Sunset Without AIDS: Protocol for A Randomized Controlled Trial of A Brief Video-Based Intervention To Improve The Ability of AIDS Prevention In Elderly Men.

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Abstract

Background: Although progress has been made in the prevention and treatment of AIDS in China, there are still a considerable number of new infections annually, especially in older men. AIDS health education for older men face a major challenge. Evidence-based, acceptable and scalable interventions are urgently needed to increase their capacity to prevent HIV. We describe a trial protocol to evaluate the effectiveness of a brief video-based intervention targeting older men's ability of AIDS prevention.

Design: This study is a randomized controlled trial. The trial will be held in the residents' activity centers of three communities.

Methods: A total of 450 older men will be randomly divided into three groups (*Sunset Without AIDS* intervention group and two control groups) for two weeks. We will assess the feasibility and acceptability of intervention through interviews. The outcomes include changes in participants' knowledge, stigma attitude, risk behaviors attitude and risk behaviors related to AIDS after two weeks and one, three, six months of intervention.

Discussion: *Sunset Without AIDS* may be an innovative way to help

older men improve AIDS prevention capabilities, fill the gap in video-based AIDS prevention education for the older men in China, and gain experience of AIDS education. This project will innovate the AIDS education ideas of older men and enrich the theoretical research content of AIDS related education of older men. The findings may also provide the basis for the research and formulation of more reasonable AIDS education strategies and prevention and control policies for the elderly.

Trial registration: Chinese Clinical Trial Registry, ChiCTR2100045708

(data assigned: 23 April 2021, <http://www.chictr.org.cn/listbycreator.aspx>).

Introduction

The AIDS epidemic among older people in China has become increasingly serious, and the number of new infections has continued to rise. At the beginning of 2017, in China's 13th Five-Year Action Plan for AIDS Control and Prevention, older people were included in the key education groups for the first time[4]. According to data released by the Chinese Center for Disease Control AIDS case reports for men over age 60, rose from 8391 in 2012 to 19815 cases in 2017[5], 24465 cases in 2018[6]. According to the World Health Organization Official WeChat figures released on December 1, 2020, the number of newly diagnosed HIV-infected persons aged 60 and above reported in China in 2019 was approximately 37000, and more than 100 cases were reported every day. This accounted for 25% of the total number of newly reported HIV infected persons and the male infected persons aged 60 and above accounted for 77% of the newly reported older infected persons in that year[7].

The main way of HIV infection in older people in China is sexual transmission, and the imbalance of sexual demand is one of the causes of AIDS infection in older people[8]. Studies have shown that people remain sexually active after the age of 50, and high-risk sexual behaviors such as having multiple sexual partners and having unprotected sex with non-mating partners are common in the older population[9]. The survey found that up to 80% of infected older men admitted to having visited prostitutes, while older women were more likely to be infected within marriage[10]. A survey showed that 94.7% of older men infected with HIV never used condoms when having sex with a commercial partner[11]. It can be seen that older men have a low degree of understanding of safe sex and do not pay attention to taking protective measures when having sex with strangers, so they are at risk of infection and transmission of HIV[9]. In addition, for many older men infected with HIV, due to insufficient AIDS-related knowledge, traditional sexual concepts, social discrimination and other existence, they often do not carry out a timely test, treatment and disclosure to their partners or family members. Therefore, it is necessary to educate older men about AIDS-related risky sex and improve the AIDS prevention capabilities.

Developing countries represented by China have problems in AIDS prevention education, such as outdated education model, poor effect of education, and uneven distribution of educational resources[12-13]. Because the literacy level of older people is generally low, it is difficult for them to acquire the correct knowledge of disease prevention. Under the influence of traditional culture, older people generally avoid talking about sex, so it is also difficult for us to really understand the changes of sexual physiology and psychology of older people. Therefore, there is an urgent need to develop innovative AIDS education model and improve the educational effect, which can be feasibly implemented in over-burdened health systems. Video-based interventions are a promising but underused way to this crisis.

As a kind of teaching media, video interventions can deliver standardized messages. At the same time, messages can be woven into engaging storylines, piloted to ensure cultural relevance, and delivered at critical teachable moments[14]. They enrich the connotation of education and realize the integration of education and entertainment. In recent years, some randomized controlled trials conducted in the United States and Africa targeting HIV infected people and high-risk populations have found that video-based interventions had a strong track record in improving health knowledge, increasing treatment adherence, promoting HIV screening and reducing sexual partners, supporting partner disclosure, and fostering attitude and behavior change[15-21]. However, there are few evidence-based studies on HIV educational video intervention in China, especially randomized controlled trials to evaluate the effects of video-based intervention on older men.

