

Randomized Controlled Trial on the Promotion of Sexual Health Using “Self-Care Interventional Package” in Men Who have Sex with Men

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Abstract

Purpose: Men who have sex with men (MSM) is a vulnerable group, who have been neglected and discriminated. Such discrimination decreases their access to health care and increases the spread of sexually transmitted infections (STIs) and human immunodeficiency virus (HIV). **Aims and Objective:** The objective is to evaluate the effectiveness of “self-care interventional package” on the promotion of sexual health, among MSM. **Materials and Methods:** A randomized controlled trial was conducted on MSM from two nongovernmental organization centers of Chandigarh, which were randomized by simple random sampling into a control and experimental group. Over a period of 1 month, a total of 115 MSM were found eligible; 55 in control group and 60 in experimental group. Data were collected by a personal interview, after taking consent, in a comfortable and private environment. The Self-Care Interventional Package on the promotion of sexual health was developed in the form of flash book and booklet, and delivered by one-to-one interaction. Three follow-ups were done weekly for motivation in both the groups. Postintervention assessment was conducted after 1 month. **Results:** There was a statistically significant ($P < 0.01$) improvement in knowledge about prevention and management of STIs and HIV, getting vaccinated for Hepatitis B and regular self check-up. Statistically significant reduction in unsafe sexual practices was noted among the MSM of experimental group. **Conclusion:** The self-care interventional package for the promotion of sexual health was effective in improving the sexual health of the MSM population.

Keywords: Human immunodeficiency virus, men who have sex with men, self-care interventional package, sexual health, sexually transmitted infection

INTRODUCTION

According to the World Health Organization (WHO), sexual health is a state of physical, mental, and social well-being about sexuality. Men who have sex with men (MSM) population is involved in unsafe sexual behavior, due to which they fall under the high-risk group (HRG) making them vulnerable to many sexually transmitted infections (STIs) and human immunodeficiency virus (HIV) infection. It is estimated by the WHO that globally nearly 1 million people, become infected every day with STI and this incidence of STIs is more in case of HRGs like MSM in comparison to general population.^[1]

Meta-analysis of studies has shown that the high risk population have greater prevalence of gonorrhoea and syphilis.^[2] According

to the CDC, about 19 million new infections occur each year globally. Fifty percent of these infections occur in young people aged 15–24 years. Chlamydia is the most common cause and the second-most common cause is Gonorrhoea in the United States.^[3] In India, syphilis is considered the most common bacterial STI among “Hijra”/transgender population. A cross-sectional community-based study in South India

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documented 13.6% prevalence of syphilis among “Hijras.” STI clinic-based studies conducted in Mumbai documented a prevalence of 11.3% among “Hijras.”^[4]

The prevalence of HIV in India is around 8.1%.^[5] Globally, every year approximately 1 million new cases of STIs are acquired in a single day.^[6] In India, 28 districts have 5% or more HIV prevalence among MSM. The overall HIV trends among these population groups are stable in north India and there is an increasing trend in the South Indian States and Delhi.^[7]

MSM have a high prevalence of STIs and HIV due to their risky sexual behavior or unsafe sexual practices. There is a need to make MSM self-reliant and self-sufficient in regards to promoting safe sex practices, regular follow-up, and periodic self-examination of the anal and genital area, vaccination, prevention, and management of STI/HIV. All these interventions could be provided with the help of a “self-care interventional package.”

Aim and objective

This study aims to assess the effectiveness of self-care interventional package on promotion of sexual health, among men who have sex with men.

MATERIALS AND METHODS

A randomized controlled trial was conducted in Chandigarh on MSM for the promotion of sexual health in two nongovernmental organization (NGO) centers of Chandigarh. The noninferiority trial was selected as NGO centers were already getting intervention under Target Intervention project of Chandigarh-State AIDS Control Society. The research was conducted between August and November 2018. Written permission was obtained from Chandigarh-State AIDS Control Society (SACS) and Ethical clearance was taken from the Institute Ethics Committee, PGIMER, Chandigarh, vide letter number INT/IEC/2018/000545 dated on April 24, 2018. A comfortable environment was provided, privacy was maintained and consent was taken from the each participant, before data collection. Trial was registered prospectively on Clinical Trials Registry of India (CTRI) (CTRI/2018/07/014894).

