

STUDY PROTOCOL

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Evaluation of an Interactive Computer-based Intervention to Safe Sex Practice for Female University Students: A Multicentred Randomized Controlled Trial

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1. Background

Sexually transmitted infections (STIs) has been identified as one of the proposed key World Health Organization (WHO) global health sector strategies, 2016-2021.[1] Human papillomavirus (HPV) is the most common STIs. Most people with HPV infection are unaware of it because it is asymptomatic. However, persistent HPV infection may cause distinct change in cervical epithelial cells which may then lead to invasive cervical cancer.[2] Cervical cancer has been the 2nd leading cause of cancer deaths among women globally.[3] The pre-clinical phase may last for 10-20 years, which allows ample time to prevent the progression to cervical cancer. On the other hand, such asymptotic phase may lead to delayed treatment and increased risk of passing on the virus to others through unprotected sex.

According to Social Hygiene Service, the incidence of diagnosed STIs have been increased by 8% over the past 4 years (2011-2014).[4] Regarding cervical cancer, around 500 cases were newly diagnosed corresponding to a crude incidence rate of 13% per 100,000 female population in 2013, compared to 9.8% 5 years ago.[5] With the increasing population, the burden of both diseases will be increased. Also, the risk of STIs and cervical cancer is predicted to be increased along with the increasing trends of premarital sex and other unsafe sexual behaviours among youth[4], technology advancement of dating apps[6], adoption of modern intimacy of engaging in compensating dating and casual sex.[7]

2. Key Issues and Problems

(1) Previous Behavioural Intervention: Outcomes

Abstinence of sex is 100% effective way to prevent STIs. However, previous systematic review has already demonstrated that abstinence education was not effective to reduce STIs while comprehensive risk reduction intervention was successful in reducing STIs.[8] In addition, WHO considers sex as a human right issue and has been promoting sexual health with the focus on a positive and respectful approach to sexuality, as well as the possibility of having pleasurable and safe sex practice and free of coercion. Indeed, accordingly to a Cochrane Review, current primary prevention interventions of preventing STIs emphasize on enhancing safe sex practice, including (1) promoting

condom use, (2) limiting sex partner, (3) avoiding causal sex, and (4) enhancing sexual communication of negotiation skills of sex refusal or condom use and assessing partner's history of STIs.[9]

(2) Previous Behavioural Intervention: Theory-driven Components

A number of effective behavioural interventions to enhance condom use or limit sex partners were designed based on theories and models such as Health Belief Model, Social Learning Theory, Theory of Planned Behaviour, Social Cognition Theory and Theory of Planned Action.[9, 10] No matter which theory or model was used, the components of the intervention to enhance safe sex practice were mainly knowledge, attitude, peer norms, self-efficacy/confidence and skills, which empowered the youth to make informed decision about sex. Owing to the realities and complexity in the context of sexual health and sexual behaviours, the logical pathway of how the interventions work is still unclear.[10]

(3) Sexual Coercion: A Key Component Missing in Previous Interventions

The previous interventions that tackle unsafe sex practice among young women seldom address sexual coercion. Sexual coercion is defined as “the use of non-physical, controlling, degrading, and manipulative tactics to obtain, or attempt to obtain, unwanted oral, vaginal, or anal intercourse, including forced penetration and sex with objects”[11]. The prevalence of sexual coercion was 20%, as reported in an International Dating Violence Study conducted on university students (including males and females) from 32 nations in 2008.[12] In Hong Kong, the prevalence of sexual coercion against female university students was around 13% in 2008 and there was no significant reduction in 2015 even though the status of women is increasing in Hong Kong.[13, 14]

Sexual coercion has been known to be highly associated with unsafe sex practice[15]. The possible process underlying this association was, first, dating violence was about relationship power dynamics and control coercion in day-to-day life between the partners, which also included contraceptive control by the perpetrators.[16] Also, some women were fear of physical violence due to

sex refusal or negotiation[17] and some women were forced to have unprotected sexual intercourse.[18] Second, social norms of seeing sex to strengthen relationship and condoms meaning lack of trust might hamper sexual communication and enable the male perpetrators to take advantage.[17] Third, sexual coercion was found in female casual and non-committed sexual relationships[19], which has been an emerging unsafe sex practice. Although the above findings were from Western literature, they were not exclusive to female youth in Hong Kong and were evidence for adding sexual coercion in the content of the proposed intervention.

