence of differential loss-to-follow-up rates by study group (aOR=1.03, 95%CI = 0.69-1.55). Table 8 summarizes the sample characteristics of participants lost-to-follow-up by group. There was very strong evidence of lower LTFU in the Port Elizabeth 1 site, compared to Cape Town (20.9% vs 35.1%, OR=0.46, 95%CI=0.30-0.71) and to Motherwell/Uitenhage (20.9% vs 33.1% LTFU, OR=0.47, 95%CI=0.30-0.73). There was very strong evidence that the odds of LTFU increased linearly with baseline age (OR=1.27, 95%CI=1.20-1.35). Compared to participants living with both parents at baseline, there was very strong evidence of increased odds of LTFU among participants living with neither parent at baseline (OR=1.30, 95%CI=1.08-1.58) and among participants living with only their father at baseline (OR=1.55, 95%CI=1.15-2.09). However, there was no evidence of higher odds of LTFU among participants who had lost one or both parents. There was weak evidence of an association between increased LTFU and having fewer baseline household residents (coef=-0.36, 95%CI=-0.72 to 0.01, p=0.06) and between increased LTFU and having a lower baseline asset index (coef=-0.01, 95%CI=-0.03 to 0.00, p=0.06).

Overall, LTFU was more common among those participants who reported more sexual risk behaviour, alcohol consumption and partner violence at baseline. Specifically, there was very strong evidence that participants who reported already having ever had sex at baseline had higher odds of LTFU (OR=1.60, 95%CI=1.38-1.84). There was also very strong evidence of higher odds of LTFU among participants reporting multiple partners in the past year at baseline (OR=1.36, 95%CI=1.15-1.60), weak evidence of increased odds of LTFU among those reporting ADS in the last year at baseline (OR=1.26, 95%CI=0.96-1.65), strong evidence of increased odds of LTFU among those reporting have ever perpetrated rape (OR=1.33, 95%CI=1.02-1.72), strong evidence of increased odds of LTFU among males reporting having ever perpetrated IPV (OR=1.27, 95%CI=1.03-1.56), and very strong evidence that odds of LTFU increased linearly with increased hazardous drinking (OR=1.15, 95%CI=1.04-1.27).

[INSERT TABLE 8 NEAR HERE]

Within groups, LTFU varied by site. Among the intervention group, the highest proportion of participants lost-to-follow-up came from Cape Town (38.6%), whereas in the control group, the highest proportion of participants lost-to-follow-up came from Motherwell/Uitenhage (32.1%). Notably, there was differential LTFU between groups in terms of reported multiple partnerships. In the control group, there was very strong evidence of higher odds of LTFU among males reporting more than one partner in the last year at baseline (OR=1.61, 95%CI=1.20-2.16) whereas there was no such evidence in the intervention group (OR=1.23, 95%CI=0.90-1.68). The opposite was true for females, with very strong evidence of higher odds of LTFU among intervention females reporting multiple partners in the last year (OR=1.69, 95%CI=1.11-2.55) but not among control females (OR=1.04, 95%CI=0.70-1.56). Similarly, while there was strong evidence of increased odds of LTFU among control participants reporting ADS at baseline (OR=1.42, 95%CI=1.00-2.02), there was no such evidence among intervention participants (OR=1.07, 95%CI=0.70-1.65).

Discussion

Very strong evidence was observed of a positive effect of the Generation Skillz intervention on HIV-related knowledge for both sexes and on reported HIV testing among males, while strong evidence of a negative effect was observed on reported multiple partners in the last six months among males, age-disparate sex (with a younger or older partner) in the last six months among females, and intimate-partner violence perpetration among males. Given that these latter three behaviours were the primary focus of the intervention, which was designed in accordance with the 17 characteristics of effective sex and HIV education programmes reported by Kirby and colleagues,[6] and given previous findings on SBHP interventions' effectiveness[28], these results are both surprising and discouraging.

The on-going process evaluation may help to answer questions of why these negative effects have been observed, and it will be important to see whether they persist, attenuate, or are reversed after the second year of the intervention through

the survey that is being conducted between February and August 2014. We have hypothesized three potential explanations. First, a partial explanation could be that the intervention increases use of Mxit, a South African social network which works on mobile phones and tablet computers, among males (81.2% in the intervention group compared to 72.5% in the control group, p=0.006) and this has been documented as a risk factor for multiple partnerships.[13] Second, there may have been one or more "coaches" who promoted negative behaviours or potentially even engaged in sexual relationships with participants. Indeed, the intervention, by its delivery mechanism, does facilitate contacts between teenage girls and young adult male coaches, many of who are 5-10 years older than the participants. Thirdly, it may be possible that increasing adolescents' awareness of certain risk factors like ADS and multiple partners might lead them to over-report these risky behaviours, as was suggested by investigators in a previous trial of an IPV reduction intervention in South Africa.[29]

On the other hand, comparing participants from intervention schools receiving the SMS campaign to those from intervention schools not receiving it, we observed strong evidence that the SMS campaign was associated with a decrease in reported multiple partners in the last six months (OR=0.75, 95%CI 0.58-0.96), despite seeing no evidence of an effect on knowledge, reported attitudes, reported gender norms or other reported behaviours. This observed effect supports previous findings in the literature that suggest that SMS campaigns can positively influence behaviour.[10,11] However, comparing the schools receiving SMS's to control schools, no evidence of difference was observed on any of the three primary behavioural outcomes. This suggests that the intervention combined with SMS's still did not produce the desired outcomes at midline.

The LTFU analysis revealed that riskier participants, older participants, and Cape Town participants had higher odds of attrition, and that the profiles of participants lost differed between the intervention and control groups. Importantly, control males reporting multiple partners at baseline had higher odds of being lost (compared to males not reporting multiple partners at baseline), while the same was

not true for intervention males reporting multiple partners at baseline. This may partly explain the observed midline difference between intervention and control groups in reported multiple partnerships and reported ADS, as the midline analysis was adjusted for baseline differences and the control group had higher odds than the intervention group of losing participants who had reported multiple partners and/or ADS at baseline. Further investigation in the process evaluation should look into reasons why the groups may have lost participants with different risk profiles.

The study had several limitations. First, self-reported data on sexual behaviour is prone to social desirability bias, which may reduce study validity,[30] and the intervention may have also influenced what participants view as socially desirable responses. The mobile-phone-based questionnaire was designed to maximize confidentiality and minimize social desirability bias, but it is possible that some participants felt that they should give answers they deemed to be socially desirable rather than truthful answers. Additionally, selection bias may have played an important role in the trial, both in terms of enrolment into the study (with nearly half of learners not participating) and in terms of follow-up. Since a higher proportion of intervention participants than control participants were lost-to-follow-up, it is possible that selection bias may have been differential. This could have led to an under-estimate of the effects (i.e., if riskier adolescents were more likely to be lost-to-follow-up) or an over-estimate of the effects (i.e., if riskier adolescents were more likely to participate at follow-up). There was a small risk of contamination between study groups, as it is possible that intervention and control participants may have interacted outside of the school context (e.g. in other community settings or activities, such as sports teams or youth groups). We expect that minimal contamination occurred, however, since no study school was within close proximity (<1km) to another school in the opposite group. Lastly, there is a possibility of recall bias, as two of the primary outcomes depend on a recall period of six months, and it is possible some participants misremembered the ages of their recent partners or the number of recent partners.

The study's findings may be generalizable to secondary schools in informal settlements in the Eastern and Western Cape (and perhaps more broadly in South Africa) but should not be generalized to all sport-based HIV prevention interventions. Indeed, many such interventions target younger participants than Generation Skillz.

In sum, while the SMS campaign has shown promise, the Generation Skillz intervention, while improving knowledge, had no significant impact on HIV stigma, self-efficacy to prevent HIV, gender-equitable norms, self-reported rape perpetration among males, self-reported age-disparate sex in the last 6 months among males, or self-reported multiple partners in the last 6 months among females, and resulted in an increase in self-reported age-disparate sex in the last 6 months among females, and an increase in self-reported multiple partners in the last 6 months among males. If the two-year follow-up survey confirms these findings, the Generation Skillz intervention or aspects of the staff delivering it will need to be modified in order to achieve its desired objectives of reducing age-disparate sex, multiple partnerships, and rape perpetration. In the meantime, based on the midline results alone, we cannot recommend implementation of Generation Skillz over standard DoE Life Orientation education. Further research will explore the GOAL Trial's qualitative process evaluation findings and the 2014 follow-up survey results.

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Contributions of authors

ZK served as Trial Director, leading trial design, management, analysis and write-up. EBK and JD led intervention design and contributed to study design and preparation. RH and SD led data collection teams and contributed to study management. HW served as statistical advisor for the trial. CF advised on the nested SMS trial and the design of the SMS campaign. DR and SDM served as co-Principal Investigators, overseeing study design and write-up. All authors reviewed drafts of the manuscript.

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Figure 1: GOAL Trial flow of participants from enrolment through 2013 follow-up

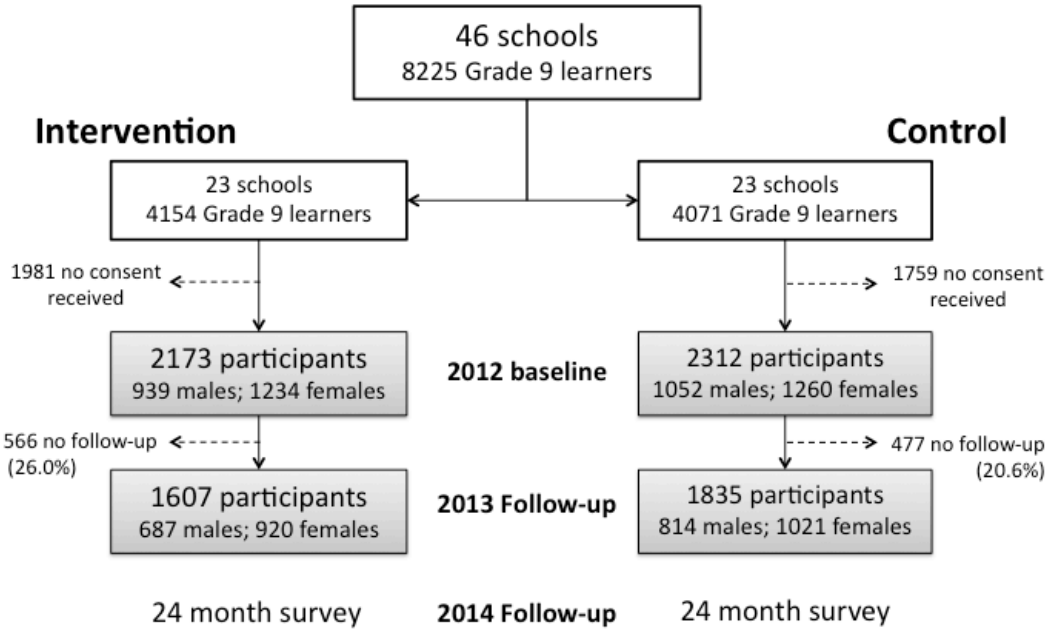


Table 1: Sample characteristics in 2013 follow-up survey (n=3442)

