

Goals for girls: a cluster-randomized trial to investigate a school-based sexual health programme amongst female learners in South Africa

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Abstract

The delivery of comprehensive sexuality education to adolescents at school is recognized as a long-term strategy to support adolescent health. Suboptimal sexual and reproductive health (SRH) outcomes among South African adolescents necessitate the ongoing development and optimization of SRH education and promotion models. We conducted a cluster-randomized controlled trial amongst secondary schools ($n = 38$) in Cape Town, South Africa, to evaluate a sport-based, near-peer-led SRH curriculum, SKILLZ, amongst female learners ($n = 2791$). Biomedical (sexually transmitted infections [STIs], human immunodeficiency virus [HIV] and pregnancy) and socio-behavioural (social support, gender norms and self-concept) outcomes were assessed pre and post intervention. Attendance at SKILLZ was low and intervention participants did not show an improvement in SRH outcomes, with HIV and pregnancy incidence remaining stable and STI prevalence remaining high and increasing in both control and intervention arms. Although evidence of positive socio-behavioural measures was present at baseline, participants

with high attendance showed further improvement in positive gender norms. SKILLZ did not demonstrate the capacity to significantly impact clinical SRH outcomes. Modest improvements in outcomes amongst high attenders suggest that the impact may be possible with improved attendance; however, in the absence of optimal attendance, alternative intervention strategies may be required to improve SRH outcomes amongst adolescents.

Introduction

The promotion of adolescent health in South Africa (SA) is critical to meet the needs of a growing youth population [1]. Health and well-being underpin adolescent development, yet adolescent sexual and reproductive health (SRH) risk is driven by challenges in navigating safe sex, power and equity in relationships, increased susceptibility to peer pressure and real and perceived barriers to accessing healthcare services [2]. SA adolescents, particularly female adolescents, sustain high rates of unintended pregnancy and sexually transmitted infections (STIs), which are associated with a number of reproductive sequelae and increase the likelihood

of human immunodeficiency virus (HIV) transmission [3–8]. In SA girls aged 15–17 years, birth rates increased by 17.9% between 2017 and 2021, despite 76.3% (95% confidence interval [CI]: 74.9–77.6%) of these pregnancies being unintended [9, 10]. To meet adolescent SRH needs, a robust combination of services that include SRH education and promotion is needed [2, 11].

Effective school-based interventions are an essential long-term strategy to improve adolescent SRH education and outcomes as they provide access to adolescents in a structured environment, independent of household and community [12–14]. School-based comprehensive sexuality education (CSE) offers one approach to imparting age-appropriate, realistic and non-judgemental SRH content. CSE interventions have shown mixed evidence regarding whether they can impact unintended pregnancy and HIV incidence although increased efficacy has been described with interventions that include a focus on gender and power relations [15–18]. CSE in SA is delivered through an in-school, national curriculum that has been criticized as insufficient to meet the SRH needs of learners, partially due to the lack of appropriate training and facilitation support for teachers [19–21]. The integration of additional SRH programming that makes use of alternative educational models presents a potential means to strengthen CSE in schools and improve SRH outcomes amongst learners [20]. Alternative models include interventions that take place after school are peer- or near-peer-led (defined here as a non-professional group facilitator of a similar age and social group to the learner, recruited from their community) and make use of activities that use sport to engage interest and present information in interactive ways [22, 23].

We conducted a cluster-randomized controlled trial to evaluate an existing sport-based, near-peer-led education programme, called SKILLZ, on biomedical and socio-behavioural SRH indicators amongst 14- to 17-year-old, female secondary school learners across secondary schools in low-income, high-density, peri-urban locations in Cape Town, SA [24–27].

Methods

Participants

Between 2018 and 2019, all secondary schools ($n = 42$) located in a single health sub-district were randomized to become to receive the SKILLZ intervention ($n = 20$ intervention schools), to not receive SKILLZ but partake in the study ($n = 20$ control schools) or to not participate in any way ($n = 2$). For logistical feasibility, study implementation was split over 2 years, with 20 schools (10 intervention and 10 control) engaged in 2018 (Cohort 1) and 20 schools (10 intervention and 10 control) engaged in 2019 (Cohort 2). Eligible learners within each school were required to be female, non-pregnant (as confirmed by human chorionic gonadotropin lateral flow pregnancy tests) and in school grades 8–10 (approximately 13–17 years old). Overall, 70–100 learners per school self-selected to participate and were followed prospectively for a period of 8 months, with a total sample target of 2800 participants.

Intervention

Control schools received the national CSE programme alone, while intervention schools received 10 SKILLZ sessions in addition to the national CSE programme. The national CSE programme is delivered by school teachers and contains information on life skills and SRH issues, with an emphasis on the consequences of early pregnancy and the importance of schooling. The SKILLZ programme was adapted from an existing, evidence-based, girl-centred and participatory sport-based curriculum informed by Social Cognitive Theory, which, compared with the CSE programme, provided a greater emphasis on gender and power relations, STIs, healthy relationships and positive self-concept [23, 28]. Girl-centred programming was adopted in response to the disproportionately high SRH burden amongst adolescent girls in SA, as well as demand from adolescent girls, who are primarily educated in co-educational environments, for a girls-only space to talk about SRH issues [23, 29, 30].

SKILLZ was delivered following a manualized curriculum that used a range of sport-based activities, including soccer drills, soccer metaphors and yoga and breathing exercises during sessions to enhance engagement with the SRH content and to provide a platform for participants to learn and apply skills in a space that is traditionally male dominant, thus challenging gender norms [23, 30]. Sessions lasted 45–60 min and were held weekly during the school term, excluding exam periods and school holidays. Overall, the programme delivered 10 sessions over two school terms (approximately 6 months). Cohort 1 participants received SKILLZ after school, while Cohort 2 participants received SKILLZ either during or after school according to the school's preference.

