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Results: The reproductive health package reduces the RSB at three months of follow up after the intervention although it was not statistically significant (AOR=0.80: 95% CI 0.28- 2.31). Further, the package significantly improves the knowledge (AOR=11.75; 95% CI 7.04- 19.63) and desirable attitudes towards reproductive health (AOR=6.13; 95% CI 3.64- 10.32).

Conclusions: The educational intervention may reduce RSB after three months. It was effective for the improvement of good knowledge and desirable attitudes on reproductive health.

Keywords: health education, randomization, reproduction, sexual behaviors, undergraduates.

I. Plain English Summary

Risky sexual behaviors are behaviors leading to unwanted pregnancies and sexually transmitted infections. This research was done to assess the success of the developed package to lessen the risky sexual behaviors. A health education package was developed with the help of available packages from other countries to suit for young adults in Sri Lanka. Then the package was introduced to a group of selected undergraduates in two universities in the Western province of Sri Lanka. Before the introduction of the package, their level of risky sexual behavior has been assessed with a paper of questions. After three months of the introduction of the package, the risk level was assessed again. The results revealed that the educational intervention may reduce risky sexual behaviors. It also revealed the improvement of the knowledge and positive attitudes on risk behaviors and reproductive health.

II. Introduction

Risky sexual behaviors (RSB) are behaviors leading to unintended pregnancies and sexually transmitted infections (STI) as defined as Centre for Disease Control (CDC) [1]. Three studies reported that the prevalence of risk behavior was higher than the level expected by parents and teachers [2, 3, 4]. Being in the age groups of adolescents and young adults, undergraduates may not be spared in practicing RSBs. Adolescents and young adults need different kinds of programs to prevent RSB. There is inconsistency among youth with respect to cognitive and social maturity and sexual experience. Therefore, interventions need to be tailor-made to meet the different requirements of different youth groups [5]. One review showed that determinants of safer sex behaviors among college students were alcohol usage, religiosity, barriers to condom use and perceived social norms. [6] Sexuality education has often concentrated on the risks associated with sexual behavior such as unintended pregnancies and STIs. Interventions for young people are usually implemented in schools, through peer educators, as community activities, and as mass media campaigns.

Several studies were performed to aim the reduction of RSB among adolescents. Two quasi-experimental studies have proven that educational interventions were effective in improving knowledge in

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reproductive health (RH) in youth [7, 8]. Another trial, which was conducted among adolescent girls between 15 to 19 years of age in India, revealed significant improvement of knowledge at one month after implementation of a RH package. [9]. Another quasi-experimental intervention targeted for adolescents of schools in China showed that an educational intervention is effective for increasing knowledge and improving attitude, not the behavior [10]. Similarly, a cluster randomized trial which was carried out to assess theoretically based sex education programme conducted by teachers revealed that the intervention did not reduce sexual risk taking in school going adolescents [11]. In contrast, another cluster randomized trial reported that in addition to sex education, skills building and motivational intervention was effective for reducing RSB among African-American male adolescents [12]. A review reported that sexual health education programs based on a comprehensive curriculum are able to improve knowledge and lessen the RSB [13]. It further reported that sex education programs do not increase sexual activity among adolescents and young people. Results from a Cochrane review showed that a combination of educational and contraceptive-promoting interventions showed the reduced the risk of unintended pregnancies among adolescents [14]. A study carried out to assess the relationship between condom availability and RSB among adolescents in high schools in Massachusetts revealed the success of programmes in human immunodeficiency virus (HIV) prevention [15].

Promoting Sexual Health is a comprehensive curriculum designed to provide information and build skills that reduce unintended pregnancies, reduce the transmission of STI including HIV and improve the quality of sexual experience [16]. The curriculum was designed for young adults in ages 18–24 years who are or to be sexually active to promote sexual health by addressing several aspects of sexuality such as the positive side of sexuality, pleasure, and satisfaction. Further, it is based on a logic model that specifies the important goals, particular behaviors that will lead to those health goals, and cognitive, sexual, psychosocial factors that affect those behaviors. Several authors have used similar contents within their interventions to reduce RSB [8, 9, 10, 11, 15, 17].

