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

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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:

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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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Helen Weiss and Caroline (Cari) Free served as members of my Advisory Committee. Helen advised on statistical elements of all of the work presented in this thesis, from the systematic review to the midline GOAL Trial results. She has reviewed and provided edits and comments on drafts of Papers 3, 4 and 5. Cari provided input into the content and structure of the Generation Skillz SMS Campaign. Elise Braunschweig Kaufman and Jeff DeCelles led the design of the Generation Skillz intervention, contributed significantly to the Intervention Design portion of Paper 2 and provided edits and comments on Papers 3 and 4. Tyler Spencer from Oxford University contributed to the design and search strategy of the Systematic Review (Paper 1) in addition to providing edits and comments on the draft of that paper.

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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I would like to extend thanks to the ethics committees at both Wits and LSHTM for reviewing and approving the trial's protocol. I would also like to thank the Editors and Reviewers at *AIDS and Behavior* for their input on Papers 1 and 4.

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

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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

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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.

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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

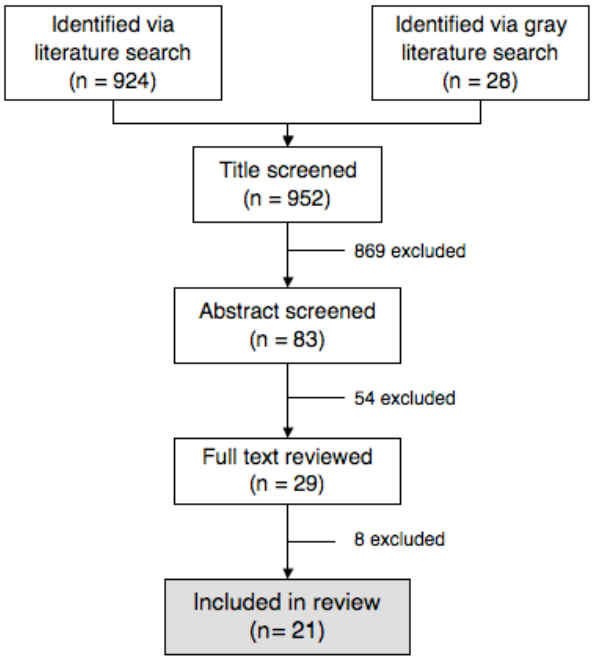

Table II: Characteristics of included studies (n=21)

		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)

