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Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial – the People Like Us (PLU) Evaluation Study

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Abstract

Introduction: Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV and other sexually transmitted infections. While HIV/STI testing rates among GBQ men are increasing worldwide, they remain suboptimal in a variety of settings.

Methods and analysis: The study is a pragmatic, randomised controlled trial design to evaluate an online video series developed by a community-based organisation in Singapore for GBQ men. A total of 300 HIV-negative, GBQ men in Singapore aged 18 to 29 years old will be recruited for this study. Participants will subsequently be randomised into the intervention arm (n=150) and the control arm (n=150). The intervention arm (n=150) will be assigned the intervention along with sexual health information via a pamphlet, while the control group (n=150) will be assigned only the sexual health information via a pamphlet. Participants should also not have watched the video prior to their participation in this study, which will be ascertained through a questionnaire. Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, Chlamydia and Gonorrhoea at the 3-month and 6-month post-intervention. Secondary outcomes include changes in self-reported risk perception for HIV and other sexually transmitted infections, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections, knowledge of HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community,

self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms.

Ethics and dissemination: The study has been approved by the National University of Singapore Institutional Review Board (S-19-059) and registered at Clinicaltrials.gov (NCT04021953). The results will be published in peer-reviewed academic journals and disseminated to community-based organisations and policymakers.

Trial registration: Clinicaltrials.gov, NCT04021953

Article summary

Strengths and limitations of this study

- The first randomised controlled trial to evaluate the efficacy of a popular web-based drama series on HIV/STI testing for young gay, bisexual and queer men in Singapore
- A collaboration with a community-based organisation in Singapore with strong public health translation potential
- Only self-reported data on HIV and other STI diagnoses are collected which cannot be validated through laboratory-confirmed tests
- While steps have been taken to mitigate contamination, the risks nonetheless exist as the intervention material is available to the public
- Sex between men is criminalised in Singapore which may impact participation among sub-populations of the target population

Introduction

A total of 37.9 million people around the world were estimated to be living with HIV at the end of 2018 [1]. Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV, relative to the general population [2, 3]. Young GBQ men are a subset of the broader GBQ male community who are especially vulnerable to HIV and other sexually transmitted infections (STI) acquisition. In Singapore, GBQ men between the age of 15 to 39 years old account for 66.3% of all incident HIV cases among GBQ men from the first reported case of HIV in 1986, up to 2018 [4].

Rates of HIV testing have also remained suboptimal among GBQ men in a variety of settings, including Southeast Asia. A study among young GBQ men in the Association of Southeast Asian Nations countries in 2015 found that 29.9% of participants had never had an HIV test, and these were more likely to be among younger GBQ men [5]. Unwillingness to know about their HIV status, the fear of a positive result, and low perceived risk of HIV acquisition were factors found to be associated with lower rates of HIV testing among young GBQ men [6, 7].

As such, there exist numerous types of interventions that aim to increase HIV testing among GBQ men. These interventions range from those that utilise aspects of peer education, outreach through social media, reminder-based systems, video-based interventions and national social marketing campaigns. These social marketing campaigns were commonly promoted in neighbourhoods where a larger population of GBQ men resided and had substantial number of businesses catering to them [8-12]. For reminder-based interventions, participants were recruited from sexual health clinics that they were, at the point of recruitment, attending, either for check-ups or testing [13-15]. With regards to the other online interventions such as outreach through social media and peer education, participants

were recruited through key websites and mobile phone apps identified to be frequented by GBQ men [16-22].

These interventions reported varying degrees of effectiveness in achieving the aims of increasing HIV testing and overall disease awareness. Reminder-based interventions, where participants were reminded every three to six months to go for testing through short message reminders sent from designated sexual health clinics, were customised to suit the participants' level of sexual activity and were effective in promoting the uptake of HIV testing [13-15]. Broader scale HIV/STI social marketing campaigns, such as "Stop the Sores" and "Stop the Drama Downunder" from the United States and Australia respectively, were generally well-received and were found to be effective in promoting HIV/STI testing, as well as participants' knowledge on HIV/STI at the population or community level [9, 11]. Interventions that collaborated with popular opinion leaders to disseminate HIV prevention messages to GBQ male social networks have also shown success in encouraging desired HIV preventive behaviours [19, 20]. However, for existing video-based interventions, evidence of their efficacies was not conclusive. In a video-based intervention study conducted in Peru between 2007 to 2008, among participants who self-identified as gay, differences in intention to test for HIV was not statistically significant between the intervention and control arm, although participants who identified as non-gay did show increased willingness to do so [22]. Several studies also assessed the efficacy of crowdsourced videos on HIV testing, and largely found that they were non-inferior to regular health marketing campaigns [18], or only had a positive effect on HIV testing rates through the use of home-based self-testing kits, but not facility-based HIV/STI testing [23].

There are, however, several limitations in the context of reach and feasibility for such interventions. For example, reminder-based and peer education-based interventions require existing health systems that can support such interventions, which may not be feasible is most

settings that do not have such services, or where GBQ male-specific clinical services are unavailable due to the criminalisation of sex between men. Furthermore, while social marketing campaigns have been effective in increasing the uptake of HIV/STI testing, such campaigns may not be feasible in Asian settings where negative perceptions of, or attitudes toward GBQ men prevail [5]. Overall, these interventions also fell short of reaching out to more niche subsets of the GBQ male communities who may be more discreet about their sexual identities and hence may not often visit gay venues or sexual health clinics where these interventions are typically offered.

The present study is novel in Asia in evaluating the effectiveness of a web drama series in achieving positive HIV/STI testing-related outcomes for young GBQ men. The videos used in the study forms the second season of an educational and web drama miniseries, People Like Us (PLU), developed by gayhealth.sg and Action for AIDS (AFA) in 2018. The first season of the miniseries was screened as a total of 10 film festivals, and won several independent film awards. It had also garnered more than 1.7 million views across various social media platforms since its launch in 2016. In spite of its popularity, little has been done to assess its efficacy in positively impacting HIV/STI testing-related outcomes. If found to be efficacious in improving HIV/STI testing-related outcomes, such web dramas may serve as complementary interventions, alongside clinically-based ones, as such web drama series have proven to be easily accessible and shareable, which may facilitate reaching GBQ men who might not have access healthcare services as a result of key structural barriers, such as stigma.

Methods and analysis

Study aims and design

This is a pragmatic, parallel group, randomised controlled trial to evaluate the efficacy of a web drama series, developed by a community-based organisation in Singapore, in increasing an individual's intention to test, self-reported testing behaviors, and self-reported regularity of testing behaviors for HIV, Syphilis, as well as other common sexually transmitted infection [24] such as Gonorrhoea and Chlamydia. The trial also aims to evaluate the impact of the web drama series on self-reported risk perception for HIV/STI, knowledge of HIV, risks associated with acquiring sexually transmitted infections and HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community, self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms. The pragmatic nature of this trial arises due to the prospect of contamination, as the web drama series had been launched in January 2019. The implications of this are further discussed later in the manuscript.

Study setting

As of end-2018, a total of 8,295 Singaporeans had been reported to the Ministry of Health (MOH) in Singapore as having acquired HIV [25]. HIV transmission in Singapore is concentrated among key populations, namely among GBQ men and heterosexual men. HIV testing is widely available at both government-run and private healthcare providers in Singapore, and under the Infectious Disease Act in Singapore, all individuals who test positive for HIV must be notified to the MOH within 72 hours of diagnosis. The anonymous HIV testing scheme was introduced in 1991; under this scheme, no personal information or identifiers are collected during HIV testing at selected clinics to encourage testing among

individuals who might otherwise be hesitant of having their identities made known to the authorities.

Singapore society has largely held negative attitudes towards GBQ men and individuals who identify as lesbian, gay, bisexual, and transgender (LGBT) [26-28]. Legally, sexual relations between consenting male individuals is also criminalised under Section 377A of the Singapore penal code, with a penalty of imprisonment for up to two years. A recent study found that Singaporeans were also not in favor of its repeal [29]. Past studies in Singapore have found that negative attitudes and structural forms of stigma and discrimination have a negative impact on HIV/STI testing among GBQ men [30, 31]. As such, interventions that do not operate beyond community spaces or sexual health clinics may not reach hidden populations of GBQ men who may fear attending or being seen in such spaces that might inadvertently lead to the disclosure of their sexual orientation.

Inclusion and exclusion criteria

Inclusion criteria for participants in this study include self-reporting at the point of recruitment (i) an HIV-negative status, or being unsure of one's HIV status; (ii) being gay, bisexual or queer with regard to sexual orientation; (iii) being of male gender, regardless of sex assigned at birth; (iv) being 18 to 29 years old; (v) being a Singapore citizen or permanent resident; (vi) and having never watched an online video drama series by Gayhealth.sg or AFA in the last year.

Exclusion criteria for participants in this study include self-reporting at the point of recruitment (i) having ever watched an online video drama series by Gayhealth.sg or AFA in the last year; (ii) an HIV-positive status; (iii) not being English-literate; and (iv) being below 18 or above 29 years old.

Procedure and randomisation

<Figure 1 about here>

A summary of study procedures may be found in Figure 1. Recruitment of participants will take place through the assistance of community-based organisations in Singapore, as well as through advertising channels in popular social and sexual networking apps among young GBQ men. Flyers will be printed and places at the premises run by community-based organisations, while social media campaigns will be run on social media and geosocial networking platforms to recruit participants. To enrol in the study, participant will have to scan a QR code or follow the direct link on the flyer, or click a link on the online advertisement to access a study enrolment questionnaire. Participants will provide consent for participation through an online participant information sheet at this point.

Participants will follow the link on the online advertisement or flyer to a survey administration website for a short screening survey where they will be asked for their contact details as well as their self-reported age, sexual orientation, gender, HIV status, and residence status to register their intent to join the cohort and for verification of eligibility by the community-based organisational partner, AFA. Participants will also be asked if they had ever watched a web drama series by Gayhealth.sg or AFA launched in the past year without naming the actual series to avoid further contamination. Should the participant be ineligible to participate, they will be redirected to a disqualification page. Throughout the entire survey process, personal identifiers will never be directly linked to survey results, so as to protect participants from potential criminal implications of disclosing their sexual activities with other men and other behaviors such as substance use.

Upon completion of the enrolment survey and verification of eligibility, a staff member at AFA will contact eligible participants to provide them with their participant ID, and to formally invite them to participate in the study through the completion of the first online baseline survey. This survey will be hosted on a survey administration website and will take about 15 to 20 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of a SGD15.00 (~USD10.84) reimbursement to participants. AFA will not have access to any baseline or follow-up survey responses for the cohort questionnaire, which will only be made available to the study team.

Upon completion of the baseline survey, participants will then be randomly assigned via block randomisation (in block sizes of 5) to the intervention condition or the control comparison condition using a computer software program. Individuals who are assigned to the intervention condition will be given a link to a series of six online videos from the PLU web drama series, along with a link to an online sexual health pamphlet tailored for GBQ men in Singapore. Individuals who were assigned to the control condition will be scheduled to receive a link to the same online sexual health pamphlet as the standard of care for GBQ men at risk of acquiring HIV/STI in Singapore. To ensure that all participants eventually receive both interventions, after the 6-month follow-up period is over, the control group will receive the link to the online videos as well. All participants will receive their assigned conditions within one week after completing the baseline survey, and will be asked to complete a quiz one week after assignment to ascertainment if participants had watched the online series and/or read the sexual health pamphlet. Participants will receive a SGD20.00 (~USD14.45) reimbursement following the completion of the quiz.

Participants will not be blinded to the group they have been assigned to, and will be told about their chances of being randomised to either group. However, participants will not have access to the content that would only be delivered at the 6-month mark. The decision to provide both groups similar materials at different times ensures that the trial remains ethical, considering we anticipate improvements in sexual health-seeking behavior, and ensures that participants remain motivated to participate, knowing that they would receive similar treatments in spite of randomisation. At the 3-month and 6-month timeframes from the baseline, AFA will contact all eligible participants to continue with their follow-up surveys. Like the baseline survey, the second and third surveys will be hosted on a survey administration website and will take about 15 to 20 minutes to complete. Participants will receive SGD15.00 (~USD10.84) reimbursement for the completion of each survey.

The intervention: People Like Us web drama series

The online intervention comprises a series of six videos, each about 10-minutes in length, constituting the second season of a popular web drama series entitled People Like Us. The series follow the love and sex lives of four ethnically-diverse GBQ men of varying socioeconomic backgrounds, as they negotiate issues of sexual health, mental health, and relationships throughout the six-part miniseries. People Like Us miniseries incorporates key sexual health messages to (i) increase viewers' knowledge and perceptions of HIV/STI risk; (ii) address homophobia and sexual orientation disclosure; (iii) increase safer-sex negotiation self-efficacy; (iv) promote positive attitudes towards condom use and other safe sex behaviors; (v) build skills and self-efficacy for practicing safer sex; (vi) provide information on HIV/STI testing and its benefits; (vii) provide information on resources for HIV/STI testing and other mental health services; and (viii) model appropriate behaviors around practicing safer sex. Each video in the six-part series ends with an educational video segment

featuring the managers and volunteers of AFA and Gayhealth.sg, who provide a brief synopsis of the episode and cover key points relevant to mental and sexual health for GBQ men. A list of episodes may also be found in Table 1.