There is a dearth of published literature on interventions for risky sexual behavior in Sri Lanka. Hettiarachchi has developed and successfully delivered a new educational intervention for teachers to increase the knowledge and attitude in sexual and RH among school children and teachers in Sri Lanka [18]. There are cultural taboos that have made it difficult for parents, teachers, and community leaders to openly discuss sexual issues among themselves or with adolescents [19]. The same cultural taboos that have hampered even marketing campaigns to promote greater use of contraceptives including condoms. This emphasizes the need for culturally sensitive reproductive education package for reducing RSB. Only those students who perform well in advance level examination are selected for state universities in Sri Lanka. Most of the university students stay away from their families. They are young adults and have more independent than school going adolescents. Therefore the university students are more vulnerable than the school children. Findings of this study are intended to inform the relevant authorities to design and deliver risk behavior reducing program for the youth in universities. Therefore, the objective was to assess the effectiveness of an educational intervention to reduce RSB among undergraduates in the selected state universities in Sri Lanka.

III. Materials and Methods

A quasi-randomized controlled trial was conducted among the second and third year undergraduates in the University of Kelaniya and the University of Sri Jayewardenepura in 2014.

The exclusion criteria were undergraduates from foreign countries due to their different socio-cultural background and clergymen undergraduates due to the sensitive nature of the selected subject.

The intervention was a health education intervention conducted by four medical officers. It consisted of two-day interactive sessions of three and a half hours, conducted one week apart. No educational sessions were conducted to the control group. The intervention was designed using the curriculum on 'Promoting Sexual Health' [16]. Expert opinion was sought from the National STD/AIDS control programme and Health Education Bureau (HEB) for adapting the curriculum. The component which aim to improve the quality of sexual experience were removed. Case studies were changed according to local culture. The baseline information on knowledge, attitudes, and behaviors on reproductive health from previous national survey was utilized for the modification of the intervention. The available 'information, education and communication' (IEC) materials on family planning, STI and RSB were used with the expert opinion for the development of new materials. The developed intervention covered relevant topics in the prevention of STIs and unintended pregnancies. It included facts on contraceptive methods, i.e. effectiveness, side effects and ways of overcoming barriers. Furthermore, it described STIs with possible consequences and informs about places for testing. Dual protection given from condom was highlighted and condom demonstration was included emphasizing the problems in use. Multiple and overlapping partners' role in STIs was discussed. A mutual monogamous relationship was encouraged and the importance of the ability to insist on condom

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use was emphasized. In addition developed self-efficacy and skills to express or refuse sex. Almost all aspects in the prevention of STI and unintended pregnancies were covered by the developed intervention. The developed intervention was pretested among a group of 20 undergraduates outside the study population to test the feasibility, accessibility, co-operation and other logistical aspects of the designed intervention. Necessary changes were made to the intervention accordingly.

The primary outcome was the reduction of RSB among undergraduates during the three months of post-intervention period. The secondary outcomes were overall knowledge and attitudes on RH among undergraduates at three months after the intervention. RSB is defined as a practice of one or more following behavior/s, having more than one sexual partner, alcohol use with sexual activities, inability to use condoms to prevent STI with commercial sex workers or non-commercial partners and inability to use contraceptives in sexual activities with commercial sex workers or non-commercial partners. The overall knowledge on reproductive health was based on the knowledge on unsafe abortions (7 statements), contraceptives (10 statements), condoms (7 statements), STIs (28 statements) and HIV/AIDS (13 statements). One mark was given for each correct answer and zero marks was given for incorrect and do not know answers. A composite score on knowledge ranged from 0 to 65 and expressed as percentages. Equal or more than 75% was categorized as good knowledge and less than 75% as average knowledge for data analysis. The overall attitudes were based on attitude towards the use of contraceptives (5 statements), condoms (8 statements) and HIV/AIDS (9 statements). Each statement comprised of five responses as strongly agree, agree, neutral, disagree, strongly disagree. One mark was allocated for desirable attitudes while minus one mark for undesirable attitudes and zero marks for neutral responses. The range was from (-22) to +22. To make the values positive, +22 was added. The composite score ranged from 0 to 44. Cutoff marks were given for desirable and undesirable attitudes according to the inter quartile range. Those who scored 75th centile or above were taken as desirable attitudes and those who scored below 75% were taken as undesirable attitudes.