	All (n=3442)				Females (n=1692)				Males (n=1302)			
	Intervention		Control		Intervention		Control		Intervention		Control	
Characteristics	n	%	n	%	n	%	n	%	n	%	n	%
Baseline surveys completed	2173		2312		1234		1260		939		1052	
Follow-up surveys completed	1607	74.0	1835	79.4	920	74.6	1021	81.0	687	73.2	814	77.4
Site												
Cape Town	668	41.6	736	40.1	350	38.0	384	37.6	318	46.3	352	43.2
Port Elizabeth 1	407	25.3	533	29.1	236	25.7	291	28.5	171	24.9	242	29.7
Port Elizabeth 2	532	33.1	566	30.8	334	36.3	346	33.9	198	28.8	220	27.0
Age												
12-14 years	48	3.0	32	1.7	28	3.0	22	2.2	20	2.9	10	1.2
15 years	357	22.2	349	19.0	255	27.7	246	24.1	102	14.9	103	12.7
16 years	543	33.8	627	34.2	319	34.7	375	36.7	224	32.6	252	31.0
17 years	355	22.1	417	22.7	192	20.9	217	21.3	163	23.7	200	24.6
18-20 years	304	18.9	410	22.3	126	13.7	161	15.8	178	25.9	249	30.6
Live with parents												
Live with both parents	530	33.0	535	29.2	301	32.7	301	29.5	229	21.5	234	22.4
Live with mother only	641	39.9	736	40.1	368	40.0	402	39.4	273	5.4	334	7.9
Live with father only	86	5.4	117	6.4	49	5.3	53	5.2	37	39.7	64	41.0
Live with neither parent	350	21.8	447	24.4	202	22.0	265	26.0	148	33.3	182	28.8
Orphan Status*												
Both parents alive	1090	67.8	1258	68.6	615	66.9	709	69.4	475	69.1	549	67.4
Single Orphan	418	26.0	445	24.3	244	26.5	235	23.0	174	25.3	210	25.8
Double Orphan	98	6.1	129	7.0	60	6.5	74	7.3	38	5.5	55	6.8
Telecomms and Social Media												
Own a sim card	1138	70.8	1267	69.1	664	72.2	729	71.4	474	69.0	538	66.1
Own a cell phone	1058	65.8	1105	60.2	604	65.7	621	60.8	454	66.1	484	59.5
Have a Mxit account	1248	77.7	1343	73.2	690	75	753	73.8	558	81.2	590	72.5
Have a Facebook account	413	25.7	505	27.5	240	26.1	275	26.9	173	25.2	230	28.3

Table 2: Intention-to-treat analysis of effect of Generation Skillz on reported behaviour (n=3442)

	All (n=3442)						Females (n=1941)						Males (n=1501)					
	Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*	
	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	103	6.4	96	5.2	1.40	0.99-1.98	48	5.2	35	3.4	**1.65**	**1.03-2.63**	55	8.0	61	7.5	1.19	0.79-1.78
Older partner (5+ years) last 6 months	53	3.6	46	2.7	1.45	0.90-2.35	35	4.1	27	2.9	1.65	0.90-3.01	18	2.9	19	2.6	1.17	0.60-2.28
Younger partner (5+ years) last 6 months	50	5.5	51	5.0	1.24	0.78-1.97	13	2.6	8	1.4	N/A		37	9.1	43	9.4	1.10	0.64-1.88
More than 1 partner last 6 months	363	22.6	364	19.8	**1.32**	**1.08-1.63**	92	10.0	94	9.2	1.15	0.85-1.57	271	39.5	270	33.2	**1.34**	**1.08-1.66**
Reported rape perpetration ever													87	12.8	104	12.7	1.07	0.71-1.62
Secondary Behavioral Outcomes																		
Ever had sex	971	60.4	1086	59.2	1.21	1.00-1.47	461	50.1	506	49.6	1.15	0.91-1.44	510	74.2	580	71.3	1.22	0.95-1.57
More than 2 lifetime partners	420	43.3	447	41.2	1.19	0.93-1.52	120	26.0	111	21.9	1.29	0.95-1.76	300	58.8	336	57.9	1.00	0.78-1.29
Currently have >1 partner	174	11.4	220	12.6	0.88	0.71-1.09	85	9.7	103	10.5	0.91	0.67-1.23	89	13.7	117	15.2	0.89	0.65-1.21
Ever tested for HIV	892	55.5	995	54.2	1.16	0.95-1.41	533	57.9	611	59.8	0.97	0.76-1.24	359	52.3	384	47.2	**1.38**	**1.11-1.72**
Tested for HIV last 12 months	538	34.1	545	30.4	1.21	0.98-1.49	332	36.4	356	35.4	1.08	0.82-1.40	206	31.0	189	24.0	**1.47**	**1.13-1.90**
Circumcised													59	8.6	77	9.5	1.16	0.73-1.84
Ever used a condom*	734	75.6	816	75.1	1.02	0.80-1.29	375	813	410	81.0	0.98	0.66-1.45	359	70.4	406	70.0	1.03	0.78-1.38
Used a condom at last sex*	592	61.0	656	60.4	1.04	0.86-1.25	293	63.4	318	62.9	1.04	0.79-1.36	299	58.6	338	58.3	1.07	0.83-1.37
Sex while drunk last 6 months	197	12.9	269	15.4	0.97	0.76-1.25	92	9.4	72	8.2	0.97	0.68-1.39	125	19.3	177	23.1	0.84	0.62-1.14
Transactional sex last 6 months	58	3.8	82	4.7	0.93	0.61-1.40	16	1.8	24	2.5	0.75	0.39-1.42	42	6.5	58	7.6	0.92	0.57-1.48
Perpetration of physical intimate-partner violence ever													244	35.5	266	32.7	**1.27**	**1.00-1.60**
Hazardous alcohol use (8+ points)†	297	18.5	331	18.0	1.12	0.92-1.36	118	12.9	116	11.4	1.16	0.88-1.54	179	26.1	215	26.5	1.01	0.80-1.28

*Via random-effects logistic regression comparing intervention vs control, adjusted for age group, school-level clustering, and baseline prevalence

†Also includes harmful and high-risk alcohol use NA = Not enough events to carry out the regression

Table 3: Intention-to-treat analysis of effect of Generation Skillz on HIV-related knowledge, reported attitudes and reported gender norms (n=3442)

	All (n=3442)						Females (n=1941)						Males (n=1502)					
	Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*		Intervention		Control		Intention To Treat*	
Scale	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI
HIV Knowledge (out of 10)	6.40	2.04	5.96	2.12	**0.39**	**0.25 to 0.53**	6.37	2.02	5.97	2.15	**0.35**	**0.17 to 0.53**	6.45	2.07	5.96	2.08	**0.44**	**0.22-0.66**
HIV Stigma (out of 3)^	2.26	0.54	2.22	0.58	0.01	-0.03 to 0.04	2.28	0.54	2.25	0.58	0.02	-0.03 to 0.07	2.22	0.54	2.18	0.58	-0.02	-0.07 to 0.04
HIV Prevention Self-Efficacy (out of 3)	2.03	0.49	2.01	0.51	-0.01	-0.05 to 0.02	2.08	0.51	2.05	0.54	0.00	-0.05 to 0.04	1.97	0.44	1.96	0.46	-0.03	-0.08 to 0.03
Gender-Equitable Norms (out of 3)	1.71	0.35	1.69	0.35	0.00	-0.02 to 0.03	1.76	0.36	1.74	0.37	0.02	-0.01 to 0.05	1.65	0.33	1.64	0.33	-0.01	-0.04 to 0.02

*Via random-effects linear regression comparing intervention to control, adjusted for school-level clustering, age group, site, and baseline scores

^Higher scores indicate more favorable attitudes towards people living with HIV

β = Coefficient for linear regression, positive numbers indicate a positive correlation

Table 4: Question-by-question analysis of differences in HIV-related knowledge between the intervention and control group (n=3442)

	All (n=3442)					
	Intervention		Control		Intention To Treat*	
Question	n	%	n	%	OR	95% CI
I can tell if someone has HIV by looking at him or her	1271	79.1	1399	76.2	1.09	0.86-1.38
Having an older sexual partner increases your risk of getting HIV	1234	76.8	1166	63.5	**1.87**	**1.46-2.41**
Using condoms during sex reduces your risk of getting HIV	943	58.7	1011	55.1	1.09	0.91-1.31
An HIV-positive mother would never give birth to an HIV-negative baby. ^	1095	68.1	1241	67.6	1.04	0.89-1.22
You are more likely to get HIV if you already have an STI	930	57.9	947	51.6	**1.30**	**1.07-1.56**
Having only one mutually faithful partner reduces your risk of getting HIV	883	55.0	954	52.0	1.04	0.86-1.25
Male circumcision reduces a man's risk of getting HIV	681	42.4	758	41.3	1.11	0.96-1.28
Legally, men are allowed to beat their wives.^	1320	82.1	1506	82.1	0.93	0.74-1.17
Drinking alcohol can increase your risk of getting HIV	1041	64.8	1007	54.9	**1.47**	**1.19-1.80**
Someone is most likely to spread HIV during the first 6-8 weeks after they get infected	888	55.3	955	52.0	**1.25**	**1.07-1.46**

Numbers and percentages shown indicate those of favourable responses

^ For these questions, false was the favourable response

*Via random-effects logistic regression, adjusted for age group, site, school-level clustering and baseline knowledge

Table 5: Intention-to-treat analysis of effect of Generation Skillz SMS campaign on reported behaviour (n=1690)

	All (n=1690)						Females (n=967)						Males (n=723)					
	SMS		No SMS		Intention To Treat*		SMS		No SMS		Intention To Treat*		SMS		No SMS		Intention To Treat*	
	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)	n	%	n	%	OR	(95% CI)
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	42	5.3	63	7.1	0.72	0.42-1.22	21	4.4	28	5.8	0.74	0.38-1.44	21	6.6	35	8.7	0.78	0.43-1.41
Older partner (5+ years) last 6 months	20	2.7	33	4.1	0.62	0.26-1.46	15	3.4	20	4.4	0.77	0.31-1.89	5	1.7	13	3.6	0.47	0.15-1.43
Younger partner (5+ years) last 6 months	22	4.9	30	5.9	0.84	0.42-1.70	6	2.3	8	3.0	N/A		16	8.4	22	9.3	N/A	
More than 1 partner last 6 months	160	20.0	221	24.8	**0.75**	**0.58-0.96**	43	8.9	56	11.5	0.83	0.53-1.31	117	36.7	165	40.8	0.78	0.55-1.09
Reported rape perpetration ever	33	14.4	58	19.0	0.65	0.33-1.29							33	14.4	58	19.0	0.65	0.33-1.29
Secondary Behavioral Outcomes																		
Ever had sex	465	58.1	558	62.7	0.76	0.54-1.07	236	49.1	253	52.1	0.88	0.62-1.26	229	71.8	305	75.5	0.64	0.43-0.95
More than 2 lifetime partners	206	44.3	238	42.7	1.22	0.92-1.63	63	26.7	65	25.7	1.31	0.83-2.05	47	10.2	40	8.6	**1.59**	**1.07-2.37**
Currently have >1 partner	88	11.6	91	10.8	1.11	0.80-1.54	47	10.2	40	8.6	N/A		41	13.5	51	13.6	1.14	0.71-1.82
Ever tested for HIV	429	53.6	522	58.7	0.79	0.59-1.05	267	55.5	302	62.1	0.70	0.48-1.02	162	50.8	220	54.5	0.90	0.65-1.25
Tested for HIV last 12 months	260	33.0	314	36.1	0.76	0.54-1.07	166	34.9	189	39.2	0.66	0.42-1.02	94	30.0	125	32.3	0.84	0.58-1.23
Circumcised													27	8.5	35	8.7	1.03	0.52-2.03
Ever used a condom*	358	77.0	418	74.9	1.21	0.87-1.69	200	84.8	199	78.7	1.94	0.99-3.78	158	69.0	219	71.8	1.00	0.66-1.51
Used a condom at last sex*	289	62.2	336	60.2	1.07	0.81-1.42	151	64.0	160	63.2	1.04	0.68-1.58	138	60.3	176	57.7	1.17	0.77-1.78
Sex while drunk last 6 months	94	12.3	121	14.3	0.84	0.60-1.18	30	6.5	51	10.9	**0.54**	**0.32-0.92**	64	21.1	70	18.6	1.06	0.60-1.90
Transactional sex last 6 months	31	4.1	31	3.7	1.23	0.62-2.46	13	2.8	5	1.1	N/A		18	5.9	26	6.9	N/A	
Perpetration of physical intimate-partner violence ever													114	35.7	144	35.6	0.96	0.69-1.33
Hazardous alcohol use (8+ points)†	157	19.6	162	18.2	1.21	0.91-1.61	68	14.1	60	12.4	1.30	0.86-1.96	89	27.9	102	25.3	1.27	0.89-1.81