The control condition: Sexual health pamphlet

The intervention group will also be provided with an online sexual health pamphlet tailored specifically to the needs of GBQ men in Singapore. This pamphlet was developed by the National Skin Centre and Department of Sexually Transmitted Infections Clinic specifically for information on sexual wellness among GBQ men. It comprises segments on HIV/STI symptoms, aetiology, information on how to seek help for HIV/STI, as well as behavioral and biomedical methods of HIV prevention.

Primary outcome measures

Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, as well as Chlamydia and Gonorrhoea at the 3-month and 6-month time frames. For example, participants will be asked "how likely are you to get tested for HIV in the next three months?", to which they respond through a 6-point Likert scale from "extremely unlikely to get tested" to "extremely likely to get tested". Self-reported testing is ascertained through the question "when did you go for you last (most recent) voluntary HIV test?" (options to respond include "never", "in the last 3 months", "in the last 6 months", "6 to 12 months ago" and "more than 1 year ago"), while self-reported regularity of testing will be measured through the question "on average, how regularly do you test for HIV?" (options to respond include "I do not test regularly", "once every few years", "once a year", "once every 6 months", "once every 3 months" and "once a month")

Secondary outcome measures

Secondary outcomes include changes in self-reported risk perception for HIV/STI, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections, knowledge of HIV pre-exposure prophylaxis, self-reported consistent condom use for anal sex with casual partners, self-reported incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community [32], self-concealment of sexual orientation [33], perceived homophobia [34], internalised homophobia [35], HIV testing self-efficacy [36] and HIV testing social norms [37].

Sample size

As the primary outcome of interest includes HIV or other STI testing in the last 3 months, we utilise data from a recent study conducted in 2018 among 1,098 GBQ men recruited through Grindr, the popular geosocial networking app [31, 38]. The study found that 50.4% of respondents reported having had a recent HIV test in the 6 months prior to the survey. Assuming a 50% increase in recent HIV testing as a result of the intervention, as data from previous studies based on the impact such a web drama series on recent HIV testing remains limited [39], a sample size of 112 in each arm will yield statistical power higher than 80% to detect a significant change for the intervention. A target sample size of 150 participants per group is proposed to account for an attrition estimate of 25% for each group across the 6-month follow up. Intention to Treat Analysis (ITT) will be employed to assess intervention efficacy on the proposed outcomes. Per-protocol analysis will also be conducted to assess the impact of attrition. Intervention efficacy will be analyzed over the entire study period (from baseline to the 6-month assessment).

Statistical analyses

The baseline equivalence of sociodemographic characteristics and sexual behavior in the intervention and comparison groups will be compared and statistically significant variables between the comparison and intervention group would be adjusted in the outcome evaluation along with the outcome at baseline. For continuous variables, a generalised linear mixed model will be employed. The mixed models will include intervention status and the time-point of assessment as fixed effects, and individuals as a random effect. Between-group effect sizes for the continuous outcome variables will be calculated using post-treatment means and their pooled observed standard deviation. For binary or count outcome variable evaluation, Poisson regression models and calculation of robust standard errors will be used to compute the crude risk ratio (RR) and adjusted RR (aRR) of the outcomes in the intervention versus the comparison group at follow-up. The default standard errors obtained by Poisson regression are typically too large; therefore, robust standard errors are needed to obtain an accurate confidence interval around the RR. Poisson rather than logistic regression will be used as the outcome was common (>10% of the study population), and thus the OR would likely overestimate the RR.

Pragmatic nature of trial

The PLU web drama series was launched in the community prior to the start of this study, and thus members of the community might have been exposed to the intervention prior to the study. However, this study was designated to continue in view of its importance in the local context to evaluate the efficacy of such web drama series, and to justify further HIV/STI prevention efforts that utilise online channels. As such, there is a possibility that control group participants may be exposed to the video series during the 6-month study period. To mitigate this, we will ensure that details of the online video intervention (i.e. title

of web series, where to access it) will not be included in the participant information sheet – only basic information on the possibility that they may be randomised to an "online video intervention" will be mentioned. Furthermore, to reduce the possibility of contamination occurring in reaction to being asked the screening question, we will avoid using the title of the web-series but instead ask the question: "Have you ever watched an online video drama series filmed by Gayhealth.sg or Action for AIDS Singapore in the past year?" as this is Gayhealth.sg/AFA's only web series launched in the past year. We will also ask participants at the 6-month mark if they had watched the video series within the past 6-months, and the time-frame during which they watched the web series. Intention-to-treat analyses will be conducted to provide a conservative estimate of the effect of the intervention, regardless of contamination.

A contamination adjusted intention-to-treat (CAITT) analysis may also be performed [40]. The authors argue that "as-treated" and "per-protocol" analyses result in non-random omission bias, while "intention-to-treat" analyses underestimate the value of receiving the treatment. In CAITT, the randomised controlled trial is treated as an instrumental variable, with treatment assignment as the "instrument." The effect of treatment assignment on outcome observed (intention to treat analysis) is adjusted by the percentage of assigned participants who ultimately receive the treatment (contamination adjustment). The authors argue that this provides a good estimate of an individual's risks and benefits of receiving a treatment, but might overestimate population level treatment benefits.

Patient and Public Involvement

The research protocol and grant application for this evaluation study was developed in collaboration with AFA, and its GBQ health programme, Gayhealth.sg. Both AFA and Gayhealth.sg represent the health interests of the wider GBQ male community and were

instrumental in the design and development of the study protocol. The intervention was developed by Gayhealth.sg and Action for AIDS Singapore in 2018 following a community needs assessment exercise that identified the pertinent sexual and mental health issues in the local GBQ male community. Results of the study will be disseminated to participants and the wider GBQ male community through both scientific seminars and community-based symposia, as well as through written, open-access reports.

Ethics and dissemination

Ethics and mitigating potential risks

Ethical issues may arise from the recruitment of participants engaging in illegal or criminal activities, such as the self-disclosure of having sex with other men, sex with minors, and the use of recreational drugs. To mitigate this risk, the main research team will not have access to any participant's personal identifiers, or access to any participants directly, which will be carried out by AFA. AFA will only collect participants' contact information to assist in following up on the surveys, and these will be stored in an encrypted database. On the other hand, staff at AFA will not have access to the survey data containing individual responses. All participants will be assigned a study identification number and these will subsequently be used for communication purposes to ensure that no personal identifiers are reflected or stored beyond the encrypted database.

Dissemination and implications for health promotion and policy

Results of the study will be made available to the public to share the results of the study with the GBQ male community, and to inform policymakers. Specifically, results of the study will be communicated in writing through study reports and peer-reviewed journal articles, and through presentations made in the community, at scientific conferences, and at

policy meetings. If found to be effective, such web drama series hold great promise to improve HIV/STI testing among GBQ men in Singapore, who are at disproportionate risk of acquiring HIV/STI relative to the general population. The organic growth and reach of the web drama series makes it a cost-effective means of improving such sexual health outcomes among GBQ men, and may serve as a model for other online interventions in Asia, and in contexts where sexual relations between men remain criminalised.

Trial status

Recruitment of participants started in September 2019, and the last participant is expected to reach the primary endpoint (6-month follow-up) in March 2020. Primary data analysis will begin in April 2020. The dissemination phase of the trial results will commence in May 2020.

(3963 words)

Author contributions: RKJT and WLK wrote the first draft of the protocol. DL, AvT, AdT, CT and SB developed the materials for the intervention condition and contributed to the details of the intervention in the manuscript. MTC provided access to the standard of care condition. RKJT, CSW, MLW and MIC obtained funding for the research. All authors conceived the study and revised the manuscript for relevant scientific content in the final version of the manuscript.

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Competing interests: None declared.

Patient consent: Patient consent obtained.

Ethics approval: Ethics approval for the protocol was obtained from the National University of Singapore Institutional Review Board (Reference Number S-19-059).

Data availability statement: Results of this study will be published and disseminated in peer-reviewed journals, as detailed in the protocol above. Deidentified participant data and data dictionaries will not be publicly available due to restrictions by the ethics board over concerns of risk to participants. The datasets generated during and/or analysed for this study will be available from the corresponding author on reasonable request, following the completion of the study. Additional documents including the study protocol and statistical analysis plan will be publicly available through this manuscript and the trial registry, Clinicaltrials.gov (NCT04021953).

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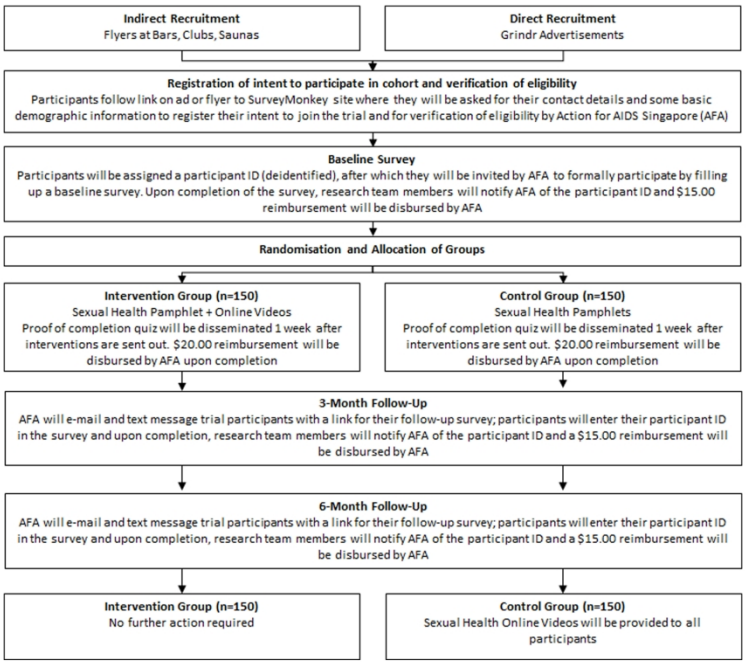
Episode	Title	Synopsis
1	Pretty in pink	At Pink Dot, Rai meets Haniff, someone from the same army camp, while Isaac hooks up with someone at his party. Meanwhile, after celebrating their month-sary, Joel introduces his Mom to Ridzwan.
2	Challenge accepted	As Rai heads out on a first date with Haniff, his Mom discovers a Pink Dot flyer. Joel asks Ridzwan to consider a challenging proposition. Meanwhile, Isaac is unable to concentrate at work and continues to experience pain while peeing.
3	Signs & omens	Rai's Mom confronts him about Pink Dot. Isaac is sexually frustrated and receives some disturbing news. Ridzwan seeks out a friend from the past for help while Rai bumps into Haniff, who treats him coldly.
4	Booty call	Rai's Mom and sister, Priya, discuss Rai's sexuality. Haniff surprisingly agrees to meet Rai again but reveals something that will change their relationship forever. Ridzwan accepts Joel's proposition but will it bring them closer?
5	Jeremy from work	Joel pays Ridzwan a surprise visit and meets Ridzwan's Mom. Rai meets Isaac for advice about Haniff. Back home, Rai's Mom attempts to reconnect with Rai.
6	A love like ours	Rai and Haniff book out of army camp together; their desires palpable, and Isaac's party friends desert him. Meanwhile, Joel's frustration with Ridzwan's secrecy reaches a breaking point.

Table 1. List of episodes and synopses of the People Like Us web drama series season two



Flowchart for study procedures and randomisation

209x297mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N.A.
Protocol version	3	Date and version identifier	N.A.
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 17
	5b	Name and contact information for the trial sponsor	N.A.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N.A.

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	5-6
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N.A.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N.A.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N.A.
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-11, 22

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9, 16
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N.A.
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15-16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N.A.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N.A.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N.A.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N.A.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N.A.
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16-17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9, 16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N.A.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N.A.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16-17
	31b	Authorship eligibility guidelines and any intended use of professional writers	N.A.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16-17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N.A.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N.A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial in Singapore – the People Like Us (PLU) Evaluation Study

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Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial in Singapore – the People Like Us (PLU) Evaluation Study

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Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial in Singapore– the People Like Us (PLU) Evaluation Study

Abstract

Introduction: Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV and other sexually transmitted infections. While HIV/STI testing rates among GBQ men are increasing worldwide, they remain suboptimal in a variety of settings.

