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Prevalence and types of rectal douches used for anal intercourse among men who have sex with men in Brazil

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Prevalence and types of rectal douches used for anal intercourse among men who have sex with men in Brazil.

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Abstract

Introduction: The practice of rectal douche (RD) is widespread among men who have sex with men (MSM), however there are no Brazilian studies on this practice and its risks for the transmission of sexual diseases and AIDS. **Method:** Between June and August of 2015, 401 MSM, over the age of 18, were interviewed regarding their sexual practices focused on RD. **Results:** Of the participants, 85% identified themselves as men, 255 as white (63.6%). Of those who performed anal sex in the past 3 months (n = 369), 197 reported having performed RD (53.4%). The most used material was a shower hose (84.5%). 94.5% have never received orientation from any health professional on this practice. There was an association between anal sex and practice of RD ($p<0.05$), there was also a higher percentage of HIV positive individuals and individuals informed about having an sexually transmitted diseases (STD) among those who perform RD ($p<0.05$). **Conclusion:** The authors propose that a discussion on RD be magnified within the STD / AIDS prevention strategy. New studies on the subject are needed to increase knowledge of health professionals and deepen the meaning of practices and beliefs that promote vulnerabilities in the MSM population. Through this knowledge professionals can trace surveillance strategies and STD/AIDS in order to prevent increased exposure and promote harm reduction and risks through appropriate guidelines.

KEYWORDS: sexual behavior, rectal douches, anal sex, male homosexual, sexually transmitted diseases, sexual education.

Strengths and limitations of this study

The study on the practice of RD among HSH is unprecedented in Brazil. Despite being used a convenience sample, the sample size (n=401) is representative of the population studied. The privacy, afforded to participants with computer use in a private setting, prevented outside interference that could inhibit the answers.

Introduction

The use of rectal douches (RD) is a practice previously used with anal sex among men who have sex with men (MSM). [1,2,3] Several commercial and non-commercial devices are used such as shower hoses, plastic bottles and syringes. [4] Solutions commonly used to perform the RD are running water and homemade products. The main reason for the practice is to clean the rectal cavity and consequent increase pleasure during the sexual act. [5] This practice is related to risk behaviors for transmission of sexually transmitted diseases (STD) and acquired immunodeficiency syndrome (AIDS). [1-4,5] The prevalence of AIDS in Brazil, in the general population, is 0.4% and 10.5% in the MSM population with an increasing trend in the proportion of cases in this group in the last ten years, from 34.6% in 2004 to 43.2% in 2013. [6] Social, epidemiological and behavioral studies are necessary to understand the social and sexual practices of specific groups and to map out prevention strategies. [7] Some studies include Latino populations, but no studies on the use of RD were conducted in Brazil. This study aims to determine the prevalence of the use of RD among MSM and establish the main substances and materials used in this practice. Through this research and knowledge gained about the practice of RD, actions for the prevention of STD/AIDS in this most vulnerable population can be proposed.

Method

Population study and design. After the approval of Opinion No. 1.100.371 (CAAE No 45107215.7.0000.5375) of the Research Ethics Committee (CEP), this study was conducted in outpatient clinics of the Center for Reference and Training- CRT / AIDS among MSM, above the age of 18, independent of HIV status, between June 20 and August 20, 2015. The methodology used to calculate the sample was a convenience sample, considering a 95% confidence interval and a maximum sample error of 5% and an estimated prevalence of 50%. The minimum sample expected was 391 participants but included a total of 401 participants. [8] Participants were approached by previously trained research investigators, having prior information about the research. Those who wished to participate were directed to a special room specifically designated for this purpose, where they were informed about the reason for the research and after signing and receiving their Informed Consent (IC) responded to a questionnaire in digital format developed in Google Docs free app ® on a laptop computer. Participants who found it difficult to respond in digital format were aided by an investigator familiar with computer usage. The questionnaire included epidemiological issues (gender, age, race,

origin, residence), orientation and sexual practices (frequency and partners) as well as the use of commercial and non commercial products to perform the RD, types of products used, frequency of such practices and risk behaviors. The questions were about practices in the last three months and in the last month prior to the interview, due to better reliability in time responses.

Statistical analysis. Participants were classified into two groups: those who perform RD and those who do not. Initially, descriptive analysis was made of these two groups, considering the socio-demographic variables. Next, analysis was made of the variables in the group of performing RD. Categorical variables were tested with Fisher's chi-square or exact test. The odds ratios and their confidence intervals were estimated. The tests used were bicaudal and the significance level was set at $p < 0.05$.

Results

Table 1 – Gender identity, age, color/race, education level, monthly income, STD and drug use and anal sex among MSM (n = 401)

	n=401	%
Gender identity (self perception)		
Men	340	84.8
Woman transexual	39	9.7
Transvestite	18	4.5
Woman	3	0.7
Undefined	1	0.2
Age (in years)		
18 - 29	192	47.9
30 - 39	135	33.7
40 - 49	59	14.7
50 - 59	12	3,0
60 - 66	3	0.7
Color/race declared		
White	255	63.6
Pardo	104	25.9
Black	24	6.0
Other	18	4.5
Educational level		
Elementary school incomplete/complete	33	8.2
High School incomplete/complete	102	25.4
College/University complete/incomplete/ Graduate studies	266	66.3
Total monthly income		
0 - 500 usd	192	47.9
$501 - 1000 usd	127	31.7
Above 1000 usd	82	20.4
STD in the last 12 months		
No	253	63.1
Yes	145	36.2
I don't know	3	0.7
Drug use during sex in the past 12 months		
YES	122	30.4
No	274	68.3
No response	5	1.2
Anal intercourse		
Did not have sexual relations	32	8.0
Only insertive anal sex	79	19.7
Only receptive anal sex	86	21.4
Both insertive and receptive anal sex	204	50.9

Of the 401 MSM participants, 389 reside in the State of São Paulo (97%), 85% identify themselves as men, 4% to 9% as transvestite and transsexual respectively. Of these, 255 declare themselves as white (63.6%) and 104 as "pardo" (dark complexioned) (25.9%). The mean age was 31.5 years. Regarding education, 66.3% started or completed college degrees or graduate studies. In terms of income, the category of up to $500.00 us presented the highest frequency of 47.9%. Among the participants, 369 (92%) had anal intercourse in the past 3 months. Of these, 86 underwent receptive anal sex and 50.9% reported having had both receptive and insertive anal sex, a total of 290 participants (72.3%) who practiced receptive anal intercourse. (Table 1)

Table 2 – Performed RD in the past 3 months and solutions, products and equipment used

RD (n=369)		%
Yes	197	53.4
No	172	46.6
Homemade solutions (n=181)[1]		
Water with soap	33	18.2
Only water	181	100.0
Products and commercial solutions (n=52)		
Fosfoenema®	19	36.5
In-M®	7	13.5
Minilax®	3	5.8
I don't remember	5	9.6
Intimate liquid soap	3	5.8
Glycerin suppository	2	3.8
Disposable kit purchased in a pharmacy or store	1	1.9
Homemade equipment used (n= 233)[1]		
Shower hose, bidet and washbasin	199	85.4
Plastic water pump	22	9.4
Disposable kit purchased in a pharmacy or store	12	5.2
Plastic bottle	11	4.7

1 -Multiple Choice

According to Table 2, those who performed anal sex in the last 3 months (n=369), 197 reported having performed RD (53.4%). Participants reported the use of more than one type of product, solution or equipment to perform RD. To perform the cleaning of the rectal canal, the main solution used was water (100.0%), followed by water with soap (18.2%). The primary homemade equipment used was the shower hose, the bidet or the wash basin (85.4%).