*Via random-effects logistic regression comparing Generation Skill + SMS vs just Generation Skillz, adjusted for age group, school-level clustering, sim card ownership, and baseline prevalence

†Also includes harmful and high-risk alcohol use NA = Not enough events to carry out the regression

Table 6: Intention-to-treat analysis of effect of Generation Skillz SMS campaign on knowledge, reported attitudes and reported gender norms (n=1690)

	All Intervention (n=1690)						Females (n=967)						Males (n=723)					
	SMS		No SMS		Intention To Treat		SMS		No SMS		Intention To Treat		SMS		No SMS		Intention To Treat	
Scale	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI	Mean	SD	Mean	SD	β	95% CI
HIV Knowledge (out of 10)	6.36	2.09	6.35	2.01	-0.06	-0.34 to 0.22	6.35	2.04	6.34	2.00	-0.03	-0.30 to 0.23	6.37	2.17	6.37	2.03	-0.03	-0.49 to 0.43
HIV Stigma (out of 3)^	2.25	0.55	2.26	0.54	-0.02	-0.08 to 0.03	2.30	0.55	2.27	0.53	-0.01	-0.08 to 0.06	2.17	0.53	2.25	0.54	-0.04	-0.12 to 0.04
HIV Prevention Self-Efficacy (out of 3)	2.04	0.50	2.02	0.48	0.01	0.04 to 0.05	2.09	0.52	2.06	0.51	-0.03	-0.10 to 0.03	1.96	0.45	1.97	0.43	0.01	-0.06 to 0.08
Gender-Equitable Norms (out of 3)	1.71	0.34	1.70	0.36	-0.01	-0.06 to 0.04	1.77	0.35	1.73	0.36	-0.01	-0.08 to 0.06	1.63	0.30	1.65	0.35	-0.01	-0.06 to 0.04

β = coefficient from random-effects linear regression comparing intervention to control, adjusted for school-level clustering, age group, site, sim card ownership and baseline scores

^Higher scores indicate more favorable attitudes towards people living with HIV

Table 7: Intention-to-treat analysis of schools receiving Generation Skillz plus SMS's vs control schools (n=2552)

	All (n=2552)						Females (n=1455)						Males (n=1097)					
	GS + SMS		Control		Intention To Treat*		GS + SMS		Control		Intention To Treat*		GS + SMS		Control		Intention To Treat*	
	n	**%**	**n**	**%**	**OR**	**(95% CI)**	**n**	**%**	**n**	**%**	**OR**	**(95% CI)**	**n**	**%**	**n**	**%**	**OR**	**(95% CI)**
Primary Behavioral Outcomes																		
Age-disparate sex last 6 months	42	5.3	94	5.4	1.04	0.64-1.71	21	4.4	34	3.5	1.26	0.64-2.48	21	6.6	60	7.7	0.85	0.48-1.48
Older partner (5+ years) last 6 months	20	2.7	46	2.9	1.01	0.55-1.87	15	3.4	27	3.0	1.15	0.52-2.53	5	1.7	19	2.7	NA	
Younger partner (5+ years) last 6 months	22	4.9	49	5.0	1.01	0.54-1.88	6	2.3	7	1.3	1.75	0.38-7.96	16	8.4	42	9.6	0.90	0.48-1.69
More than 1 partner last 6 months	160	20.0	346	19.8	0.98	0.74-1.29	43	8.9	87	8.9	0.93	0.62-1.39	117	36.7	259	33.3	1.13	0.85-1.50
Reported rape perpetration ever													33	10.3	100	12.9	0.74	0.47-1.15

*Via random-effects logistic regression comparing Generation Skillz + SMS vs Control, adjusted for age group, school-level clustering, and baseline prevalence

NA = Not enough events to carry out the regression

Table 8: Loss-to-follow-up by study group and baseline characteristics (n=4435)

	All baseline participants, unique IDs (n=4435)						Intervention (n=2142)						Control (n=2293)					
	Not Lost		Lost		Difference*		Not Lost		Lost		Difference*		Not Lost		Lost		Difference*	
Baseline Characteristics	n	%	n	%	OR	95% CI	n	%	n	%	OR	95% CI	n	%	n	%	OR	95% CI
Group																		
Control	1661	72.4	632	27.6	1.00													
Intervention	1465	68.4	677	31.6	1.03	0.69-1.55												
Sex																		
Male	1373	69.6	600	30.4	1.00		631	67.9	298	32.1	1.00		743	71.2	301	28.8	1.00	
Female	1753	71.2	709	28.8	1.10	0.96-1.26	834	68.8	379	31.2	1.07	0.88-1.30	918	73.5	331	26.5	1.12	0.93-1.36
Site																		
Cape Town	1022	64.9	552	35.1	1.00		502	61.4	316	38.6	1.00		520	68.8	236	31.2	1.00	
Port Elizabeth 1	1230	79.1	325	20.9	0.46	0.30-0.71	600	77.9	170	22.1	0.37	0.18-0.77	630	80.3	155	19.8	0.56	0.34-0.90
Port Elizabeth 2	874	66.9	432	33.1	0.98	0.64-1.50	363	65.5	191	34.5	0.82	0.41-1.66	511	68.0	241	32.1	1.15	0.71-1.85
Baseline age																		
12-14 years	696	77.8	199	22.2	1.00		363	75.6	117	24.4	1.00		333	80.2	82	19.8	1.00	
15 years	1028	74.8	346	25.2	1.16	0.94-1.42	486	70.0	208	30.0	1.30	0.99-1.72	542	79.7	138	20.3	1.01	0.74-1.37
16 years	720	69.0	323	31.0	**1.50**	**1.21-1.87**	331	67.0	163	33.0	1.49	1.11-2.01	389	70.9	160	29.1	1.52	1.11-2.07
17 years	388	62.8	230	37.2	**2.05**	**1.61-2.61**	176	61.1	112	38.9	1.99	1.42-2.78	212	64.2	118	35.8	2.10	1.49-2.96
18-20 years	294	58.2	211	41.8	**2.48**	**1.92-3.20**	109	58.6	77	41.4	2.32	1.57-3.43	185	58.0	134	42.0	2.58	1.82-3.65
Live with parents																		
Live with both parents	1072	71.8	421	28.2	1.00		525	69.0	236	31.0	1.00		547	74.7	185	25.3	1.00	
Live with mother only	1259	71.6	499	34.8	1.03	0.88-1.21	594	71.0	243	29.0	0.94	0.75-1.18	665	72.2	256	27.8	1.13	0.90-1.42
Live with father only	163	65.2	87	28.4	**1.55**	**1.15-2.09**	69	62.7	41	37.3	**1.59**	**1.02-2.47**	94	67.1	46	32.9	**1.53**	**1.02-2.29**
Live with neither parent	601	67.8	285	32.2	**1.30**	**1.08-1.58**	263	63.8	149	36.2	**1.39**	**1.06-1.82**	338	71.3	136	28.7	1.24	0.95-1.62
Orphan status																		
Both parents alive	2233	70.7	924	29.3	1.00		1038	67.5	499	32.5	1.00		1195	73.8	425	67.3	1.00	
Single Orphan	719	70.2	305	29.8	1.06	0.91-1.25	351	71.2	142	28.8	0.88	0.70-1.12	368	69.3	163	25.8	**1.27**	**1.02-1.59**
Double Orphan	174	68.5	80	31.5	1.15	0.86-1.53	76	67.9	36	32.1	0.95	0.62-1.47	98	69.0	44	7.0	1.35	0.91-1.98
Ever had sex																		
No	1463	76.0	462	24.0	1.00		707	73.6	254	26.4	1.00		756	78.4	208	21.6	1.00	
Yes	1513	66.2	772	33.8	**1.60**	**1.38-1.84**	688	64.2	384	35.8	**1.59**	**1.29-1.95**	825	68.0	388	32.0	**1.62**	**1.32-1.98**