The University of Kelaniya and the University of Sri Jayewardenepura were selected as the intervention group and the control group respectively by tossing a coin. Ten clusters were selected randomly from all the clusters in each university. A cluster was defined as a tutorial group or a whole batch according to the structure of the selected undergraduate's group. We expected that the intervention will reduce the RSB from 13% to 6% among undergraduates [4]. Therefore, the calculated sample size was 301 for each group considering power as 80% and a false positive rate of 5%.

The developed intervention was introduced with IEC materials and all sections were discussed in detail. The opportunities were given to clarify any doubts. The intervention was conducted in the lecture halls for ten groups of undergraduates. Informed written consent was taken from the participants. A pre-tested self-administered questionnaire was used to assess pre and post-intervention data. The questionnaire comprised of five sections, the section I on socio-demographic and economic characteristics of the undergraduates, section II on other risk behaviors including alcohol, smoking and illicit narcotic drugs, section III on knowledge in selected aspects of RH, section IV on attitudes in selected aspects of RH, and section V on sexual behavior. The validity of the questionnaire was ensured by assessing the face, content and consensual validity. Content validity was assessed by checking whether or not all aspects of measures were covered using literature review and expert opinion. Consensual validity was determined by assessing the agreement of the experts on whether or not the conceptual definition has been used appropriately in the tool. A multi-disciplinary panel of experts in the fields of public health and reproductive health was used for assessment of validity. On the data collection day, the selected undergraduates (the tutorial group or batch which was identified) were taken to a separate lecture hall. The participants were seated with appropriate gaps from each other to maintain confidentiality. An envelope was given to each participant to hand over the filled questionnaire.

Baseline data between the intervention and the control groups were analyzed using the chi-square test. The effectiveness of the intervention was assessed by comparing post-interventional data between intervention and control groups, the results were expressed as odds ratios (OR) and its 95% confidence intervals (CI). Baseline imbalances were controlled by applying multiple logistic regression. Sensitivity analysis was performed assuming that all participants who did not complete the follow-up data in the intervention group had high risk of RSB, average knowledge and undesirable attitudes, and those who were in the control group had a low risk of RSB, good knowledge and desirable attitudes.

IV. Results

Of 309 undergraduates who were eligible and invited, only 300 post-interventional data could be collected from the intervention group. Of 427 undergraduates who were eligible and invited in the control group, 297 participated in the post-interventional assessment.

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There were no statistically significant differences in the intervention and the control groups with respect to sex, ethnicity, religion, age and marital status (Table 1).

The proportion of undergraduates staying at boarding places were higher among the control group than the intervention group (p<0.001). The control group had more undergraduates with family income ≤50,000 rupees per month than the intervention group (p=0.014). There were more undergraduates in Bio-Science stream in the intervention group (35.9%) than the control group (7.0%) (p<0.001). With regard to school type, the control group consisted of 35.9% from mixed schools (both girls and boys) compared to 44.6% in the intervention group (p=0.04). There were no differences with regard to the importance of religion and participating in religious activities between intervention and control groups. With regard to the availability of relatives and friends to discuss sexually related issues, there was no difference between the groups.

Significant differences were observed between the intervention and the control groups with regard to some risk behaviors before the intervention. Attended nightclub ever in life, usually going to cinema halls, taken alcohol ever and using internet >2 hours per day showed significant differences between the two groups. (Table 2)

The undergraduates in the intervention group reported a higher percentage of good knowledge on contraceptives (p<0.001) than the control group (Table 3).

Knowledge on condoms, knowledge on HIV/AIDS, knowledge on STIs and overall knowledge on RH did not show significant differences between the two groups. There were no differences with regard to attitudes in contraceptives, condoms, HIV/AIDS or overall attitudes in RH among undergraduates between the intervention and the control groups (Table 3 and 4). There was no significant difference of RSB within last three months between the intervention and the control group before the intervention (Table 4).

There was no significant difference observed between the intervention and the control group after three months of intervention with related to RSB (OR=1.39, 95% CI 0.81-2.39) (Table 4). However the adjusted OR was 0.8 (95% CI 0.28-2.31) which indicate a lower risk of RSB of the intervention group even though it was not statistically significant.