Table 3 – Practice of RD related to the motives for performing it before and after receptive anal intercourse in the past 3 months (n=197)

Motive RD	Before				After			
	Always		Sometimes or Never		Always		Sometimes or Never	
	n	%	n	%	n	%	n	%
Cleaning / hygene	84	42.6			21	10.7		
Anal intercourse is more pleasurable	34	17.2						
Not necessary			69	35			153	77.7
Dislike it			53	26.9				
Unplanned encounter			89	44.2			34	17.2
I had sex with a condom							136	69
Others	7	3.5	7	3.5	8	4	12	6

1 - Multiple Choice

Among those who did receptive anal sex (n=197), the main reason to perform the RD before sex was cleanliness / hygiene and to have the most pleasurable anal sex. Of those who said they sometimes or never performed the RD before anal sex, the main reason was that they find it unnecessary or dislike it. Of those who reported sometimes or never have performed RD after anal sex, the main reason was that they find it unnecessary or they have sex with a condom. (Table 3)

Table 4 – Prevalence of RD and the sexual behavior of participants

		RD - Last 3 Months				value of p	OR	OR (I.C. 95%)	
		No		Yes					
		n	%	n	%			inferior	superior
Receptive anal sex	No	97	54.8%	16	7.1%	<0.001	1		
	Yes	80	45.2%	208	92.9%		15.76	8,75	28.39
Partner	Men and women	15	10.3%	9	4.0%	0.020	1		
	Only men	130	89.7%	215	96.0%		2.76	1.17	6.48
Type of sex partner	Principal or steady	57	39,30%	81	36,20%	0,541	1		
	Different partners	88	60,70%	143	63,90%	0,596	1,14	0,743	1759
Receptive anal sex - condom use by partner	Never	12	12.2%	22	10.0%	0.327	1		
	Sometimes	28	28.6%	82	37.1%	0.808	1.10	0.51	2.38
	Always	58	59.2%	117	52.9%	0.265	1.60	0.70	3.64
Receptive anal sex - use of commercial lubricant	Never	12	12.8%	20	8.9%	0.356	1		
	Sometimes	35	37.2%	74	33.0%	0.209	1.66	0.75	3.66
	Always	47	50.0%	130	58.0%	0.570	1.27	0.56	2.88
Orientation with a health professional about RD	No	168	94.9%	210	93.8%		1		
	Yes	9	5.1%	14	6.3%	0.619	1.24	0.53	2.95
Satisfactory orientation with a health professional about RD	No	11	47.8%	15	39.5%		1		
	Yes	12	52.2%	23	60.5%	0.523	1.41	0.49	4.00
Paid for sex – last 12 months	No	148	83.6%	180	80.4%		1		
	Yes	29	16.4%	44	19.6%	0.402	1.25	0.74	2.09
Sex with an HIV positive partner in the last 12months	No	55	31.6%	62	27.7%	0.632	1		
	Yes	36	20.7%	53	23.7%	0.348	1.31	0.75	2.28
	Don't know	83	47.7%	109	48.7%	0.517	1.16	0.73	1.85
HIV tested – last 12 months	No	14	8.0%	12	5.4%		1		
	Yes	161	92.0%	211	94.6%	0.297	1.53	0.69	3.40
HIV test results	Negative	128	73.6%	163	73.4%	0.002	1		
	Positive	18	10.3%	44	19.8%	0.032	1.92	1.06	3.48
	Don't know	28	16.1%	15	6.8%	0.011	0.42	0.22	0.82
Diagnosed with a STD - last 12 months	No	124	72.1%	136	60.7%		1		
	Yes	48	27.9%	88	39.3%	0.019	1.67	1.09	2.56

There was an association between receptive anal sex and practice of RD ($p < 0.05$), showing that there is a higher percentage of individuals who have receptive anal sex, doing or not doing insertive anal sex, in the group that did RD. Individuals who did receptive anal sex are 9.87 times more likely to have done RD in the last three months than those who do not have receptive anal sex ($p < 0.001$; OR 9.87, 95% CI 5.31 to 18.35). There was a higher percentage of individuals who did RD among those who had receptive anal sex, sex only with men and among those who had partners who always or sometimes used condoms and always or sometimes used lubricant in the last three months compared to the group that did not do RD ($p < 0.05$). There was also a higher

percentage of HIV positive individuals and individuals who informed of having had a STD among those who do RD (p=0.002). There are indications that individuals with only male partners are 2.48 times more likely to have done RD in the last three months than the one with men and women partners. (Table 4)

Discussion

The results of the study indicate that the practice of RD is common in MSM population before performing receptive anal sex, with a prevalence of 53.4%. These results coincide with other studies, with a prevalence of 52% and 66%. [5,9] It is evident that the practice is carried out with homemade products and materials and objects not designed for this purpose. Of those who used non-commercial products (n=233), 199 used a shower hose to introduce flowing water into the anus (84.5%). A study with 4992 MSM indicated that 52% do RD, and 43.3% do it frequently, and 87.6% do it before and 27.4% after sex. Of those doing RD after sexual intercourse stated that the main reason was to prevent STD/AIDS (12.7%). The most used product was tap water (65.7%). [9] A qualitative study interviewed 24 MSM and assessed that the RD is a widespread practice and little understood, and that discussions on the subject have been limited to the physical aspects and risk of STD/AIDS.[10] It was observed in this study that there were significant differences among those who had anal sex with a receptive partner who used a condom and insertive anal sex with lubricant use ($p<0.05$). There was also a higher percentage of HIV positive individuals and individuals who reported having had a STD among those who do RD ($p<0.05$). These results are consistent with the study of 1725 participants from 5 continents on practices relating to the RD, where 93% report use of non-commercial product (93%) and water (82%) to perform the RD. The study also indicates an increased risk of STD/AIDS 74% among those who perform RD when compared to those who do not perform the practice (odds ratio = 1.74; 95% CI, 1.01 to 3.00) .[5] These findings indicate that RD is associated with risky behavior. Studies on the MSM population, have investigated the prevalence of STD/AIDS, but have not addressed the behavioral aspects that can bring about beliefs and values related to sexual practices in specific populations of greater vulnerability. Regarding the practice of RD, this study verified that 94.2% of MSM participants have never been oriented by health care professionals about it. One aspect that should be considered is the use of shared objects to perform the RD. This practice can permit the transmission of pathogens when they could still be viable in the presence of organic matter and may

have had contact with the injured anal mucosa or epithelium of the intestino.[11-14] The study was conducted at a state referral center for the prevention and treatment of STDs and AIDS which aided in the recruitment of an MSM population. The interviewed sample is representative of the MSM population, but new studies on the subject are necessary to better understand this practice in the various regions of the country. The instrument used for data collection (online survey) provided responsiveness and convenience in organizing the collected data. The privacy, afforded to participants with computer use in a private setting, prevented outside interference that could inhibit the answers. New approaches to the meaning of RD for this population should be developed to deepen the understanding of the subject.

Conclusion

The prevalence of RD is 53.4%. The materials most used to perform the practice are products not intended for that purpose, such as shower hoses. Water is the most widely used product for RD. There was an association between the practice of RD and individuals with HIV positive and people who informed that they had a STD ($p<0.05$). This study indicates that the practice is common among the MSM population and that this group does not receive information from health professionals about the risks involved in this practice, highlighting the need to include guidelines on the subject in STD/AIDS prevention programs, as well as staff training to address the matter in MSM populations. The authors propose that the discussion on RD is expanded within the STD / AIDS prevention strategy. New studies on the subject are needed to increase the knowledge of health professionals and deepen the meaning of practices and beliefs that promote vulnerabilities in the MSM population. Through this knowledge surveillance strategies and STD/AIDS can be traced in order to prevent increased exposure and promote harm reduction and risks through appropriate guidelines.

Authors' Contributions:

LCRL: study conception and design, interpretation of results, drafting of manuscript; RJCS: supervision of data analysis, interpretation of results and manuscript preparation. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Other data can be requested by email: luizlamblet7@gmail.com.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1
Objectives	3	State specific objectives, including any prespecified hypotheses	1
Methods			
Study design	4	Present key elements of study design early in the paper	1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	1
Bias	9	Describe any efforts to address potential sources of bias	1
Study size	10	Explain how the study size was arrived at	1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	1
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	1
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	1
		(*b*) Report category boundaries when continuous variables were categorized	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	1
Discussion			
Key results	18	Summarise key results with reference to study objectives	1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	1
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	1
Generalisability	21	Discuss the generalisability (external validity) of the study results	1
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

1 – included

NA - not applicable.