Partners in last 12 months (all)																		
None or one	2220	72.2	853	27.8	1.00		1064	70.0	456	30.0	1.00		1156	74.4	397	25.6	1.00	
Two or more	649	66.0	335	34.0	**1.36**	**1.15-1.60**	293	64.5	161	35.5	**1.36**	**1.07-1.72**	356	67.2	174	32.8	**1.37**	**1.09-1.70**
Partners in last 12 months (males)																		
None or one	796	72.6	300	27.4	1.00		367	69.5	161	30.5	1.00		429	75.5	139	24.5	1.00	
Two or more	476	66.2	243	33.8	**1.42**	**1.14-1.75**	223	67.0	110	33.0	1.23	0.90-1.68	253	65.5	133	35.5	**1.61**	**1.20-2.16**
Partners in last 12 months (females)																		
None or one	1424	72.0	553	28.0	1.00		697	70.3	295	29.7	1.00		727	73.8	258	26.2	1.00	
Two or more	173	65.3	92	34.7	1.30	0.97-1.73	70	57.9	51	42.2	**1.68**	**1.11-2.55**	103	71.5	41	28.5	1.04	0.70-1.56
Age-disparate sex in last 12 months																		
No	2796	71.0	1140	29.0	1.00		1316	68.7	601	31.4	1.00		1480	73.3	539	26.7	1.00	
Yes	180	65.7	94	34.3	1.26	0.96-1.65	79	68.1	37	31.9	1.07	0.70-1.65	101	63.9	57	36.1	**1.42**	**1.00-2.02**
Alcohol use (AUDIT)																		
Normal (<8)	2618	71.5	1044	28.5	1.00		1238	69.3	549	30.7	1.00		1380	73.6	495	26.4	1.00	
Hazardous (8-15)	341	68.2	159	31.8	1.07	0.87-1.32	156	66.7	78	33.3	0.97	0.71-1.32	185	69.6	81	30.5	1.17	0.88-1.56
Harmful (16-19)	96	62.8	57	27.3	1.38	0.97-1.97	40	59.7	27	40.3	1.28	0.75-2.17	56	65.1	30	34.9	1.47	0.92-2.36
Dependent (20+)	71	59.2	49	40.8	**1.61**	**1.09-2.37**	31	57.4	23	42.6	1.52	0.85-2.73	40	60.6	26	39.4	**1.69**	**1.00-2.85**
Ever perpetrated rape																		
No	1082	71.1	439	28.9	1.00		504	68.8	229	31.2	1.00		578	73.4	210	26.7	1.00	
Yes	219	64.8	119	35.2	1.33	1.02-1.72	95	66.9	47	33.1	1.19	0.79-1.79	124	63.3	72	36.7	**1.47**	**1.04-2.06**
Physical IPV ever (males)																		
No	913	71.7	361	28.3	1.00		422	68.1	198	31.9	1.00		491	75.1	229	24.9	1.00	
Yes	461	66.0	238	34.1	1.27	1.03-1.56	209	67.6	100	32.4	1.00	0.73-1.36	252	64.6	47	35.4	**1.56**	**1.18-2.08**
Baseline Characteristics	**mean**	**SD**	**mean**	**SD**	**Coef**	**95%CI**	**mean**	**SD**	**mean**	**SD**			**mean**	**SD**	**mean**	**SD**		
# of people in household	5.45	5.70	5.09	5.60	-0.36	-0.72 to 0.01	5.45	5.34	4.84	2.10	**-0.56**	**-0.99 to -0.13**	5.44	6.00	5.37	7.75	-0.08	-0.68 to 0.52
Asset index	0.71	0.20	0.69	0.21	-0.01	-0.03 to 0.00	0.71	0.21	0.70	0.20	-0.01	-0.03 to 0.01	0.71	0.20	0.69	0.22	**-0.02**	**-0.04 to 0.00**

*Assessed via random-effects logistic regression adjusted for school-level clustering

Overall discussion and conclusions

The GOAL Trial is the first randomised controlled trial (RCT) of a sport-based HIV prevention (SBHP) intervention to be carried out, and one of the first RCTs carried out in the growing Sport-for-Development (SFD) sector. Prior to the trial, evidence on the effective of SBHP interventions had come only from observational and quasi-experimental studies, many only assessing effects on HIV-related knowledge and reported attitudes over a short period of follow-up. With a cluster-randomised design, two years of follow-up, an innovative mobile-phone-assisted methodology for conducting self-administered questionnaires, and primary behavioural outcomes that are closely linked to South Africa's HIV epidemic, the GOAL Trial represents an important step forward for evaluation of SBHP interventions and for the SFD sector in general. Given the lack of scientific evidence in the sector, researchers have called for more rigorous evaluations and openly questioned whether the 'impact' rhetoric of practitioners, policymakers, and funders focused on SFD has been overly optimistic.[1]

Summary of findings by research question

Globally, what is the evidence of effectiveness for sport-based HIV prevention interventions, particularly for young people?

Prior to the GOAL Trial, no randomised controlled trials of sport-based HIV prevention interventions had been carried out. The systematic review provided strong evidence that SBHP interventions have at least a short-term effect on HIV-related knowledge, stigma, self-efficacy, reported communication, and reported recent condom use. There was no overall evidence of effects on uptake of HCT or other HIV-related services, but few studies had assessed this. Limited follow-up data suggested that intervention effectiveness on knowledge, attitudes, and communication may diminish over time. There was no evidence either way, however, on whether they can reduce HIV, STI or unintended pregnancy rates. There was also no evidence to suggest that these interventions have had negative effects. More rigorous intervention studies are needed to determine

whether these effects are consistent across multiple settings and whether SBHP interventions have an effect on biological outcomes, such as HIV incidence and STI incidence.

What are the patterns of reported sexual risk behaviour among male and female adolescents in informal settlements in Cape Town and Port Elizabeth, South Africa?

High prevalence of reported risk behaviour was observed, in particular among males, with 20.5% reporting three or more partners in the last year, 22.5% reported currently having more than one sexual partner, 23.5% screening positive for hazardous or harmful alcohol use, 18.2% reporting having ever perpetrated rape, and 35.7% reporting having ever perpetrated physical intimate-partner violence. Important sex differences were observed in reported sexual behavior and alcohol use. After adjusting for age and site, males had roughly 2.5-times higher odds of reporting having ever had sex, roughly 4.5-times higher odds of reporting having three or more sexual partners in the last 12 months, roughly 4-times higher odds of reporting currently having multiple sexual partners, and 2-times higher odds of screening positive for hazardous alcohol use. Females, however, had 2-times higher odds of reporting having had an age-disparate older partner in the last year (11.0% vs 2.4%).

Is social media use associated with reported multiple partnerships in the last year, age-disparate sex in the last year, and/or reported hazardous alcohol use among this population?

Among females, having a Facebook account was associated with reported multiple partnerships in the last year (AOR=1.81, 95%CI=1.19-2.74), age-disparate sex in the last year (AOR=1.96, 95%CI=1.16-3.32) and hazardous alcohol use (AOR=1.97, 95%CI=1.41-2.74). Using Mxit—a popular mobile instant messaging application—was associated with higher odds of reported multiple partnerships in the last year among both males (AOR=1.70, 95%CI=1.35-2.14) and females (AOR=1.45, 95%CI=1.07-1.96) and with hazardous alcohol use

among both males (AOR=1.47, 95%CI=1.14-1.90) and females (AOR=1.50, 95%CI=1.18-1.90).

Over one year, does the Generation Skillz intervention reduce reported age-disparate sex, multiple partnerships, and/or rape perpetration among this population?

The midline GOAL Trial results were mixed and surprisingly disappointing in terms of the Generation Skillz intervention's effect on reported sexual risk behaviour. While there was very strong evidence of an increase in HIV-related knowledge for both sexes ($p<0.001$) and on reported HIV testing ever ($p=0.004$) and in the past 12 months ($p=0.004$) among males, there was also strong evidence of an increase in reported multiple partners in the last six months among males ($p=0.007$), reported age-disparate sex (with a younger or older partner) in the last six months among females ($p=0.037$), and intimate-partner violence perpetration among males ($p=0.047$). Given that these latter three behaviours were the primary focus of the intervention, which was designed in accordance with the 17 characteristics of effective sex and HIV education programmes,[2] these results are both surprising and discouraging. That said, the LTFU analysis suggested that the intervention group had lower attrition than the control group of participants who were already sexual-risk-takers at baseline, perhaps providing a partial explanation of the observed midline differences. It may be that this type of sport-based, behavioural intervention can be effective in changing peer supported positive behaviours—such as HIV testing and male circumcision—but are less effective or ineffective in influencing more deeply seated norms surrounding sexual relationships, such as age-disparate sex and multiple partnerships.

Generation Skillz Utshintsho interventions were delivered shortly after each school completed its midline survey and well before the results were analysed, so it was not possible to consider the midline results in deciding whether to go ahead with the booster sessions. Had the booster been scheduled for later on,

the DSMB may have decided to terminate the trial on the basis of the negative effects on certain reported behavioural outcomes observed at midline. On the other hand, it may be that the Generation Skillz Utshintsho intervention will mitigate or reverse the observed negative effects.

Does sending biweekly SMS messages to participants for one year enhance the effectiveness of Generation Skillz in improving HIV-related knowledge, reported attitudes, and/or reported behaviour over one year?

Comparing participants from intervention schools receiving the SMS campaign to those from schools not receiving it, we observed strong evidence of a positive effect of the SMS campaign on reported multiple partners in the last six months (OR=0.75, 95%CI=0.58-0.96). There was strong evidence of a positive effect of the SMS campaign on reported sex while drunk in the last six months among females (OR=0.54, 95%CI=0.34-0.92). There was no evidence of an effect on knowledge, reported attitudes, reported gender norms or other primary behavioural outcomes. Comparing the schools receiving the SMS's to control schools, there was no evidence of difference in any of the three primary behavioural outcomes.

Strengths

This was a relatively large RCT with a rich baseline and midline data set containing reported data on a wide range of outcomes of public health importance in a population with one of the highest HIV prevalences in the world. The data collection approach ensured strict confidentiality, minimizing potential observer/interviewer bias and maximizing the amount of usable data, through validation rules and complex skip patterns. The study's use of mobile phones for confidential, self-administered data collection was commended by peer reviewers as 'novel' and 'innovative'. Robust statistical methods were used, adjusting for school-level clustering, age and site differences between groups, and cluster-level baseline outcomes (to ensure that any observed effects were not merely products of baseline differences). The follow-up rate, while lower

than expected and hoped, was understandable, given the mobility of the study population.

Limitations

There are several important limitations in the GOAL Trial. First, due to the smaller-than-anticipated sample size and the Trial Advisory Committee's decision to forego biomarker data collection at follow-up, the trial's primary outcomes rely on self-reported behavioural data. Concerns about the validity of self-reported sexual behaviour data have been well documented, with males commonly over-reporting and females commonly under-reporting the number of partners and sexual activity.[3-5] The use of confidential mobile-phone-based, self-administered questionnaires (rather than face-to-face interviews or written self-administered questionnaires) may have helped to reduce social desirability bias in the GOAL Trial.[6] Nevertheless, it is possible that social desirability bias may have influenced participants' responses and/or that the intervention may have influenced perceptions of socially desirable answers rather than truly influencing behaviour. One would not expect this to explain the observed harmful effects of Generation Skillz in increasing self-reported behavioural outcomes, though it is possible that the intervention may have increased participants' awareness of risky behaviours and that this increased their likelihood of disclosing multiple sexual partners, age-disparate partners, or intimate-partner violence. There is precedent for this from a previous HIV prevention and IPV trial in South Africa.[7]

Selection bias—often a challenge in cluster-randomised trials[8]—presents another limitation. Importantly, a large proportion of the registered students did not enrol in the trial at baseline, primarily due to lack of having obtained written parental consent. Since youth who are able to obtain a parental signature may be systematically different from youth who are not able to obtain a parental signature (i.e. they might have a stronger relationship with their parents or a more supportive household), this may have resulted in the GOAL Trial sample having a less risky behavioural profile than the population of Grade 9 learners as a whole. Further selection bias may have arisen through loss-to-follow-up,[9]

which was differential between study groups (20.6% in the control group; 26.0% in the intervention group). Again, this would not seem to explain the observed negative behavioural effects. Indeed, since one would expect those lost-to-follow-up (e.g., school dropouts) to tend to be riskier than those followed-up, the differential loss-to-follow-up observed in the GOAL Trial would be expected to influence the effect in favour of the intervention group (which lost a larger proportion of participants from baseline to midline) rather than the control group. This said, some studies, for example a cohort study of commercial sex workers in Kenya,[10] have found the opposite – that more risk behaviour is associated with lower odds of loss-to-follow-up. Thus, it is plausible that both the negative and the positive effects observed in the GOAL Trial were influenced by loss-to-follow-up. Subsequent analysis should assess baseline differences between those were and were not lost-to-follow-up.