Overall good knowledge on reproductive health was higher (52.2%) among the intervention group compared to the control group (12.8%) at three months after the intervention (OR=7.48, 95% CI 4.97 -11.26) (Table 4). Even after adjustment for baseline imbalances, it remained higher (adjusted OR=11.75; 95% CI 7.04-19.63). The overall positive attitudes towards RH among undergraduates was higher in the intervention group (50.7%) compared to the control group (26.9%). The difference was significant statistically (OR=2.79, 95% CI 1.98 -3.92) (Table 4). Even after adjustment for baseline imbalances it was higher (adjusted OR = 6.13; 95% CI 3.64-10.32). The sensitivity analysis has not changed the direction of the association with any outcome (Supplementary Table 1).

Table 1: Socio-demographic, economics and other basic characteristics among intervention group and control group

Variable		Intervention N=309 n (%)	Control N=427 n (%)	χ2 p value
Sex	Male	87 (28.2)	127 (29.7)	0.22
	Female	222 (71.8)	300 (70.3)	0.64
Ethnicity	Sinhalese	306 (99.0)	399 (93.4)	13.9
	Muslim	3 (1.0)	28 (6.6)	<0.001
Religion	Buddhist	290 (93.9)	388 (90.9)	2.2
	Non Buddhist	19 (6.1)	39 (9.1)	0.14
Resident [1]	Boarding place	197 (63.8)	332 (77.9)	17.8
	Home/Relative	112 (36.2)	94 (22.1)	<0.001
Age[2]	≤ 22 years	99 (32.1)	125 (29.5)	0.59
	≥ 23 years	209 (67.9)	299 (70.5)	0.44
Marital status[1]	Unmarried	305 (98.7)	418 (97.9)	0.68
	Ever married	4 (1.3)	9 (2.1)	0.41
Family income (Rs.)[3]	<50000	242 (84.3)	363 (90.5)	6.1
	>50000	45 (15.7)	38 (9.5)	0.014
Financial assistance (Rs.)[4]	<3000	200 (92.2)	343 (93.0)	0.12
	>3000	17 (7.8)	26 (7.0)	0.72
Academic year	Second	192 (62.1)	241 (56.4)	2.4
	Third	117 (37.9)	186 (43.6)	0.12
Study stream	Non-Biology	199 (64.4)	397 (93.0)	95.0
	Biology	110 (35.6)	30 (7.0)	<0.001

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School type [5]	Non-mixed	104 (44.6)	112 (35.9)	4.26
	Mixed	129 (55.4)	200 (64.1)	0.04
Importance of religion	Very important	257 (83.2)	350 (82.0)	0.18
	Not very important	52 (16.8)	77 (18.0)	0.67
Participating religious activities[6]	Weekly or more	141 (45.9)	205 (48.6)	0.50
	Less than weekly	166 (54.1)	217 (51.4)	0.48
Access to a relative to talk in sexual issues	Yes	238 (77.0)	315 (73.8)	1.02
	No	71 (23.0)	112 (26.2)	0.31
Access to a friend to talk in sexual issues	Yes	266 (86.1)	384 (89.9)	2.57
	No	43 (13.9)	43 (10.1)	0.11

[1]missing data= 1, [2] missing data= 4 [3]missing data =48, [4]missing data=150 [5]missing data=191 [6]missing data=7

Table 2: Baseline risk behaviors among undergraduates by the intervention Group and the control group