The study included the MSM who were more than 18 years of age and were in regular contact with selected NGO centers, from the last 3 months and were willing to participate in the study. MSM who were suffering from any known mental illness were excluded from the study.

We could not find out any similar study to calculate sample size, thus, the sample size was calculated based on the pilot study results using online software; (Faul F. *et al.*-2009 - Statistical power analysis using G*Power 3.1).^[8] The calculated sample size was 110 considering 95% confidence levels, 80% power while estimated effect size was 0.29688. Overall, 115 participants were estimated for present study after consideration of 5% drop out rate.

There are a total three NGO centers working in collaboration with Chandigarh-SACS to prevent STI/HIV among MSM through target intervention project. Two NGO centers were used for the main study which caters a population of 1100 MSM while third one NGO center, which caters population of 800 MSM, was selected for a pilot study. Both NGO centers were selected by simple random sampling into an experimental group and control group. Then, random number table was used to select 60 participants each for control and experimental group. The participants were called with the help of peer educator of NGO centers and were informed to be a part of this study. Over a period of 1 month, 55 participants were eligible as a control group and 60 as an experimental group, hence a total of 115 MSM were included in the study [Figure 1].

Personal interview was used as a method for data collection. The interview schedule was used to collect data which included the following: (1) sociodemographics, (2) assessment of sexual health, substance abuse, and sexual practices, (3) knowledge assessment regarding STIs and HIV/AIDS, and (4) practices related to prevention and treatment of STIs and HIV/AIDS.

The self-care interventional package on the promotion of sexual health was developed in the form of flash book and booklet and was validated from experts in the field of nursing and community medicine. The package informed about causes, risk factors, sign and symptoms, testing, prevention and treatment of STIs and HIV/AIDS.

After baseline assessment, education and counseling were done to experimental group participants by face-to-face interaction which allowed feedback to be taken and all the doubts of the participants could be cleared and participants also had the opportunity to ask questions. Need-based counseling was also done. Colored flash-book in the Hindi language was used to make teaching effective. Booklet was also given to them for ready reference. The booklet in addition to theoretical description about STIs and HIV; also contained pictorial presentation of various sexually transmitted diseases, of how to use a condom correctly, of genital self-examination (GSEM), and of self-examination of anal region (SEAR).^[9]

At interval of 1 week, three follow-ups were conducted for each participant of the experimental and control group either by calling them at the NGO center or telephonically. This was done for motivating them for safe sex practices. End-line/postintervention assessment was conducted after 1 month in both the groups by interviewing the participants as per interview schedule. After end-line assessment of control group, self-care interventional package along with motivational session was also given to them.

Data were entered and analyzed using the Statistical Package for the Social Science system (SPSS) version 24 (IBM SPSS Statistics for Windows, Version 24.0; Armonk, NY, USA: IBM Corp.). Chi-square test was used to