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Abstract

Introduction: The practice of rectal douching (RD) is conducted among men who have sex with men (MSM), and various products and materials are used; however, there are no Brazilian studies on this practice and its risks to the transmission of sexually transmitted infections (STI) and HIV. **Method:** Between June and August 2015, 401 MSM over 18 years of age were interviewed about sexual practices associated with RD in the last 3 months. Descriptive statistical analyses were conducted by associating rectal douching with the reported sexual behavior. **Results:** Among the respondents, 85% identified themselves as men, 4% as transvestites and 9% as transsexual; 255 declared to be white (63.6%) and 104 declared to be brown (25.9%). From those who had performed anal sex in the last 3 months (n = 369), 197 reported having used RD (53.4%). The most commonly used material was a shower hose (84.5%) and the main product was water (93%). Of those interviewed, 94.5% have never received guidelines from health professionals on this practice and its potential risks. Receptive anal intercourse (RAI) and rectal douching were associated ($p < 0.001$). **Conclusions:** New studies on the subject are required to extend health professionals knowledge and deploy new strategies of surveillance and prevention of STI/HIV in order to avoid increased exposure and promote a reduction of damage and risks through appropriate guidelines.

Keywords: Sexual behavior, rectal douching, anal intercourse, homosexual man, sexually transmitted infections, sexual education.

Abbreviations:

AIDS-Acquired immunodeficiency syndrome

ARVT – Antiretroviral therapy

HIV – Human immunodeficiency virus

MSM – Men who have sex with men

RAI – Receptive anal intercourse

STI – Sexually transmitted infections

SUS – Unified Health Service (Sistema Único de Saúde)

Strengths and limitations of this study

The study on the practice of RD among HSH is unprecedented in Brazil. Despite being used a convenience sample, the sample size (n=401) is representative of the population studied. The privacy, afforded to participants with computer use in a private setting, prevented outside interference that could inhibit the answers.

Introduction. Rectal douching (RD) is commonly performed before anal intercourse among men who have sex with men (MSM).[1, 2, 3] Several commercial and non-commercial devices, such as shower hoses, plastic bottles and syringes, are used.[4] Products commonly used to perform RD are running water and homemade solutions, and the main reason to conduct this practice is to clean the rectal cavity and therefore increase pleasure during sex.[5.6] However, this practice can alter anal tissues and is associated with risk behavior that may facilitate the transmission of sexually transmitted infections (STI) and HIV.[1-4.6] In Brazil, in 2014, 734 thousand people were believed to be living with HIV or human immunodeficiency syndrome (AIDS), which translates as 0.4% of the general population. Among the 15 to 49 years of age population, the prevalence is 0.6%.[7] Studies carried out in Brazil, between 2009 and 2013, among MSM population, show HIV prevalence rates of 10.5%.[8] One of the main causes of the spread of HIV among MSM is receptive anal intercourse (RAI). [9] The proportion of cases among this group tended to increase in the last ten years, from 34.6% in 2004 to 43.2% in 2013.[7] Social, biological, behavioral and epidemiological studies are needed so that one can understand social and sexual practices among the MSM population and, therefore, trace preventive strategies due to risks related to anal sex.[5.9-11] This study aims to determine the prevalence of RD use between MSM and establish the main substances and materials associated with this practice.

Method

Study site. The study was conducted after being authorized by Report nº 1,100,371 (CAAE nº 45107215.7.0000.5375) by the Ethics and Research Committee (CEP) from the Reference and Training Center (CRT/AIDS). The study was conducted in three different clinics of the institution: the transvestites and transsexuals clinic; the clinic to monitor patients with HIV/AIDS and the serological testing and counseling clinic. **Study population and inclusion criteria.** The study included a population of MSM

from the CRT/AIDS regardless of serological HIV status, 18 years of age or older. Respondents were included in the survey after voluntary accepting to participate in the study when visiting the mentioned clinics to receive treatment, guideline or to be tested for STI/HIV. **Participant recruitment to the study**. Participants were recruited by researchers trained in advance. After deciding to participate, participants were taken into a room designated for the purpose of this study in each of the clinics. There, they received all the necessary information about the aim of the research and signed the Term of Clarification and Freely Consenting (TFCC). After receiving a copy of the TFCC, participants answered a digital questionnaire on a laptop. Participants who had difficulties filling the data digitally were assisted by the field researcher who helped with the use of the computer. **Data collecting period**. The data was collected between June 20th and August 20th, 2015. **Research tool.** The questionnaire applied addressed epidemiological issues (sex, age, race, origin, residence), sexual orientation and sexual practices (frequency and partners), as well as the use of commercial and non-commercial products when performing RD (types of products used, frequency of these practices and risk behavior). The questions addressed practices performed between the last 3 months and the last month before the interview, due to better time reliability. After adjustments, the questionnaire was formatted in the free app Google Docs® and tested in a pre-test. **Pre-test**. The researchers applied 5 questionnaires in order to test the understanding of the content and to carry out adjustments to the instrument. These questionnaires were not included in the study. **Sample design and sample size**. The methodology used to calculate the sample came from a sample of convenience, considering a confidence interval of 95% and a maximum of 5% sampling error and estimated prevalence of RD use of 50%. The minimum sample was 391 participants, from a total of 401 respondents included.[12] **Statistical treatment of the sample**. Respondents were classified into 2 groups: those who use and those who do not use RD. Initially, a descriptive analysis of these two groups was conducted, considering social and demographic variables. The following analysis was made considering the variables in the group who performed RD. Categorical variables were tested with the Chi-square test or Fisher's exact. The chance reasons ("odds ratio") and the respective confidence intervals were estimated. The tests used were bi-flow rates and the level of significance was $p < 0.05$.

Results

Table 1 – Gender identity, age, race/color, education, monthly income, STI, drug abuse and anal sexual intercourse among MSM (n = 369)

	n = 369	%
Gender identity (self perception)		
Man	316	85,6
Transsexual	33	8,9
Transvestite	17	4,6
Woman	2	0,5
Not yet defined	1	0,3
Age (in years)		
18 - 29	175	47,4
30 - 39	129	35,0
40 - 49	51	13,8
50 - 59	12	3,3
60 - 66	2	0,5
Color/race declared		
White	236	64,0
Brown	95	25,8
Black	24	6,5
Other	14	3,8
Formal education		
Middle school finished/unfinished	29	7,9
High school finished/unfinished	86	23,3
Undergraduate student (complete/incomplete) / Graduated	254	68,8
Total monthly income		
BRL 0 to 2000	175	47,4
BRL 2001 to 4000	117	31,7
BRL over 4000	77	20,9
STI over last 12 months		
No	234	63,4
Yes	134	36,3
I don't know	1	0,3
Drug use during intercourse - last 12 months		
Yes	186	50,4
No	183	49,6
Anal intercourse		
Insertive anal intercourse only	79	21,4
RAI only	86	23,3
RAI and insertive	204	55,3

Among the 401 participants, 369 (92%) had had anal intercourse in the past 3 months. Among these, 86 performed RAI and 50.9% responded having had RAI and insertive intercourse, a total of 290 participants (72.3%) who have practiced receptive anal intercourse. Among MSM who had had anal intercourse in the last 3 months, 314 reside in the State of São Paulo (85.1%), 85.6% identified themselves as men, 4.6% as transvestites and 8.9% as transsexuals. Among these, 236 declared to be white (64%) and 104 declared to be brown (25.8%). Average age in years: 31. With regard to schooling, 68.8% are undergraduate students (initiated or completed college/university) or graduate students. With regard to monthly income, the highest frequent group has received an income of up to BRL 2000.00 (47.4%). (Table 1)

Table 2 – RD use in the last 3 months, solutions, products and equipment used

RD (n = 369)		%
Yes	197	53,4
No	172	46,6
Homemade products (n = 181)[1]		
Water + soap	33	18,2
Water only	181	100,0
Commercial products and solutions (n = 52)		
Fosfoenema ®	19	36,5
In-M®	7	13,5
Minilax®	3	5,8
I don't remember	5	9,6
Intimate liquid soap	3	5,8
Glycerin suppository	2	3,8
Disposable Kit purchased at pharmacy or store	1	1,9
Homemade equipment used (n = 233)[1]		
Shower hose, bidet or sink	199	85,4
Plastic water pump	22	9,4
Disposable kit purchased at pharmacy or store	12	5,2
Plastic bottle	11	4,7

1 - multiple choice

According to Table 2, among those who performed anal intercourse in the last 3 months (n = 369), 197 reported RD use (53.4%). The participants declared using more than one type of product, solution or equipment to perform RD. To clean the rectal canal, the main solution used was water (100.0%), followed by water and soap (18.2%). The main equipment used was a shower hose, a bidet or a sink (85.4%).