Methods and analysis: The study is a pragmatic, randomised controlled trial design to evaluate an online video series developed by a community-based organisation in Singapore for GBQ men. A total of 300 HIV-negative, GBQ men in Singapore aged 18 to 29 years old will be recruited for this study. Participants will subsequently be randomised into the intervention arm (n=150) and the control arm (n=150). The intervention arm (n=150) will be assigned the intervention along with sexual health information via a pamphlet, while the control group (n=150) will be assigned only the sexual health information via a pamphlet. Participants should also not have watched the video prior to their participation in this study, which will be ascertained through a questionnaire. Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, Chlamydia and Gonorrhoea at the 3-month and 6-month post-intervention. Secondary outcomes include changes in self-reported risk perception for HIV and other sexually transmitted infections, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections, knowledge of HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community,

self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms.

Ethics and dissemination: The study has been approved by the National University of Singapore Institutional Review Board (S-19-059) and registered at Clinicaltrials.gov (NCT04021953). The results will be published in peer-reviewed academic journals and disseminated to community-based organisations and policymakers.

Trial registration: Clinicaltrials.gov, NCT04021953

Article summary

Strengths and limitations of this study

- The first randomised controlled trial to evaluate the efficacy of a popular web-based drama series on HIV/STI testing for young gay, bisexual and queer men in Singapore
- A collaboration with a community-based organisation in Singapore with strong public health translation potential
- Only self-reported data on HIV and other STI diagnoses are collected which cannot be validated through laboratory-confirmed tests
- While steps have been taken to mitigate contamination, the risks nonetheless exist as the intervention material is available to the public
- Sex between men is criminalised in Singapore which may impact participation among sub-populations of the target population

Introduction

A total of 37.9 million people around the world were estimated to be living with HIV at the end of 2018 [1]. Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV, relative to the general population [2, 3]. Young GBQ men are a subset of the broader GBQ male community who are especially vulnerable to HIV and other sexually transmitted infections (STI) acquisition. In Singapore, GBQ men between the age of 15 to 39 years old account for 66.3% of all incident HIV cases among GBQ men from the first reported case of HIV in 1986, up to 2018 [4].

Rates of HIV testing have also remained suboptimal among GBQ men in a variety of settings, including Southeast Asia. A study among young GBQ men in the Association of Southeast Asian Nations countries in 2015 found that 29.9% of participants had never had an HIV test, and these were more likely to be among younger GBQ men [5]. Unwillingness to know about their HIV status, the fear of a positive result, and low perceived risk of HIV acquisition were factors found to be associated with lower rates of HIV testing among young GBQ men [6, 7].

As such, there exist numerous types of interventions that aim to increase HIV testing among GBQ men. These interventions range from those that utilise aspects of peer education, outreach through social media, reminder-based systems, video-based interventions and national social marketing campaigns. These social marketing campaigns were commonly promoted in neighbourhoods where a larger population of GBQ men resided and had substantial number of businesses catering to them [8-12]. For reminder-based interventions, participants were recruited from sexual health clinics that they were, at the point of recruitment, attending, either for check-ups or testing [13-15]. With regards to the other online interventions such as outreach through social media and peer education, participants

were recruited through key websites and mobile phone apps identified to be frequented by GBQ men [16-22].

These interventions reported varying degrees of effectiveness in achieving the aims of increasing HIV testing and overall disease awareness. Reminder-based interventions, where participants were reminded every three to six months to go for testing through short message reminders sent from designated sexual health clinics, were customised to suit the participants' level of sexual activity and were effective in promoting the uptake of HIV testing [13-15]. Broader scale HIV/STI social marketing campaigns, such as "Stop the Sores" and "Stop the Drama Downunder" from the United States and Australia respectively, were generally well-received and were found to be effective in promoting HIV/STI testing, as well as participants' knowledge on HIV/STI at the population or community level [9, 11]. Interventions that collaborated with popular opinion leaders to disseminate HIV prevention messages to GBQ male social networks have also shown success in encouraging desired HIV preventive behaviours [19, 20]. However, for existing video-based interventions, evidence of their efficacies was not conclusive. In a video-based intervention study conducted in Peru between 2007 to 2008, among participants who self-identified as gay, differences in intention to test for HIV was not statistically significant between the intervention and control arm, although participants who identified as non-gay did show increased willingness to do so [22]. Several studies also assessed the efficacy of crowdsourced videos on HIV testing, and largely found that they were non-inferior to regular health marketing campaigns [18], or only had a positive effect on HIV testing rates through the use of home-based self-testing kits, but not facility-based HIV/STI testing [23].

There are, however, several limitations in the context of reach and feasibility for such interventions. For example, reminder-based and peer education-based interventions require existing health systems that can support such interventions, which may not be feasible is most

settings that do not have such services, or where GBQ male-specific clinical services are unavailable due to the criminalisation of sex between men. As such, these interventions may fall short of reaching out to more niche subsets of the GBQ male communities who may be more discreet about their sexual identities and hence may not often visit gay venues or sexual health clinics where these interventions are typically offered [24]. Furthermore, while social marketing campaigns have been effective in increasing the uptake of HIV/STI testing, such campaigns may not be feasible in settings such as Asia where negative perceptions of, or attitudes toward GBQ men prevail [5]. There have been, however, successes for the impact of social marketing campaigns on HIV/STI testing in the region such as the 'I Test, Do You?' campaign in Vietnam, and the 'TestXXX' campaigns across the capitals of Thailand, Vietnam, The Philippines, and Indonesia [25, 26].

The present study is novel in Asia in evaluating the effectiveness of a web drama series in achieving positive HIV/STI testing-related outcomes for young GBQ men. The videos used in the study forms the second season of an educational and web drama miniseries, People Like Us (PLU), developed by gayhealth.sg and Action for AIDS (AFA) in 2018 (https://www.gayhealth.sg/plu/). The first season of the miniseries was screened as a total of 10 film festivals, and won several independent film awards. It had also garnered more than 1.7 million views across various social media platforms since its launch in 2016. In spite of its popularity, little has been done to assess its efficacy in positively impacting HIV/STI testing-related outcomes. If found to be efficacious in improving HIV/STI testing-related outcomes, such web dramas may serve as complementary interventions, alongside clinically-based ones, as such web drama series have proven to be easily accessible and shareable, which may facilitate reaching GBQ men who might not have access healthcare services as a result of key structural barriers, such as stigma.

Methods and analysis

Study aims and design

This is a pragmatic, parallel group, randomised controlled trial to evaluate the efficacy of a web drama series, developed by a community-based organisation in Singapore, in increasing an individual's intention to test, self-reported testing behaviors, and self-reported regularity of testing behaviors for HIV, Syphilis, as well as other common sexually transmitted infection [27] such as Gonorrhoea and Chlamydia. The trial also aims to evaluate the impact of the web drama series on self-reported risk perception for HIV/STI, knowledge of HIV, risks associated with acquiring sexually transmitted infections and HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community, self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms. The pragmatic nature of this trial arises due to the prospect of contamination, as the web drama series had been launched in January 2019. The implications of this are further discussed later in the manuscript.

Study setting

As of end-2018, a total of 8,295 Singaporeans had been reported to the Ministry of Health (MOH) in Singapore as having acquired HIV [28]. HIV transmission in Singapore is concentrated among key populations, namely among GBQ men and heterosexual men. With regard to HIV testing uptake, about 71.7% of Singapore residents living with HIV are estimated to know their HIV status as of end-2014 [29]. While GBQ men are more likely than their heterosexual counterparts to be diagnosed through voluntary screening, only 20.0% of incident cases among GBQ men were detected through such means for incident HIV cases

reported in the year 2018, compared to 9% among heterosexual individuals. Community-based organizations have actively and regularly promoted HIV and other STI testing in venues frequented by GBQ men and older heterosexual men in Singapore since the beginning of the HIV epidemic [30], there are to our knowledge no available published studies that evaluate the efficacy of these interventions on individual or community-level testing.

HIV testing is widely available at both government-run and private healthcare providers in Singapore, and under the Infectious Disease Act in Singapore, all individuals who test positive for HIV must be notified to the MOH within 72 hours of diagnosis. The anonymous HIV testing scheme was introduced in 1991; under this scheme, no personal information or identifiers are collected during HIV testing at selected clinics to encourage testing among individuals who might otherwise be hesitant of having their identities made known to the authorities. HIV testing is thus only available through facility-based testing, without any options for self-testing or home-based testing as of end-2019.

Singapore society has largely held negative attitudes towards GBQ men and individuals who identify as lesbian, gay, bisexual, and transgender (LGBT) [31-33]. Legally, sexual relations between consenting male individuals is also criminalised under Section 377A of the Singapore penal code, with a penalty of imprisonment for up to two years. A recent study found that Singaporeans were also not in favor of its repeal [34]. Past studies in Singapore have found that the anticipation of such forms of sexual orientation-based stigma as well as structural forms of stigma and discrimination have a negative impact, while the availability of prompts or peer influence, and accessibility of services were found to have a positive impact on HIV/STI testing among GBQ men [24, 35, 36]. This intervention, with its focus on promoting knowledge of available HIV/STI prevention services in Singapore, modelling HIV/STI prevention-related and other health-seeking behaviors, and normalizing

GBQ male relationships in Singapore, is thus hypothesized to address some of these barriers to the uptake of HIV/STI testing.

Inclusion and exclusion criteria

Inclusion criteria for participants in this study include self-reporting at the point of recruitment (i) an HIV-negative status, or being unsure of one's HIV status; (ii) being gay, bisexual or queer with regard to sexual orientation; (iii) being of male gender, regardless of sex assigned at birth; (iv) being 18 to 29 years old; (v) being a Singapore citizen or permanent resident; (vi) and having never watched an online video drama series by Gayhealth.sg or AFA in the last year.

Exclusion criteria for participants in this study include self-reporting at the point of recruitment (i) having ever watched an online video drama series by Gayhealth.sg or AFA in the last year; (ii) an HIV-positive status; (iii) not being English-literate; and (iv) being below 18 or above 29 years old.

Procedure and randomisation

<Figure 1 about here>

A summary of study procedures may be found in Figure 1. Recruitment of participants will take place through the assistance of community-based organisations in Singapore, as well as through advertising channels in popular social and sexual networking apps among young GBQ men. Flyers will be printed and places at the premises run by community-based organisations, while social media campaigns will be run on social media and geosocial networking platforms to recruit participants. To enrol in the study, participant

will have to scan a QR code or follow the direct link on the flyer, or click a link on the online advertisement to access a study enrolment questionnaire. Participants will provide consent for participation through an online participant information sheet at this point.

Participants will follow the link on the online advertisement or flyer to a survey administration website for a short screening survey where they will be asked for their contact details as well as their self-reported age, sexual orientation, gender, HIV status, and residence status to register their intent to join the cohort and for verification of eligibility by the community-based organisational partner, AFA. Participants will also be asked if they had ever watched a web drama series by Gayhealth.sg or AFA launched in the past year without naming the actual series to avoid further contamination. Should the participant be ineligible to participate, they will be redirected to a disqualification page. Throughout the entire survey process, personal identifiers will never be directly linked to survey results, so as to protect participants from potential criminal implications of disclosing their sexual activities with other men and other behaviors such as substance use.

Upon completion of the enrolment survey and verification of eligibility, a staff member at AFA will contact eligible participants to provide them with their participant ID, and to formally invite them to participate in the study through the completion of the first online baseline survey. This survey will be hosted on a survey administration website and will take about 15 to 20 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of a SGD15.00 (~USD10.84) reimbursement to participants. AFA will not have access to any baseline or follow-up survey responses for the cohort questionnaire, which will only be made available to the study team.

Upon completion of the baseline survey, participants will then be randomly assigned in blocks of six in a 1:1 ratio to the intervention condition or the control comparison condition using a web-based randomization platform (http://www.sealedenvelope.com) to ensure even allocation. Individuals who are assigned to the intervention condition will be given a link to a series of six online videos from the PLU web drama series, along with a link to an online sexual health pamphlet tailored for GBQ men in Singapore. Individuals who were assigned to the control condition will be scheduled to receive a link to the same online sexual health pamphlet as the standard of care for GBQ men at risk of acquiring HIV/STI in Singapore. To ensure that all participants eventually receive both interventions, after the 6-month follow-up period is over, the control group will receive the link to the online videos as well. All participants will receive their assigned conditions within one week after completing the baseline survey, and will be asked to complete a quiz one week after assignment to ascertainment if participants had watched the online series and/or read the sexual health pamphlet. Participants will receive a SGD20.00 (~USD14.45) reimbursement following the completion of the quiz.

Participants will not be blinded to the group they have been assigned to, and will be told about their chances of being randomised to either group. However, participants will not have access to the content that would only be delivered at the 6-month mark. The decision to provide both groups similar materials at different times ensures that the trial remains ethical, considering we anticipate improvements in sexual health-seeking behavior, and ensures that participants remain motivated to participate, knowing that they would receive similar treatments in spite of randomisation. At the 3-month and 6-month timeframes from the baseline, AFA will contact all eligible participants to continue with their follow-up surveys. Like the baseline survey, the second and third surveys will be hosted on a survey

administration website and will take about 15 to 20 minutes to complete. Participants will receive SGD15.00 (~USD10.84) reimbursement for the completion of each survey.