SKILLZ aimed to create a 'safe space' for participants to not only be physically safe from harm but have the freedom to express themselves and build a network of supporters [23]. SKILLZ sessions were therefore facilitated by trained, near-peer 'caring coaches' (age 18–30 years and median age 25 years), with a ratio of 1 coach per 25 participants. Near-peer was defined as an individual who identified as female, aged ≤ 30 years and resided in the study area. When recruiting coaches, these criteria were equally considered. The educational qualification level required for coaches was the completion of secondary school. Coaches received a 1-week training programme and thereafter weekly professional development sessions. Coach mentoring and fidelity checks were performed by a designated master coach, who had worked a minimum of 3 years as a coach in other SKILLZ programmes in a similar setting.

Outcomes

The primary objective was to determine whether SRH programming, additional and complementary to the national CSE programme, could significantly improve biomedical (STI, pregnancy and HIV) and socio-behavioural indicators (social support, self-concept and gender norms) of sexual health amongst female adolescents. This sample was deemed sufficient to determine a 50% hypothesized reduction in pregnancy incidence in the

intervention arm with 83% power, assuming a 20% pregnancy incidence among participants [31,] an estimated intracluster correlation coefficient of 0.06 and a two-sided alpha of 0.05 [26, 32]. A power computation was performed using the ado-program 'clustersampsi' in Stata 14 [33]. During the design of SKILLZ, factors at the individual, relationship and community (school) levels with the potential to modify the intervention effect on the outcomes were considered. Mediating outcomes were hypothesized to include perceived social support and norms; degree of empowerment; self-concept and self-efficacy; trust in the healthcare system, the schools and the near-peer 'coaches' and perceived stigma. Factors considered to influence the fidelity of programme implementation included participant, school and coach receptivity to and understanding of SKILLZ, perceived appropriateness and relevancy of SKILLZ and potential barriers and enablers to attendance.

Cohort 2 modifications

Following poor attendance in Cohort 1, an *ad-hoc*, unplanned evaluation of barriers and enablers to attendance was conducted that included staff feedback (group discussions and anonymous surveys) and participant feedback (self-administered post-intervention feedback survey on self-reported SKILLZ attendance, session acceptability and logistical barriers and enablers to attendance). While the outcomes will be discussed in subsequent publications, the impact of this evaluation on the study design was that for Cohort 2, schools were allowed to choose to receive the programme either in-school or after-school and participants were sent additional session reminders via WhatsApp [34].

Ethical considerations

Ethical approval was obtained from the University of Cape Town Human Research Ethics committee (REF 138/2018) as well as the research directorate of the Western Cape Department of Education. As the research was non-therapeutic, of minimal risk, but delivered sometimes sensitive SRH content, a parental proxy consent waiver

was used such that potentially vulnerable learners were not excluded by parental refusal [35]. Learners were informed and supported equally to opt for (i) parental consent with learner assent or (ii) self-consent without the need for parental consent. All students opted for the latter option. A letter for their parent/guardian was provided to all participants informing them of the study. Participants received a R25 food voucher per study visit, but no reimbursement for SKILLZ sessions. The trial is registered with International Standard Randomised Controlled Trial Number (ISRCTN) Trials at ISRCTN77395422 <https://www.isrctn.com/ISRCTN77395422>.

Study procedures

There were two study visits, which took place at baseline and approximately 8 months, independently from SKILLZ sessions. At baseline, all participants additionally completed a demographic registration form. Both study visits included a nurse-facilitated health screening that included testing for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoea* (NG), HIV, pregnancy and the completion of a sexual risk assessment and SRH history, including current contraceptive use. A paper-based 30-point socio-behavioural questionnaire was self-administered, which included measures of social support, self-concept and gender norms and expectations using Likert scale ratings that were hypothesized to be mediators of SRH outcomes. This questionnaire was modified from an existing questionnaire used to evaluate SKILLZ programmes in similar settings in order to allow for comparison of results between this study and previous SKILLZ evaluations as well as routine programmatic monitoring [23, 36–38]. The questionnaire is provided as a supplementary material.

Study visits were conducted by school, such that all participants at a single school were seen within a 1- to 2-day period. All final visits were scheduled to take place 8 months post baseline; however, the interval between visits varied by school according to school timetables and by individual participant according to the number of follow-up attempts

required. Participants were included in the analysis if their study interval fell within 6–10 months post-baseline.

Clinical procedures

HIV testing was conducted according to SA national testing guidelines using rapid diagnostic tests, with pre- and post-test counselling. Pregnancy testing was performed using HCG urine strips according to the manufacturer's guidelines. STI screening was performed using nucleic acid amplification test-based GeneXpert® CT/NG assay (Cepheid, Sunnyvale, CA, USA). HIV and pregnancy tests were carried out by a trained nurse/counsellor, while self-collected vaginal swabs were collected to test for the presence of STIs. HIV and pregnancy results were provided at the time of testing, while STI results were delivered post health screening in person, phone or letter (with signature on receipt).

Attendance

SKILLZ attendance was captured on paper-based registers and electronically. Participants were reminded to attend sessions during school and, exclusively in Cohort 2, via a voluntary, closed WhatsApp group. Participants who arrived late to sessions but did not miss core content were marked as having attended. Participants who attended seven or more sessions overall met the pre-determined criteria for programme graduation and were provided with a certificate and medal [30].