Table 3 – Reasons for the practice of RD and difficulties associated with RD before and after RAI in last 3 months (n = 197)[1]

Reason – RD always BEFORE	**n**	**%**
Cleaning/hygiene	84	42,6
More pleasurable anal intercourse	34	17,2
It is a preference of the partner	6	3,0
Constipation	1	0,5
Reason – RD sometimes or never BEFORE	**n**	
Unnecessary	69	35,0
Do not like it	53	26,9
Unplanned sexual encounter	46	23,4
Did not have time	43	21,8
Have no information on RD	6	3,0
Think it is unhealthy	1	0,5
Reason – RD always AFTER	**n**	
Cleaning/hygiene	21	10,7
Partner did not use condom	7	3,6
Previous RD was not adequate	1	0,5
Reason – RD sometimes or never AFTER	**n**	
Unnecessary	153	77,7
I had sex with a condom	136	69,0
Unplanned sexual encounter	34	17,2
Ignorance	4	2,0
Hygiene	3	1,5
I don't like it	2	1,0
I evacuated afterwards	1	0,5
I've read that it isn't recommended	1	0,5
I used a laxative product	1	0,5
Difficulties – RD	**n**	
Pain	33	16,8
Bleeding	13	6,6
Trauma/injury to the anus	13	6,6
Cramps	4	2,0
Nuisance	2	1,0
Burnt	2	1,0
Medical contraindication	1	0,5
Presence of hemorrhoid	1	0,5
Dryness	1	0,5

1 - multiple choice

Among the 197 participants who used RD, the main reasons for the practice of rectal douching before sex was cleaning/hygiene and also to make anal intercourse more pleasurable. The main reasons among those who reported sometimes or never performing RD before anal intercourse was regarding it unnecessary or disliking the practice. Among the RD after anal intercourse group, respondents mainly regarded it unnecessary or declared having used a condom. The greatest difficulties reported when performing RD were pain and bleeding. (Table 3)

Table 4 - RD Prevalence and participants' sexual behavior (n = 369)

		RD - last 3 months				value of p	OR	OR (I.C. 95%)	
		no		yes					
		N	%	n	%			inferior	superior
RAI	No	70	19,0%	11	3,0%	<0,001	1		
	Yes	102	27,6%	186	50,4%		11,60	5,88	22,91
Partner	men only	158	42,8%	187	50,7%	0,238	1		
	men and women	14	3,8%	10	2,7%		0,60	0,26	1,40
Guidance from health professional on RD	No	166	45,0%	183	49,6%	0,133	1		
	Yes	6	1,6%	14	3,8%		2,12	0,80	5,63
Paid for sex - last 12 months	No	143	38,8%	158	42,8%	0,468	1		
	Yes	29	7,8%	39	10,6%		1,22	0,72	2,07
Drug use during intercourse - last 12 months	No	92	24,9%	106	28,7%	0,951	1		
	Yes	80	21,7%	91	24,7%		0,99	0,66	1,49
Sex with HIV positive partner - last 12 months	No	43	11,7%	57	15,4%	0,585	1		
	Yes	44	11,9%	43	11,7%	0,301	0,74	0,41	1,31
	does not know	85	23,0%	97	26,3%	0,550	0,86	0,53	1,41
HIV test result	Negative	126	34,1%	148	40,1%	0,008	1		
	Positive	19	5,2%	36	9,8%	0,121	1,61	0,88	2,95
	does not know	27	7,3%	13	3,5%	0,013	0,41	0,20	0,83
STI over last 12 months	No	117	31,7%	118	32,0%	0,106	1		
	Yes	55	14,9%	79	21,4%		1,42	0,93	2,19

In simple logistic regression, there was an association between RD use among those who have RAI ($p < 0.001$), as seen on Table 4.

Discussion

The results of this study indicate that the practice of RD is common among MSM population before RAI, with a prevalence of 53.4%. These results are consistent with other studies, with prevalence of 52% to 66%. [6, 11, 13] This study has shown that RD is performed with homemade products and materials and objects which were not designed for this purpose. Among those who used non-commercial products (n = 233), 199 used a shower hose to introduce water in the anus (84.5%). The results are consistent with studies conducted with participants from 5 continents about RD related practices, where 93% of the respondents (n = 1339) reported using non-commercial products (93%) and water (82%) to perform RD. The study indicates 74% increased risk of STI/HIV between those who use RD when compared to those who do not perform it (odds ratio =

1.74; 95% CI, 1.01 -3.00)[6]. These findings indicate that RD is associated with risk behavior. Studies on the MSM population commonly investigate the prevalence of STI/HIV among the group; however, they have not commonly approached behavioral aspects that can bring information on beliefs and values related to sexual practices in specific populations of greater vulnerability. A study on the use of RD in 16 US cities conducted through an online questionnaire responded by 4992 MSM indicated that 52% use RD, 43.3% of which perform it often, 87.6% before sex and 27,4% after sex. Among those who performed RD after sexual intercourse, the main reason was to prevent STI/HIV infection (12.7%). The main product used was tap water (65.7%). The authors question the risk contradictions on the use of water to perform RD due to amendment of the rectum epithelium, considering that intimate lubricants are water-based.[13] This question is relevant because the scientific literature generally affirms that RD removes beneficial bacteria and the surface layer of the intestinal epithelium, which could potentially increase the risk of HIV transmission among MSM. On the other hand, there is a lack of research on these practices, even though several guidelines on the practice of anal intercourse are provided to patients by health professionals.[14] Our study demonstrated that 94.6% of the participants have never received professional guidance on RD practice. These data reinforce the need to better study RD practice so that guidelines on the subject are standardized, or even to determine whether microbicide products should be prescribed during preparation for anal intercourse.[1-4] Our study raises a discussion on the use of shared objects to perform RD. In Brazil, information on the use of household and disposable objects for the practice of RD is disseminated among those who practice anal intercourse. These materials and equipments are available in homes and places associated with the practice of sex, and there are no guarantees about its hygiene, as well as frequency of use and sharing. The practice of sharing materials may allow the transmission of pathogens when they may still be viable in the presence of organic matter and have contact with the injured anal mucosa or intestinal epithelium.[15-17] The study was conducted in a State's reference center of research, prevention and treatment that complies with the public policies of the Ministry of Health for the prevention and treatment of patients with STI and HIV in Brazil. The public health policy of the country guarantees serologic tests for the detection of HIV and other STIs as well as treatment and follow-up through the Unified Health System (SUS) to the population. Collecting data in such institution allowed the recruitment of

patients undergoing treatment with anti-retroviral therapy (HAART) and members of the MSM population who were in the clinic to perform serological tests or receive guidance from health professionals. The sample interviewed is representative of the MSM population, but new studies on the subject should be conducted in order to understand this practice in the various regions of the country. The instrument used for collecting data (online questionnaire) provided fast answers and a practical way to organize the collected data. The private environment, with the use of a computer in a private room, prevented external interference that could inhibit responses.

Conclusions

The prevalence of RD use is 53.4%. The materials used to carry out the practice are not intended for this purpose, such as shower hoses. Water is the most commonly used product for the practice of RD. The practice of RD was associated with RAI. The study indicates that the practice is common among MSM population and also that this group does not receive information from healthcare professionals about the risks associated with this practice, therefore demonstrating the need to include guidance on the topic on the STI/HIV preventive programs, as well as professional preparation to address the subject among the MSM population. The authors propose that the discussion on RD be magnified within the STI/HIV preventive strategies; it is also necessary to discuss the use of microbicides associated with the practice of RAI. New studies on the subject are required to extend health professionals knowledge and deploy new strategies of surveillance and prevention of STI/HIV in order to avoid increased exposure and promote a reduction of damage and risks through appropriate guidelines.