In recognizing that evidence-based, accessible, and scalable interventions to improve the ability of older men to prevent HIV are critical, our team developed a brief video-based intervention. Below we describe the protocol of our randomized controlled trial to evaluate its effectiveness to improve older men's AIDS prevention ability in China. This intervention, called *Sunset Without AIDS*, is a 2-week experiment, and includes components designed to increase AIDS-related knowledge, improve AIDS prevention motivation, and strengthen AIDS prevention behaviors among older men.

Theoretical Framework

In conceptualizing the video, the Information-Motivation-

Behavioral Skills Model (IMB Skills Model) was selected based on their demonstrated ability to promote behavior change in HIV/STD interventions. This Model, believing that the prevention of AIDS requires comprehensive intervention from three aspects: AIDS-related information, motivation, and behavior skills[22]. *Sunset Without AIDS* includes all components of the IMB model and integrates other evidence-based video techniques to promote behavior change such as video modeling (visual and active demonstrations of desired behaviors) and gain-framed messaging. The combination of *Sunset Without AIDS* and IMB model is shown in Table 1.

Video Content Development

Sunset Without AIDS was developed through an iterative multi-step process involving a team of people living with HIV, researchers, clinicians, health workers, and other stakeholders. Literature research, investigation and interviews with older people, and Delphi expert consultation method were adopted to determine the educational core content of video design. The development of video content was through a community participatory approach, in-depth research and interviewed with older people and people with HIV/AIDS to ensure that the educational content was acceptable and compelling. Ultimately, the study advisory group identified key areas that the intervention should target: increase AIDS-related knowledge; improve AIDS prevention motivation; and reduce high-risk sexual behaviors related to AIDS among older men. Write scripts based on the true stories of old people infected with HIV. The script underwent iterative review and editing by the and scriptwriter, until the expert advisory group felt the script addressed these issues in a compelling fashion.

The video was produced through a partnership with Creative Graphic Studio, a company with expertise in making health promotion videos. The result was a film 25 minutes long, named *Sunset Without AIDS*. The characters in the video were all experienced actors and they spoke in Chinese. *Sunset Without AIDS* consists of two parts, one is the story content of approximately 18 minutes, the other is expert guidance of approximately 7 minutes. The story content depicted a female protagonist, Li Li, 68 years old, who went to the hospital for examination because she had a cold for several months and did not get better. After being newly diagnosed with HIV, the film portrayed her a series of complex psychological activities. The cause of her infection was traced to her husband Wang Yong, another 71-years-old protagonist who lost his sense of social existence and value after retirement. At the same time, Li Li often refused to meet his sexual needs and he believed that he was no longer fertile. Then, under the egging of his neighbor (a lonely old man living alone), he failed to refuse temptation and chose a low-priced prostitute to solve the loneliness. Therefore, Wang Yong was infected with HIV through heterosexual contact outside marriage and illegal commercial sex without effective protection. Li Li was infected after having marital sex with her husband. At the end of the story, although Li Li and her husband experienced quarreling, complaining

and suffering, they faced the situation bravely with the help and support of their family. They not only received the treatment actively, but also acted as volunteers to carry out AIDS propaganda and education for the older people around them. At the end of the story, about 7 minutes of expert guidance was added to the video, mainly including AIDS-related knowledge, attitude and behavior guidance.

In the *Sunset Without AIDS*, the video provides information about the main route of infection in the older population, the importance of HIV prevention and the education on HIV testing and treatment. Older men can experience the whole process of HIV infection through this brief video, perceive the risk of AIDS and the severity of the disease, thereby learning knowledge and skills, increasing awareness of AIDS prevention, reducing risky behaviors. Figure 1, *Sunset Without AIDS*. Figure 2, The story content of *Sunset Without AIDS*. Figure 3, The expert guidance content of *Sunset Without AIDS*.

Aim

The aim of the study was to evaluate the effect of *Sunset Without AIDS* intervention on improving the ability of AIDS prevention in older men.