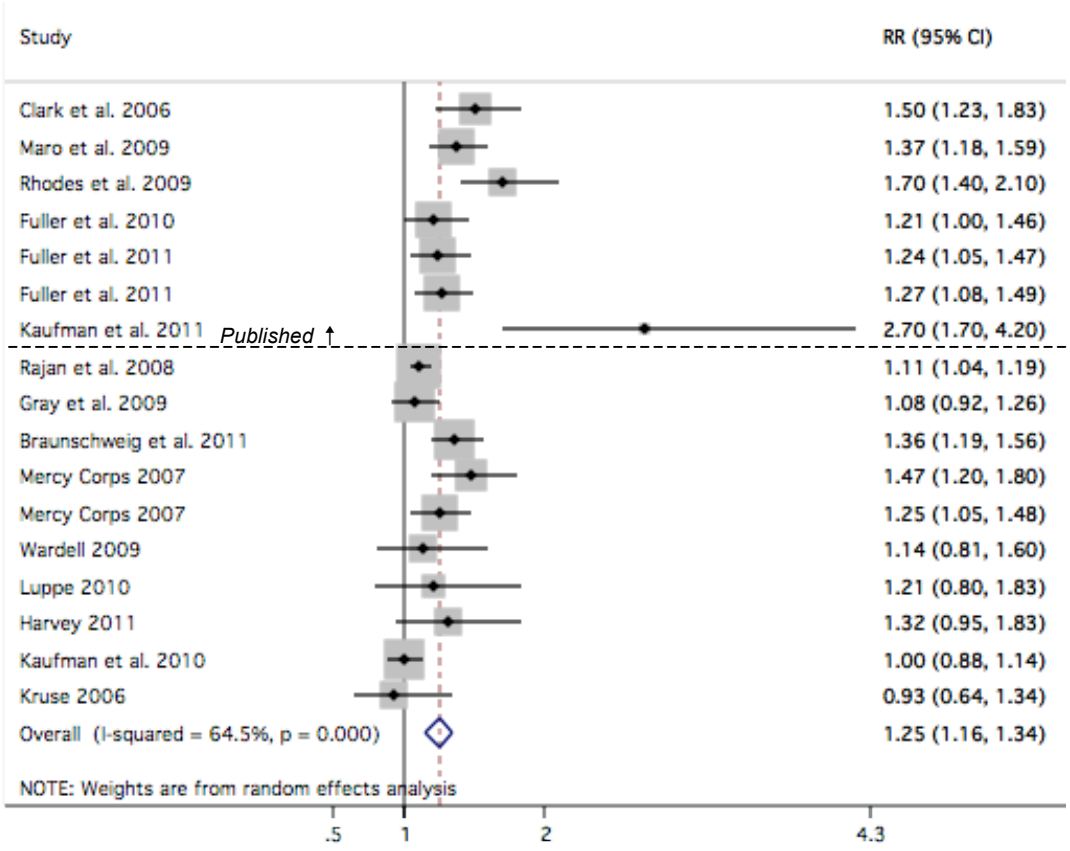

Figure 3: Random-effects meta-analysis for effects on stigma (n=11 studies)

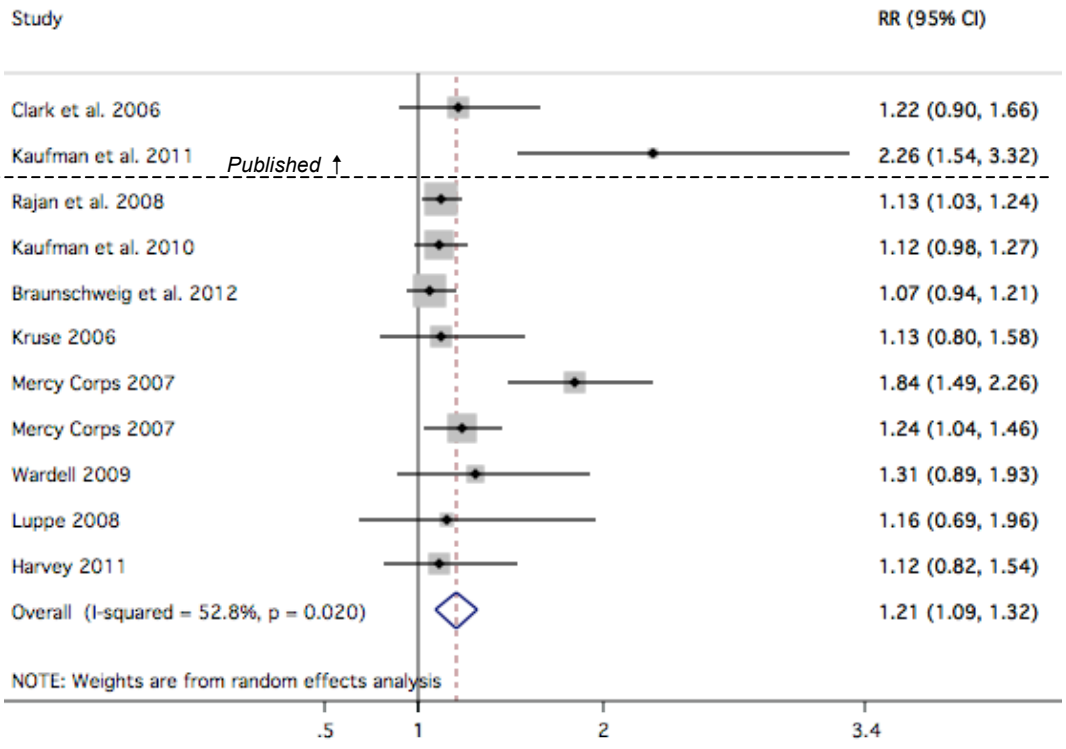

Figure 4: Random-effects meta-analysis for effects on self-efficacy (n=5 studies)