Authors' Contributions:

LCRL: study conception and design, interpretation of results, drafting of manuscript; RJCS: supervision of data analysis, interpretation of results and manuscript preparation. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Other data can be requested by email: luizlamblet7@gmail.com.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1
Objectives	3	State specific objectives, including any prespecified hypotheses	1
Methods			
Study design	4	Present key elements of study design early in the paper	1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	1
Bias	9	Describe any efforts to address potential sources of bias	1
Study size	10	Explain how the study size was arrived at	1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	1
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	1
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	1
		(*b*) Report category boundaries when continuous variables were categorized	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	1
Discussion			
Key results	18	Summarise key results with reference to study objectives	1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	1
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	1
Generalisability	21	Discuss the generalisability (external validity) of the study results	1
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

1 – included

NA - not applicable.

BMJ Open

Prevalence and types of rectal douches used for anal intercourse among men who have sex with men in Brazil

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Prevalence and types of rectal douches used for anal intercourse among men who have sex with men in Brazil.

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Abstract

Introduction: The practice of rectal douching (RD) is conducted among men who have sex with men (MSM), and various products and materials are used; however, there are no Brazilian studies on this practice and its risks to the transmission of sexually transmitted infections (STI) and HIV. **Method:** Between June and August 2015, 401 MSM over 18 years of age were interviewed about sexual practices associated with RD in the last 3 months. Descriptive statistical analyses were conducted by associating rectal douching with the reported sexual behavior. **Results:** Among the respondents, 85,6% identified themselves as men, 14,4% as transgenders; 255 declared to be white (63.6%) and 104 declared to be brown (25.9%). From those who had performed anal sex in the last 3 months (n = 369), 197 reported having used RD (53.4%). The most commonly used material was a shower hose (84.5%) and the main product was water (93%). Of those interviewed, 94.5% have never received guidelines from health professionals on this practice and its potential risks. Receptive anal intercourse (RAI) and rectal douching were associated ($p < 0.001$). **Conclusions:** The use of rectal douching is a common practice amongst the HSH population at stake here. Health professionals need to deepen their knowledge about the matter. Authors propose the discussion of RD practice and its association to the usage of rectal microbicides for a possible enhancement of both the prevention strategy and the reduction of harm to the vulnerable population.

Keywords: Sexual behavior, rectal douching, anal intercourse, homosexual man, sexually transmitted infections, sexual education.

Abbreviations:

AIDS-Acquired immunodeficiency syndrome

ARVT – Antiretroviral therapy

HIV – Human immunodeficiency virus

MSM – Men who have sex with men

RAI – Receptive anal intercourse

STI – Sexually transmitted infections

SUS – Unified Health Service (Sistema Único de Saúde)

Strengths

Strengths :
- pioneering study in Brazil;
- basis for discussion of the issue in the country;
- data collection tool (online survey) of free access.

Limitations:
- unrepresentative sample of MSM.

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Method

Study site. The study was conducted after being authorized by Report nº 1,100,371 (CAAE nº 45107215.7.0000.5375) by the Ethics and Research Committee (CEP) from the Reference and Training Center (CRT/AIDS). The study was conducted in three different clinics of the institution: the transgender clinic; the clinic to monitor patients with HIV/AIDS and the serological testing and counseling clinic. **Study population and inclusion criteria.** The study included a population of MSM from the CRT/AIDS

regardless of serological HIV status, 18 years of age or older. Respondents were included in the survey after voluntarily accepting to participate in the study when visiting the mentioned clinics to receive treatment, guideline or to be tested for STI/HIV. **Participant recruitment to the study**. Participants were recruited by researchers trained in advance. After agreeing on participating on the research, participants were taken into a specific room for this study in each one of the clinics. There, they received all the necessary information about the aim of the research and signed the Term of Clarification and Freely Consenting (TFCC). After receiving a copy of the TFCC, participants answered a digital questionnaire on a laptop. Participants who had difficulties filling the data digitally were assisted by the field researcher who helped with the use of the computer. **Data collecting period**. The data was collected between June 20th and August 20th, 2015. **Research tool.** The questionnaire applied addressed epidemiological issues (sex, age, race, origin, residence), sexual orientation and sexual practices (frequency and partners), as well as the use of commercial and non-commercial products when performing RD (types of products used, frequency of these practices and risk behavior). The questions addressed practices performed between the last 3 months and the last month before the interview, due to better time reliability. After adjustments, the questionnaire was formatted in the free app Google Docs® and tested in a pre-test. **Pre-test**. The researchers applied 5 questionnaires in order to test the understanding of the content and to carry out adjustments to the instrument. These questionnaires were not included in the study. **Sample design and sample size**. The methodology used to calculate the sample came from a sample of convenience, considering a confidence interval of 95% and a maximum of 5% sampling error and estimated prevalence of RD use of 50%. The minimum sample was 391 participants, from a total of 401 respondents included.[12] **Statistical treatment of the sample**. Respondents were classified into 2 groups: those who use and those who do not use RD. Initially, a descriptive analysis of these two groups was conducted considering social and demographic variables. The following analysis was made considering the variables in the group who performed RD. Categorical variables were tested with the Chi-square test or Fisher's exact. The chance reasons ("odds ratio") and the respective confidence intervals were estimated. The tests used were bi-flow rates and the level of significance was $p < 0.05$.

Results

Table 1 – Gender identity, age, race/color, education, monthly income, STI, drug abuse and anal sexual intercourse among MSM (n = 369)

	n = 369	%
Gender identity		
Man	316	85,6
Transgender	53	14,4
Age (in years)		
18 - 29	175	47,4
30 - 39	129	35,0
40 - 49	51	13,8
50 - 59	12	3,3
60 - 66	2	0,5
Color/race declared		
White	236	64,0
Brown	95	25,8
Black	24	6,5
Other	14	3,8
Formal education		
Middle school finished/unfinished	29	7,9
High school finished/unfinished	86	23,3
Undergraduate student (complete/incomplete) / Graduated	254	68,8
Total monthly income		
BRL 0 to 2000	175	47,4
BRL 2001 to 4000	117	31,7
BRL over 4000	77	20,9
STI over last 12 months		
No	234	63,4
Yes	134	36,3
I don't know	1	0,3
Drug use during intercourse - last 12 months		
Yes	186	50,4
No	183	49,6
Anal intercourse		
Insertive anal intercourse only	79	21,4
RAI only	86	23,3
RAI and insertive	204	55,3

Among the 401 participants, 369 (92%) had had anal intercourse in the past 3 months. Among these, 86 performed RAI and 50.9% responded having had RAI and insertive intercourse, a total of 290 participants (72.3%) who have practiced receptive anal intercourse. Among MSM who had had anal intercourse in the last 3 months, 314 reside in the State of São Paulo (85.1%), 85.6% identified themselves as men and 14,4% as transgenders. Among these, 236 declared to be white (64%) and 104 declared to be brown (25.8%). Average age in years: 31. With regard to schooling, 68.8% are undergraduate students (initiated or completed college/university) or graduate students. With regard to monthly income, the highest frequent group has received an income of up to BRL 2000.00 (47.4%). Drugs used to have sex were: alcoholic drink; marijuana; cocaine; viagra, cialis or levitra; poppers; ecstasy; ketamine; GHB; crystal / methamphetamine; crack and LSD. STI acquired in the last 12 months by respondents

were: hepatitis, chlamydia, genital, rectal or anal warts (HPV, human papillomavirus), gonorrhea, rectal gonorrhea, genital herpes, syphilis and HIV. (Table 1)

Table 2 – RD use in the last 3 months, solutions, products and equipment used

RD (n = 369)		%
Yes	197	53,4
No	172	46,6
Homemade products (n = 181)[1]		
Water + soap	33	18,2
Water only	181	100,0
Commercial products and solutions (n = 52)		
Fosfoenema ®	19	36,5
In-M®	7	13,5
Minilax®	3	5,8
I don't remember	5	9,6
Intimate liquid soap	3	5,8
Glycerin suppository	2	3,8
Disposable Kit purchased at pharmacy or store	1	1,9
Homemade equipment used (n = 233)[1]		
Shower hose, bidet or sink	199	85,4
Plastic water pump	22	9,4
Disposable kit purchased at pharmacy or store	12	5,2
Plastic bottle	11	4,7

1 - multiple choice

According to Table 2, among those who performed anal intercourse in the last 3 months (n = 369), 197 reported RD use (53.4%). The participants declared using more than one type of product, solution or equipment to perform RD. To clean the rectal canal, the main solution used was water (100.0%), followed by water and soap (18.2%). The main equipment used was a shower hose, a bidet or a sink (85.4%).