Generalizability

The loss of Soweto as a trial site limited the GOAL Trial's generalizability. The results should not be generalized to secondary schools in South Africa as a whole for several reasons. First, informal urban settlements differ economically and socially from rural settings as well as from formal urban settings. They tend to have higher HIV prevalence, higher unemployment, and higher rates of violence and crime.[11] Secondly, Xhosa culture differs from other cultures around South Africa, in terms of traditions, gender norms, and perceptions of male circumcision.[12,13] Including Soweto in the trial would have provided a much more diverse and culturally representative sample. The findings may be able to be generalized—taking into consideration the aforementioned selection bias caveats—to informal settlement schools in Cape Town, Port Elizabeth, and perhaps other predominantly Xhosa informal urban communities in the Eastern and Western Cape.

The results should likewise neither be generalized to all of Grassroot Soccer's interventions nor all SBHP interventions. As the systematic review identified, many previously evaluated SBHP interventions (including those of Grassroot

Soccer) work with younger adolescents than Generation Skillz. Additionally, other SBHP interventions use quite different approaches, some quite curriculum-based and others less structured.

On-going work and next steps

Endline GOAL Trial surveys began in February 2014 and will continue through August 2014. As of 10 April 2014, 1205 endline surveys had been completed in Cape Town and Port Elizabeth. The same analysis and deduplication approach used with the midline data will be used with the endline data. The endline analysis will help us to understand (a) whether the positive and negative effects observed at midline remain consistent after two years of follow-up and (b) whether the Generation Skillz Utshintsho sessions influence the intervention's effects positively, negatively or neutrally. As the SMS campaign was not continued into the second year of follow-up, the endline survey will only be able to tell whether the effect of the previous SMS's sent in 2012-2013 persisted into 2014. One would anticipate that the effect of the SMS's would diminish over time, as has been observed with other short-term HIV prevention interventions followed over long-term studies.[14]

A process evaluation of Generation Skillz and the GOAL Trial began in 2013 and is the subject of another doctoral candidate's research. Using primarily qualitative methods (in-depth interviews, focus group discussions, observation of trainings and interventions) in addition to attendance and 'coach support visit' data collected by Grassroot Soccer, the process evaluation should help to answer questions of why the Generation Skillz intervention was not successful in achieving its objectives in 2012-2013 and how the organisation might modify either the content, format, or delivery of the intervention to increase its effectiveness. We expect findings from the process evaluation to begin emerging in 2014, with the analysis and write-up finishing in 2015.

Further analysis of the quantitative GOAL midline results could explore:

A. Whether there is any evidence of dose-response (i.e. is the number of sessions attended associated with gains in knowledge and/or with any of the negative behavioural effects observed?);
B. Whether and, if so, how participants lost-to-follow-up differ from those who completed midline questionnaires;
C. Whether there is evidence of effect modification of the SMS campaign by sim card, mobile phone ownership, and/or Mxit use;
D. Whether traced participants (i.e. those followed up outside of school) exhibited different patterns of reported behaviour and how this compared between groups;
E. Risk factors (apart from Generation Skillz participation) for reported multiple partners in the last six months;
F. Risk factors for reported rape and intimate-partner violence perpetration (note: this is the topic of another paper not presented in this thesis);
G. Whether adjusting for survey date or month affects the observed effects (since the recall period was only six months, some participants' recall period would have included the holidays, while others would have only included term time. Sexual behaviour may differ during different times of the year);

Several researchers on the GOAL Trial (Kaufman, DeCelles, Weiss and Ross) led another cluster-randomised trial in 2013-2014, assessing the effectiveness of a single-session SBHP intervention developed and implemented by Grassroot Soccer in increasing uptake of voluntary medical male circumcision among adult male soccer players in Bulawayo, Zimbabwe.[15] The trial enrolled 47 teams and 735 men aged 18-50 years. The findings, which will be presented at the 20th International AIDS Conference in Melbourne, Australia, present promising evidence that the 'Make The Cut' intervention increases the odds of VMMC uptake by nearly 10-fold or, in absolute terms, by roughly 4 percent over four months of follow-up, compared to a control group receiving no intervention.[16] A further trial of Make The Cut is being carried out in Bulawayo in 2015 to assess

whether a modified version of the intervention is effective in increasing uptake among adolescent males. Together with the positive effect of Generation Skillz on reported HIV testing uptake among males and previous evidence of effects of the HoMBReS intervention on HCT uptake in the US,[17] there is now growing evidence of the effectiveness of SBHP interventions in increasing uptake of HIV-related services among males. Given the urgent need for and potential of public health impact of scaling up VMMC coverage in Southern Africa[18,19] as well as the consistently lower HCT uptake rates among men relative to women in the region,[20,21] policymakers and practitioners should still consider sport-based interventions in designing programmes to increase demand for HIV-related services among young and adult men, despite the findings of the GOAL Trial reported here.

Final Thoughts

As the first RCT of a sport-based HIV prevention intervention and one of the first RCTs in the Sport-for-Development sector, the GOAL Trial marks an important step forward in advancing evaluation of a programming area that, despite growing funding streams, has lacked high-quality evidence. The trial's midline results raise important questions for GRS and its peer organisations working in SBHP. What about the intervention led male participants to be more likely to take up HCT? Why was the same effect not observed for females? Why might an SBHP intervention focused on reducing multiple partnerships, age-disparate sex, and intimate partner violence actually increase reports of these three outcomes, at least by some groups of participants?

The mobile and online technology tools used in the GOAL Trial (discussed in Linking Section 1) may be of interest to trialists currently using paper and/or spreadsheets or other electronic ways of collecting data. Overall, ODK and Force.com combined for a powerful and cost-effective trial operations suite. Building on the experience in the GOAL Trial, the MCUTS Trials, and consulting work with other research organizations, the doctoral candidate and colleagues are working to develop a Force.com-based application for use in trial

management, tracking research sites, staff, participants, survey completion, equipment, and more. Since the start of the GOAL Trial, several projects connected to LSHTM have begun using ODK for mobile data collection in Zimbabwe, Malawi, and India.

Our study team encountered numerous operational challenges during the GOAL Trial. First and foremost, there were regulatory challenges, such as longer than expected delays in local ethics approval, the lack of approval from the Gauteng Department of Education, and the requirement to use written (opt-in) rather than passive (opt-out) parental consent. There were—as is the norm in research studies in resource-limited settings—significant logistical challenges, including coordinating schedules with dozens of teachers and school administrators, dealing with poor and inconsistent Internet access (particularly in Port Elizabeth), and frequent teacher and student absenteeism. Additionally, there were safety-related challenges, with cases of students or gangsters attempting to steal the study phones, notable bouts of gang violence occurring in at least two schools, and tracing of participants who did not attend the midline follow-up survey requiring requiring that staff visit notoriously unsafe neighbourhoods. These challenges explain the basis of some of the aforementioned study limitations, particularly those related to selection bias.

It is important to consider that the GOAL Trial was carried out in a real-world programmatic context, rather than a carefully controlled clinical context. Singal and colleagues recently highlighted some of the key differences between this type of 'effectiveness' trial and more clinical 'efficacy' trials, noting that the former tend to have stronger external validity while the latter have stronger internal validity.[22] Indeed, many of the challenges encountered in implementation of Generation Skillz in the context of the GOAL Trial have also been encountered by GRS in delivery of its interventions outside of a trial context. For example, while schools were willing to cooperate, on the whole, neither the survey teams nor the GRS Coaches had full control of the study or intervention environment. Young people's attendance in the intervention was

imperfect and unpredictable. Occasionally, schools or teachers would change the schedule without notifying GRS. The intervention or survey team ran into periodic car and transport problems, such as cars being double-booked or under maintenance during a scheduled survey or intervention session. Two schools had outbursts of gang violence that resulted in temporary shut downs and changes of timelines for both data collection and intervention delivery. Participants in both groups may have had exposure to other HIV prevention programmes. These are all challenges that an organisation implementing HIV prevention education in informal settlements in South Africa might indeed run into. Hence, while the trial lacked a tightly controlled clinical environment, it approximated the real-world delivery of a sport-based HIV prevention intervention in informal settlement schools.

Conclusion

Prior to the GOAL Trial, the observational and quasi-experimental research on sport-based HIV prevention (including a preliminary pre/post evaluation of Generation Skillz in South Africa) provided promising evidence of effects on knowledge and reported attitudes, with a potential effect on reported condom use. No studies had found any evidence of negative effects. The baseline results provided insight into the high prevalence of certain reported risk behaviours in this population of informal settlement adolescents in Cape Town and Port Elizabeth, in particular reported recent multiple partners, age-disparate sex, hazardous alcohol use, and rape perpetration. Noteworthy associations emerged from the baseline, some of which were consistent with previous literature (i.e. sexual risk behaviour with alcohol use) and some of which were novel (i.e. social media use with reported multiple partners, age-disparate sex, and alcohol use).

The GOAL Trial midline results were consistent with the previous literature in terms of finding very strong evidence of a positive effect on knowledge and partially consistent in terms of finding a positive effect on reported HIV testing uptake among males. They were inconsistent, however, in not finding an effect on reported attitudes and in finding evidence of negative effects on reported

multiple partners in the last six months and reported intimate-partner violence perpetration among males and reported age-disparate sex in the last six months among females. The midline findings thus proved surprising and disappointing, raising questions of why the intervention might have a negative effect on reported behaviour. Meanwhile, the trial found encouragingly strong evidence that participants at schools receiving the Generation Skillz SMS Campaign had lower odds of reporting multiple partners in the last six months. In sum, the findings suggest that SMS's should be included in the Generation Skillz intervention, that the intervention was effective in improving knowledge among boys and girls and uptake of HCT among boys, but that the intervention was ineffective in reducing reported multiple partnerships in the last six months, age-disparate sex in the last six months, and rape perpetration, and may even have led to an increase in each of these reported outcomes.