Data analysis

The comparison of outcomes between intervention and control arms and across study visits (baseline and final) was analysed overall and by cohort using a difference-in-difference analysis technique, accounting for the fact that randomization occurs at the level of the school and not the individual participant. Demographic and sexual risk data reported at registration and during baseline health screening were reported. Those attending less than 7 of the 10 SKILLZ sessions were labelled as low

attenders; those attending 7 or more sessions (graduates) were labelled as high attenders. In Cohort 2, differences in mean attendance and proportion graduating between delivery models (in-school versus after-school) were additionally analysed. The cross-sectional prevalence of CT and NG at baseline and the final study visit was reported. All summary statistics were calculated and compared taking the design effect due to cluster randomization into account through the use of the STATA SVY analysis modules [3]. For two-way tables, the Rao-Scott second-order correction to the Pearson chi-square statistics was used to allow for the cluster design [40]. Within-participant change of STI infection and between-group comparisons of within-participant change were estimated with a multilevel mixed-effect Poisson model with random effects for participants nested within schools and for schools to capture association within participants and associations within schools. This was repeated for all participants by cohort and for participants who only attended at least seven visits, with visit intervals (time between baseline and the final study visits) between 6 and 10 months. The prevalence of HIV, pregnancy and contraceptive use at baseline and the final study visits was reported but not statistically compared due to a high number of missing values that would have potentially biased the findings.

Analysis of the socio-behavioural questionnaires was conducted to quantify programme influence on attitudes, beliefs, gender and self-constructs. Descriptive analyses of pre/post-questionnaires were carried out for all variables. For binary questions (yes/no), frequencies and percentages were calculated by arm and stratified by cohort. Changes between visits across and within arms were compared using multilevel Poisson mixed-effect models with random effects for participants nested within schools and for schools to capture associations within participants and associations within schools. The incidence rate ratio was calculated by comparing prevalence at the final visit to prevalence at the baseline visit. The reliability of composite measures was determined using the Cronbach alpha statistic. For all composite

measures, scores were assigned to each Likert response option (i.e. 1 = 'Strongly disagree' to 5 = 'Strongly agree'). Mean scores and standard deviations were calculated at pre and post visits. A multilevel mixed-effect linear regression model was used to analyse these composite scores, with random effects for school and participant. Effect sizes are reported as absolute differences between baseline and final study visits.

Results

Of the 42 schools randomized, 38 completed the study (18 in Cohort 1; 20 in Cohort 2). Two schools withdrew mid-implementation due to a change in local policy that was interpreted as disallowing the provision of health services by external providers. Of 2791 participants, 44.39% (1239) participated in Cohort 1 and 55.61% (1552) participated in Cohort 2. Overall, 73.62% of all participants attended both study visits, while 24.0% (489) participants were lost to follow up and uncontactable across multiple follow-up attempts. Reasons for nonattendance at the final study visit included post-enrolment exclusion due to not meeting age/grade eligibility criteria (6.84%), transfer to another school (3.57%), withdrawal or decline (13.99%) or death (0.30%) (Fig. 1).

Participant characteristics

Participant demographics were similar across arms and cohorts (Table I). The mean age at enrolment was similar at 15.34 and 15.19 years in the intervention and control arms, respectively, with no significant difference in age between Cohorts 1 and 2. An even distribution of participants self-classified as single (49.04%) or in a relationship (43.68%) at baseline, with 37.20% (1803) reporting ever having sex. Of which, 11.65% (210) had more than one sexual partner in the last 3 months, 7.54% (136) engaged in transactional sex, 6.52% (182) reported unprotected sex without the use of a condom, 20.63% (372) had sex while under the influence of alcohol/drugs and 8.64% (241) had