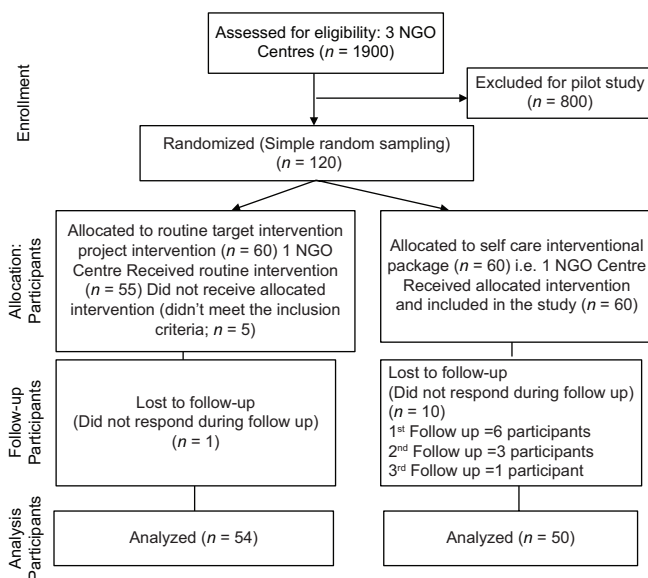


Figure 1: CONSORT Flow diagram

analyze the data and a $P < 0.05$ was considered as the value of statistical significance.

RESULTS

The experimental group, mean age was 23.3 years and that of the control group was 25.7 years. The groups were found to be homogeneous and comparable in terms of their education, current living status, and monthly income ($P < 0.05$).

In the control group, there was no difference at baseline and end-line assessment in all the parameters assessing unsafe sexual practices. There was a significant reduction in the unsafe sexual practices of MSM in the experimental group when compared with the baseline practices ($P < 0.05$) [Table 1].

When the knowledge about what is STIs, how it is spread, how to do self-care, when to get tested and how to prevent STIs (i.e., knowledge about vaccination) was assessed; it was noted that in the control group there was no difference at baseline and end line. While the same parameters when assessed in the experimental group, a significant improvement in knowledge was noted postintervention ($P < 0.01$) [Table 2].

When HIV/AIDS knowledge and practices were assessed, about what is HIV/AIDS, the available facilities for its diagnosis and treatment and how a person can get HIV/AIDS; the control group did not show a change in their knowledge for the mentioned parameters between baseline and end-line. The experimental group showed a significant improvement in their knowledge postintervention ($P < 0.001$) [Table 2]. It was noted that all the participants of the experimental group during postintervention knew that HIV/AIDS could spread through unprotected sex with an infected person and through sharing infected needles. There was a significant improvement (48.3% vs. 74%) in the number of MSM who got their HIV testing done on their own initiative.

Percentage improvement after using self-care interventional package across various parameters such as safer sexual practices, improvement in knowledge, and self check-up is depicted in Figure 2.

DISCUSSION

MSM face various challenges to become sexually healthy. Hence, a need was felt for the capacity building of MSM to make them aware regarding self-care. Hence, the present study was conducted to develop and implement a self-care interventional package on the promotion of sexual health among MSM.

A baseline assessment was done with the help of semi-structured interview schedule by face-to-face interview. As the National AIDS Control Organization-National Integrated Biological and Behavioural Surveillance 2014-2015 had reported that 3.5% of MSMs did not have any formal education.^[10]

Unsafe sexual practices, such as anal sex without a condom, sexual activity under intoxication, and alcohol/drug use, increase the risk of STIs and HIV. In this study before the intervention, the point prevalence of anal sex without a condom was 36.7% in the experimental group and after the intervention; the point prevalence was reduced to 11.7% which was statistically significant, whereas in control group no significant change was observed. With the help of self-care interventional package, periodic self check-up of the anal and genital area was promoted, MSMs were taught how to use mirror for a self check-up of the anal and genital region, when and how frequently to perform and what are the sign and symptoms of STIs for what they have to assess.^[11] Before intervention weekly, self-check of the anal and genital area was done by 3.3% of MSM in the experimental group. However, after intervention significantly high percentage of MSM from the experimental group (78%) were performing weekly self-check of anal and genital area; while in the control group, no significant change was observed. The self-care interventional package has shown a positive effect on improvement in knowledge of MSM regarding the transmission of STIs/HIV, sign and symptoms, test and treatment available, regular self check-up. After the implementation of self-care interventional package on the promotion of sexual health, MSM got vaccinated with Hepatitis-B which shows that self-care package has made them self-aware and self-efficient to being vaccinated against Hepatitis-B. A similar study was done to associate the sexual risk of HIV and poor self-care behavior with syndemics (co-occurring psychosocial problems) and the result suggested that syndemics are not directly linked with condom-less sex, but the association may be a result of lack of condom self-efficacy.^[12] The study concluded that by creating self-efficacy, risk of other psychosocial problems or STIs burden could be reduced.