Methods/design

Four hundred and fifty participants will be allocated to one of the three randomized groups after completing a baseline survey. To reduce contamination, the three groups will be from separate areas. Participants are required to complete the assessment two weeks later and one-month, three-month, six-month follow up visit after the intervention. Our hypotheses are: (1) Compared with older men in the control groups, those in the *Sunset Without AIDS* intervention group will have a deeper awareness of AIDS, less AIDS-related stigma, and fewer AIDS-related risk behaviors; (2) Comparison between *Sunset Without AIDS* intervention group and normal video group, the former group integrated various knowledge and behavioral skills into the story. So, it will have better acceptability and feasibility. Figure 4 shows the study flowchart.

Trial setting

The trial will take place in Luzhou, a city of Sichuan province in China. Luzhou, with registered population 5.08 million, located in the southeast of Sichuan Province, is the adjacent city of four province Sichuan, Yunnan, Guizhou and Chongqing. It is also the area where the HIV/AIDS epidemic is rising rapidly in Sichuan Province[23]. The trial will be held in the residents' activity centers of three communities (Fangshan community of Fangshan Town, Kuangchang community of Kuangchang town and Jiangbei community of Jiangbei town).

Recruitment of participants

We will recruit 450 older men in multiple communities through on-site recruitment. The three towns, Fangshan Town, Jiangbei Town and Kuangchang Town, have basically the same economic and cultural

level in Luzhou city. Two or three communities will be randomly selected from each town and a total of 150 older men will be recruited from these communities. Research assistants will deliver talks to all participants, describing the trial and working with community staff to identify eligible participants. When the participants agree to join in the research and complete the follow-up measurement, an informed consent form will need to be signed for confirmation. To be eligible for trial participation, individuals must meet all the following inclusion criteria:

1. Male aged over 60 years old.
2. Clear consciousness, no mental illness and serious visual impairment, have certain reading ability and language expression ability.
3. Plans to stay in the trial catchment area for over 6 months.

Exclusion criteria include any of the following:

1. Ongoing or already on AIDS education intervention.
2. Cognitive and mental impairment and inability to communicate properly, move outside of blurred vision or blindness.

Sample size and adherence

The sufficient statistical power to detect changes in AIDS knowledge, attitude and behaviors after the intervention are considered in sample size calculation, and 135 participants are needed in each group to maintain 80% statistical power. Assuming the attrition rate is 10%, the sample size of each group is determined to be 150, and the total sample size is 450. To motivate participants to stay in the trial, we will use intrinsic reward to help participants adhere to the intervention and follow up. Participants will receive some prizes for each assessment. In addition, after completing the research, each participant will also receive a reward of 50 RMB in cash.

Randomization and allocation concealment

Participants will be randomly assigned to one of the three intervention groups on a 1:1:1 basis. Opaque envelopes will be prepared for randomization. In 450 envelopes, each will contain a note with the words “*Sunset Without AIDS* intervention group” or “Normal video group” or “Lecture group” (150 envelopes per group). Participants (n=450) will be randomly assigned a computer number from 1 to 450, and they will randomly select an envelope in the numbering order. For each envelope selected by participants, the total number of envelopes will be reduced by one until the end. Participants who selected the envelopes in sequence will open the envelopes in front of the staff and will be assigned to different groups according to the information on the envelope. Another staff will record the allocation information of the participants. The data analysts are blinded to the allocation. All trial investigators and interviewers will also remain blinded.

Intervention group overview

***Sunset Without AIDS* intervention group**

Participants in *Sunset Without AIDS* intervention group will receive a 25-min intervention. They will be required to watch the *Sunset Without AIDS* video in its entirety once a week for two weeks. During the broadcast, a member of research team will be responsible for answering questions. After two weeks of intervention, the effect of the intervention will be evaluated using the same questionnaire as applied in the baseline survey. At the same time, the acceptability and feasibility of the video will be evaluated through face-to-face interviews with participants.

To ensure the compliance of participants, participants will be recognized and rewarded after completing twice video viewing sessions and a two-week follow-up assessments.

Normal video group

Participants in normal video group will receive a 25-min of AIDS education video intervention downloaded from the website of the Chinese CDC. Intervention times and duration are the same as *Sunset Without AIDS* group. The video contains the same educational contents as the *Sunset Without AIDS*. The only difference is that it is a popular science propaganda video, which lacks a storyline and is not specifically aimed at older people.