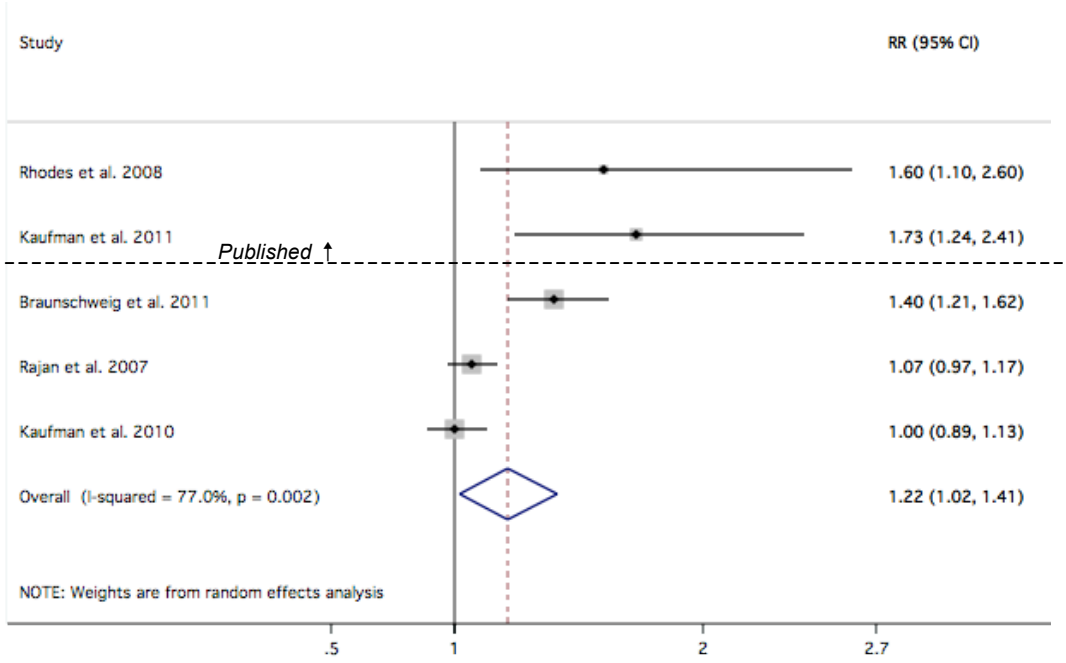

Figure 5: Random-effects meta-analysis for effects on communication (n=5 studies)

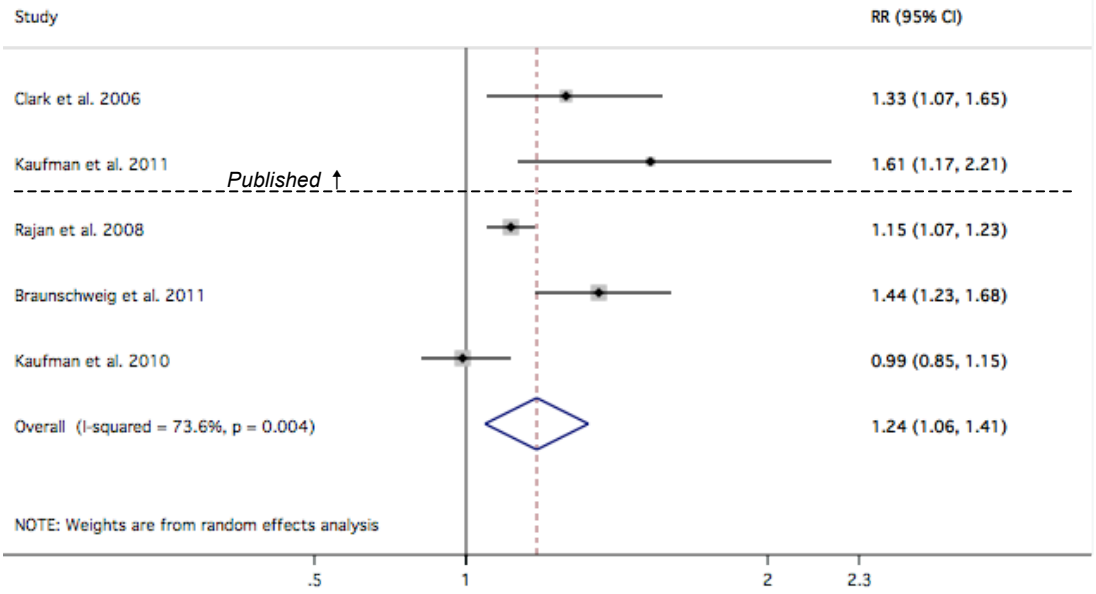

Table V: Systematic review search terms

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

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COVER SHEET FOR EACH 'RESEARCH PAPER' INCLUDED IN A RESEARCH THESIS

Please be aware that one cover sheet must be completed for each 'Research Paper' included in a thesis.