Variable	Intervention N=309 n (%)	Control N=427 n (%)	$\chi 2$ p value
Attend night clubs*			
Yes	12 (3.9)	4 (0.9)	7.25
No	297 (96.1)	420 (99.1)	0.007
Attend nightclubs in previous one month			
Yes	6 (1.9)	3 (0.7)	2.28
No	303 (98.1)	424 (99.3)	0.13
Using Internet facilities			
Yes	290 (93.9)	378 (88.5)	6.07
No	19 (6.1)	49 (11.5)	0.014
Using Internet facilities >2 hours per day			
Yes	105 (34.0)	95 (22.2)	12.46
No	204 (66.0)	332 (77.8)	<0.001
Going to cinema halls*			
Yes	187 (60.5)	219 (51.5)	5.85
No	122 (39.5)	206 (48.5)	0.02
Going to cinema halls in last month			
Yes	30 (9.7)	27 (6.3)	2.88
No	279 (90.3)	400 (93.7)	0.09
Had taken alcohol ever			
Yes	85 (27.5)	76 (17.8)	9.89
No	224 (72.5)	351 (82.2)	0.002
Had taken alcohol in last three months			
Yes	48 (15.5)	42 (9.8)	5.42
No	261 (84.5)	385 (90.2)	0.02
Had smoked ever			
Yes	33 (10.7)	30 (7.0)	3.06
No	276 (89.3)	397 (93.0)	0.08
Had smoked in last three months			
Yes	18 (5.8)	19 (4.4)	0.71
No	291 (94.2)	408 (95.6)	0.39
Had taken Cannabis ever			
Yes	15 (4.9)	13 (3.0)	1.61
No	294 (95.1)	408 (95.6)	0.21
Had taken Cannabis in last three months			
Yes	4 (1.3)	5 (1.2)	0.02
No	305 (98.7)	422 (98.8)	0.88
Had physical fighting in last year			
Yes	14 (4.5)	16 (3.7)	0.28
No	295 (95.5)	411 (96.3)	0.59
Had physical fighting in university life			
Yes	18 (5.8)	21 (4.9)	0.29
No	291 (94.2)	406 (95.1)	0.59

*missing data=3 **missing data=2

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Table 3: Baseline knowledge and attitude on reproductive health among the undergraduates by the intervention and the control Group

Knowledge/Attitude	Intervention N=309 n (%)	Control N=427 n (%)	$\chi 2$ p value
Contraceptives			
Good knowledge	112 (36.2)	88 (20.6)	22.15
Average Knowledge	197 (63.8)	339 (79.4)	<0.001
Condoms			
Good knowledge	126 (40.8)	156 (37.2)	0.95
Average Knowledge	183 (59.2)	268 (62.8)	0.33
STI			
Good knowledge	42 (13.6)	62 (14.5)	0.13
Average Knowledge	267 (86.4)	365 (85.5)	0.72
HIV/AIDS			
Good knowledge	172 (56.2)	244 (57.4)	0.10
Average Knowledge	134 (43.8)	181 (42.6)	0.75
Contraceptives			
Desirable attitude	85 (27.5)	113 (26.5)	0.10
Undesirable attitude	224 (72.5)	314 (73.5)	0.75
Condoms			
Desirable attitude	92 (29.9)	140 (32.8)	0.71
Undesirable attitude	216 (70.1)	287 (67.2)	0.40
HIV/AIDS			
Desirable attitude	127 (41.1)	174 (40.9)	0.002
Undesirable attitude	182 (58.9)	251 (59.1)	0.96

[1]missing data=5, [2]missing data=1, [3]missing data=2

Table 4: Risky sexual behavior, knowledge and attitude on reproductive health among undergraduates' pre and post-intervention

Outcomes	Pre-intervention			Post-intervention			
	Intervention group N=309	Control group N=427	OR 95 % CI p value	Intervention group N=300	Control group N=297	OR 95 % CI p value	AOR 95 % CI p value
Risky sexual behavior			1.36 (0.89-2.1) 0.16			1.39 0.81-2.39 0.23	0.8 * 0.28-2.31 0.68
Yes	48 (15.5)	51 (11.9)		34 (11.3)	25 (8.4)		
No	261 (84.5)	376 (88.1)		266 (88.7)	272 (91.6)		
Overall knowledge on reproductive health			2.02 1.34- 3.0 <0.001			7.48 4.97- 11.26 <0.001	11.75 ** 7.04-19.63 <0.001
Good knowledge	63 (20.4)	48 (11.2)		157 (52.3)	38 (12.8)		
Average knowledge	246 (79.6)	379 (88.8)		143 (47.7)	259 (87.2)		
Overall attitudes in reproductive health			1.04 0.74-1.46 0.82			2.79 1.98-3.92 <0.001	6.13 *** 3.64-10.32 <0.001
Desirable attitudes	79 (25.6)	106 (24.8)		152 (50.7)	80 (26.9)		
Undesirable attitudes	230 (74.4)	321 (75.2)		148 (49.3)	217(73.1)		

OR odds ratio, AOR adjusted odds ratio

* Adjusted for pre-intervention RSB, attended night club in last one month, reside outside the home and bio-science stream.