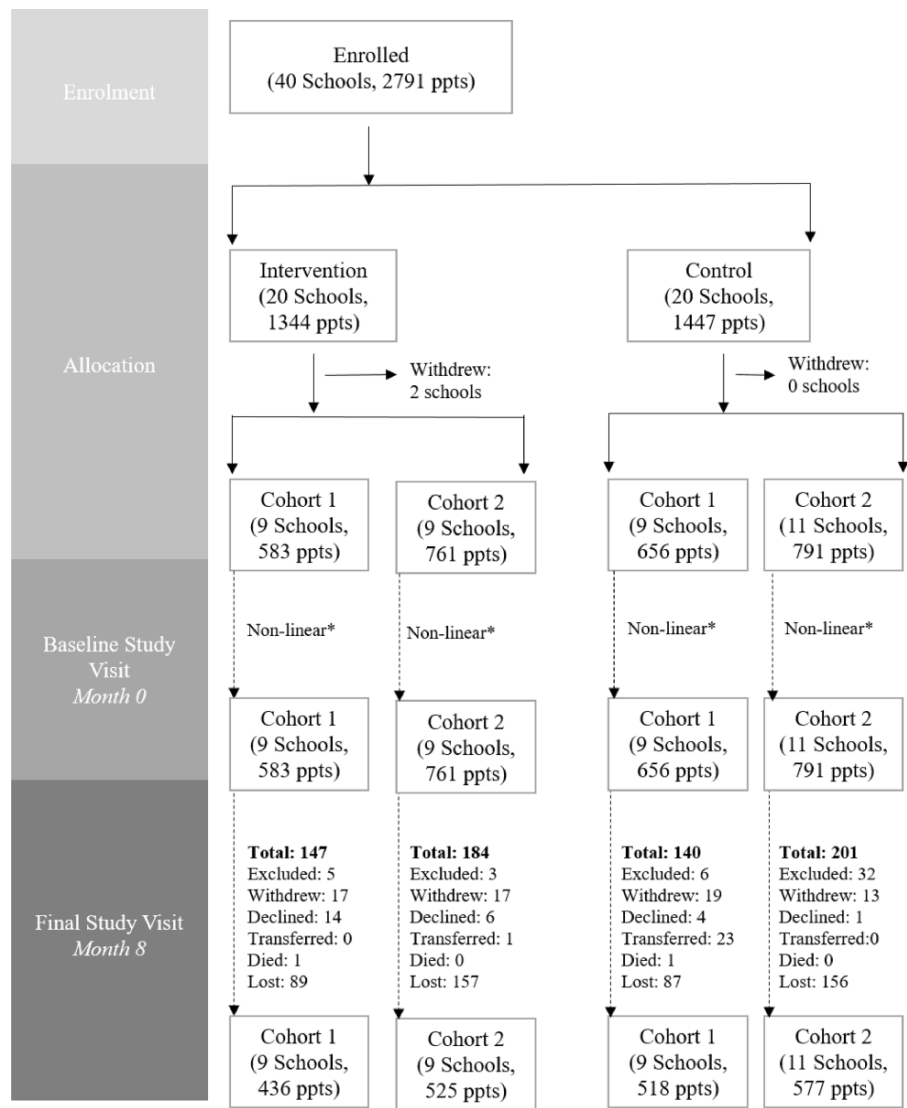


Fig. 1. CONSORT diagram. *Non-linear: not all enrolled participants attended the baseline visit.

been forced to have sex or perform sexual acts. On average, individual questions within the study's self-administered questionnaire had a non-response rate of less than 5%.

Attendance at sessions

In the *ad-hoc* evaluation conducted between cohorts, 78.34% (340/434) reported their interest in

the sessions as 8/10 or higher. Despite this, attendance was low in both Cohort 1 and 2, with a mean attendance rate of 44.20% (standard error (SE) 5.22%, 95% CI: 33.18–55.22%) and 47.17% (SE 4.90%, 95% CI: 36.81–57.52%), respectively. Overall, 41.14% participants did not participate in any session (44.43% Cohort 1 participants; 38.63% Cohort 2 participants), and 353 (26.25%)

Table 1. Participant demographics by arm, using combined data from both cohorts

	Intervention arm	Control arm	P-value
Age at enrolment			
Mean (SD)	15.34 (1.53)	15.19 (1.44) years	0.629
Minimum–maximum	12–21 years	8–20 years	–
Ethnicity			
Black African	829 (61.78%)	949 (65.58%)	0.6518
Coloured	442 (32.89%)	447 (30.89%)	
Indian/Asian/White/other	19 (2.76%)	3 (0.21%)	
Unknown	54 (4.02%)	48 (3.32%)	
Home language			
Afrikaans	70 (5.21%)	104 (7.19%)	0.6607
English	407 (30.28%)	351 (24.26%)	
IsiXhosa	803 (59.75%)	928 (64.13%)	
Other	13 (0.97%)	20 (1.39%)	
Unknown	51 (3.79%)	44 (3.04%)	
Birthplace			
Eastern Cape	189 (14.06%)	187 (12.92%)	0.3384
Western Cape	1002 (74.55%)	1165 (80.51%)	
Other SA province	34 (2.53%)	35 (2.42%)	
Unknown	119 (8.85%)	60 (4.15%)	
Type of housing			
Brick	975 (72.54%)	998 (68.97%)	0.7586
Shack	306 (22.77%)	368 (25.43%)	
Unknown	63 (4.59%)	81 (5.60%)	
No. of days hungry in the past week			
Never	1068 (79.46%)	1138 (78.65%)	0.7432
1–2 days	131 (9.75%)	165 (11.40%)	
>3 days	71 (5.28%)	65 (4.49%)	
Unknown	79 (5.46%)	74 (5.51%)	
Primary caregiver			
Mother	943 (70.16)	1003 (69.32%)	0.5347
Other relative	296 (22.03%)	340 (23.50%)	
Non-relative (incl. boyfriend)	13 (0.97%)	5 (0.35%)	
Self	7 (0.52)	17 (1.17)	
Unknown	85 (6.31%)	82 (5.67%)	
Relationship status			
Single	718 (49.65%)	652 (48.51%)	
In a relationship	610 (42.19%)	572 (42.56)	
Other/unknown	118 (8.16%)	120 (8.93%)	
Ever had sex (yes)	479 (33.13)	464 (34.52%)	
Unprotected sex (without a condom) in the past 3 months	94 (6.99%)	88 (6.09%)	
>1 Sexual partner in the past 3 months (yes)	65 (4.50%)	47 (3.50%)	
Transactional sex (yes)	39 (2.70%)	44 (3.27%)	
Sex under the influence of alcohol or drugs (yes)	116 (8.02%)	89 (6.62%)	
Forced to have sex or perform sexual acts (yes)	125 (8.64%)	116 (8.63%)	

participants were not exposed to a sufficient number of SKILLZ sessions of the integrated programme to merit ‘graduation’. Cohort 2 schools that opted for SKILLZ sessions during school

showed higher attendance and significantly higher graduation rates (50.24% versus 18.69%, $P < 0.05$) than schools that self-selected to receive the SKILLZ programme after-school (Fig. 2).