The intervention: People Like Us web drama series

The online intervention comprises a series of six videos, each about 10-minutes in length, constituting the second season of a popular web drama series entitled People Like Us. The series follow the love and sex lives of four ethnically-diverse GBQ men of varying socioeconomic backgrounds, as they negotiate issues of sexual health, mental health, and relationships throughout the six-part miniseries. People Like Us miniseries incorporates key sexual health messages to (i) increase viewers' knowledge and perceptions of HIV/STI risk; (ii) address homophobia and sexual orientation disclosure; (iii) increase safer-sex negotiation self-efficacy; (iv) promote positive attitudes towards condom use and other safe sex behaviors; (v) build skills and self-efficacy for practicing safer sex; (vi) provide information on HIV/STI testing and its benefits; (vii) provide information on resources for HIV/STI testing and other mental health services; and (viii) model appropriate behaviors around practicing safer sex. Each video in the six-part series ends with an educational video segment featuring the managers and volunteers of AFA and Gayhealth.sg, who provide a brief synopsis of the episode and cover key points relevant to mental and sexual health for GBQ men. A list of episodes may also be found in Table 1.

The control condition: Sexual health pamphlet

The intervention group will also be provided with an online sexual health pamphlet tailored specifically to the needs of GBQ men in Singapore. This pamphlet was developed by the National Skin Centre and Department of Sexually Transmitted Infections Clinic specifically for information on sexual wellness among GBQ men. It comprises segments on

HIV/STI symptoms, aetiology, information on how to seek help for HIV/STI, as well as behavioral and biomedical methods of HIV prevention.

Primary outcome measures

Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, as well as Chlamydia and Gonorrhoea at the 3-month and 6-month time frames. For example, participants will be asked "how likely are you to get tested for HIV in the next three months?", to which they respond through a 6-point Likert scale from "extremely unlikely to get tested" to "extremely likely to get tested". Self-reported testing is ascertained through the question "when did you go for you last (most recent) voluntary HIV test?" (options to respond include "never", "in the last 3 months", "in the last 6 months", "6 to 12 months ago" and "more than 1 year ago"), while self-reported regularity of testing will be measured through the question "on average, how regularly do you test for HIV?" (options to respond include "I do not test regularly", "once every few years", "once a year", "once every 6 months", "once every 3 months" and "once a month")

Secondary outcome measures

Secondary outcomes include changes in self-reported risk perception for HIV/STI, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections, knowledge of HIV pre-exposure prophylaxis, self-reported consistent condom use for anal sex with casual partners, self-reported incidence of sexually transmitted infections, and other scales validated among GBQ men in other settings such as connectedness to the lesbian, gay, bisexual and transgender (LGBT) community [37], self-concealment of sexual

orientation [38], perceived homophobia [39], internalised homophobia [40], HIV testing self-efficacy [41] and HIV testing social norms [42].

Sample size

As the primary outcome of interest includes HIV or other STI testing in the last 3 months, we utilise data from a recent study conducted in 2018 among 1,098 GBQ men recruited through Grindr, the popular geosocial networking app [24, 43]. The study found that 50.4% of respondents reported having had a recent HIV test in the 6 months prior to the survey. Assuming a 50% increase in recent HIV testing as a result of the intervention, as data from previous studies based on the impact such a web drama series on recent HIV testing remains limited [44], a sample size of 112 in each arm will yield statistical power higher than 80% to detect a significant change for the intervention, based on calculations generated by a web-based software (http://www.clincalc.com). A target sample size of 150 participants per group is proposed to account for an attrition estimate of 25% for each group across the 6-month follow up. Intention to Treat Analysis (ITT) will be employed to assess intervention efficacy on the proposed outcomes. Per-protocol analysis will also be conducted to assess the impact of attrition. Intervention efficacy will be analyzed over the entire study period (from baseline to the 6-month assessment).

Statistical analyses

The baseline equivalence of sociodemographic characteristics and sexual behavior in the intervention and comparison groups will be compared and statistically significant variables between the comparison and intervention group would be adjusted in the outcome evaluation along with the outcome at baseline. For continuous variables, a generalised linear mixed model will be employed. The mixed models will include intervention status and the

time-point of assessment as fixed effects, and individuals as a random effect. Between-group effect sizes for the continuous outcome variables will be calculated using post-treatment means and their pooled observed standard deviation. For binary or count outcome variable evaluation, logistic regression models will be used to compute the crude odds ratios (OR) and adjusted odds ratios (aOR) of the outcomes in the intervention versus the comparison group at follow-up. Statistical significance will be set at $p<0.05$ without any adjustment across the multiple, unique primary outcomes. Statistical analyses will be conducted using the statistical software STATA version 15 (Stata Corp, College Station, TX, USA).

Pragmatic nature of trial

The PLU web drama series was launched in the community prior to the start of this study, and thus members of the community might have been exposed to the intervention prior to the study. However, this study was designated to continue in view of its importance in the local context to evaluate the efficacy of such web drama series, and to justify further HIV/STI prevention efforts that utilise online channels. As such, there is a possibility that control group participants may be exposed to the video series during the 6-month study period. To mitigate this, we will ensure that details of the online video intervention (i.e. title of web series, where to access it) will not be included in the participant information sheet – only basic information on the possibility that they may be randomised to an "online video intervention" will be mentioned. Furthermore, to reduce the possibility of contamination occurring in reaction to being asked the screening question, we will avoid using the title of the web-series but instead ask the question: "Have you ever watched an online video drama series filmed by Gayhealth.sg or Action for AIDS Singapore in the past year?" as this is Gayhealth.sg/AFA's only web series launched in the past year. While the generic nature of the question may result in under-reporting of viewing the video series, all participants will

eventually be able to view the video series and report if they had viewed any of the episodes prior to, or during the study period. Specifically, participants in the treatment group will be asked if they had previously watched any of the episodes when they submit the intervention completion survey one week after the completion of their baseline survey, while the control group will receive a link to all six episodes of the video intervention alongside their final survey at the 6-month mark, and will be asked specifically which episodes that they have watched prior to, or during the intervention period. Intention-to-treat analyses will be conducted to provide a conservative estimate of the effect of the intervention, regardless of contamination.

A contamination adjusted intention-to-treat (CAITT) analysis may also be performed [45]. The authors argue that "as-treated" and "per-protocol" analyses result in non-random omission bias, while "intention-to-treat" analyses underestimate the value of receiving the treatment. In CAITT, the randomised controlled trial is treated as an instrumental variable, with treatment assignment as the "instrument." The effect of treatment assignment on outcome observed (intention to treat analysis) is adjusted by the percentage of assigned participants who ultimately receive the treatment (contamination adjustment). The authors argue that this provides a good estimate of an individual's risks and benefits of receiving a treatment, but might overestimate population level treatment benefits.

At this point, the study team will rely on self-reported outcomes such as testing behaviors and HIV/STI diagnoses as it is presently not possible to link clinic attendance, or laboratory-confirmed diagnostic tests for HIV and other STI to individual participants. These issues have arisen due to ethical concerns around linking participants' personal information to survey results, which collects information on criminalized behavior such as sexual intercourse with other men, among participants in the sample. However, the findings of this proposed study will serve as a proof-of-concept for future studies that may be able to obtain

funding and state support for other means of testing, such as the use of self-testing kits for HIV and other STI.

Patient and Public Involvement

The research protocol and grant application for this evaluation study was developed in collaboration with AFA, and its GBQ health programme, Gayhealth.sg. Both AFA and Gayhealth.sg represent the health interests of the wider GBQ male community and were instrumental in the design and development of the study protocol. The intervention was developed by Gayhealth.sg and Action for AIDS Singapore in 2018 following a community needs assessment exercise that identified the pertinent sexual and mental health issues in the local GBQ male community. Results of the study will be disseminated to participants and the wider GBQ male community through both scientific seminars and community-based symposia, as well as through written, open-access reports.

Ethics and dissemination

Ethics and mitigating potential risks

Ethical approval for this study was granted by the National University of Singapore Institutional Review Board (Reference Number S-19-059). Ethical issues may arise from the recruitment of participants engaging in illegal or criminal activities, such as the self-disclosure of having sex with other men, sex with minors, and the use of recreational drugs. To mitigate this risk, the main research team will not have access to any participant's personal identifiers, or access to any participants directly, which will be carried out by AFA. AFA will only collect participants' contact information to assist in following up on the surveys, and these will be stored in an encrypted database. On the other hand, staff at AFA will not have access to the survey data containing individual responses. All participants will

be assigned a study identification number and these will subsequently be used for communication purposes to ensure that no personal identifiers are reflected or stored beyond the encrypted database.

Dissemination and implications for health promotion and policy

Results of the study will be made available to the public to share the results of the study with the GBQ male community, and to inform policymakers. Specifically, results of the study will be communicated in writing through study reports and peer-reviewed journal articles, and through presentations made in the community, at scientific conferences, and at policy meetings. If found to be effective, such web drama series hold great promise to improve HIV/STI testing among GBQ men in Singapore, who are at disproportionate risk of acquiring HIV/STI relative to the general population. The organic growth and reach of the web drama series makes it a cost-effective means of improving such sexual health outcomes among GBQ men, and may serve as a model for other online interventions in Asia, and in contexts where sexual relations between men remain criminalised.

Trial status

Recruitment of participants started in September 2019, and the last participant is expected to reach the primary endpoint (6-month follow-up) in March 2020. Primary data analysis will begin in April 2020. The dissemination phase of the trial results will commence in May 2020.

(3963 words)

Author contributions: RKJT and WLK wrote the first draft of the protocol. DL, AvT, AdT, CT and SB developed the materials for the intervention condition and contributed to the

details of the intervention in the manuscript. MTC provided access to the standard of care condition. RKJT, CSW, MLW and MIC obtained funding for the research. All authors conceived the study and revised the manuscript for relevant scientific content in the final version of the manuscript.

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Competing interests: None declared.

Patient consent: Patient consent obtained.

Ethics approval: Ethics approval for the protocol was obtained from the National University of Singapore Institutional Review Board (Reference Number S-19-059).

Data availability statement: Results of this study will be published and disseminated in peer-reviewed journals, as detailed in the protocol above. Deidentified participant data and data dictionaries will not be publicly available due to restrictions by the ethics board over concerns of risk to participants. The datasets generated during and/or analysed for this study will be available from the corresponding author on reasonable request, following the completion of the study. Additional documents including the study protocol and statistical analysis plan will be publicly available through this manuscript and the trial registry, Clinicaltrials.gov (NCT04021953).

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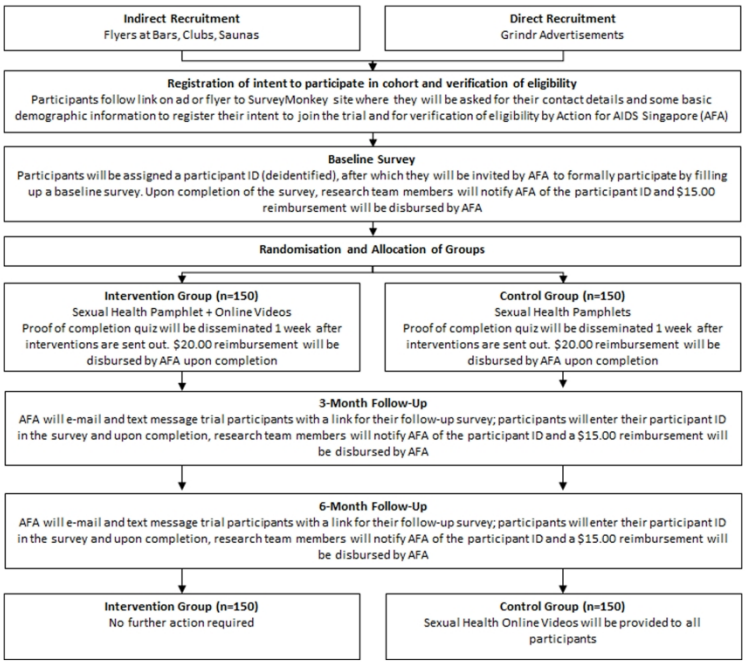
Episode	Title	Synopsis
1	Pretty in pink	At Pink Dot, Rai meets Haniff, someone from the same army camp, while Isaac hooks up with someone at his party. Meanwhile, after celebrating their month-sary, Joel introduces his Mom to Ridzwan.
2	Challenge accepted	As Rai heads out on a first date with Haniff, his Mom discovers a Pink Dot flyer. Joel asks Ridzwan to consider a challenging proposition. Meanwhile, Isaac is unable to concentrate at work and continues to experience pain while peeing.
3	Signs & omens	Rai's Mom confronts him about Pink Dot. Isaac is sexually frustrated and receives some disturbing news. Ridzwan seeks out a friend from the past for help while Rai bumps into Haniff, who treats him coldly.
4	Booty call	Rai's Mom and sister, Priya, discuss Rai's sexuality. Haniff surprisingly agrees to meet Rai again but reveals something that will change their relationship forever. Ridzwan accepts Joel's proposition but will it bring them closer?
5	Jeremy from work	Joel pays Ridzwan a surprise visit and meets Ridzwan's Mom. Rai meets Isaac for advice about Haniff. Back home, Rai's Mom attempts to reconnect with Rai.
6	A love like ours	Rai and Haniff book out of army camp together; their desires palpable, and Isaac's party friends desert him. Meanwhile, Joel's frustration with Ridzwan's secrecy reaches a breaking point.