** Adjusted for pre-intervention knowledge on reproductive health, reside outside the home and bio-science stream.

*** Adjusted for pre-intervention attitudes on reproductive health, pre-intervention knowledge on reproductive health and bio-science stream.

V. Discussion

The intervention was not effective for reducing RSB at three months after the intervention. The overall knowledge and desirable attitudes on RH had been improved significantly in the intervention group when compared to the control group after three months of the intervention.

The two groups were allocated to the intervention and control group randomly to minimize selection bias. Contamination effect was minimized by selecting two separate universities for the intervention

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and control groups. There are only four universities in the western province, therefore considering a university as a cluster is not adequate for a cluster randomized trial. We randomly selected 10 clusters from each university. Even though we did not consider cluster effect for the calculation of sample size and statistical analysis. It was not feasible to conduct a cluster randomized trial within a university due to a risk of contamination. Some of the published results from RH interventions based on quasi-experimental studies [7, 8, 9, 10]. It is natural to have a higher rate of loss to follow up among the control group as they were not intended for any benefits. The selection of three months of follow up period was done according to available literature and considering the feasibility of the collection of post-interventional data [12]. However, one study reported that the time period of three months may not be adequate to detect a significant reduction of RSB [9]. Further, the undergraduates in our study were a low-risk cohort and therefore the usefulness of the intervention is limited. However, the intervention maybe effective for more vulnerable adolescents who have fallen out of the education system. The impact of the un-blindness of the investigators did not affect the outcome assessments as the use of a self-administered questionnaire. Further, the blindness of the participants was not feasible for health educational intervention. After controlling the baseline imbalance between the intervention and the control group, changed the effect of the intervention from harmful effect to a protective effect for RSB. However, it was not statistically or practically significant.

In contrast to our findings, a similar type of health education intervention carried out among male adolescents in America has improved RSB among them [12]. Even though the follow-up period was similar they have used different IEC materials such as videos, games, exercises and role-playing. The observed difference of results in the present study could be due to methodological variations, the difference in intervention curriculum and the baseline characteristics of the study population. A review of sexual education interventions to assess the impact on sexual behaviors revealed that sex education programmes were effective at reducing RSB among adolescents and young people [13]. The review revealed the effectiveness of reducing the number of sexual partners, increasing condom usage and increasing contraceptive usage.

Reproductive health-related information can be delivered successfully by health education interventions in various academic institutions through various channels. Knowledge and attitudes were improved among school-going adolescents by delivering a health educational intervention directed at school teachers in a district of Sri Lanka [18]. It represented a different study population; school children in Grade nine were educated through their teachers. Knowledge and attitude improvement were observed among them and their evidence supports the findings of the present study. Another health educational intervention among female students between 15 to 19 years of age carried out in India, reported improvement of knowledge in reproductive health after one month of post-intervention [9].

VI. Conclusions

The educational intervention may reduce RSB after three months. It was effective for the improvement of good knowledge and desirable attitudes on reproductive health. Our study shows that educated youth improved their knowledge and attitudes about reproductive health, which is not surprising with their educational backgrounds. The intervention can be applied even for youths in working places without many alterations. However further research is needed to assess whether RSB for this group is improved in the long term follow them up.

VII. Limitations

Follow up period after the intervention was three months period which may be inadequate to see significant changes in behavior. Even though it was unfeasible, unblinding of the participants might underreport of their self-assessed RSB.

Declaration

Ethics approval and consent to participate: Ethical clearance was taken from the Ethical Review Committee, Faculty of Medicine, University of Kelaniya. Administrative clearance was obtained from the Vice Chancellors and Deans of the selected faculties. Informed written consent was obtained from the participants.

Consent for publication: Not applicable.

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

Clinical Trial registry: SLCTR/2014/003, registered on 1st of Feb 2014

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Authors' contributions: Both authors have contributed equally to the design the study. UP and CA analyzed and interpreted the data. UP was responsible for the conduct of the literature review and implementation of study and a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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List of Abbreviations

CDC: center for disease control.
CI: Confidence intervals.
HIV: Human immunodeficiency virus.
OR: Odds ratio.
RH: reproductive health.
RSB: Risky sexual behavior.
STI: sexually transmitted infections.

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