In the present study, the package was effective as the statistically significant improvement was noticed in the number of MSMs who got their HIV testing done on their initiative ($P < 0.001$) in the experimental group. Woodford

Table 1: Baseline and end-line comparison of sexual practices in men who have sex with men in control and experimental groups (n=115)

Sexual practices	Control group			Experimental group		
	Baseline (n=55), n (%)	End line (n=54), n (%)	χ^2 (df) P	Baseline (n=60), n (%)	End line (n=50), n (%)	χ^2 (df) P
Anal sex with male/hijra sexual partners without using a condom (in last 1 month)	14 (25.5)	15 (27.8)	1.21 (3) 0.75	22 (36.7)	7 (11.7)	9.59 (2) <0.01
Experience of a condom breaking during anal sex (in the last month)	2 (3.6)	7 (13.0)	5.42 (4) 0.24	2 (3.3)	1 (1.7)	6.29 (2) 0.04
Taken or given any gifts in the last 1 month to have sex with a male partner	14 (25.5)	21 (38.9)	3.14 (2) 0.07	10 (16.7)	4 (8.0)	6.80 (2) 0.03
Experienced forced sex within the last 1 month	4 (7.3)	8 (14.3)	1.58 (2) 0.45	3 (5.0)	3 (6.0)	6.69 (2) 0.03
Sexual encounter after alcohol/drug use (last-month)						
0 (No activity)	22 (40.0)	22 (40.7)	0.41 (2) 0.81	30 (50.0)	19 (38.0)	22.31 (2) <0.01
Any activity (1 or>1)	17 (30.9)	19 (34.5)		17 (28.3)	9 (15.0)	
Do not remember/do not know/no response/do not want to tell/not applicable	16 (29.1)	14 (25.5)		13 (21.7)	32 (53.3)	

Table 2: Baseline and end-line comparison of knowledge and practices of men who have sex with men in control and experimental groups regarding sexually transmitted infections and human immunodeficiency virus acquired immunodeficiency syndrome (n=115)

Variables	Control group participants giving the correct answer		P (by χ^2 test)	Experimental group participants giving the correct answer		P (by χ^2 test)
	Base line (n=55), n (%)	End line (n=54), n (%)		Base line (n=60), n (%)	End line (n=50), n (%)	
STIs are infections transmitted by sexual contacts	24 (43.6)	28 (51.9)	0.39	23 (38.3)	46 (92)	<0.01
STIs are commonly spread by unsafe sexual activities with an infected person	19 (34.5)	22 (44.7)	0.50	17 (28.3)	46 (92)	<0.01
With a mirror can check own genitals and anal area for infections/injuries	6 (10.9)	6 (11.1)	0.99	11 (18.3)	43 (86)	<0.01
Weekly self-check-ups of genitals and anal area to be done to check for any kind of infection or injury	5 (9.1)	9 (16.7)	0.23	2 (3.3)	39 (78)	<0.01
Every 3 months, MSMs should get tested for STIs	16 (29.1)	13 (24.1)	0.55	4 (6.7)	43 (86)	<0.01
Vaccines like hepatitis B, HPV help to prevent respective STIs	6 (10.9)	6 (11.1)	0.97	-	44 (88)	<0.01
HIV is a virus and AIDS is the advanced stage disease of HIV infection	42 (76.4)	45 (83.3)	0.36	38 (63.3)	49 (98)	<0.001
There are 23 ICTCs (HIV testing centers) available in Chandigarh	14 (25.5)	15 (27.8)	0.69	28 (46.7)	44 (88)	<0.001
Treatment for HIV/AIDS can be taken from GMCH-32 and PGIMER Chandigarh	23 (41.8)	26 (48.1)	0.50	11 (18.3)	41 (82.0)	<0.001