Table 1. List of episodes and synopses of the People Like Us web drama series season two



Flowchart for study procedures and randomisation

209x297mm (300 x 300 DPI)

EVALUATION OF eHEALTH VIDEOS FOR THE SINGAPOREAN GAY, BISEXUAL, AND QUEER MALE COMMUNITY

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Consultant, Division of Infectious Diseases
National Center for Infectious Diseases

Institute: Saw Swee Hock School of Public Health
National University of Singapore

You are receiving this invitation to participate in this study as a user or patron of the services rendered by our community partners. Your participation is entirely voluntary, and you may withdraw from this study at any point without any penalty.

This study is interested in finding out more about the effectiveness of health-related online content targeted at young gay, bisexual, and queer (GBQ) men in Singapore. Specifically, among Singaporean (citizen or PR), self-identified gay, bisexual, or queer men, aged 18 to 29 years old who are HIV-negative or do not know their HIV status. Should you not fall within these criteria of respondents, you may choose to stop your participation at this point.

The results of this study will contribute to the pool of research on the social and cultural aspects of physical and psychological health and well-being among gay, bisexual, and queer men in Singapore, and may be shared with organizations or policy makers to positively impact and/or inform policies or interventions that affect gay or bisexual men.

For purposes of administration and follow-up, our non-governmental organization (NGO) partner, Action for AIDS Singapore (AFA) will collect and have access to your contact details based on your chosen preferred mode of communication upon enrollment in this study. No member of the research team will have direct access to your personal identifiers.

While the staff at AFA will assist the research team in managing the trial and its participants, no member of the AFA team will have access to your survey responses, which will be collected by the research team instead. This is done so that your responses will never be directly linked to your personal identifiers. Upon your agreement to participate in this study, you will be assigned a participant ID, which will be used for all future correspondences between AFA and the research team.

This research study has been approved by the National University of Singapore Institutional Review Board with respect to the treatment of individuals participating in this research.

Purpose of this research study
The study aims to follow participants across six (6) months to find out more about the changes in their health behaviours in response to receiving health-related online content at the start of the study period. Specifically, we will be evaluating the efficacy sexual health interventions that are tailored for gay, bisexual, and queer men in the Singaporean context.

Procedures
Recruitment
We estimate that we will require a total of 300 participants for the study. Study participants will be enrolled in the trial through direct (advertising through online portals) and indirect (through venue or NGO partners) recruitment. Participants will be followed-up on for a period of six (6) months from the point of their baseline survey, which includes a 1-week evaluation period from the start of the trial, and a survey at the 3-month and 6-month mark, from the start of your participation in the trial.

Enrolment into study and verification of eligibility
Participants follow the recruitment link provided on the online advertisement or physical flyer to a Surveymonkey (independent survey software service provider) site where they will be asked for their contact details and some basic demographic information to register their intent to join the cohort and for verification of eligibility by the NGO partner, AFA. Only AFA will have access to your contact information. This is a deliberate attempt to delink your behavioral survey responses from any personal identifiers.

Baseline survey
Thereafter, a staff member at AFA will contact eligible participants to provide them with their participant ID, and to formally invite them to participate in the trial through the completion of the first online baseline survey. This survey will be hosted on an online survey administration software (e.g. Surveymonkey) and will take about 15 to 20 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of the $15.00 reimbursement to participants.

Randomization and assignment of treatment
The online content that we hope to evaluate for this study includes an online sexual health e-pamphlet and a series of sexual health videos. All participants will have access to both components by the end of the trial.

Upon agreement to join us in our trial, a computer will then randomize and allocate each person into one of two possible groups, like the flip of a coin. Neither the researcher nor the participant can decide which treatment the participant receives.

As mentioned above, you will be randomly assigned into one of two possible groups. The only difference between either group would be your access to the series of sexual health videos.

Regardless of your assigned group, you will be required to complete the videos and/or read through the e-pamphlet within 1 week following the completion of your baseline survey. A link will be provided 1 week after you have been given the interventions that will lead you to a survey page with a few questions to evaluate your understanding of the interventions' content.

A staff member at AFA will contact you upon successful completion of the baseline survey to provide you with a link to the assigned intervention. The same staff member will contact you again 1 week after that to provide you with the proof of completion survey. This quiz should take no longer than 5 to 10 minutes to complete.

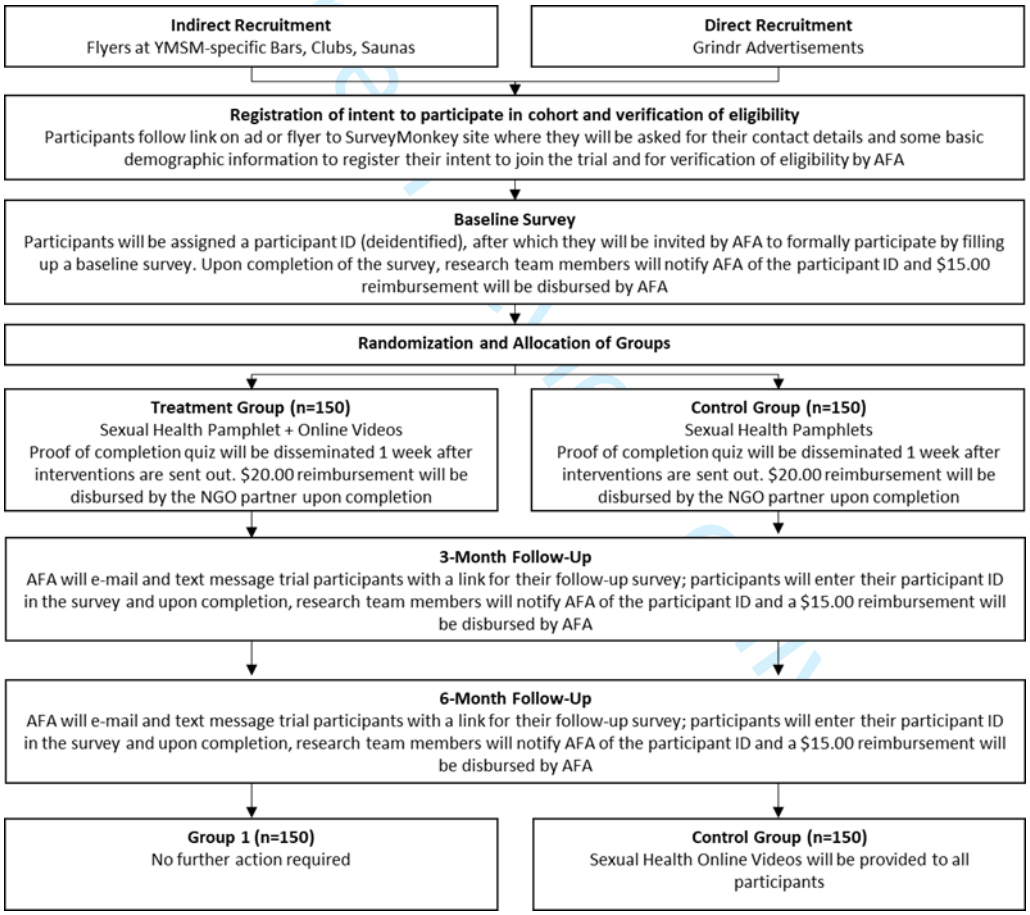
Follow-up surveys

At the 3-month and 6-month marks from participation, a staff member at AFA will contact all eligible participants to continue with their follow-up surveys. Like the baseline survey, the 2nd and 3rd surveys will be hosted on an online survey administration software (e.g. Surveymonkey) and will take about 10 to 15 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of the $15.00 reimbursement to participants, for both the 2nd and 3rd follow-up surveys.

Administration of survey and follow-up procedures

All participants will only ever be in contact with the study team's NGO partner, AFA, to protect the anonymity of all participants. The study team will not have access to any of the contact details provided at any point and only the NGO partner will contact participants to fill up the survey online. A participant ID will be issued to participants so that both the research team and NGO partners may refer to the same deidentified number for purposes of administration.

A summary of all study-related procedures may be found in the flow chart below:



Possible risks or benefits

The potential risks of taking part in the surveys are minimal. Some questions may reveal criminal activity on the part of participants due to the Misuse of Drugs Act and Section 377A of the Penal Code, but risks are mitigated as the research team will do its best to ensure that personal identifiers will not be directly linked to survey responses. Some questions could make participants feel uncomfortable, but any participants may choose to skip any question or drop out of the study without any penalty at any point in time.

The data collected will be relevant for public health practitioners, program managers, and policy makers in the field of HIV prevention, specifically in decision making and evidence-based policy making processes.

Compensation
Participants will receive reimbursement for their participation and successful completion of each of the three surveys that will be administered at the baseline ($15.00), 3-month ($15.00), and 6-month ($15.00) mark of the study. Participants will also receive reimbursement ($20.00) upon successful completion of the assigned modules.

Right of refusal to participate and withdrawal
Your decision whether or not to participate is completely voluntary and will not affect your current or future relations with any institution. If you decide to participate, you are free to withdraw at any point by informing the NGO partner and all your data will be discarded.

Confidentiality
Responses will be confidential, as data will only be published or shared with collaborators (e.g. community and NGO partners) in its aggregated form, and not as individual responses that may risk the identification of participants. Data will be kept password-locked in Qualtrics, or in a password-locked dataset or spreadsheet at all times. As the survey is solely disseminated through our community and NGO partners' existing contact lists, the researchers have no direct access to respondents of this survey. Only the principal investigator and the thesis supervisor will have access to the eventual dataset. Upon completion of the research study, the NGO partner will destroy all documents containing personal data of the participants to further protect their identities.

Contact Details
In the interest of your anonymity and confidentiality for your participation in this study, you may contact Action for AIDS at (+65) 6254 0212, should you have any questions or require any clarification about the study procedures, how the results will be utilized for research, and for more information on the findings of the study, if available.

If you have been enrolled in the study but had forgotten your assigned Participant ID, please get in touch with the staff member that contacted you during enrolment to request for your Participant ID. Alternatively, you may contact Action for AIDS at (+65) 6254 0212 and request to speak to the Pink Carpet Y cohort manager.

Should you wish to contact the research team, you may approach the principal investigator (Tan Kay Jin Rayner), by phone at (65) 9187 8576 or by e-mail (Rayner.tan@u.nus.edu).

For an independent opinion regarding the research and the rights of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board (Attn: Dr Chan Tuck Wai, at telephone (+65) 6516 1234 or email at irb@nus.edu.sg).

Participant's Declaration

I understand that participation is voluntary. Refusal to participate will involve no penalty. I may discontinue participation at any time without penalty or loss of accrued benefits (benefits are accrued in proportion to the amount of study completed or as otherwise stated by the researcher) to which I am otherwise entitled. I declare that I am at least 18 years of age. If I am affiliated with the National University of Singapore, my decision to participate, decline, or withdraw from participation will have no effect on my status at or future relations with the National University of Singapore. I have read and fully understood the contents of this form, and hereby give consent to the National University of Singapore to collect, use and disclose and/or process my responses for the purpose(s) described in this form.

By clicking the "Continue/Next" button, I consent to participate in this study and agree to all of the above.

If you do not wish to participate in the survey, you may close the browser now to exit.

[Next Button]

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N.A.
Protocol version	3	Date and version identifier	N.A.
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 17
	5b	Name and contact information for the trial sponsor	N.A.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N.A.

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	5-6
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N.A.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N.A.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N.A.
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-11, 22

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9, 16
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N.A.
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15-16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N.A.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N.A.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N.A.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N.A.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N.A.
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16-17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9, 16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N.A.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N.A.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16-17
	31b	Authorship eligibility guidelines and any intended use of professional writers	N.A.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16-17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N.A.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N.A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial in Singapore – the People Like Us (PLU) Evaluation Study

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Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trialin Singapore – the People Like Us (PLU) Evaluation Study

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Effect of a web drama video series on HIV and other sexually transmitted infection testing among gay, bisexual and queer men: study protocol for a community-based, pragmatic, randomised controlled trial in Singapore– the People Like Us (PLU) Evaluation Study

Abstract

Introduction: Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV and other sexually transmitted infections. While HIV/STI testing rates among GBQ men are increasing worldwide, they remain suboptimal in a variety of settings.