Table 3 – Reasons for the practice of RD and difficulties associated with RD before and after RAI in last 3 months (n = 197)[1]

Reason – RD always BEFORE	**n**	**%**
Cleaning/hygiene	84	42,6
More pleasurable anal intercourse	34	17,2
It is a preference of the partner	6	3,0
Constipation	1	0,5
Reason – RD sometimes or never BEFORE	**n**	
Unnecessary	69	35,0
Do not like it	53	26,9
Unplanned sexual encounter	46	23,4
Did not have time	43	21,8
Have no information on RD	6	3,0
Think it is unhealthy	1	0,5
Reason – RD always AFTER	**n**	
Cleaning/hygiene	21	10,7
Partner did not use condom	7	3,6
Previous RD was not adequate	1	0,5
Reason – RD sometimes or never AFTER	**n**	
Unnecessary	153	77,7
I had sex with a condom	136	69,0
Unplanned sexual encounter	34	17,2
Ignorance	4	2,0
Hygiene	3	1,5
I don't like it	2	1,0
I evacuated afterwards	1	0,5
I've read that it isn't recommended	1	0,5
I used a laxative product	1	0,5
Difficulties – RD	**n**	
Pain	33	16,8
Bleeding	13	6,6
Trauma/injury to the anus	13	6,6
Cramps	4	2,0
Nuisance	2	1,0
Burnt	2	1,0
Medical contraindication	1	0,5
Presence of hemorrhoid	1	0,5
Dryness	1	0,5

1 - multiple choice

Among the 197 participants who used RD, the main reasons for the practice of rectal douching before sex was cleaning/hygiene and also allowing for more pleasurable anal intercourse. The main reasons among those who reported "sometimes or never" performing RD before anal intercourse regarded it as "unnecessary" or "disliking the practice". Among the RD after anal intercourse group, respondents mainly regarded it "unnecessary" or declared "having used a condom". The greatest difficulties reported when performing RD were pain and bleeding. (Table 3)

Table 4 - RD Prevalence and participants' sexual behavior (n = 369)

		RD - last 3 months				value of p	OR	OR (I.C. 95%)	
		no		yes					
		N	%	n	%			inferior	superior
RAI	No	70	19,0%	11	3,0%	<0,001	1		
	Yes	102	27,6%	186	50,4%		11,60	5,88	22,91
Partner	men only	158	42,8%	187	50,7%	0,238	1		
	men and women	14	3,8%	10	2,7%		0,60	0,26	1,40
Guidance from health professional on RD	No	166	45,0%	183	49,6%	0,133	1		
	Yes	6	1,6%	14	3,8%		2,12	0,80	5,63
Paid for sex - last 12 months	No	143	38,8%	158	42,8%	0,468	1		
	Yes	29	7,8%	39	10,6%		1,22	0,72	2,07
Drug use during intercourse - last 12 months	No	92	24,9%	106	28,7%	0,951	1		
	Yes	80	21,7%	91	24,7%		0,99	0,66	1,49
Sex with HIV positive partner - last 12 months	No	43	11,7%	57	15,4%	0,585	1		
	Yes	44	11,9%	43	11,7%	0,301	0,74	0,41	1,31
	does not know	85	23,0%	97	26,3%	0,550	0,86	0,53	1,41
HIV test result	Negative	126	34,1%	148	40,1%	0,008	1		
	Positive	19	5,2%	36	9,8%	0,121	1,61	0,88	2,95
	does not know	27	7,3%	13	3,5%	0,013	0,41	0,20	0,83
STI over last 12 months	No	117	31,7%	118	32,0%	0,106	1		
	Yes	55	14,9%	79	21,4%		1,42	0,93	2,19

In simple logistic regression, there was an association between RD use among those who have RAI ($p < 0.001$), as seen on Table 4.

Discussion

The results of this study indicate that the practice of RD is common among MSM population before RAI, with a prevalence of 53.4%. These results are consistent with other studies, with prevalence of 52% to 66%. [6, 11, 13] This study has shown that RD is performed with homemade products and materials and objects which were not designed for this purpose. Among those who used non-commercial products (n = 233), 199 used a shower hose to introduce water in the anus (84.5%). The results are consistent with a study conducted with participants from 5 continents concerning RD related practices, where 93% of the respondents (n = 1339) reported using non-commercial products (93%) and water (82%) to perform RD. The study indicates 74% increased risk of STI/HIV between those who use RD when compared to those who do not perform it

(odds ratio = 1.74; 95% CI, 1.01 -3.00) [6]. These findings indicate that RD is associated with risk behavior. Studies on the MSM population commonly investigate the prevalence of STI/HIV among the group; however, they have not commonly approached behavioral aspects that can bring information on belevies and values related to sexual practices in specific populations of greater vulnerability. A study on the use of RD in 16 US cities conducted through an online questionnaire responded by 4992 MSM indicated that 52% use RD, 43.3% of which perform it often, 87.6% before sex and 27,4% after sex. Among those who performed RD after sexual intercourse, the main reason was to prevent STI/HIV infection (12.7%). The main product used was tap water (65.7%). The authors question the risk contradictions on the use of water to perform RD due to amendment of the rectum epithelium, considering that intimate lubricants are water-based.[13] This question is relevant because scientific literature generally affirms that RD removes beneficial bacteria and the surface layer of the intestinal epithelium, which could potentially increase the risk of HIV transmission among MSM. [5,13] On the other hand, there is a lack of research on these practices, even though several guidelines on the practice of anal intercourse are provided to patients by health professionals.[14] Our study demonstrated that 94.6% of the participants have never received professional guidance on RD practice. Health professionals should be more aware of the RD practice so that the guidelines can be passed on more adequately to MSM population. Moreover, the potential use of formulated rectal microbicides douche amongst the MSM population should be discussed.[1-4, 15] The study was conducted at a state reference, research Center for prevention and treatment, which complies with the Ministry of Health`s public policies for prevention and treatment of STI and HIV patients in Brazil. The public health policy of the country guarantees serologic tests for the detection of HIV and other STIs as well as treatment and follow-up through the Unified Health System (SUS) to the population. Collecting data in such institution allowed the recruitment of patients undergoing treatment with anti-retroviral therapy (HAART) and members of the MSM population who were in the clinic either to perform serological tests or to receive guidance from health professionals. It was a large, clinic-based sample, yet the findings cannot be generalized for the whole MSM population. New studies on the subject should be conducted in order to understand this practice in the various regions of the country. The instrument used for collecting data (online questionnaire) provided fast answers and proved to be a practical way of organizing the

collected data. The specific room arranged for the task with the use of a computer in a private room, prevented external interference that could inhibit responses.

Conclusions

The use of rectal douching is a common practice amongst the HSH population at stake here. Health professionals need to deepen their knowledge about the matter. Authors propose the discussion of RD practice and its association to the usage of rectal microbicides for a possible enhancement of both the prevention strategy and the reduction of harm to the vulnerable population.

Authors' Contributions:

LCRL: study conception and design, interpretation of results, drafting of manuscript; RJCS: supervision of data analysis, interpretation of results and manuscript preparation. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Other data can be requested by email: luizlamblet7@gmail.com.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1
Objectives	3	State specific objectives, including any prespecified hypotheses	1
Methods			
Study design	4	Present key elements of study design early in the paper	1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	1
Bias	9	Describe any efforts to address potential sources of bias	1
Study size	10	Explain how the study size was arrived at	1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	1
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	1
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	1
		(*b*) Report category boundaries when continuous variables were categorized	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	1
Discussion			
Key results	18	Summarise key results with reference to study objectives	1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	1
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	1
Generalisability	21	Discuss the generalisability (external validity) of the study results	1
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

1 – included

NA - not applicable.