1. For a 'research paper' already published

1.1. Where was the work published? .....

1.2. When was the work published? .....

1.2.1. If the work was published prior to registration for your research degree, give a brief rationale for its inclusion

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1.4. Have you retained the copyright for the work? **Yes / No**
If yes, please attach evidence of retention.
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2. For a 'research paper' prepared for publication but not yet published

2.1. Where is the work intended to be published? ..... **African Journal of AIDS Research**

2.2. Please list the paper's authors in the intended authorship order

Kaufman ZA, Braunschweig EN, DeCelles J, Daniels D, Ross DA

2.3. Stage of publication – Not yet submitted / Submitted / Undergoing revision from peer reviewers' comments / In press

3. For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)

.....

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**

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

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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)

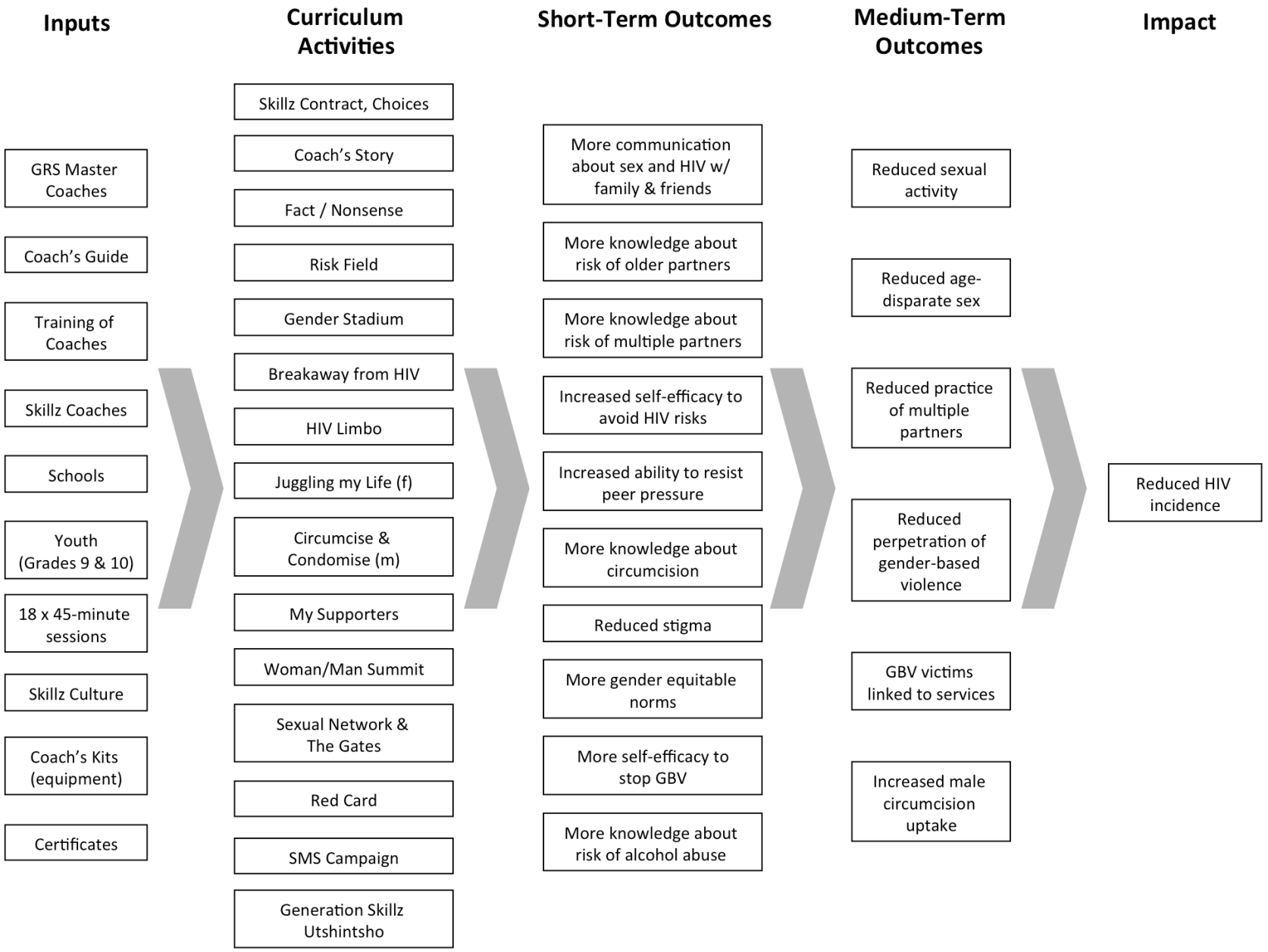
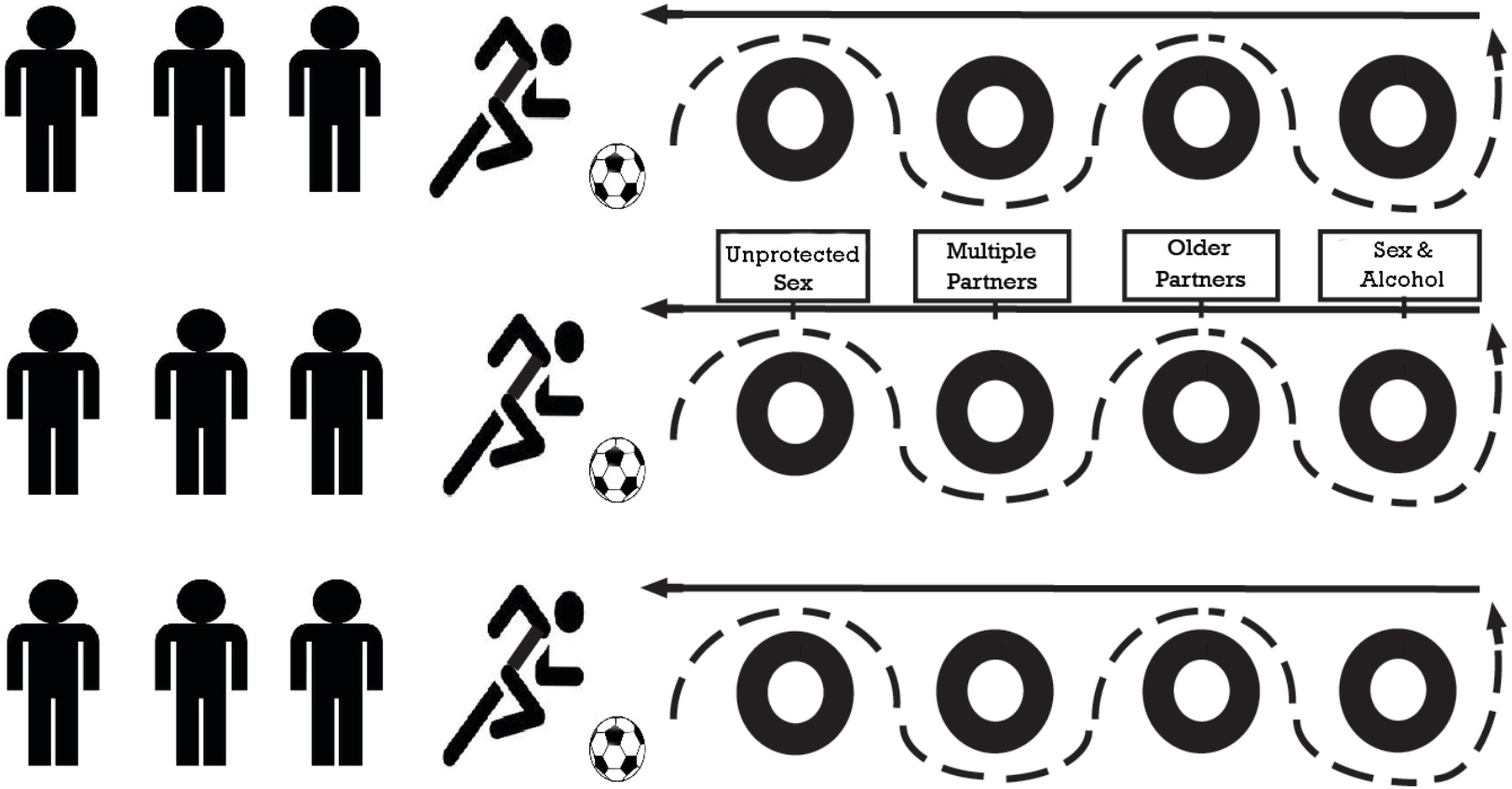