Lecture group

Participants will receive health lecture related to AIDS once a week for 25 minutes each time. The total time is the same as the time required by *Sunset Without AIDS* intervention group and normal video group. An AIDS expert will hold a health lecture on AIDS prevention and the educational content of the lecture is the same as that in the videos. The whole intervention will be carried out once a week for 2 weeks.

Contamination and intervention fidelity

To help ensure intervention fidelity and reduce contamination, we developed and revised multiple strategies. Some of the key strategies are listed in Table 2.

Assessments

Once participants' eligibility is determined, they will be scheduled for baseline assessment. All participants will receive a face-to-face questionnaire independently. Baseline assessments last approximately 30 minutes and include demographic items, AIDS-related knowledge items, AIDS-related stigma attitude items, AIDS-related behaviors attitude items and AIDS-related behaviors items. After two weeks of intervention, the participants will be assessed with the same questionnaire while evaluating the feasibility and acceptability of intervention. We will also assess participants using the same questionnaire at one, three, six months follow-up after the intervention. A schedule of enrolment, interventions,

and assessments are outlined in Table 3.

Outcomes and data collection

The outcome is a composite measure of AIDS-related knowledge, AIDS-related stigma attitude, AIDS-related behaviors attitude and AIDS-related behaviors after two weeks and one, three, six months of intervention. At the same time, the acceptability and feasibility of intervention will be also evaluated after two weeks later. Composition of data monitoring committee is composed of special personnel who are responsible for the supervision of the data collection process.

AIDS-related knowledge will be assessed through a self-designed questionnaire. The item of the questionnaire is designed according to the part of the contents for older people in the Core Knowledge of AIDS Prevention And Control Publicity And Education[25] issued by Chinese CDC. There are 10 items in total, one point for a correct answer. The higher the score, means the more knowledge participants have learned. The content validity of the questionnaire was evaluated after being consulted by six experts, the item-level CVI (I-CVI) and the scale-level CVI (S-CVI) were both 1.000.

AIDS-related stigma attitude will be assessed through the Chinese version of Zelaya's HIV/AIDS Stigma Scale, which was firstly compiled by Zelaya[26]. The scale, which included 24 items in total, was sinicized by Xing Haiyan in 2014[27]. Chinese version of Zelaya AIDS Discrimination Scale, the Cronbach's α coefficient of the scale was 0.91, and the Cronbach's α coefficient of each dimension was 0.79-0.87. It consisted of four dimensions (fear of infection, stigma prejudice, personal discrimination, social discrimination), with six items for each dimension, a total of 24 items. There were 18 negative items and 6 positive items, and the answers were strongly agree, agree, uncertain, oppose, strongly disagree. Positive items are recorded as 1, 2, 3, 4, 5 points in turn, while negative ones are the opposite. The higher the score of discriminatory attitude, the more serious AIDS discrimination.

AIDS-related behaviors attitude will be assessed through an eight-item questionnaire, with one point for each correct answer. The higher the score, the lower the risk of participants engaging in AIDS-related behaviors. Similarly, the content validity of the questionnaire was evaluated, the item-level CVI (I-CVI) was 0.830-1.000 and the scale-level CVI (S-CVI) was 0.875. AIDS-related behaviors will be assessed for whether and how often participants have risk behaviors related to AIDS risky. The fewer AIDS-related risk behaviors the participants have, the better their ability to prevent HIV/AIDS will be.

Statistical methods

Descriptive statistics will be used to show the baseline characteristics of the arm. To measure the outcome, analysis of Variance (ANOVA) will be used to find out whether there have differences on the incidence of AIDS-related behaviors, AIDS-related knowledge and attitude (stigma attitude and behaviors attitude) scores among the three arms after two weeks of intervention and one, three, six months of follow-up. The same intervention will use the chi-square test and the two-sample t test for the two weeks later and one, three, six months outcome. Intention-to-treat analysis will be used to account for the

influence of attrition. $P \leq 0.05$ will be deemed statistically significant. All analyses will be performed using SPSS software.

Ethical considerations

This trial has been approved by the ethics committee of affiliated hospital of university (No:KY2021071) and the Clinical Trials (ChiCTR2100045708). If the investigators elect to make important modifications to the protocol, amendments will be submitted to both the ethics Committee and the Clinical Trials. Participants who sign up will be screened, for those who meet the inclusion criteria, we will issue informed consent to them, and inform them in detail of the study purpose and process, number of participants, study duration, potential risks and benefits, random allocation, data confidentiality, etc. All information and written notices will be in Chinese and every participant will sign an informed consent. If the participant is unable to read, the staff will read the informed consent to the participant in full and the participant will mark his or her own fingerprint to express consent, the entire process must be witnessed by a third party not involved in the trial.