BMJ Open

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Secondary Subject Heading:	Infectious diseases, Public health, Sexual health
Keywords:	sexual behavior, sexual education, rectal douching, anal intercourse, homosexual man, sexually transmitted infections

Prevalence and types of rectal douches used for anal intercourse among men who have sex with men in Brazil

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ABSTRACT

Introduction: Rectal douching (RD) is practised among men who have sex with men (MSM), and various products and materials are used. There have been no studies in Brazil on this practice and its risks in the transmission of sexually transmitted infections (STI) and HIV. **Method:** Between June and August 2015, 401 MSM over the age of 18 were interviewed about their sexual practices associated with RD over the last 3 months. RD was associated with the reported sexual behaviour, and descriptive statistical analyses were conducted on the same. **Results:** Among the respondents, 85.6% identified themselves as men and 14.4% as transgender; 255 declared themselves to be white (63.6%) and 104 to be mixed (25.9%). From among those who had performed anal sex within the last 3 months (n = 369), 197 reported having used RD (53.4%). The most commonly used material was a shower hose (84.5%) and the main product used was water (93%). Of those interviewed, 94.5% never received guidelines from health professionals on this practice and its potential risks. Receptive anal intercourse and RD were found to be associated ($p < 0.001$). **Conclusions:** RD is a common practice amongst the MSM population. Health professionals must deepen their knowledge of this. We propose studies in Brazil on the practice of RD that—from that knowledge strategies for prevention and harm reduction—can be incorporated to the vulnerable populations.

Keywords: Sexual behaviour, rectal douching, anal intercourse, homosexual men, sexually transmitted infections, sexual education.

Abbreviations:

AIDS – Acquired immunodeficiency syndrome

HIV – Human immunodeficiency virus

MSM – Men who have sex with men

RAI – Receptive anal intercourse

STI – Sexually transmitted infections

Strengths and limitations of this study

Strengths:
- pioneering study in Brazil
- basis for discussion of the issue in the country

Limitations:
- unrepresentative sample of MSM

INTRODUCTION

Rectal douching (RD) is commonly performed before anal intercourse among men who have sex with men (MSM).[1,2,3] Several commercial and non-commercial devices, such as shower hoses, plastic bottles and syringes, are used.[4] Tap water and homemade solutions are most commonly used in RD. The primary reason for this practice is to clean the rectal cavity and therefore increase pleasure during sex.[5,6] However, this practice can alter anal tissues and is associated with risky behaviour that may facilitate the transmission of sexually transmitted infections (STI) and the human immunodeficiency virus (HIV).[1-4,6] HIV prevalence in Brazil is estimated to be 0.4% in the general population and 0.6% in the 15–49-year-old age group. Studies conducted between 2009 and 2013 in Brazil in the MSM population show an HIV prevalence rate of 10.5%.[7,8] One of the main avenues of the spread of HIV among MSM is receptive anal intercourse (RAI).[9] The proportion of cases among this group has tended to increase over the last 10 years, from 34.6% in 2004 to 43.2% in 2013.[7] Social, biological, behavioural and epidemiological studies are needed to understand social and sexual practices among the MSM population and therefore trace new preventive strategies due to risks related to anal sex.[5,9-11] This study aims to determine the prevalence of RD among MSM and to establish the main substances and materials associated with this practice.

METHOD

Study site. The study was conducted after being authorized by Report nº 1,100,371 (CAAE nº 45107215.7.0000.5375) by the Ethics and Research Committee of the Reference and Training Centre (CRT/AIDS). The study was conducted in three different clinics of the CRT/AIDS: the transgender clinic; the clinic for monitoring patients with HIV/AIDS and the serological testing and counselling clinic. **Study population and inclusion criteria.** The study included a population of MSM from CRT/AIDS regardless of serological HIV status and of 18 years of age or older. Respondents were included in the survey after voluntarily agreeing to participate in the study during a visit to the above-mentioned clinics to receive treatment or guidelines or

to be tested for STI/HIV. **Participant recruitment for the study.** Participants were recruited by researchers trained in advance. After agreeing to participate in the study, participants were taken into a room specifically set aside for this study at each of the clinics. There, they received all necessary information about the aim of the study and signed the Terms of Clarification and Freely Consenting (TFCC). After receiving a copy of the TFCC, participants answered a digital questionnaire using a laptop. Participants who had difficulty completing the questionnaire digitally were assisted by a field researcher to use the computer. **Data-collection period.** Data were collected between 20 June and 20 August, 2015. **Research tools.** The questionnaire addressed epidemiological issues (sex, age, race, origin, and residence), sexual orientation and sexual practices (frequency and partners) and the use of commercial and non-commercial products when performing RD (types of products used, frequency of these practices and risk behaviours). The questions addressed practices during the last 3 months and the last month before the interview, for better time reliability. After being adjusted, the questionnaire was formatted in the free application Google Docs and tested in a pre-test. **Pre-test.** The researchers used five questionnaires to test understanding of the content and to carry out adjustments to the instrument. These questionnaires were not included in the study. **Sample design and sample size.** The methodology used to calculate the sample came from a convenience sample, considering a confidence interval of 95% and a maximum sampling error of 5% and an estimated prevalence of RD use of 50%. For these calculations, the minimum sample should include 391 participants. The present study had 401 participants.[12] **Statistical treatment of the sample.** Respondents were classified into two groups: those who use and those who do not use RD. Initially, the descriptive analysis of these two groups was conducted considering social and demographic variables. The following analysis was performed considering the variables for those in the group who performed RD. The categorical variables were tested with the Chi-square test or Fisher's exact test. The odds ratio and the respective confidence intervals were estimated. The tests used were bi-flow rates and the level of significance was $p < 0.05$.

RESULTS

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RAI only	86	23,3
RAI and insertive	204	55,3

Of the research participants, 369 (92%) had anal intercourse in the past 3 months. (Table 1) Among these, 86 reported to have performed RAI and 50.9% responded having had RAI and insertive intercourse. Among MSM who had had anal intercourse within the last 3 months, 314 resided in the State of São Paulo (85.1%), 85.6% identified themselves as men and 14.4% as transgender. Among these, 236 declared themselves to be white (64%) and 104 declared themselves to be mixed (25.8%). Their average age in years was 31. With regard to schooling, 68.8% are undergraduate students (initiated or completed college/university) or graduate students. With regard to monthly income, the most frequent group (47.4%) had received an income of up to BRL 2000.00 Drugs used in connection with sex were: alcoholic drinks, marijuana, cocaine, viagra, cialis or levitra, poppers, ecstasy, ketamine, GHB, crystal/methamphetamine, crack and LSD. STIs acquired in the last 12 months by respondents were: hepatitis;

chlamydia; genital, rectal or anal warts (HPV, human papillomavirus); gonorrhoea; rectal gonorrhoea; genital herpes; syphilis; and HIV.

Table 2 – RD use in the last 3 months: solutions, products and equipment

RD (n = 369)		%
Yes	197	53,4
No	172	46,6
Homemade products (n = 181)[1]		
Water + soap	33	18,2
Water only	181	100,0
Commercial products and solutions (n = 52)		
Fosfoenema ®	19	36,54
In-M®	7	13,46
Minilax®	3	5,77
I don't remember	5	9,62
Intimate liquid soap	3	5,77
Glycerin suppository	2	3,85
Disposable Kit purchased at pharmacy or store	13	25,00
Homemade equipment used (n = 232)[1]		
Shower hose, bidet or sink	199	85,78
Plastic water pump	22	9,48
Plastic bottle	11	4,74

1 - multiple choice

According to Table 2, of those who performed anal intercourse within the last 3 months (n = 369), 197 reported RD use (53.4%). The participants declared having used more than one type of product, solution or equipment to perform RD. To clean the rectal canal, the main solution used was water (100.0%), followed by water and soap (18.2%). The main equipment used was a shower hose, a bidet or a sink (85.4%).