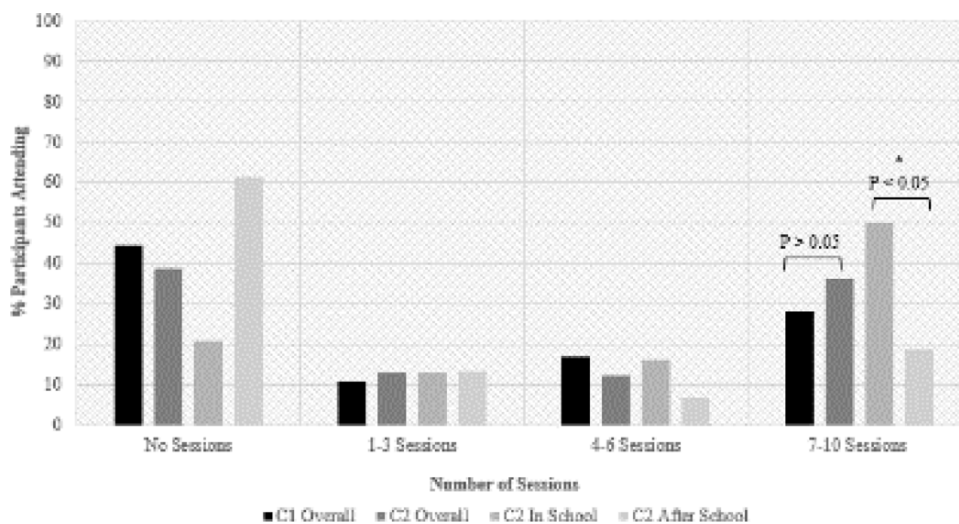


Fig. 2. SKILZ attendance per cohort and per delivery model, indicating whether in-school or after-school delivery models were used.

Sexually transmitted infections

STI prevalence was high, with 24.30% (intervention arm) and 19.58% (control) testing positive for either CT or NG at baseline, and a high rate of NG/CT co-infection. Rates of both CT and NG were higher amongst participants who reported ever having sex at baseline (34.32% and 10.86%, respectively) compared with those who reported never having had sex (5.75% and 2.91%, respectively) and those who did not answer the question (14.18% and 6.13%, respectively). Both arms saw an increase in the prevalence of at least one STI between study visits and the prevalence rose to 25.19% in the intervention arm and 24.33% in the control. There were no significant differences in STI prevalence (CT, NG or CT/NG co-infection) between arms or between cohorts (Table II). This finding held true when considering Cohorts 1 and 2 graduates combined; however, compared with control participants, Cohort 2 graduates (high attenders) showed a lower increase in GC prevalence ($P = 0.030$) and an observable but non-significant lower increase in CT/GC co-infection ($P = 0.083$) (Fig. 3 and Table II). Restricting the analysis to only participants who reported ever having had sex,

overall or by cohort, reported the same trends as described for the full group (Table II). STI incidence between study visits did not differ between arms or cohorts. Of positive cases, 10.09% and 1.02% of participants had a matched positive test for CT and NG, respectively, between study visits, indicating that even if baseline STIs were not treated, the majority of infections at the second study visit were new infections.

Pregnancy

Pregnancy incidence was low in the intervention (10, 1.04%) and control (10, 0.91%) arms (Table III). A small proportion of participants in each arm, 5.72% (55) and 4.66% (51), declined a pregnancy test at the final study visit. Self-reported contraceptive use at baseline was 17.04% (211) overall, with 18.75% (252) and 20.68% (299) of participants in the intervention and control arms, respectively, reporting current contraceptive use, mostly an injectable method. Between study visits, there was an increase of 9.00% and 8.78% in self-reported contraception uptake in the intervention and control arms, respectively.

Table II. Prevalence of STIs (CT and NG) overall, by cohort, amongst high attenders (≥ 7 SKILLZ sessions), and considering only the participants who are sexually active

	Intervention arm			Control arm			Difference between arms
	Baseline study visit	Final study visit	Change (ratio and 95% CI)	Baseline study visit	Final study visit	Change (ratio and 95% CI)	
Cohorts 1 and 2							
Visit retention (no attended/no enrolled)	1070	901		1241	1044		
CT positive (%)	17.66	19.53	1.10 (0.89–1.36)	14.42	18.39	1.30 (1.06–1.60)	0.263
GC positive (%)	6.64	5.66	0.87 (0.61–1.25)	5.16	5.94	1.14 (0.80–1.63)	0.295
CT and GC positive (%)	4.39	4.00	0.94 (0.60–1.45)	3.06	3.35	1.10 (0.69–1.76)	0.610
CT and GC negative (%)	80.09	78.80	0.98 (0.89–1.09)	83.48	79.02	0.95 (0.86–1.04)	0.554
Subgroup who attended ≥7 visits and visit intervals within 6–10 months							
CT positive (%)	19.16	23.86	1.24 (0.87–1.78)	13.27	19.07	1.44 (1.10–1.88)	0.533
GC positive (%)	7.32	5.61	0.77 (0.40–1.47)	4.52	5.39	1.19 (0.74–1.92)	0.286
CT and GC positive (%)	5.57	4.21	0.75 (0.36–1.59)	2.92	3.78	1.30 (0.72–2.32)	0.263
CT and GC negative (%)	79.09	74.74	0.94 (0.78–1.14)	85.13	79.33	0.93 (0.83–1.05)	0.902
Subgroup including only sexually active participants							
CT positive (%)	35.66	35.04	1.10 (0.89–1.36)	32.98	32.81	1.30 (0.06–1.60)	0.263
GC positive (%)	12.33	10.23	0.83 (0.54–1.27)	9.38	9.89	1.05 (0.68–1.64)	0.445
CT and GC positive (%)	8.85	7.67	0.87 (0.53–1.42)	5.90	5.84	0.99 (0.56–1.75)	0.729
CT and GC negative (%)	60.86	62.40	1.03 (0.86–1.23)	63.54	63.15	0.99 (0.84–1.18)	0.806
Cohort 1							
Visit retention (no attended/no enrolled)	368	395		493	493		
CT positive (%)	17.93	20.76	1.19 (0.96–1.65)	11.36	16.63	1.40 (0.99–1.97)	0.503
(continued)							

(continued)

Table II. (Continued)