STIs: Sexually transmitted infections, MSM: Men who have sex with men, HPV: Human papillomavirus, AIDS: Acquired immunodeficiency syndrome, HIV: Human immunodeficiency virus, ICTCs: Integrated counselling and testing centre, GMCH-32: Government medical college and hospital, sector 32 Chandigarh

MR *et al.* have also reported that “promoting HIV testing in these high-risk populations require interventions at several levels to reduce HIV-related stigma and addressing the fears of consequences of testing”.^[13]

Another study conducted in Chennai on integrated in-person and mobile phone delivered counseling and text messaging to reduce HIV transmission risk among male sex workers. The study reported that mobile phone use can avoid the challenges of face to face communication such as lack of anonymity and

time consumption. They reported a reduction in the number of condoms less anal sex through the use of mobile phone delivered sexual risk reduction interventions like counseling.^[14] The “Self Care Interventional Package” used in the current study required a face-to-face communication which will help to reduce the stigma among MSM. The integrated mobile phone technology to counsel HRGs in addition to a formal face-to-face interaction will help in a long-term follow-up, by reaching larger numbers of the high-risk population and would avoid or reduce loss to follow-up.

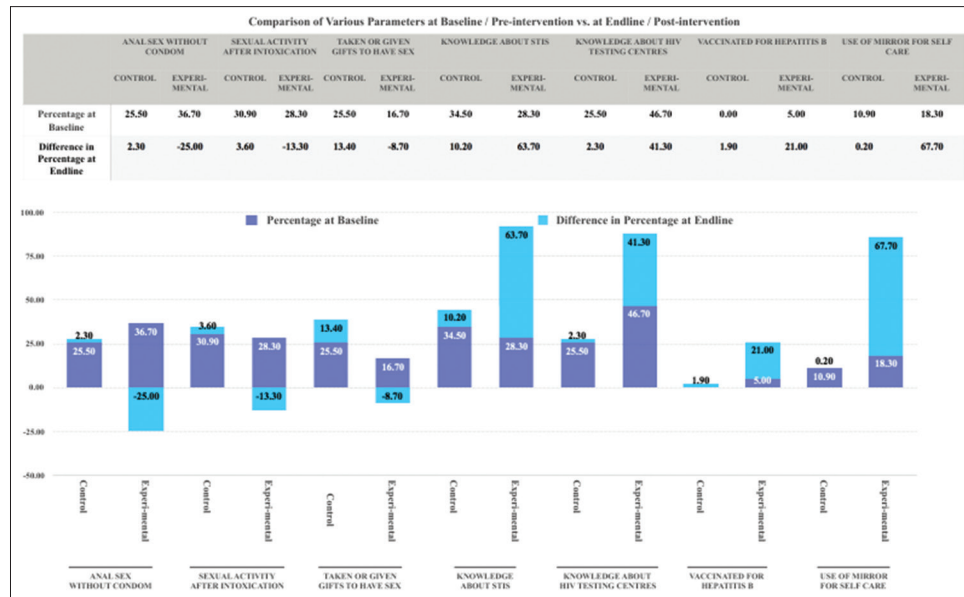


Figure 2: Comparison of various parameters at baseline/preintervention versus at end-line/postintervention

CONCLUSION

The self-care interventional package was found to be an effective method of promotion of sexual health among MSM. There was reduction in unsafe sexual practices, improvement in knowledge about STIs and HIV/AIDS, Hepatitis-B vaccination and self check-up by practicing GSEM and SEAR. Based on the study findings, it is recommended for community health nurse, health-care physician and NGO staff, to use this package for all the HRG population to promote their sexual health status and make them self-efficient and inculcate within them the concept of self-care.

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Conflicts of interest

There are no conflicts of interest.

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