Methods and analysis: The study is a pragmatic, randomised controlled trial design to evaluate an online video series developed by a community-based organisation in Singapore for GBQ men. A total of 300 HIV-negative, GBQ men in Singapore aged 18 to 29 years old will be recruited for this study. Participants will subsequently be randomised into the intervention arm (n=150) and the control arm (n=150). The interventionarm (n=150) will be assigned the intervention along with sexual health information via a pamphlet, while the control group (n=150) will be assigned only the sexual health information via a pamphlet.Participants should also not have watched the video prior to their participation in this study, which will be ascertained through a questionnaire. Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, Chlamydia and Gonorrhoea at the 3-month and 6-month post-intervention. Secondary outcomes include changes in self-reported risk perception for HIV and other sexually transmitted infections, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections,knowledge of HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community,

self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms.

Ethics and dissemination: The study has been approved by the National University of Singapore Institutional Review Board (S-19-059) and registered at Clinicaltrials.gov (NCT04021953). The results will be published in peer-reviewed academic journals and disseminated to community-based organisations and policymakers.

Trial registration: Clinicaltrials.gov, NCT04021953

Article summary

Strengths and limitations of this study

- The first randomised controlled trial to evaluate the efficacy of a popular web-based drama series on HIV/STI testing for young gay, bisexual and queer men in Singapore
- A collaboration with a community-based organisation in Singapore with strong public health translation potential
- Only self-reported data on HIV and other STI diagnoses are collected which cannot be validated through laboratory-confirmed tests
- While steps have been taken to mitigate contamination, the risks nonetheless exist as the intervention material is available to the public
- Sex between men is criminalised in Singapore which may impact participation among sub-populations of the target population

Introduction

A total of 37.9 million people around the world were estimated to be living with HIV at the end of 2018 [1]. Gay, bisexual and queer (GBQ) men are at disproportionately higher risk of acquiring HIV, relative to the general population [2, 3]. Young GBQ men are a subset of the broader GBQ male community who are especially vulnerable to HIV and other sexually transmitted infections (STI) acquisition. In Singapore, GBQ men between the age of 15 to 39 years old account for 66.3% of all incident HIV cases among GBQ men from the first reported case of HIV in 1986, up to 2018 [4].

Rates of HIV testing have also remained suboptimal among GBQ men in a variety of settings, including Southeast Asia. A study among young GBQ men in the Association of Southeast Asian Nations countries in 2015 found that 29.9% of participants had never had an HIV test, and these were more likely to be among younger GBQ men [5]. Unwillingness to know about their HIV status, the fear of a positive result, and low perceived risk of HIV acquisition were factors found to be associated with lower rates of HIV testing among young GBQ men [6, 7].

As such, there exist numerous types of interventions that aim to increase HIV testing among GBQ men. These interventions range from those that utiliseaspects of peer education, outreach through social media, reminder-based systems, video-based interventions and national social marketing campaigns. These social marketing campaigns were commonly promoted in neighbourhoods where a larger population of GBQ men resided and had substantial number of businesses catering to them [8-12]. For reminder-based interventions, participants were recruited from sexual health clinics that they were, at the point of recruitment, attending, either for check-ups or testing [13-15]. With regards to the other online interventions such as outreach through social media and peer education, participants

were recruited through key websites and mobile phone apps identified to be frequented by GBQ men [16-22].

These interventions reported varying degrees of effectiveness in achieving the aims of increasing HIV testing and overall disease awareness. Reminder-based interventions, where participants were reminded every three to six months to go for testing through short message reminders sent from designated sexual health clinics, were customised to suit the participants' level of sexual activity and were effective in promoting the uptake of HIVtesting[13-15]. Broader scale HIV/STIsocial marketing campaigns, such as "Stop the Sores" and "Stop the Drama Downunder" from the United States and Australia respectively, were generally well-received and were found to be effective inpromotingHIV/STI testing, as well as participants' knowledge on HIV/STI at the population or community level[9, 11]. Interventions that collaborated with popular opinion leaders to disseminate HIV prevention messages to GBQ male social networks have also shown success in encouraging desired HIV preventive behaviours [19, 20]. However, for existing video-based interventions, evidence of their efficacies was not conclusive. In a video-based intervention study conducted in Peru between 2007 to 2008, among participants who self-identified as gay, differences in intention to test for HIV was not statistically significant between the intervention and control arm, although participants who identified as non-gay did show increased willingness to do so [22]. Several studies also assessed the efficacy of crowdsourced videos on HIV testing, and largely found that they were non-inferior to regular health marketing campaigns[18], or only had a positive effect on HIV testing rates through the use of home-based self-testing kits, but not facility-based HIV/STI testing [23].

There are, however, several limitations in the context of reach and feasibility for such interventions. For example, reminder-based and peer education-based interventions require existing health systems that can support such interventions, which may not be feasible is most

settings that do not have such services, or where GBQ male-specific clinical services are unavailable due to the criminalisation of sex between men. As such, these interventions mayfall short of reaching out to more niche subsets of the GBQ male communities who may be more discreet about their sexual identities and hence may not often visit gay venues or sexual health clinics where these interventions are typically offered[24].Furthermore, while social marketing campaigns have been effective in increasing the uptake of HIV/STI testing, such campaigns may not be feasible in settings such as Asia where negative perceptions of, or attitudes toward GBQ men prevail [5]. There have been, however, successes for the impact of social marketing campaigns on HIV/STI testing in the region such as the 'I Test, Do You?' campaign in Vietnam, and the 'TestXXX' campaigns across the capitals of Thailand, Vietnam, The Philippines, and Indonesia [25, 26].

The present study is novel in Asia in evaluating the effectiveness of a web drama series in achieving positive HIV/STI testing-related outcomes for young GBQ men. The videos used in the study forms the second season of an educational and web drama miniseries, People Like Us (PLU), developed by gayhealth.sg and Action for AIDS (AFA) in 2018 (https://www.gayhealth.sg/plu/). The first season of the miniseries was screened as a total of 10 film festivals, and won several independent film awards. It had also garnered more than 1.7 million views across various social media platforms since its launch in 2016. In spite of its popularity, little has been done to assess its efficacy in positively impacting HIV/STI testing-related outcomes. If found to be efficacious in improving HIV/STI testing-related outcomes, such web dramas may serve as complementary interventions, alongside clinically-based ones, as such web drama series have proven to be easily accessible and shareable, which may facilitate reaching GBQ men who might not have access healthcare services as a result of key structural barriers, such as stigma.

Methods and analysis

Study aims and design

This is a pragmatic, parallel group, randomised controlled trial to evaluate the efficacy of a web drama series, developed by a community-based organisation in Singapore, in increasing an individual's intention to test, self-reported testing behaviors, and self-reported regularity of testing behaviors for HIV, Syphilis, as well as other common sexually transmitted infection [27] such as Gonorrhoea and Chlamydia. The trial also aims to evaluate the impact of the web drama series on self-reported risk perception for HIV/STI, knowledge of HIV, risks associated with acquiring sexually transmitted infections and HIV pre-exposure prophylaxis, consistent condom use for anal sex with casual partners, incidence of sexually transmitted infections, connectedness to the lesbian, gay, bisexual and transgender (LGBT) community, self-concealment of sexual orientation, perceived homophobia, internalised homophobia, HIV testing self-efficacy and HIV testing social norms. The pragmatic nature of this trial arises due to the prospect of contamination, as the web drama series had been launched in January 2019. The implications of this are further discussed later in the manuscript.

Study setting

As of end-2018, a total of 8,295 Singaporeans had been reported to the Ministry of Health (MOH) in Singapore as having acquired HIV[28]. HIV transmission in Singapore is concentrated among key populations, namely among GBQ men and heterosexual men. With regard to HIV testing uptake, about 71.7% of Singapore residents living with HIV are estimated to know their HIV status as of end-2014 [29]. While GBQ men are more likely than their heterosexual counterparts to be diagnosed through voluntary screening, only 20.0% of incident cases among GBQ men were detected through such means for incident HIV cases

reported in the year 2018, compared to 9% among heterosexual individuals. Community-based organizations have actively and regularly promoted HIV and other STI testing in venues frequented by GBQ men and older heterosexual men in Singapore since the beginning of the HIV epidemic [30], there are to our knowledge no available published studies that evaluate the efficacy of these interventions on individual or community-level testing.

HIV testing is widely available at both government-run and private healthcare providers in Singapore, and under the Infectious Disease Act in Singapore, all individuals who test positive for HIV must be notified to the MOH within 72 hours of diagnosis. The anonymous HIV testing scheme was introduced in 1991; under this scheme, no personal information or identifiers are collected during HIV testing at selected clinics to encourage testing among individuals who might otherwise be hesitant of having their identities made known to the authorities.HIV testing is thus only available through facility-based testing, without any options for self-testing or home-based testing as of end-2019.

Singapore society has largely held negative attitudes towards GBQ men and individuals who identify as lesbian, gay, bisexual, and transgender (LGBT) [31-33]. Legally, sexual relations between consenting male individuals is also criminalised under Section 377A of the Singapore penal code, with a penalty of imprisonment for up to two years. A recent study found that Singaporeans were also not in favor of its repeal [34]. Past studies in Singapore have found that the anticipation of such forms of sexual orientation-based stigma as well as structural forms of stigma and discriminationhave a negative impact, while the availability of prompts or peer influence, and accessibility of services were found to have a positive impact on HIV/STI testing among GBQ men[24, 35, 36]. This intervention, with its focus on promoting knowledge of available HIV/STI prevention services in Singapore, modelling HIV/STI prevention-related and other health-seeking behaviors, and normalizing

GBQ male relationships in Singapore, is thus hypothesized to address some of these barriers to the uptake of HIV/STI testing.

Inclusion and exclusion criteria

Inclusion criteria for participants in this study include self-reporting at the point of recruitment (i) an HIV-negative status, or being unsure of one's HIV status; (ii) being gay, bisexual or queer with regard to sexual orientation; (iii) being of male gender, regardless of sex assigned at birth; (iv) being 18 to 29 years old; (v) being a Singapore citizen or permanent resident; (vi) and having never watched an online video drama series by Gayhealth.sg or AFA in the last year.

Exclusion criteria for participants in this study include self-reporting at the point of recruitment (i) having ever watched an online video drama series by Gayhealth.sg or AFA in the last year; (ii) an HIV-positive status; (iii) not being English-literate; and (iv) being below 18 or above 29 years old.

Procedure and randomisation

<Figure 1 about here>

A summary of study procedures may be found in Figure 1. Recruitment of participants will take place through the assistance of community-based organisations in Singapore, as well as through advertising channels in popular social and sexual networking apps among young GBQ men. Flyers will be printed and places at the premises run by community-based organisations, while social media campaigns will be run on social media and geosocial networking platforms to recruit participants. To enrol in the study, participant

will have to scan a QR code or follow the direct link on the flyer, or click a link on the online advertisement to access a study enrolment questionnaire. Participants will provide consent for participation through an online participant information sheet at this point(See Supplementary File).

Participants will follow the link on the online advertisement or flyer to a survey administration website for a short screening survey where they will be asked for their contact details as well as theirself-reported age, sexual orientation, gender, HIV status, and residence status to register their intent to join the cohort and for verification of eligibility by the community-based organisational partner, AFA.Participants will also be asked if they had ever watched a web drama series by Gayhealth.sg or AFA launched in the past year without naming the actual series to avoid further contamination. Should the participant be ineligible to participate, they will be redirected to a disqualification page. Throughout the entire survey process, personal identifiers will never be directly linked to survey results, so as to protect participants from potential criminal implications of disclosing their sexual activities with other men and other behaviors such as substance use.

Upon completion of the enrolment survey and verification of eligibility, a staff member at AFA will contact eligible participants to provide them with their participant ID, and to formally invite them to participate in the study through the completion of the first online baseline survey. This survey will be hosted on a survey administration website and will take about 15 to 20 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of a SGD15.00 (~USD10.84) reimbursement to participants. AFA will not have access to any baseline or follow-up survey responses for the cohort questionnaire, which will only be made available to the study team.

Upon completion of the baseline survey, participants will then be randomly assigned in blocks of six in a 1:1 ratio to the intervention condition or the control comparison condition using a web-based randomization platform(http://www.sealedenvelope.com) to ensure even allocation. Individuals who are assigned to the intervention condition will be given a link to a series of six online videos from the PLU web drama series, along with a link to an online sexual health pamphlet tailored for GBQ men in Singapore. Individuals who were assigned to the control condition will be scheduled to receive a link to the same online sexual health pamphlet as the standard of care for GBQ men at risk of acquiring HIV/STI in Singapore.To ensure that all participants eventually receive both interventions, after the 6-month follow-up period is over, the control group will receive the link to the online videos as well. All participants will receive their assigned conditions within one week after completing the baseline survey, and will be asked to complete a quiz one week after assignment to ascertainment if participants had watched the online series and/or read the sexual health pamphlet. Participants will receive a SGD20.00 (~USD14.45) reimbursement following the completion of the quiz.