	Intervention arm			Control arm			Difference between arms
	Baseline study visit	Final study visit	Change (ratio and 95% CI)	Baseline study visit	Final study visit	Change (ratio and 95% CI)	
GC positive (%)	6.25	5.82	0.97 (0.54–1.74)	5.48	6.49	1.12 (0.67–1.87)	0.719
CT and GC positive (%)	4.35	4.30	1.03 (0.52–2.05)	3.25	2.84	0.82 (0.4–1.69)	0.657
CT and GC negative (%)	80.16	77.72	(0.97 (0.82–1.14)	86.41	79.72	0.93 (0.81–1.06)	0.675
Subgroup who attended ≥ 7 visits and visit intervals within 6–10 months							
CT positive (%)	27.45	31.68	1.16 (0.70–1.92)	12.21	17.49	1.43 (0.91–2.24)	0.542
GC positive (%)	6.86	9.90	1.44 (0.55–3.79)	6.49	5.70	0.88 (0.44–1.76)	0.413
CT and GC positive (%)	5.88	5.94	1.01 (0.32–3.13)	4.20	3.42	0.82 (0.34–1.97)	0.770
CT and GC negative (%)	71.57	64.36	0.90 (0.64–1.26)	85.50	80.23	0.94 (0.78–1.13)	0.828
Subgroup including only sexually active participants							
CT positive (%)	36.36	36.36	1.19 (0.86–1.65)	35.16	31.28	1.40 (0.99–1.97)	0.503
GC positive (%)	9.09	10.61	1.19 (0.57–2.48)	8.79	11.73	1.31 (0.57–2.98)	0.862
CT and GC positive (%)	6.61	8.08	1.22 (0.53–2.86)	5.49	5.03	0.92 (0.31–2.74)	0.682
CT and GC negative (%)	61.16	61.11	1.00 (0.75–1.33)	61.54	62.01	1.01 (0.73–1.39)	0.970
Cohort 2							
Visit retention (no attended/no enrolled)	702	506		748	551		
CT positive (%)	17.52	18.58	1.04 (0.80–1.37)	16.44	19.96	1.26 (0.97–1.63)	0.336
GC positive (%)	6.84	5.53	0.81 (0.51–1.30)	4.95	5.44	1.16 (0.72–1.89)	0.302
CT and GC positive (%)	4.42	3.75	0.86 (0.49–1.54)	2.94	3.81	1.38 (0.75–2.52)	0.274
CT and GC negative (%)	80.06	79.64	0.99 (0.88–1.13)	81.55	78.40	0.96 (0.85–1.08)	0.659
Subgroup who attended ≥ 7 visits and visit intervals within 6–10 months							
CT positive (%)	14.59	19.57	1.34 (0.81–2.20)	13.92	20.05	1.44 (1.03–2.01)	0.806
GC positive (%)	7.57	4.26	0.43 (0.17–1.12)	3.3	5.19	1.57 (0.80–3.07)	0.030*
CT and GC positive (%)	5.41	3.26	0.60 (0.22–1.65)	2.12	4.01	1.89 (0.84–4.24)	0.083
CT and GC negative (%)	83.24	80.43	0.97 (0.77–1.21)	84.91	78.77	0.93 (0.80–1.08)	0.768
Subgroup including only sexually active participants							
CT positive (%)	35.32	33.68	1.04 (0.80–1.37)	32.27	33.83	1.26 (0.97–1.63)	0.336
GC positive (%)	13.89	9.84	0.71 (0.40–1.24)	9.57	8.65	0.90 (0.52–1.57)	0.547
CT and GC positive (%)	9.92	7.25	0.73 (0.38–1.41)	6.03	6.39	1.06 (0.54–2.08)	0.439
CT and GC negative (%)	60.71	63.73	1.05 (0.83–1.33)	64.18	63.91	1.00 (0.81–1.23)	0.744

* - statistical significance ($P < 0.05$).

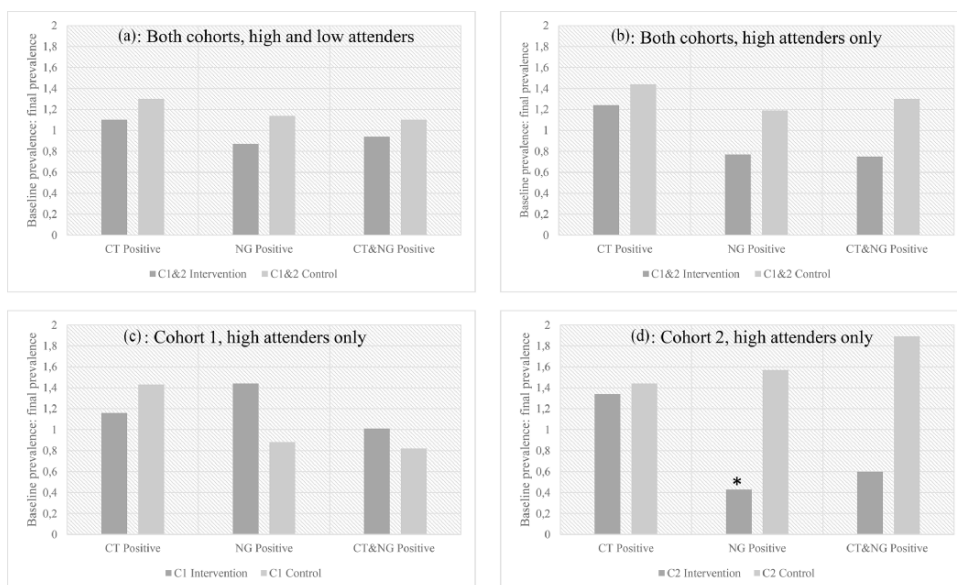


Fig. 3. Changes in STI prevalence from baseline to the final study visit, only considering participants who had both a baseline and a final study visit STI test. Bar graphs a–d show the ratio of baseline prevalence to post-intervention prevalence with <1 indicating a reduction in prevalence and >1 indicating an increase in prevalence for CT alone, NG alone and CT/NG co-infection. Graph a shows findings from low and high attenders, in both cohorts. Graph b shows data from both cohorts, only high attenders. Graph c shows only Cohort 1 data, only considering high attenders. Graph d shows only Cohort 2 data, only considering high attenders. *Indicates a significant difference between intervention and control arms.