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Annexes

Annex A: Lists of participating schools

Table 1: List of Cape Town schools participating in the GOAL Trial

School Name	Community	RCT Group	Site
Bulumko Secondary	Khayelitsha	Intervention	Cape Town
Chris Hani S.S.S.	Khayelitsha	Control	Cape Town
Dr. Nelson Mandela	Crossroads	Control	Cape Town
ID.Mkhize	Gugulethu	Control	Cape Town
Intlanganiso	Khayelitsha	Intervention	Cape Town
Intshukumo	Gugulethu	Intervention	Cape Town
Joe Slovo High School	Khayelitsha	Control	Cape Town
Khulani	Langa	Intervention	Cape Town
Langa High	Langa	Control	Cape Town
Manyano S.S	Khayelitsha	Intervention	Cape Town
Masiyile S.S.S.	Khayelitsha	Control	Cape Town
Matthew Goniwe	Khayelitsha	Control	Cape Town
Sithembele Matiso	Gugulethu	Intervention	Cape Town
Sivile High	Khayelitsha	Intervention	Cape Town
Thembelihle	Khayelitsha	Control	Cape Town
Uxolo High	Khayelitsha	Intervention	Cape Town

Table 2: List of Port Elizabeth schools participating in the GOAL Trial

School Name	Community	RCT Group	Site
Chubekile	Kwazakhele	Intervention	Port Elizabeth 1
Cowan	New Brighton	Control	Port Elizabeth 1
Ithembelihle	New Brighton	Intervention	Port Elizabeth 1
Khwezi Lomso	Zwide	Intervention	Port Elizabeth 1
Loyiso	Zwide	Control	Port Elizabeth 1
Lwandle Kazi	New Brighton	Intervention	Port Elizabeth 1
Lwazilwethu	Zwide	Control	Port Elizabeth 1
Masibambane	Kwazakhele	Control	Port Elizabeth 1
Ndzondelelo	Zwide	Intervention	Port Elizabeth 1
Newell	New Brighton	Control	Port Elizabeth 1
Sakhisizwe	Zwide	Control	Port Elizabeth 1
Sophakama	New Brighton	Intervention	Port Elizabeth 1
Thamsanqa	Kwazakhele	Intervention	Port Elizabeth 1
Thembalabantu	Zwide	Control	Port Elizabeth 1
Tyhilulwazi	Zwide	Control	Port Elizabeth 1
Cingani	Motherwell	Intervention	Port Elizabeth 2
Kwa Magxaki	Kwa Magxaki	Control	Port Elizabeth 2
Lungisa	KwaDwesi	Intervention	Port Elizabeth 2
Masiphathisane	Motherwell	Control	Port Elizabeth 2
Mfesane	Motherwell	Control	Port Elizabeth 2
Mlungisi	Uitenhage	Control	Port Elizabeth 2
Molly Black Burn	Uitenhage	Intervention	Port Elizabeth 2
Motherwell High School	Motherwell	Intervention	Port Elizabeth 2
Ncedo	Motherwell	Control	Port Elizabeth 2
Nkululeko	Uitenhage	Control	Port Elizabeth 2
SEK Mqhayi	KwaDwesi	Intervention	Port Elizabeth 2
Solomon Mahlangu	Uitenhage	Intervention	Port Elizabeth 2
Thanduxolo	Uitenhage	Intervention	Port Elizabeth 2
V.M.Khwinana	Uitenhage	Control	Port Elizabeth 2
Zanolwazi	Despatch	Control	Port Elizabeth 2

Wits Institute for Reproductive Health & HIV (WRHI)	London School of Hygiene and Tropical Medicine (LSHTM)
HREC # Mxxxxxx	**REC Study #**
Parental/Guardian Consent Form for Study Participant	

Consent Form Version Date: 20 FEBRUARY 2012
Title of Study: GOAL Trial: Sport-based HIV prevention in South African Schools
Principal Investigator: David Ross, PhD (LSHTM), Sinead Delany-Moretlwe MBBCh, PhD
LSHTM Department: Infectious Disease Epidemiology
LSHTM Phone number: +44 20 7927 2264
Email Address: david.ross@lshtm.ac.uk

Co-Investigators: Zachary Kaufman, MSc **Funding Source:** MAC AIDS Fund
Telephone number: 071 590 0820 **Contact email:** zachary.kaufman@lshtm.ac.uk

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Hello. I am currently working for Grassroot Soccer, the Wits Reproductive Health and HIV Institute, and the London School of Hygiene and Tropical Medicine on a project with young people in Cape Town and Port Elizabeth. We are interested in exploring HIV risk among young people. We would like to invite you to invite your child or the young person in your care to participate in this study.

Some general things you should know about research studies

The young person is being asked to take part in a research study. You will also need to give permission for the young person in your care to be in this study. Your decision to allow him/her to join the study is voluntary—that means it is up to both of you. You may refuse to allow him/her to join, or you may withdraw him/her from the study, for any reason and at any time. The decision to refuse to participate or withdraw from the study will not affect the ability of the young person in your care to attend school or any other services you or he/she normally receive. If the young person decides he/she does not want to consent to participate in the study, even if you have already given consent, the young person will not be enrolled in the study.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from him/her being in the research study. There also may be risks to being in some research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You can ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to assess the effectiveness of a sports-based HIV prevention intervention being delivered in South African schools.

If you agree for him/her to participate in this study, we will ask the young person to complete a 45-minute questionnaire and to provide a dried blood spot.

What will participants enrolled in the study be asked to do?

All participants in the study will be asked to complete a questionnaire that will ask the young person information about some personal issues such as your family, HIV knowledge and sexual behaviour. Participants will enter their answers to the questionnaire using a mobile phone to give them more privacy during the self-interview. Trained study team members will be present to assist participants in completing the questionnaire and answer any questions they may have.

All participants will also be asked to provide a blood sample. We will collect a very small amount of blood (less than 5 ml, or about a teaspoon full) using one finger prick. The blood will be put on filter paper, which will be securely stored for at least the next three years. The stored dried blood spot may be tested for HIV and/or other infections or health conditions as part of this or other research studies. This will only be done with the written approval of the Wits and LSHTM Research Ethics Committees.

At the end of the study (in 2015), the young person will have the opportunity to be told the result of his/her HIV test. If he/she chooses to be told the result, he/she will receive counselling before and after the test. Prior to 2015, it will not be possible for our study staff to tell the young person their HIV status because tests will not run on the blood samples until 2015. If he/she tests positive at the end of the study, he/she will be linked to a qualified local treatment provider for support.

Study Significance

HIV infection is common among young people across the world and in our community. South Africa has the largest number of people living with HIV of any country in the world. In this study we are interested in assessing whether a sports-based intervention is effective so that we can inform future efforts to prevent HIV.

How many people will take part in this study?

There will be approximately 9,600 learners at 48 secondary schools in Cape Town and Port Elizabeth participating in this research study.

How long will this study last?

The young person's participation in this study will last a maximum of one hour in this first stage. He/she will complete a questionnaire and be asked to provide a small blood sample. This will take place after school hours. We will want to interview the young person at least once per year for at least the next three years, asking him/her to complete the questionnaire again. At the end of the study in three years' time, he/she will be asked to provide another blood sample.

What are the possible benefits from being in this study?

There are no direct monetary benefits to participating in the study. However, the young person's school may be selected to receive a special sport-based HIV prevention programme and he/she may have the opportunity to participate. He/she will also benefit from receiving HIV counselling in 2015, and if he/she wants to, he/she will learn his/her HIV status, and, if necessary, be referred to treatment, care, and support services. Additionally, he/she will receive refreshments and a small token of appreciation (like a wristband) each time he/she completes a questionnaire as part of this study.

What are the possible risks or discomforts from being in this study?

It is possible the young person may find some of the questionnaire questions distressing. He/she does not have to answer any question he/she does not wish to answer. If the questions raise concerns of a personal nature we can refer him/her to professional organisations that will try to assist him/her. Whether or not he/she takes up this referral will be his/her choice. Finger prick HIV tests do not result in much discomfort. The young person's finger may slightly sting for a second. The young person may experience anger or distress if he/she learns that he/she is infected with HIV. We will refer him/her to a government clinic for care if he/she is infected with HIV and he/she will be provided free HIV treatment and care at the clinic.

How will privacy be protected?

___________________________________ ____________
Signature of Person Obtaining Consent **Date**

Study ID Number: __________________

All efforts will be made to keep the young person's personal information confidential. He/she will be identified by a code number known only to the study staff. This number – not his/her name – will be used on all information about him/her. The young person's name will not written on any blood spots or test results. The young person's name will never be used in any publication or presentation about the research study. Personal information about the young person will not be released without his/her written permission.

It is important for you to know that all information the young person provides to study staff during the study is confidential. We cannot disclose any information to you as the parent/guardian. In addition, the result of HIV and HSV-2 testing is confidential and we cannot provide the results to you, but only to the young person and, with his/her permission, to healthcare workers he/she wishes to consult.

Will it cost you anything to be in this study?
There will be no costs for being in the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. I will be happy to answer any questions you have about the study. We will be holding a parents' meeting on ________________ at ______. If you have questions or concerns after that, you should contact the researchers listed on the first page of this form. The young person will be given an opportunity to ask any questions before each session begins.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the University of the Witwatersrand Human Research Ethics Committee. Please phone 011-717-2301 to be directed to one of the chairpersons of the committee. If you have questions about this specific research project please call the study manager, Zak Kaufman on 071 590 0820 or the co-Principal Investigator Dr. Sinead Delany-Moretlwe at WRHI on 082 377 6275 or email sdelany@wrhi.ac.za

- -

Parent/Guardian Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to allow my child/the young person to whom I am guardian to participate in this research study.

___________________________________ ___________________________
Signature of Participant's Parent/Guardian **Date**

_____________________________________ ___________________________
Printed Name of Parent/Guardian **Name of study participant**

Address: _______________________________ **Phone:** _____________________

____

Goal Trial Assent Form

Wits Institute for Reproductive Health & HIV (WRHI)	London School of Hygiene and Tropical Medicine (LSHTM)
HREC # Mxxxxxx	**REC Study #**
Assent to Participate in a Research Study	
Grade 9 learners	

Assent Form Version Date: 23 JANUARY 2012
Title of Study: GOAL Trial: Sports-based HIV prevention in South African Schools
Principal Investigator: David Ross, BMBCh, PhD (LSHTM), Sinead Delany-Moretlwe MBBCh, PhD (WRHI)
LSHTM Department: Infectious Disease Epidemiology
LSHTM Phone number: +44 20 7927 2264
Email Address: david.ross@lshtm.ac.uk

Co-Investigators: Zachary Kaufman, MSc
Funding Source: MAC AIDS Fund
Study Contact telephone number: 071 590 0820
Study Contact email: zachary.kaufman@lshtm.ac.uk

_____

Hello. My name is _____ and I am currently working for Grassroot Soccer, the Wits Reproductive Health and HIV Institute, and the London School of Hygiene and Tropical Medicine on a project with young people in ____. We are interested in exploring HIV risk among young people. I would like to invite you to participate in this study.

Some general things you should know about research studies

You are being asked to take part in a research study. Your parent or guardian needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. Your decision to join the study is voluntary—that means it is up to you. You may refuse to join the study, or you may withdraw from the study, for any reason and at any time. The decision to refuse to participate or withdraw from the study will not affect your ability to attend school or to receive any other services you normally receive.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in some research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You can ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to assess the effectiveness of a sports-based HIV prevention intervention being delivered in South African schools.

If you agree to participate in this study, we will ask you to complete a 45-minute questionnaire and to provide a very small blood sample.

What will participants enrolled in the study be asked to do?

All participants in the study will be asked to complete a questionnaire that will ask you information about some personal issues such as your family, HIV knowledge and sexual behaviour. You will enter your answers to the questionnaire on a mobile phone to give you more privacy during the self-interview. Trained study team members will be present to assist you in completing the questionnaire and answer any questions you may have.

All participants will also be asked to provide a blood sample. We will collect a very small amount of blood for this test (less than 5 ml, or about a teaspoon full) using one finger prick. The blood will be put on filter paper, which will be securely stored for at least the next three years. The stored dried blood spot may be tested for HIV and/or other infections or health conditions as part of this or other research studies. This will only be done with the written approval of the Wits and LSHTM Research Ethics Committees.

At the end of the study (in 2015), you will have the opportunity to be told the result of your HIV test. If you choose to be told the result, you will receive counselling before and after the test. Prior to 2015, it will not be possible for our study staff to tell you your HIV status because tests will not run on the blood samples until 2015. If you test positive at the end of the study, you will be linked to a qualified local treatment provider for support.

Study Significance

HIV infection is common among young people across the world and in our community. South Africa has the largest number of people living with HIV of any country in the world. In this study we are interested in assessing whether a sports-based intervention is effective so that we can inform future efforts to prevent HIV.