Participants will not be blinded to the group they have been assigned to, and will be told about their chances of being randomised to either group. However, participants will not have access to the content that would only be delivered at the 6-month mark. The decision to provide both groups similar materials at different times ensures that the trial remains ethical, considering we anticipate improvements in sexual health-seeking behavior, and ensures that participants remain motivated to participate, knowing that they would receive similar treatments in spite of randomisation.At the 3-month and 6-month timeframes from the baseline, AFA will contact all eligible participants to continue with their follow-up surveys. Like the baseline survey, the second and third surveys will be hosted on asurvey

administration website and will take about 15 to 20 minutes to complete. Participants will receive SGD15.00 (~USD10.84) reimbursement for the completion of each survey.

The intervention: People Like Us web drama series

The online intervention comprises a series of six videos, each about 10-minutes in length, constituting the second season of a popularweb drama series entitled People Like Us.The series follow the love and sex lives of four ethnically-diverse GBQ men of varying socioeconomic backgrounds, as they negotiate issues of sexual health, mental health, and relationships throughout the six-part miniseries.People Like Us miniseries incorporates key sexual health messages to(i) increase viewers' knowledge and perceptions of HIV/STI risk; (ii) address homophobia and sexual orientation disclosure; (iii) increase safer-sex negotiation self-efficacy; (iv) promote positive attitudes towards condom use and other safe sex behaviors; (v) build skills and self-efficacy for practicing safer sex; (vi) provide information on HIV/STI testing and its benefits; (vii) provide information on resources for HIV/STI testing and other mental health services; and (viii) model appropriate behaviors around practicing safer sex.Each video in the six-part series ends with an educational video segment featuring the managers and volunteers of AFA and Gayhealth.sg, who provide a brief synopsis of the episode and cover key points relevant to mental and sexual health for GBQ men. A list of episodes may also be found in Table 1.

The control condition: Sexual health pamphlet

The intervention group will also be provided with an online sexual health pamphlettailored specifically to the needs of GBQ men in Singapore. This pamphletwas developed by the National Skin Centre and Department of Sexually Transmitted Infections Clinic specifically for information on sexual wellness among GBQ men. It comprises

segments on HIV/STI symptoms, aetiology, information on how to seek help for HIV/STI, as well as behavioral and biomedical methods of HIV prevention.

Primary outcome measures

Primary outcomes for this evaluation are changes in self-reported intention to test for, actual testing for, and regularity of testing for HIV, Syphilis, as well as Chlamydia and Gonorrhoea at the 3-month and 6-month time frames. For example, participants will be asked "how likely are you to get tested for HIV in the next three months?", to which they respond through a 6-point Likert scale from "extremely unlikely to get tested" to "extremely likely to get tested". Self-reported testing is ascertained through the question "when did you go for you last (most recent) voluntary HIV test?" (options to respond include "never", "in the last 3 months", "in the last 6 months", "6 to 12 months ago" and "more than 1 year ago"), while self-reported regularity of testing will be measured through the question "on average, how regularly do you test for HIV?" (options to respond include "I do not test regularly", "once every few years", "once a year", "once every 6 months", "once every 3 months" and "once a month")

Secondary outcome measures

Secondary outcomes include changes in self-reported risk perception for HIV/STI, knowledge of HIV, knowledge of risks associated with acquiring sexually transmitted infections,knowledge of HIV pre-exposure prophylaxis, self-reported consistent condom use for anal sex with casual partners,self-reported incidence of sexually transmitted infections, and other scales validated among GBQ men in other settings such as connectedness to the lesbian, gay, bisexual and transgender (LGBT) community[37], self-concealment of sexual

orientation[38], perceived homophobia[39], internalised homophobia[40], HIV testing self-efficacy [41] and HIV testing social norms [42].

Sample size

As the primary outcome of interest includes HIV or other STI testing in the last 3 months, we utilise data from a recent study conducted in 2018 among 1,098 GBQ men recruited through Grindr, the popular geosocial networking app [24, 43]. The study found that 50.4% of respondents reported having had a recent HIV test in the 6 months prior to the survey. Assuming a 50% increase in recent HIV testing as a result of the intervention, as data from previous studies based on the impact such a web drama series on recent HIV testing remainslimited[44], a sample size of 112 in each arm will yield statistical power higher than 80% to detect a significant change for the intervention, based on calculations generated by a web-based software (http://www.clincalc.com). A target sample size of 150 participants per group is proposed to account for an attrition estimate of 25% for each group across the 6-month follow up. Intention to Treat Analysis (ITT) will be employed to assess intervention efficacy on the proposed outcomes. Per-protocol analysis will also be conducted to assess the impact of attrition. Intervention efficacy will be analyzed over the entire study period (from baseline to the 6-month assessment).

Statistical analyses

The baseline equivalence of sociodemographic characteristics and sexual behavior in the intervention and comparison groups will be compared and statistically significant variables between the comparison and intervention group would be adjusted in the outcome evaluation along with the outcome at baseline. For continuous variables, a generalised linear mixed model will be employed. The mixed models will include intervention status and the

time-point of assessment as fixed effects, and individuals as a random effect. Between-group effect sizes for the continuous outcome variables will be calculated using post-treatment means and their pooled observed standard deviation. Logistic and Poisson regression models will be employed for binary and count outcome data, respectively. Statistical significance will be set at $p<0.05$ without any adjustment across the multiple, unique primary outcomes. Statistical analyses will be conducted using the statistical software STATA version 15 (Stata Corp, College Station, TX, USA).

Pragmatic nature of trial

The PLU web drama series was launched in the community prior to the start of this study, and thus members of the community might have been exposed to the intervention prior to the study. However, this study was designated to continue in view of its importance in the local context to evaluate the efficacy of such web drama series, and to justify further HIV/STI prevention efforts that utilise online channels. As such, there is a possibility that control group participants may be exposed to the video series during the 6-month study period. To mitigate this, we will ensure that details of the online video intervention (i.e. title of web series, where to access it) will not be included in the participant information sheet – only basic information on the possibility that they may be randomised to an "online video intervention" will be mentioned. Furthermore, to reduce the possibility of contamination occurring in reaction to being asked the screening question, we will avoid using the title of the web-series but instead ask the question: "Have you ever watched an online video drama series filmed by Gayhealth.sg or Action for AIDS Singapore in the past year?" as this is Gayhealth.sg/AFA's only web series launched in the past year. While the generic nature of the question may result in under-reporting of viewing the video series, all participants will eventually be able to view the video series and report if they had viewed any of the episodes

prior to, or during the study period. Specifically,participants in the treatment group will be asked if they had previously watched any of the episodes when they submit the intervention completion survey one week after the completion of their baseline survey, while the control group will receive a link to all six episodes of the video intervention alongside their final survey at the 6-month mark, and will be asked specifically which episodes that they have watched prior to, or during the intervention period.Intention-to-treat analyses will be conducted to provide a conservative estimate of the effect of the intervention, regardless of contamination.

A contamination adjusted intention-to-treat (CAITT) analysis may also be performed [45]. The authors argue that "as-treated" and "per-protocol" analyses result in non-random omission bias, while "intention-to-treat" analyses underestimate the value of receiving the treatment. In CAITT, the randomised controlled trial is treated as an instrumental variable, with treatment assignment as the "instrument." The effect of treatment assignment on outcome observed (intention to treat analysis) is adjusted by the percentage of assigned participants who ultimately receive the treatment (contamination adjustment). The authors argue that this provides a good estimate of an individual's risks and benefits of receiving a treatment, but might overestimate population level treatment benefits.

At this point, the study team will rely on self-reported outcomes such as testing behaviors and HIV/STI diagnoses as it is presently not possible to link clinic attendance, or laboratory-confirmed diagnostic tests for HIV and other STI to individual participants. These issues have arisen due to ethical concerns around linking participants' personal information to survey results, which collects information on criminalized behavior such as sexual intercourse with other men, among participants in the sample. However, the findings of this proposed study will serve as a proof-of-concept for future studies that may be able to obtain

funding and state support for other means of testing, such as the use of self-testing kits for HIV and other STI.

Patient and Public Involvement

The research protocol and grant application for this evaluation study was developed in collaboration with AFA, and its GBQ health programme, Gayhealth.sg. Both AFA and Gayhealth.sg represent the health interests of the wider GBQ male community and were instrumental in the design and development of the study protocol. The intervention was developed by Gayhealth.sg and Action for AIDS Singapore in 2018 following a community needs assessment exercise that identified the pertinent sexual and mental health issues in the local GBQ male community. Results of the study will be disseminated to participants and the wider GBQ male community through both scientific seminars and community-based symposia, as well as through written, open-access reports.

Ethics and dissemination

Ethics and mitigating potential risks

Ethical approval for this study was granted by the National University of Singapore Institutional Review Board (Reference Number S-19-059). Ethical issues may arise from the recruitment of participants engaging in illegal or criminal activities, such as the self-disclosure of having sex with other men, sex with minors, and the use of recreational drugs. To mitigate this risk, the main research team will not have access to any participant's personal identifiers, or access to any participants directly, which will be carried out by AFA. AFA will only collect participants' contact information to assist in following up on the surveys, and these will be stored in an encrypted database. On the other hand, staff at AFA will not have access to the survey data containing individual responses. All participants will

be assigned a study identification number and these will subsequently be used for communication purposes to ensure that no personal identifiers are reflected or stored beyond the encrypted database.

Dissemination and implications for health promotion and policy

Results of the study will be made available to the public to share the results of the study with the GBQ male community, and to inform policymakers. Specifically, results of the study will be communicated in writing through study reports and peer-reviewed journal articles, and through presentations made in the community, at scientific conferences, and at policy meetings. If found to be effective, such web drama series hold great promise to improve HIV/STI testing among GBQ men in Singapore, who are at disproportionate risk of acquiring HIV/STI relative to the general population. The organic growth and reach of the web drama series makes it a cost-effective means of improving such sexual health outcomes among GBQ men, and may serve as a model for other online interventions in Asia, and in contexts where sexual relations between men remain criminalised.

Trial status

Recruitment of participants started in September 2019, and the last participant is expected to reach the primary endpoint (6-month follow-up) in March 2020. Primary data analysis will begin in April 2020. The dissemination phase of the trial results will commence in May 2020.

(4388 words)

Author contributions: RKJT and WLK wrote the first draft of the protocol. DL, AvT, AdT, CT and SB developed the materials for the intervention condition and contributed to the

details of the intervention in the manuscript. MTC provided access to the standard of care condition. RKJT, CSW, MLW and MIC obtained funding for the research. All authors conceived the study and revised the manuscript for relevant scientific content in the final version of the manuscript.

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Competing interests: None declared.

Patient consent: Patient consent obtained.

Ethicsapproval: Ethics approval for the protocol was obtained from the National University of Singapore Institutional Review Board (Reference Number S-19-059).

Data availability statement: Results of this study will be published and disseminated in peer-reviewed journals, as detailed in the protocol above. Deidentified participant data and data dictionaries will not be publicly available due to restrictions by the ethics board over concerns of risk to participants. The datasets generated during and/or analysed for this study will be available from the corresponding author on reasonable request, following the completion of the study. Additional documents including the study protocol and statistical analysis plan will be publicly available through this manuscript and the trial registry, Clinicaltrials.gov (NCT04021953).

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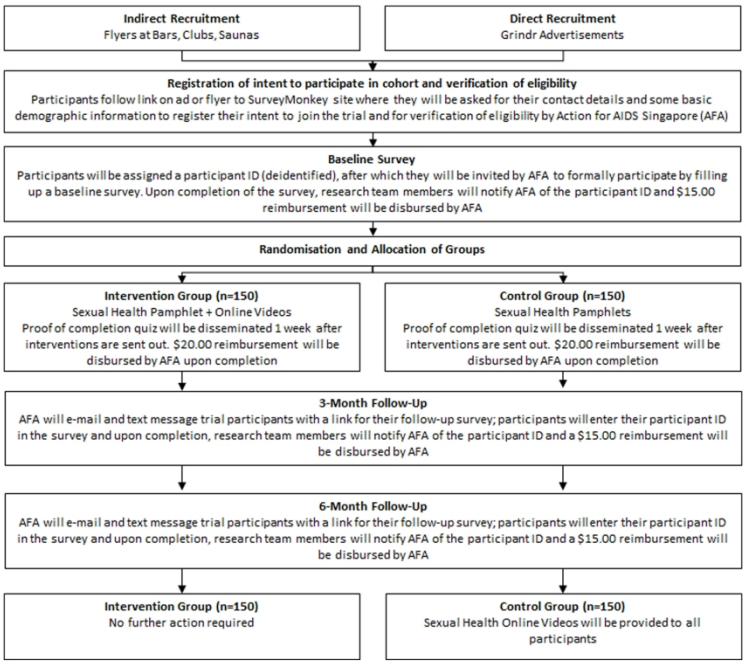
Episode	Title	Synopsis
1	Pretty in pink	At Pink Dot, Rai meets Haniff, someone from the same army camp, while Isaac hooks up with someone at his party. Meanwhile, after celebrating their month-sary, Joel introduces his Mom to Ridzwan.
2	Challenge accepted	As Rai heads out on a first date with Haniff, his Mom discovers a Pink Dot flyer. Joel asks Ridzwan to consider a challenging proposition. Meanwhile, Isaac is unable to concentrate at work and continues to experience pain while peeing.
3	Signs & omens	Rai's Mom confronts him about Pink Dot. Isaac is sexually frustrated and receives some disturbing news. Ridzwan seeks out a friend from the past for help while Rai bumps into Haniff, who treats him coldly.
4	Booty call	Rai's Mom and sister, Priya, discuss Rai's sexuality. Haniff surprisingly agrees to meet Rai again but reveals something that will change their relationship forever. Ridzwan accepts Joel's proposition but will it bring them closer?
5	Jeremy from work	Joel pays Ridzwan a surprise visit and meets Ridzwan's Mom. Rai meets Isaac for advice about Haniff. Back home, Rai's Mom attempts to reconnect with Rai.
6	A love like ours	Rai and Haniff book out of army camp together; their desires palpable, and Isaac's party friends desert him. Meanwhile, Joel's frustration with Ridzwan's secrecy reaches a breaking point.