Table III. HIV and pregnancy testing outcomes at baseline and 8 months

	Intervention arm		Control arm	
	Baseline, %	8 months, %	Baseline, %	8 months, %
HIV testing				
HIV positive	13 (0.97)	8 (0.83)	12 (0.83)	10 (0.91)
HIV negative	689 (51.26)	859 (89.29)	758 (52.42)	1014 (92.60)
Declined to test	642 (47.77)	95 (9.88)	676 (46.75)	71 (6.48)
Pregnancy testing				
Positive pregnancy test	10 (0.74)	10 (1.04)	10 (0.69)	10 (0.91)
Negative pregnancy test	1036 (77.08)	897 (93.24)	1220 (84.37)	1034 (94.43)
Decline to test	298 (22.17)	55 (5.72)	216 (14.94)	51 (4.66)

HIV

High rates of HIV testing were observed, with over half (54.91%) of participants having previously tested for HIV and 48.42% having done so in the preceding year. HIV prevalence was low with 13 (0.97%) and 12 (0.83%) positive tests at baseline in the intervention and control arms,

respectively, of which the majority (20, 80%) were known to be HIV positive (Table III). A large proportion of participants (intervention arm: 642, 47.77%; control: 676, 46.75%) declined to test at baseline, while in the final visit, only 9.88% (95) and 6.48% (71) declined to test per arm, respectively.

Table IV. Self-reported indicators of social support systems

Social support systems	Intervention arm			Control arm			<i>P</i> -value
	Baseline, %	8 months, %	IRR (95% CI)	Baseline, %	8 months, %	IRR (95% CI)	
Is there an older person to support you if you have a problem (yes)	92.56	93.62	1.011 (0.93–1.10)	92.93	92.00	0.98 (0.91–1.08)	0.728
Is there an older person you can talk to about sex (yes)	60.81	65.68	1.08 (0.97–1.2)	60.95	63.70	1.04 (0.94–1.15)	0.632

IRR, incidence rate ratio.

Socio-behavioural risk factors and attitudes

There was strong evidence of existing social support systems at baseline. >60% reported an older confidant they could talk to about sex while >90% reported an older person would support them if they had a problem. There was no difference in support across arms, cohorts or between high and low attenders at the final study visit (Table IV). Similarly, at baseline, control and intervention participants showed strong positive perceptions of themselves and their bodies and disagreed that they felt hopeless about their futures. These perceptions were maintained at 8 months, and no difference was found between arms overall or when disaggregated by cohort or level of SKILLZ attendance (Table V).

Participants in both arms and cohorts showed evidence of positive gender norms and expectations at baseline, with especially strong disagreement that men have the right to sex in a relationship, that it is ok for men to hit their girlfriends or that a girl suggesting condom use implies promiscuity. These perceptions were retained at the final study visit with no differences between arms or cohorts although high attenders in the intervention arm were more likely to express strong disagreement that condom promotion implied promiscuity ($P = 0.024$). Considering the agency to dictate safe sex practices, the majority of participants in both arms agreed that it was their decision to use a condom, regardless of their partner's demands.

High- and low-attending intervention participants were overall more likely to strongly agree with this statement at the second study visit compared with control participants ($P = 0.003$). Although participants in both arms disagreed at baseline and the final study visit that it was a man's responsibility to make decisions in a relationship, Cohort 2 intervention participant views shifted towards strong disagreement at the final study visit ($P = 0.012$), with high attenders showing a more significant shift ($P = 0.003$).

Participants did vary in their view of female roles in society, with almost equal numbers agreeing and disagreeing that a 'woman's role is to take care of the house and children' at both baseline and the final study visit. There was no difference in this view between arms or by cohort; however, high-attending SKILLZ participants in Cohort 2 did show a significant shift towards strong disagreement ($P = 0.011$). While all participants strongly agreed that passing matric was important for their future and rejected the statement that education for boys was more important than girls, intervention participants were more likely to strongly disagree with the latter statement than control participants ($P = 0.023$).

Discussion

Adolescent girls in this cluster randomised controlled trial demonstrated significant unmet SRH

Table V. Outcomes by arm from a self-administered socio-behaviour questionnaire completed at baseline and final study visits

	Intervention arm (Cohorts 1 and 2)		Control arm (Cohorts 1 and 2)		<i>P</i> -value (Cohorts 1 and 2)
	Baseline	8 months	Baseline	8 months	
Self-concept (median, Interquartile range (IQR) 25–75%)					
I feel good about myself	5 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	0.464
I feel good about my body	4 (4–5)	5 (4–5)	5 (4–5)	5 (4–5)	0.285
I feel hopeless about my future	2 (1–2)	2 (1–2)	2 (1–2)	2 (1–2)	0.603
Gender norms and expectations (median, IQR 25–75%)					
Role of women is to take care of the house and children	3 (2–4)	3 (1–4)	3 (2–4)	2 (1–4)	0.886
Man's responsibility to make decisions in a relationship	2 (1–2)	2 (1–2)	2 (1–2)	2 (1–2)	0.084
Man's right to sex in a relationship	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)	0.765
At times ok for a man to hit his girlfriend	1 (1–2)	1 (1–2)	1 (1–2)	1 (1–2)	0.784
When a girl suggests a condom, it means she has sex with many people	2 (1–2)	1 (1–2)	2 (1–2)	1 (1–2)	0.318
Agency to dictate safe sex practices (median, IQR 25–75%)					
It is my decision to use a condom, regardless of what my partner wants	4 (4–5)	4 (4–5)	4 (4–5)	4 (4–5)	0.003*
Attitude towards school (median, IQR 25–75%)					
Passing matric well is very important for my future	5 (5–5)	5 (5–5)	5 (5–5)	5 (5–5)	0.595
It is more important for boys to be educated than girls	2 (1–3)	2 (1–3)	2 (1–3)	2 (1–3)	0.023*
If a girl falls pregnant, she should drop out of school	2 (1–2)	1 (1–2)	2 (1–2)	2 (1–2)	0.692

Likert scales were used to score the questionnaires, where a score of 1 indicated strong disagreement and a score of 5 indicated strong agreement.