How many people will take part in this study?

There will be approximately 12,000 learners at 60 secondary schools in Soweto, Cape Town, and Port Elizabeth participating in this research study.

How long will your part in this study last?

Your participation in this study will last a maximum of two hours in this first stage. You will complete a questionnaire and be asked to undergo HIV counseling and testing. This will take place after school hours. We will follow-up with you at least once per year for at least the next three years and ask you to complete the questionnaire again. At the end of the study in three years' time, you will be asked to provide another blood sample.

What are the possible benefits from being in this study?

There are no direct monetary benefits to participating in the study. However, your school may be selected to receive a special sport-based HIV prevention programme and you may have the opportunity to participate. If you choose to receive your test results at the end of the study, you will benefit from receiving HIV counselling, learning your HIV status, and, if necessary, being referred to treatment, care, and support services. Additionally, you will receive refreshments and a small incentive (like a wristband) each time you complete a questionnaire as part of this study.

What are the possible risks or discomforts involved from being in this study?

It is possible you may find some of the questionnaire questions distressing. You do not have to answer any question you do not wish to answer. If the questions raise concerns of a personal nature we can refer you to professional organisations that will try to assist you. Finger prick HIV tests do not result in much discomfort. Your finger may slightly sting for a

second. You may experience anger or distress if you learn that you are infected with HIV. We will refer you to a government clinic for care if you are infected with HIV and you will be provided free treatment and care at the clinic.

How will your privacy be protected?

All efforts will be made to keep your personal information confidential. You will be identified by a code number known only to the study staff. This number – not your name – will be used on all information about you. Your name will not be written on any blood samples or test results. Your name will never be used in any publication or presentation about the research study. Personal information about you will not be released without your written permission. Even your parents will not be told the information that you share with us, unless you ask us to share it.

Will it cost you anything to be in this study?

There will be no costs for being in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form. You will be given an opportunity to ask any questions before the questionnaires begins.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the University of the Witwatersrand Human Research Ethics Committee. Please phone 011-717-2301 to be directed to one of the chairpersons of the committee. If you have questions about this specific research project please call the study manager, Zak Kaufman on 071 590 0820 or the co-Principal Investigator Dr. Sinead Delany-Moretlwe at WRHI on 082 377 6275 or email sdelany@wrhi.ac.za

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Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Person Obtaining Assent Date

_____

Printed Name of Person Obtaining Assent

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
SOUTH AFRICA



THE SOUTH AFRICAN COCHRANE CENTRE

SOUTH AFRICAN COCHRANE CENTRE

PO Box 19070, Tygerberg, 7505, South Africa;
Francie van Zijl Drive, Parow Valley, Cape Town
Tel: +27 21 938 0438; Fax: +27 21 938 0836
E-mail: cochrane@mrc.ac.za

THE COCHRA
COLLABORAT

11 February 2014

To Whom It May Concern:

RE: GOAL Trial: Behavioural Effectiveness of Sport-based HIV Prevention in Sou African Schools.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) databas is my pleasure to inform you that your application to our registry has been accepted. Y unique identification number for the registry is **PACTR201402000767141**

Please be advised that your trial is registered under an initiative within our system that allow us to capture data of trials that are already in progress or completed. As such, yo trial registration may not adhere to the mandates set forth by the International Commit of Medical Journal Editors for registration requirements, and it is your duty to be transparent to any journal that may ask about the retrospective status of your registrat

Please note you are responsible for updating your trial, or for informing us of changes your trial. Additionally, please provide us with copies of your ethical clearance letters a we must have these on file (via email, post or fax) at your earliest convenience if you h not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR
PAN AFRICAN CLINICAL TRIALS REG

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mr Zachary Kaufman

CLEARANCE CERTIFICATE	M111192
PROJECT	Sports -Based HIV Prevention in South African Schools: A Cluster-Randomised Trial
INVESTIGATORS	Mr Zachary Kaufman.
DEPARTMENT	Wits Reproductive Health Research unit
DATE CONSIDERED	25/11/2011
M1111920DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

[redacted]

DATE 29/02/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr S Delany-Moretlwe

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

OBSERVATIONAL/INTERVENTIONS RESEARCH ETHICS COMMITTEE

23 February 2012

David Ross & Zachary Kaufman

Dear David and Zachary

Study Title: **GOAL Trial: Sport-based HIV prevention in South African schools**
LSHTM ethics ref: **6131**
Department: **Epidemiology and Population Health**

Thank you for your email of 22/02/12, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair>.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*	
LSHTM ethics application	n/a		
Protocol	V2.0	23/02/12	
Information Sheet	V1.0	23/02/12	
Consent form	V1.0	23/02/12	

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form.

Yours sincerely,



Professor Andrew J Hall
Chair

WESTERN CAPE
Education Department
Provincial Government of the Western Cape

**RES
EAR
CH**

awyngaar@pgwc.gov. za
tel: +27 021 476 9272
Fax: 0865902282
Private Bag x9114, Cape Town, 8000
wced.wcape.gov.za

REFERENCE: 20111908-0033
ENQUIRIES: Dr A T Wyngaard

Mr Zac Kaufman
London School of Higiene and Tropical Medicine
London

Dear Mr Zac Kaufman

RESEARCH PROPOSAL: SPORTS BASED HIV PREVENTION IN SOUTH AFRICAN SCHOOLS A CLUSTER RANDOMISED TRIAL

Your application to conduct the above-mentioned research in schools in the Western Cape has been approved subject to the following conditions:

1. Principals, educators and learners are under no obligation to assist you in your investigation.
2. Principals, educators, learners and schools should not be identifiable in any way from the results of the investigation.
3. You make all the arrangements concerning your investigation.
4. Educators' programmes are not to be interrupted.
5. The Study is to be conducted from **19 January 2012 till 30 September 2013**
6. No research can be conducted during the fourth term as schools are preparing and finalizing syllabi for examinations (October to December).
7. Should you wish to extend the period of your survey, please contact Dr A.T Wyngaard at the contact numbers above quoting the reference number.
8. A photocopy of this letter is submitted to the principal where the intended research is to be conducted.
9. Your research will be limited to the list of schools as forwarded to the Western Cape Education Department.
10. A brief summary of the content, findings and recommendations is provided to the Director: Research Services.
11. The Department receives a copy of the completed report/dissertation/thesis addressed to:

    The Director: Research Services
    Western Cape Education Department
    Private Bag X9114
    CAPE TOWN
    8000

We wish you success in your research.

Kind regards.
Signed: Audrey T Wyngaard
for: **HEAD: EDUCATION**
DATE: 06 October 2011

London School of Hygiene & Tropical Medicine
Research Grants & Contracts Office
Keppel Street, London WC1E 7HT

Tel +44 (0) 20 7927 2626 (direct) Fax +44 (0) 20 7580 5636
e-mail: patricia.henley@lshtm.ac.uk
www.intra.lshtm.ac.uk/trials

Our ref: QA371

16 January 2012

Mr Zachary Kaufman
PhD Candidate
Faculty of Epidemiology and Population Health
LSHTM

Dear Mr Kaufman,

Re: Sports-based HIV prevention in South African schools: a cluster-randomised trial

As the authorised representative for the London School of Hygiene & Tropical Medicine (LSHTM), I can confirm that LSHTM will act as the identified Research Sponsor, the organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial, for the above titled project. I can confirm that the research proposal has been reviewed, assessed and registered by the Clinical Trials Sub-Committee.

It is the Chief Investigator's responsibility to ensure that members of the research team comply with all local regulations applicable to the performance of the project, including, but not limited to: the Declaration of Helsinki (2008), ICH Good Clinical Practice Guidelines (1996), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Research Governance Framework for Health and Social Care (2005), the Data Protection Act (1998) and the Human Tissue Act (2004).

LSHTM carries Non Negligent Harm Insurance and Professional Negligence Insurance applicable to this study:

	Non Negligent Compensation	**Medical Malpractice**
Insurer	Lloyds (MarketForm)	Lloyds (MarketForm)
Certification No.	11/00066390	11/00066391
Finance Cover	£5 million pounds sterling	£10 million pounds sterling

The Non-Negligent harm policy is worldwide, with the exception of the United States and Canada. The policy is subject to terms, conditions and exceptions.

LSHTM Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM policies and procedures, as well as successful contract and agreement negotiations from the Research Grants and Contracts Office, where relevant, before the study commences.

A copy of the ethics and regulatory approval letters **must** be sent to the Clinical Trials QA Manager prior to the study commencing. Sponsorship is dependent on obtaining local approval for all sites where the research is being conducted. It is recommended that all members of the study team attend Good Clinical Practice (GCP) training every two years.

Yours sincerely,

[redacted]

Patricia Henley
Clinical Trials QA Manager
on behalf of the Clinical Trials Sub-Committee

POLICY DOCUMENT COVERING SPONSORSHIP, WITH REGARD TO CLINICAL TRIALS

The main responsibilities of Sponsor delegated to the Chief/Principal investigator are:

(i) Authorisations

- Obtain favourable opinion from ethics committee
- Request clinical trial authorisation (CTA) from Regulatory Authority (as required)
- Study submitted to public database (eg www.clinicaltrials.gov)
- Give notice of amendments to the protocol
- Give notice a trial has ended

(ii) Good Clinical Practice and conduct (GCP)

- Put and keep in place arrangements to adhere to GCP
- Ensure all members of study team receive appropriate training in GCP
- Take appropriate urgent safety measures

(iii) Pharmacovigilance

- Keep records of all adverse events reported by investigators
- Ensure recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARS)
- Ensure investigators are informed of SUSARS
- Ensure all SUSARS including those in third countries entered into European database
- Provide annual list of suspected serious adverse reactions and a safety report

(iv)Trial Management

- Quality Control (monitoring)
- Medical Expertise
- Data Handling, and Record Keeping
- Investigator Selection
- Delegation of Responsibilities
- Record access for QA/QC and regulatory inspectors
- Clinical Trial/Study Reports
- Study Design

(v) Investigational Medicinal Product (IMP)

- Ensure Investigational Medicinal Products are available to participants free of charge
- Information on IMP kept up to date
- Manufacturing, Packaging, Labelling, and Coding of IMP
- Supplying and Handling of IMP

The main responsibilities retained by the Sponsor are:

(i) RGCO / Finance

- Contracts & Agreements
- Compensation to Subjects and Investigators
- Financing
- Confirmation of indemnity

(ii) Clinical Trials QA Manager

- Project review and organisational risk assessment
- Quality Assurance (audits)
- Investigation of non-compliance

NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Zachary Kaufman

to certify that you have successfully completed the six hour, required course on

Good Clinical Practices

Expires: 03 October, 2015



Elizabeth A. Buttrey, Training Coordinator
Clinical Coordinating Center

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No.HHSN271200522081C.