Table 3 – Reasons for the practice of RD and difficulties associated with RD before and after RAI in last 3 months (n = 197)[1]

Reason – RD always BEFORE	**n**	**%**
Cleaning/hygiene	84	42,6
More pleasurable anal intercourse	34	17,2
It is a preference of the partner	6	3,0
Constipation	1	0,5
Reason – RD sometimes or never BEFORE	**n**	
Unnecessary	69	35,0
Do not like it	53	26,9
Unplanned sexual encounter	46	23,4
Did not have time	43	21,8
Have no information on RD	6	3,0
Think it is unhealthy	1	0,5
Reason – RD always AFTER	**n**	
Cleaning/hygiene	21	10,7
Partner did not use condom	7	3,6
Previous RD was not adequate	1	0,5
Reason – RD sometimes or never AFTER	**n**	
Unnecessary	153	77,7
I had sex with a condom	136	69,0
Unplanned sexual encounter	34	17,2
Ignorance	4	2,0
Hygiene	3	1,5
I don't like it	2	1,0
I evacuated afterwards	1	0,5
I've read that it isn't recommended	1	0,5
I used a laxative product	1	0,5
Difficulties – RD	**n**	
Pain	33	16,8
Bleeding	13	6,6
Trauma/injury to the anus	13	6,6
Cramps	4	2,0
Nuisance	2	1,0
Burnt	2	1,0
Medical contraindication	1	0,5
Presence of hemorrhoids	1	0,5
Dryness	1	0,5

1 - multiple choice

Among the 197 participants who used RD, the main reasons for the practice of RD before sex were cleanliness or hygiene and greater pleasure during anal intercourse. The main reasons among those who reported 'sometimes or never' performing RD before anal intercourse regarded it as 'unnecessary' or 'disliked the practice'. Among the RD after anal intercourse group, respondents mainly regarded it 'unnecessary' or declared themselves to 'have used a condom'. The greatest difficulties reported when performing RD were pain and bleeding. (Table 3)

Table 4 - RD Prevalence and participants' sexual behaviour (n = 369)

		RD - last 3 months				value of p	OR	OR (I.C. 95%)	
		no		yes					
		N	%	n	%			inferior	superior
RAI	No	70	19,0%	11	3,0%	<0,001	1		
	Yes	102	27,6%	186	50,4%		11,60	5,88	22,91
Partner	men only	158	42,8%	187	50,7%	0,238	1		
	men and women	14	3,8%	10	2,7%		0,60	0,26	1,40
Guidance from health professional on RD	No	166	45,0%	183	49,6%	0,133	1		
	Yes	6	1,6%	14	3,8%		2,12	0,80	5,63
Paid for sex - last 12 months	No	143	38,8%	158	42,8%	0,468	1		
	Yes	29	7,8%	39	10,6%		1,22	0,72	2,07
Drug use during intercourse - last 12 months	No	92	24,9%	106	28,7%	0,951	1		
	Yes	80	21,7%	91	24,7%		0,99	0,66	1,49
Intercourse with HIV positive partner - last 12 months	No	43	11,7%	57	15,4%	0,585	1		
	Yes	44	11,9%	43	11,7%	0,301	0,74	0,41	1,31
	does not know	85	23,0%	97	26,3%	0,550	0,86	0,53	1,41
HIV test result	Negative	126	34,1%	148	40,1%	0,008	1		
	Positive	19	5,2%	36	9,8%	0,121	1,61	0,88	2,95
	does not know	27	7,3%	13	3,5%	0,013	0,41	0,20	0,83
STI over last 12 months	No	117	31,7%	118	32,0%	0,106	1		
	Yes	55	14,9%	79	21,4%		1,42	0,93	2,19

In simple logistic regression, there was an association between RD use among those who have RAI ($p < 0.001$), as seen in Table 4.

DISCUSSION

The results of this study indicate that the practice of RD is common among the MSM population before RAI, with a prevalence of 53.4%. These results are consistent with other studies showing prevalence of 52% to 66%.[6,11,13] This study has revealed that RD is performed with homemade products and materials and objects not designed for this purpose. Among those who used non-commercial products (n = 233), 199 used a shower hose to introduce water into the anus (84.5%). These results are consistent with a study conducted with participants from five continents concerning RD-related practices, where 93% of the respondents (n = 1339) reported using non-commercial products (93%) and water (82%) to perform RD. The study indicates a 74% increased risk of STI/HIV between those who use RD and those who do not perform it (odds ratio

= 1.74; 95% CI, 1.01 -3.00).[6] These findings indicate that RD is associated with risky behaviour. Studies on the MSM population commonly investigate the prevalence of STI/HIV among this population; however, these studies do not usually address the behavioural aspects related to the information on beliefs and values of sexual practices in specific populations of greater vulnerability. A study on the use of RD in 16 US cities conducted through an online questionnaire with 4992 MSM respondents indicated that 52% use RD, 43.3% perform it often and 87.6% use RD before sex and 27.4% after sex. Among those who performed RD after sexual intercourse, the main reason was to prevent STI/HIV infection (12.7%). The main product used was tap water (65.7%). The authors question the contradiction in the risk of changing the rectal epithelium attributed to the use of water to perform RD, considering that intimate lubricants are water-based.[13] This question is relevant because scientific literature generally affirms that RD removes beneficial bacteria and the surface layer of the intestinal epithelium, which could potentially increase the risk of HIV transmission among MSM.[5,13] However, research on these practices is insufficient, even though several guidelines on the practice of anal intercourse are provided to patients by health professionals.[14] Our study demonstrated that 94.6% of the participants have never received professional guidance on the practice of RD. Health professionals should deepen their knowledge of RD in the MSM population. New prevention strategies have been proposed, such as pre-exposure oral therapy. The use of gel or rectal microbicides in showers has also been studied in the MSM population. Understanding the use of RD in Brazil will determine the feasibility of introducing these possible HIV transmission prevention strategies in this vulnerable population.[1-4,15] The study was conducted at a state reference research centre for prevention and treatment of STI and HIV, which complies with the Ministry of Health's public policies for the prevention and treatment of STI and HIV patients in Brazil. The public health policy of the country guarantees serologic tests for the detection of HIV and other STIs as well as treatment and follow-up through the Unified Health System to the population. Collecting data in such institutions allowed the recruitment of patients undergoing the anti-retroviral therapy treatment and members of the MSM population who were in the clinic either to get serologically tested or to receive guidance from health professionals. This was a large, clinic-based sample, but the findings cannot be generalized for the whole MSM population. New studies on the subject should be conducted to understand this practice in the various regions of the

country. The instrument used for data collection (online questionnaire) provided quick responses and proved to be a practical way of organizing the collected data. The room set aside for the task and the use of a computer prevented external interference that could inhibit responses.

CONCLUSIONS

The use of RD is a common practice in the MSM population. Health professionals need to deepen their knowledge of this matter. Further studies are needed to understand this practice in Brazil among the MSM population. From these studies, new knowledge and strategies may be proposed for the prevention of STI/HIV in this vulnerable population.

AUTHORS' CONTRIBUTIONS:

LCRL: study conception and design, interpretation of results, drafting of manuscript; RJCS: supervision of data analysis, interpretation of results and manuscript preparation. All authors read and approved the final manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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DATA SHARING STATEMENT

Other data can be requested by email: luizlamblet7@gmail.com.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1
Objectives	3	State specific objectives, including any prespecified hypotheses	1
Methods			
Study design	4	Present key elements of study design early in the paper	1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	1
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	1
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	1
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	1
Bias	9	Describe any efforts to address potential sources of bias	1
Study size	10	Explain how the study size was arrived at	1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	1
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	1
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	NA
		(*d*) *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	1
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA

Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	1
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	1
		(*b*) Report category boundaries when continuous variables were categorized	1
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	1
Discussion			
Key results	18	Summarise key results with reference to study objectives	1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	1
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	1
Generalisability	21	Discuss the generalisability (external validity) of the study results	1
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

1 – included

NA - not applicable.