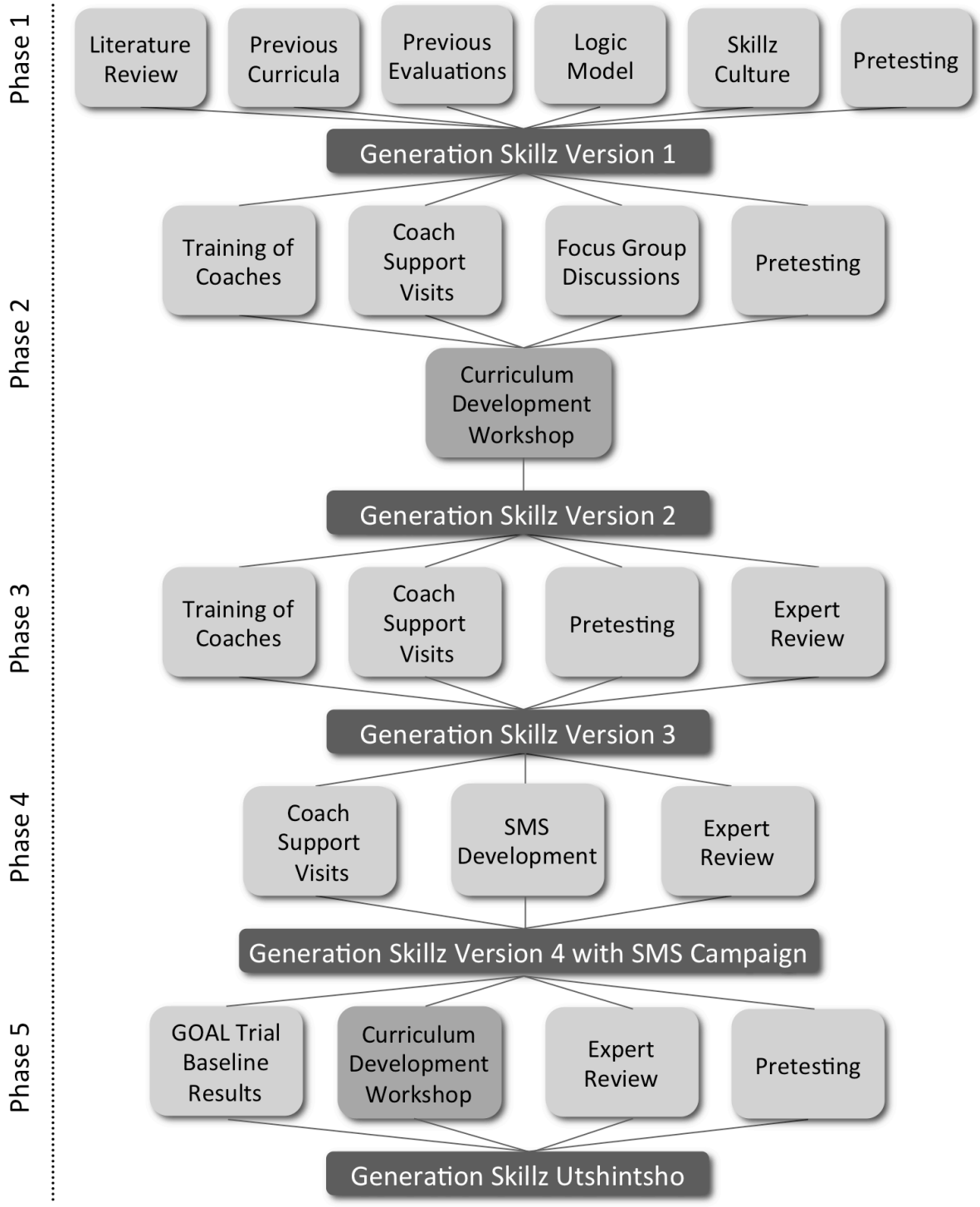
Figure 2: Risk Field (example Generation Skillz activity) diagram