ANNEX F: GOAL TRIAL BASELINE QUESTIONNAIRE (ENGLISH)

Note: This questionnaire is completed via a handheld mobile phone using Open Data Kit software. Some questions will have longer picklists of values than can fit on this summary document. This document is meant to summarize the questionnaire items in a printable view.	
Question/Item	**Type of data or possible values**
Participant ID Number	Number
Date of survey	Date
Phone ID	Number
Start Time	Date/Time
End Time	Date/Time
Please answer as honestly as possible.	
Example: This phone survey tool is pretty cool, isn't it?	
Great - Swipe the screen to start.	
Section 1: Basics & Demographics First, I'm going to ask some questions about yourself and your household.	
What is your sex?	MaleFemale
How old are you?	Number
In what year were you born?	Year
In what month were you born?	Month
On what day of the month were you born?	Day
How would you describe your race?	Black, coloured, indian, white, other
What language do you speak most at home?	Xhosa, afrikaans, english, zulu, sotho, other
What best describes your living quarters?	Shack, flat, house, other
Do you live with your mother?	Yes or No
Do you live with your father?	Yes or No
Is your mother alive?	Yes or No
Is your father alive?	Yes or No
How many people live in your household?	Number
Who is the head of your household?	Mother, father, brother or sister, myself, other family member, other non-family member
What is your mother's highest level of education?	None, some primary, completed primary, some secondary, matric, higher
What is your father's highest level of education?	None, some primary, completed primary, some secondary, matric, higher
Do you have a television in your household?	Yes or No
Do you have a radio in your household?	Yes or No
Do you have piped water in your household?	Yes or No
Do you have a running car at your household?	Yes or No
What is the main type of toilet facility used in your household?	Yes or No
Do you own a mobile phone?	Yes or No
Do you own a sim card?	Yes or No
Do you have an email address?	Yes or No
Do you have a facebook account?	Yes or No
Do you have a Mxit account?	Yes or No
How often do you use facebook, Mxit or other social networks?	Never- Daily or almost daily
How often do you use the internet for reasons other than social networking?	Never- Daily or almost daily
Does someone else in your household own a mobile phone?	Yes or No
Is there anyone in your household who you know or think has HIV?	Yes or No
Is there anyone you know personally who has or had HIV?	Yes or No
Do you know anyone personally who died of HIV or AIDS?	Yes or No
Section 2: HIV Knowledge Now, I'm going to present some statements about HIV.	
I can tell if someone has HIV by looking at him or her	TrueFalse
Having an older sexual partner increases your risk of getting HIV	TrueFalse
Using condoms during sex reduces your risk of getting HIV	TrueFalse
An HIV-positive mother would never give birth to an HIV-negative baby.	TrueFalse
You are more likely to get HIV if you already have an STI	TrueFalse
Having only one mutually faithful partner reduces your risk of getting HIV	TrueFalse
Male circumcision reduces a man's risk of getting HIV	TrueFalse
Legally, men are allowed to beat their wives.	TrueFalse
Drinking alcohol can increase your risk of getting HIV	TrueFalse
Someone is most likely to spread HIV during the first 6-8 weeks after they get infected	TrueFalse
Section 3: HIV Attitudes and Communication Thanks! Now, I'm going to ask some questions about how you feel in general.	
I am certain I can avoid getting HIV	Strongly Agree - Strongly Disagree
I am certain I can say no to sex if I don't want it	Strongly Agree - Strongly Disagree
I am certain I can stick to only one sexual partner at a time	Strongly Agree - Strongly Disagree
It is hard for me to resist peer pressure	Strongly Agree - Strongly Disagree
I am certain I can avoid having a sexual relationship with an older man even if he offers me gifts or money	Strongly Agree - Strongly Disagree
I am confident that I could use a condom correctly.	Strongly Agree - Strongly Disagree
If my partner did not want to use a condom, I could convince him or her to use one	Strongly Agree - Strongly Disagree
I want to know my HIV status and am willing to take a test	Strongly Agree - Strongly Disagree
I would not want to sit near a classmate with HIV.	Strongly Agree - Strongly Disagree
I would be willing to care for a family member with HIV	Strongly Agree - Strongly Disagree
People with HIV should be ashamed of themselves	Strongly Agree - Strongly Disagree
A teacher with HIV should not be allowed to work in a school.	Strongly Agree - Strongly Disagree
A man who gets circumcised at a clinic is not a real man.	Strongly Agree - Strongly Disagree
I would consider getting circumcised at a clinic.	Strongly Agree - Strongly Disagree
I am comfortable talking about sex with my friends	Strongly Agree - Strongly Disagree
I am comfortable talking about sex with a parent or guardian	Strongly Agree - Strongly Disagree
I have talked about HIV with a friend in the past 2 months	Yes or No
I have talked about HIV with a parent or guardian in the past 2 months	Yes or No
Section 4: Depression Keep up the good work! Now I'm going to ask some questions about how you felt during the last week.	
During the past week I was bothered by things that usually don't bother me.	Rarely - All of the time
During the past week I did not feel like eating, my appetite was poor	Rarely - All of the time
During the past week I felt I could not cheer myself up even with the help of family and friends	Rarely - All of the time
During the past week I had trouble keeping my mind on what I was doing	Rarely - All of the time
During the past week I felt depressed	Rarely - All of the time
During the past week I felt that everything I did was an effort	Rarely - All of the time
During the past week I thought my life had been a failure	Rarely - All of the time
During the past week I felt fearful	Rarely - All of the time
During the past week my sleep was restless	Rarely - All of the time
During the past week I talked less than usual	Rarely - All of the time

ANNEX F: GOAL TRIAL BASELINE QUESTIONNAIRE (ENGLISH)

Question/Item	Type of data or possible values
Section 5: Gender Norms You're halfway done! Now, I'm going to ask some questions about relations between men and women in society.	
A woman should obey her husband.	Strongly Agree - Strongly Disagree
A woman should choose her own friends even if her boyfriend or husband disapproves.	Strongly Agree - Strongly Disagree
Men should share the work around the home such as doing the dishes or cleaning or cooking.	Strongly Agree - Strongly Disagree
Sometimes a man may have a good reason to hit his girlfriend or wife.	Strongly Agree - Strongly Disagree
A woman can refuse to have sex with her husband if she does not want it for any reason.	Strongly Agree - Strongly Disagree
If a wife does something wrong she should expect her husband to punish her.	Strongly Agree - Strongly Disagree
A man cannot control himself when he gets sexually aroused.	Strongly Agree - Strongly Disagree
A woman should expect to be taught how to behave by her husband.	Strongly Agree - Strongly Disagree
A woman should not expect the fathers of her children to give her money	Strongly Agree - Strongly Disagree
A woman has the right to refuse to have sex if she knows her partner is having sex with other women.	Strongly Agree - Strongly Disagree
Section 6: Sexual History Now I'm going to ask some questions about your sexual history.	
Some people your age have had sex and others have not. Have you ever had sex?	Yes or No
Which of the following best describes your experience the first time you had sex?	Willing, persuaded, tricked, raped
How old were you the first time you had sex?	Number
Have you ever used a condom?	Yes or No
Did you use a condom the first time you had sex?	Yes or No
How many sexual partners have you had in your lifetime?	1, 2, 3 or 4, 5 to 7, 8 to 10, More than 10
How many sexual partners have you had in the last 12 months?	1, 2, 3 or 4, 5 to 7, 8 to 10, More than 10
Do you currently have a sexual partner?	Yes or No
Did you use a condom the last time you had sex?	Yes or No
In the past 12 months, have you had sex after drinking alcohol?	Yes or No
In the past 12 months, have you given or received money, drugs, food, transport or a place to stay in exchange for sex?	Yes or No
In the past 12 months, have you ever had more than one sexual partner at the same time?	Yes or No
How old was the oldest partner you had sex with in the last 12 months?	Number
How old was the youngest partner you had sex with in the last 12 months?	
Some men have sex with other men. Have you ever had sex with another man?	Yes or No
The first time you had sex with a man did you have sex against your will?	Yes or No
Section 7: Forced Sex I have a few more questions about things you may have done with current or previous girlfriends.	
Have you ever forced your current or previous girlfriend to have sex with you when she did not want to?	Yes or No
Have you ever forced your current or previous girlfriend to do something sexual that she did not want to do?	Yes or No
Have you ever forced a woman or girl who was not your girlfriend to have sex with you?	Yes or No
Have you ever had sex with a woman or girl when she was too drunk or drugged to say whether she wanted it or not?	Yes or No
Have you done any of these things in the past 12 months?	Yes or No
Section 8: Medical History Now I'm going to ask some general questions about your medical history.	
Are you currently pregnant?	Yes or No
Have you ever been pregnant?	Yes or No
How many times have you been pregnant?	once, twice, 3 times, more than 3 times
What was your age at first pregnancy?	Number
Have you ever been told by a female partner that you have made them pregnant?	Yes or No
Have you ever had a sexually transmitted infection (STI)?	Yes or No
Did you get it treated?	Yes or No
Are you circumcised?	Yes or No
Where were you circumcised?	Clinic/hospital, In the bush, don't remember
Have you ever been tested for HIV?	Yes or No
Have you been tested for HIV in the last 12 months?	Yes or No
How would you assess your own personal risk of getting HIV?	No risk, low risk, some risk, high risk
Section 9: Alcohol Use Now I am going to ask you some questions about your use of alcoholic drinks.	
How often do you have a drink with alcohol?	Never, Once a month or less, 2-4 times a month, 2-3 times a week, 4+ times a week
How many drinks with alcohol do you have on a typical day when you are drinking?	1 or 2, 3 or 4, 5 or 6, 7 to 9, 10 or more
How often do you have six or more drinks on one occasion?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you found that you were not able to stop drinking once you had started?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you failed to do what was normally expected from you because of drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
Have you or someone else been injured as a result of your drinking?	No; yes, not in last year; yes during last year
Has a relative or friend or health worker been concerned about your drinking or suggested you drink less?	No; yes, not in last year; yes during last year
I am going to ask some questions about this.	
Have you ever threatened to hurt a partner?	Yes or No
Have you ever slapped a partner or thrown something at her that could hurt her?	Yes or No
Have you ever pushed or shoved a partner?	Yes or No
Have you ever hit a partner with a fist or with something else that could hurt her?	Yes or No
Have you ever kicked, dragged, beaten, choked or burned a partner?	Yes or No
Have you ever threatened to use or actually used a gun, knife or other weapon against a partner?	Yes or No
Have you done any of these things in the past 12 months?	Yes or No
physical. I am going to ask some questions about this.	
Has a partner ever threatened to hurt you?	Yes or No
Has a partner ever slapped you or thrown something at you that could hurt you?	Yes or No
Has a partner ever pushed or shoved you?	Yes or No
Has a partner ever hit you with a fist or with something else that could hurt you?	Yes or No
Has a partner ever kicked, dragged, beaten, choked or burned you?	Yes or No
Has a partner ever threatened to use or actually used a gun, knife or other weapon against you?	Yes or No
Have any of these things happened in the past 12 months?	Yes or No
Section 11: Acceptability of Open Data Kit: You're done with all the tough stuff! Just a couple more questions for feedback.	
How easy or difficult was it to use this phone for the survey?	Very difficult - Very easy
How well do you feel you understood the questions on this survey?	Not at all - All questions
How well were you able to answer questions on the survey HONESTLY?	Not at all - All questions
How comfortable did you feel taking this survey?	Very uncomforatble - Very comfortable
Do you prefer this type of survey (on a phone) or a pen-and-paper survey?	Phone, Pen-and-Paper, No preference
Thanks for participating in the survey. You can now hand your phone back to the administrator.	