Table 1. List of episodes and synopses of the People Like Us web drama series season two



Flowchart for study procedures and randomisation

209x297mm (300 x 300 DPI)

EVALUATION OF eHEALTH VIDEOS FOR THE SINGAPOREAN GAY, BISEXUAL, AND QUEER MALE COMMUNITY

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Dr. Wong Chen Seong
Consultant, Division of Infectious Diseases
National Center for Infectious Diseases

Institute: Saw Swee Hock School of Public Health
National University of Singapore

You are receiving this invitation to participate in this study as a user or patron of the services rendered by our community partners. Your participation is entirely voluntary, and you may withdraw from this study at any point without any penalty.

This study is interested in finding out more about the effectiveness of health-related online content targeted at young gay, bisexual, and queer (GBQ) men in Singapore. Specifically, among Singaporean (citizen or PR), self-identified gay, bisexual, or queer men, aged 18 to 29 years old who are HIV-negative or do not know their HIV status. Should you not fall within these criteria of respondents, you may choose to stop your participation at this point.

The results of this study will contribute to the pool of research on the social and cultural aspects of physical and psychological health and well-being among gay, bisexual, and queer men in Singapore, and may be shared with organizations or policy makers to positively impact and/or inform policies or interventions that affect gay or bisexual men.

For purposes of administration and follow-up, our non-governmental organization (NGO) partner, Action for AIDS Singapore (AFA) will collect and have access to your contact details based on your chosen preferred mode of communication upon enrollment in this study. No member of the research team will have direct access to your personal identifiers.

While the staff at AFA will assist the research team in managing the trial and its participants, no member of the AFA team will have access to your survey responses, which will be collected by the research team instead. This is done so that your responses will never be directly linked to your personal identifiers. Upon your agreement to participate in this study, you will be assigned a participant ID, which will be used for all future correspondences between AFA and the research team.

This research study has been approved by the National University of Singapore Institutional Review Board with respect to the treatment of individuals participating in this research.

Purpose of this research study
The study aims to follow participants across six (6) months to find out more about the changes in their health behaviours in response to receiving health-related online content at the start of the study period. Specifically, we will be evaluating the efficacy sexual health interventions that are tailored for gay, bisexual, and queer men in the Singaporean context.

Procedures
Recruitment
We estimate that we will require a total of 300 participants for the study. Study participants will be enrolled in the trial through direct (advertising through online portals) and indirect (through venue or NGO partners) recruitment. Participants will be followed-up on for a period of six (6) months from the point of their baseline survey, which includes a 1-week evaluation period from the start of the trial, and a survey at the 3-month and 6-month mark, from the start of your participation in the trial.

Enrolment into study and verification of eligibility
Participants follow the recruitment link provided on the online advertisement or physical flyer to a Surveymonkey (independent survey software service provider) site where they will be asked for their contact details and some basic demographic information to register their intent to join the cohort and for verification of eligibility by the NGO partner, AFA. Only AFA will have access to your contact information. This is a deliberate attempt to delink your behavioral survey responses from any personal identifiers.

Baseline survey
Thereafter, a staff member at AFA will contact eligible participants to provide them with their participant ID, and to formally invite them to participate in the trial through the completion of the first online baseline survey. This survey will be hosted on an online survey administration software (e.g. Surveymonkey) and will take about 15 to 20 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of the $15.00 reimbursement to participants.

Randomization and assignment of treatment
The online content that we hope to evaluate for this study includes an online sexual health e-pamphlet and a series of sexual health videos. All participants will have access to both components by the end of the trial.

Upon agreement to join us in our trial, a computer will then randomize and allocate each person into one of two possible groups, like the flip of a coin. Neither the researcher nor the participant can decide which treatment the participant receives.

As mentioned above, you will be randomly assigned into one of two possible groups. The only difference between either group would be your access to the series of sexual health videos.

Regardless of your assigned group, you will be required to complete the videos and/or read through the e-pamphlet within 1 week following the completion of your baseline survey. A link will be provided 1 week after you have been given the interventions that will lead you to a survey page with a few questions to evaluate your understanding of the interventions' content.

A staff member at AFA will contact you upon successful completion of the baseline survey to provide you with a link to the assigned intervention. The same staff member will contact you again 1 week after that to provide you with the proof of completion survey. This quiz should take no longer than 5 to 10 minutes to complete.

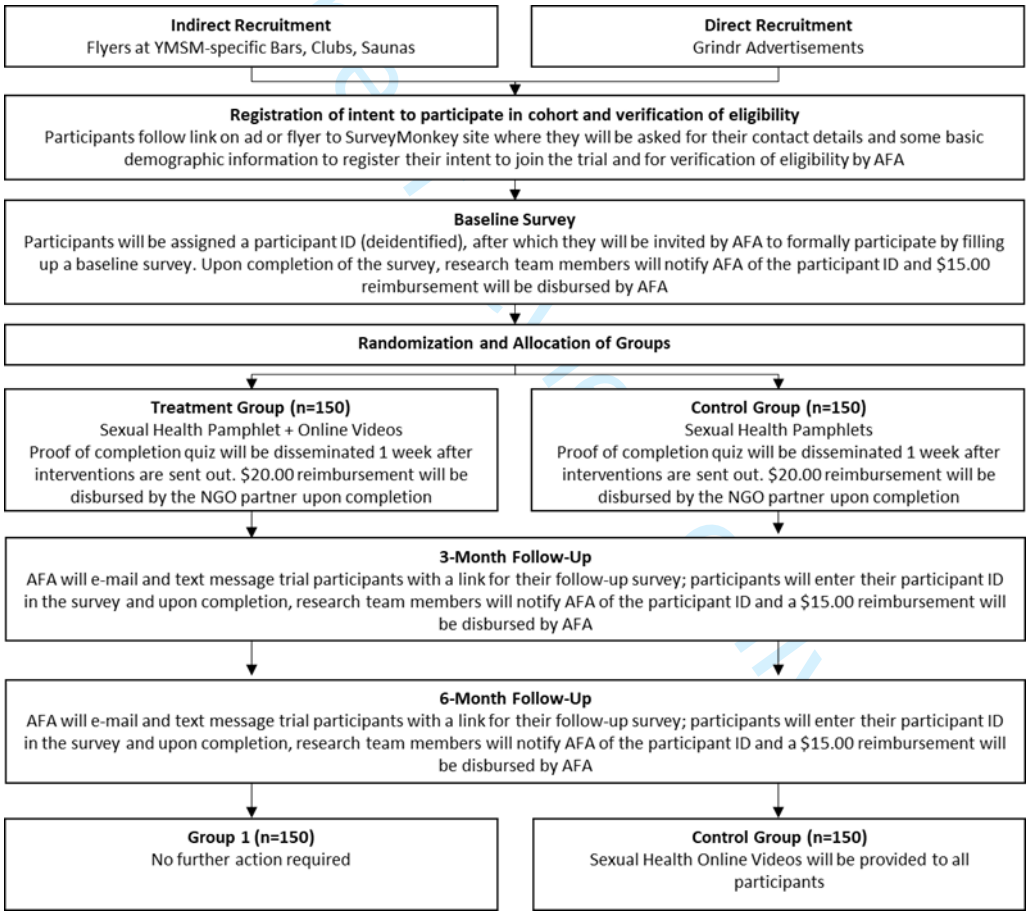
Follow-up surveys

At the 3-month and 6-month marks from participation, a staff member at AFA will contact all eligible participants to continue with their follow-up surveys. Like the baseline survey, the 2nd and 3rd surveys will be hosted on an online survey administration software (e.g. Surveymonkey) and will take about 10 to 15 minutes to complete. Participants will be prompted to enter their participant ID at the start of the survey so that upon completion, the research team will be able to notify the team at AFA on the completion of the survey, which will allow for direct disbursement of the $15.00 reimbursement to participants, for both the 2nd and 3rd follow-up surveys.

Administration of survey and follow-up procedures

All participants will only ever be in contact with the study team's NGO partner, AFA, to protect the anonymity of all participants. The study team will not have access to any of the contact details provided at any point and only the NGO partner will contact participants to fill up the survey online. A participant ID will be issued to participants so that both the research team and NGO partners may refer to the same deidentified number for purposes of administration.

A summary of all study-related procedures may be found in the flow chart below:



Possible risks or benefits

The potential risks of taking part in the surveys are minimal. Some questions may reveal criminal activity on the part of participants due to the Misuse of Drugs Act and Section 377A of the Penal Code, but risks are mitigated as the research team will do its best to ensure that personal identifiers will not be directly linked to survey responses. Some questions could make participants feel uncomfortable, but any participants may choose to skip any question or drop out of the study without any penalty at any point in time.

The data collected will be relevant for public health practitioners, program managers, and policy makers in the field of HIV prevention, specifically in decision making and evidence-based policy making processes.

Compensation
Participants will receive reimbursement for their participation and successful completion of each of the three surveys that will be administered at the baseline ($15.00), 3-month ($15.00), and 6-month ($15.00) mark of the study. Participants will also receive reimbursement ($20.00) upon successful completion of the assigned modules.

Right of refusal to participate and withdrawal
Your decision whether or not to participate is completely voluntary and will not affect your current or future relations with any institution. If you decide to participate, you are free to withdraw at any point by informing the NGO partner and all your data will be discarded.

Confidentiality
Responses will be confidential, as data will only be published or shared with collaborators (e.g. community and NGO partners) in its aggregated form, and not as individual responses that may risk the identification of participants. Data will be kept password-locked in Qualtrics, or in a password-locked dataset or spreadsheet at all times. As the survey is solely disseminated through our community and NGO partners' existing contact lists, the researchers have no direct access to respondents of this survey. Only the principal investigator and the thesis supervisor will have access to the eventual dataset. Upon completion of the research study, the NGO partner will destroy all documents containing personal data of the participants to further protect their identities.

Contact Details
In the interest of your anonymity and confidentiality for your participation in this study, you may contact Action for AIDS at (+65) 6254 0212, should you have any questions or require any clarification about the study procedures, how the results will be utilized for research, and for more information on the findings of the study, if available.

If you have been enrolled in the study but had forgotten your assigned Participant ID, please get in touch with the staff member that contacted you during enrolment to request for your Participant ID. Alternatively, you may contact Action for AIDS at (+65) 6254 0212 and request to speak to the Pink Carpet Y cohort manager.

Should you wish to contact the research team, you may approach the principal investigator (Tan Kay Jin Rayner), by phone at (65) 9187 8576 or by e-mail (Rayner.tan@u.nus.edu).

For an independent opinion regarding the research and the rights of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board (Attn: Dr Chan Tuck Wai, at telephone (+65) 6516 1234 or email at irb@nus.edu.sg).

Participant's Declaration

I understand that participation is voluntary. Refusal to participate will involve no penalty. I may discontinue participation at any time without penalty or loss of accrued benefits (benefits are accrued in proportion to the amount of study completed or as otherwise stated by the researcher) to which I am otherwise entitled. I declare that I am at least 18 years of age. If I am affiliated with the National University of Singapore, my decision to participate, decline, or withdraw from participation will have no effect on my status at or future relations with the National University of Singapore. I have read and fully understood the contents of this form, and hereby give consent to the National University of Singapore to collect, use and disclose and/or process my responses for the purpose(s) described in this form.

By clicking the "Continue/Next" button, I consent to participate in this study and agree to all of the above.

If you do not wish to participate in the survey, you may close the browser now to exit.

[Next Button]

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N.A.
Protocol version	3	Date and version identifier	N.A.
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 17
	5b	Name and contact information for the trial sponsor	N.A.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N.A.

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	5-6
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11-12
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N.A.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N.A.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N.A.
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-11, 22

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9, 16
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N.A.
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15-16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N.A.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14-16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N.A.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N.A.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N.A.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	N.A.
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16-17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9, 16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N.A.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N.A.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16-17
	31b	Authorship eligibility guidelines and any intended use of professional writers	N.A.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16-17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N.A.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N.A.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.