Source: *Generation Skillz Curriculum*, Version 4

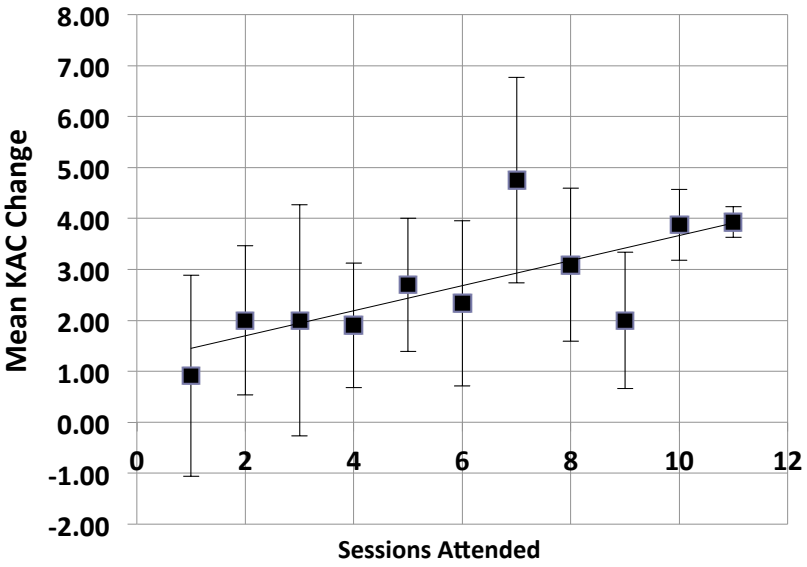
Caption: *In Risk Field, participants dribble a soccer ball in between cones representing HIV-related risks—multiple partners, sex and alcohol, older partners, etc. In the first round, if a player hits a cone, s/he must complete three push-ups or star jumps, representing the consequences of the risk 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



Linear regression*
β = 0.20
95% CI = 0.08-0.33
p = 0.002

***Adjusted for age and site**

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**

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   I led on trial design, data analysis, drafting of the paper and write-up.

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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.

Neither the entire paper nor any of its content has been submitted, published, or accepted by another journal. The paper will not be submitted elsewhere if accepted for publication in *Contemporary Clinical Trials*.

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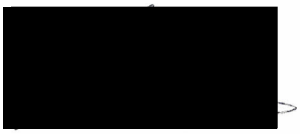
All authors have reviewed and approved the manuscript, as well as contributed to its content.

Thank you for your consideration.

Sincerely,



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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

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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]

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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.

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Figure 1: GOAL Trial participant flow diagram

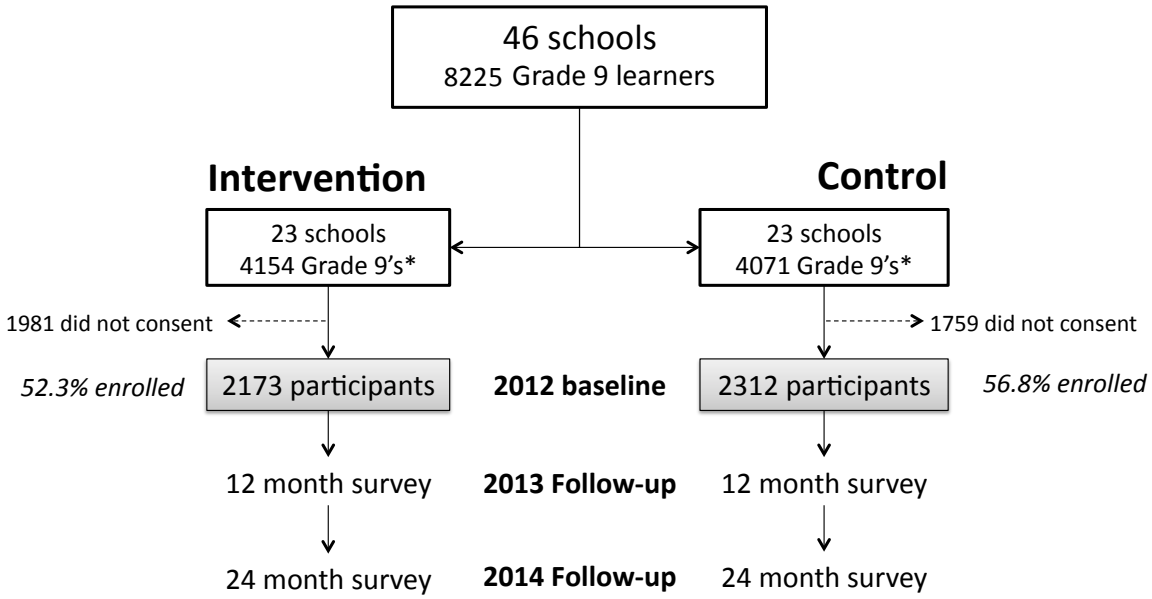

Table 1: Enrolment by group and by site

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