* - statistical significance ($P < 0.05$).

needs, with an incredibly high prevalence of STIs across the entire study population, including amongst participants who reported no prior sexual activity. STI prevalence increased further during the follow-up period. Access to STI testing services is severely limited in SA, where the public healthcare system uses syndromic management approaches to screen and treat STIs, resulting in asymptomatic cases often going undetected [41, 42].

Against a high backdrop of unintended pregnancy in this age group [9, 10], the population further reported relatively low contraceptive use.

A recent study of a combination HIV prevention programme for adolescent girls, in the same South African schools, similarly reported very low uptake of contraceptives even if they had been exposed to the multi-component intervention [43] and found that 53% of self-reported sexually active learners had ever been pregnant (where 36% reported a first pregnancy before 18 years). This differs from the current study, where pregnancy incidence was unexpectedly low, which suggests that with the high rate of loss to follow up (24%), incident cases of pregnancy may have gone undetected [21, 36, 44].

In contrast, HIV prevalence was as expected, very low in this age group, with positive cases mostly known and on treatment and a high level of previous HIV testing, consistent with the known concentration of targeted HIV testing and care services in the study area [21, 27]. The presence of STIs, however, increases the risk of HIV acquisition if exposed, and this risk, coupled with unprotected sexual encounters and a high HIV community burden, may make this adolescent population especially vulnerable to future HIV infection.

This study provided a unique opportunity to determine the true STI prevalence rates amongst adolescent girls in school, confirming their alignment with the high prevalence rates seen in other South African studies amongst adolescent girls and young women (AGYW) initiating HIV pre-exposure prophylaxis, which indicate a high degree of unprotected sexual activity and, as such, a high theoretical risk of HIV infection and unintended pregnancy [4, 6]. Given the low actual HIV and pregnancy prevalence, this heightened risk may have gone unrecognized without the accompanying STI testing.

The SKILLZ programme aimed to reduce the risk of poor SRH outcomes through the delivery of SRH information and by building self-confidence and agency, providing peer-support systems and strengthening positive gender norms and expectations. However, in this study, participants were already found to have strong existing support structures, positive self-perception and largely empowered stances on female gender roles at baseline. Few statistically significant improvements in these measures were identified, mainly among high attenders of the programme. However, these hypothesized mechanisms of change were insufficient to mediate improvements in SRH-related behaviours and indicate that additional social and structural interventions are necessary to achieve the intended effect of this programme.

Neither SKILLZ nor the national CSE programme alone was effective in improving SRH outcomes, with STI prevalence rising equally in intervention and control schools. The only exception

was a lesser increase in NG prevalence amongst high attenders at the SKILLZ programme in Cohort 2. Alongside improvements in socio-behavioural measures amongst high attenders, this may indicate programmatic impact, where increased exposure to curriculum content and a greater chance of developing a good relationship with the coach facilitator could strengthen protective attitudes and sexual behaviours. However, this cannot be attributed to the programme with certainty, and it must be considered that participants with sufficient ability to overcome barriers to attendance may be generally less vulnerable to poor SRH outcomes than poor attenders.

Overall, the low attendance at the SKILLZ programme and the failure to overcome barriers to attendance despite programme modification were major limitations to conducting a robust evaluation of the program's potential for impact. SKILLZ is an evidence-based programme that has been delivered successfully in SA and in other sub-Saharan African countries with generally high, consistent attendance according to programmatic data. This SKILLZ curriculum was designed to complement specific gaps in the national curriculum, with extensive community engagement including adolescent participation and strong qualitative evidence (to be reported elsewhere) of programme acceptability among participants and school staff. While a comprehensive assessment of the implementation lessons will be provided in a separate publication, it is evident that in the context of evident SRH need, existing positive attitudes and gender norms among adolescents and limited resources to deliver interventions, alternative programmes that go beyond education and empowerment must be considered. A recent evaluation of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)'s Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) programmes in sub-Saharan Africa found that in order to generate improved SRH outcomes, multilevel combination prevention programmes that address individual, biological and structural vulnerabilities by layering education programmes with healthcare services and social protection measures, such as

cash transfers, and that are enabled by systematic engagement with communities, families and sexual partners of AGYW are needed [45].

Conclusion

The high and increasing prevalence of STIs in this young, female adolescent population in low-resourced secondary schools in Cape Town, SA, confirmed the urgent need for effective SRH interventions. In light of the positive findings of positive gender norms, strong support systems and strong self-concept and alongside the evident barriers to attendance at this programme, future interventions could consider more comprehensive approaches that go beyond education and empowerment and include ways to directly support SRH service access and delivery.

Supplementary data

Supplementary data are available at *HEAL* online

Author contributions

L.G.B., N.P., N.A., C.C. and C.P. conceptualized, designed and analysed the presented work. C.P., C.C., D.L. and N.A. were involved in the coordination, implementation and data collection, with supervision from the co-primary investigators L.G.B. and N.P. F.L. led the data analysis. C.P. and C.C. drafted the initial manuscript, and all authors reviewed the manuscript and approved the final version.

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Conflict of interest statement

None declared.

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