Discussion

At present, some developed countries have designed and developed AIDS educational videos under the guidance of relevant theories and models, and their research contents mainly focus on the problems of high-risk sexual behaviors, multiple sexual partners, early pregnancy, drug abuse, disclosure, HIV detection and other issues of HIV infected people and high-risk groups. Although these videos enhanced the pertinence of educational videos on AIDS and other sexually transmitted diseases, due to regional, cultural and ethnic differences, they did not conform to the national characteristics of AIDS infection among older people in China. Therefore, their promotion and application were limited. In China, The awareness rate of AIDS among older people is low[28]. The AIDS preventive education for them is crucial.

To meet the need of AIDS education of older men, a brief video *Sunset Without AIDS* was developed. As mentioned above, *Sunset Without AIDS* can provide knowledge and skills to older men to prevent AIDS. Whether older men are interested in and using it is the key point to this study. If the video does not appeal to older men, it will not be popularized among them, nor have educational significance. Compared with many other interventions, *Sunset Without AIDS* is designed to be closer to the lives of older people, which may increase viewers' willingness to watch the video and prevent AIDS. This intervention can not only save the cost of education and reduces the waste of human resources, but also can vividly show the way of HIV infection and its performance if infected with HIV by means of films. At the same time, under the guidance of experts, strengthening the consolidation of relevant knowledge can improve the effect of education.

By evaluating a brief video-based, scalable and locally developed and culturally tailored tool to improve the ability of older men to prevent AIDS, three arms were designed in this trial, including one intervention arm and two control arms. To critically examine the implementation of *Sunset Without AIDS*, we will also examine participant satisfaction, intervention fidelity, contamination, and time-motion data. By

comparing the intervention group with the normal video group, it can be found whether the *Sunset Without AIDS* is attractive and is better than a popular science propaganda video in improving participants' AIDS prevention ability. By comparing the intervention group and lecture group, we can figure out whether only a brief video-based intervention is different from a traditional health lecture intervention. By comparing each group before and after the intervention, we can see the difference in the effect of video-based interventions and health lecture intervention in AIDS education. This randomized controlled trial will critically evaluate this video-based intervention to improve the ability of AIDS prevention in older men. It will provide an evidence for the choice of AIDS education methods for older men.

Limitations

As with any research design, the trial also has potential limitations. In the follow-up observation, the time may be too long to lead to participants loss. We attempted to address this concern by giving each person some prizes to motivate the participants to continue to participate in the study. In addition, if necessary, it can be traced through the information about the participants set aside on the informed consent.

Abbreviations

IMB: Information-Motivation- Behavioral; AIDS: Acquired Immune Deficiency Syndrome; HIV: Human Immunodeficiency Virus; STD: Sexually Transmitted Disease; CDC: Centers for Disease Control; CVI: Content Validity Index; ANOVA: Analysis of Variance.

Declarations

Trial Status Chinese Clinical Trial Registry, ChiCTR2100045708

(data assigned:23 April 2021,<http://www.chictr.org.cn/listbycreator.aspx>).

The recruitment began on June 1, 2021 and has been completed around July 10.

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Authors'contributions YC is the principal investigator of the trial. JR, ML, YW, YC and YL contributed to the original protocol and assisted in revisions of the protocol versions. JR, ML and YL drafted the manuscript. All authors are significantly involved in the trial preparation and conduct.

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Availability of data and materials The datasets used and/or analyzed as well as data collection forms and model consent forms of the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate This trial has been approved by the ethics committee of affiliated hospital of university (No:KY2021071) and the Clinical Trials (ChiCTR2100045708). Based on the principle of informed consent, this study was anonymous and voluntary.

Consent for publication All authors read and approved the final manuscript.

Competing interests No conflict of interest has been declared by the authors.

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Tables

Due to technical limitations, table 1, 2 and 3 are only available as a download in the Supplemental Files section.

Figures

Figure 1

Sunset Without AIDS.

Figure 2

The story content of Sunset Without AIDS.

Figure 3

The expert guidance content of Sunset Without AIDS.

Figure 4

Study flowchart.

Supplementary Files

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