(4) Previous Behavioural Intervention: Mode of Delivery

Previous behavioural interventions to enhance safe sex practice were conducted in different modes, including face-to-face individual counselling, face-to-face group interventions, reading materials or interactive computer-based interventions (ICBI). A Cochrane Meta-analysis evaluated 15 RCTs of behavioural interventions on safe sex practice found that the effect of ICBI were more effective in improving the knowledge about sexual health (Moderate Effect, SMD 0.72, 95% CI 0.27 to 1.18) compared with face-to-face interventions (Small Effect, SMD 0.36, 95% CI 0.13 to 0.58).[10] In addition, ICBI have a small effect on safe sex practice (SMD 0.16, 95% CI 0.02 to 0.30) and an effect on condom use (OR 1.75, 95% CI 1.18 to 2.59) in comparison to leaflets.[10]

In addition, the advantages of using ICBI are because (1) sexual health information delivery can be less embarrassing;[10] (2) intervention access can be anonymous and at own convenience time;[10] (3) both randomisation and personalized risk-tailored message can be easily done through the online technology;[10] (4) the online platform can facilitate data collection and coordination;[10] and (5) the ICBI, if proven to be effective, can be easily translated into practice, such as part of student services in various institutions not only in Hong Kong but also worldwide.

3. Purpose

The primary objective is to evaluate the efficacy of an interactive computer-based intervention specially designed for female university students to adopt safer sex practice. The proposed ICBI would aim to improve the knowledge, attitudes, norms, self-efficacy of negotiation and communication in condom use and sexual consent, as well as reducing sexual coercion among young females.

4. Significance

The proposed study is relevant in preventing unsafe sex practices and the associated high risk with STIs, which is an alarming issue among Hong Kong youths. Given the increasing trend of premarital sex and inconsistent condom use among Hong Kong college students, there is an urge to provide comprehensive STIs risk reduction intervention with a focus on addressing sexual coercion for females.

This study would enable evaluation of the acceptability of ICBI in sexual health education and improve STIs risk reduction intervention to advocate safe sexual behaviors among college population. Such cost-effective intervention could be translated as part of the student service to empower young females with the knowledge about sexual coercion and sexual consent as well as promoting safe sexual practices on university campus.

5. Study Design

Design

A multi-centred randomized controlled trial (RCT) design as recommended by the Cochrane review for evaluating the sexual health intervention effect.[9]

Subjects and setting

Female university students (n = 500), across disciplines and year of study, will be recruited from five universities with dormitory or residential halls in Hong Kong. The eligibility criteria are listed below.

The inclusion criteria are:

- Female university students aged at least 18 years

- Able to read Chinese or understand Cantonese
- Unmarried
- Having intimate partners in the past 12 months
- Did not receive any sexual health information including formal face-to-face or online education/ training courses related to contraceptives and sexually transmitted diseases from university, hospitals, clinics and non-governmental organizations in the past 12 months

The exclusion criteria are:

- Unwilling to complete the questionnaires at 3 time points
- Pregnant women and postnatal women
- With psychiatric illness

Interactive Computer-Based Intervention (ICBI)

The ICBI will be conducted based on Health Belief Model (HBM)[20] and the Continuum of Conflict and Control (CCC).[21] HBM is selected because it was found to be effective in adopting safer sex practice in previous studies[9, 10]. CCC is selected because it emphasizes on level of violence and indicates that sexual coercion can occur without physical violence and with minimal fear, which strengthen the knowledge about sexual coercion and sexual consent of condom use and sex refusal. There are 4 components of the ICBI which will be delivered in 3 phases:

(1) Perceived Susceptibility and Perceived Severity:

Eight questions will be asked to estimate the individual STIs and cervical cancer risks by the Harvard Cancer Risk Index. (28) Based on the answers, personalized results will be shown and indicate what factors have raised her risk and what factors have lowered her risk of getting STIs and cervical cancer.

(2) Perceived Benefits and Perceived Barriers:

Knowledge-based information including knowledge about STIs and cervical cancer including its statistics, development, possible symptoms, and prevention methods will be given in text-format. There will also be questions to facilitate the students to think about which positive and negative features of condom use in scales. Therefore, the

participants will be able to offer personal feedback and provide a chance for them to reflect which benefits or barriers that matter to the individuals most.

(3) Cue to Action:

Condom use procedures and tips, web links for local STI testing and cervical screening programme, HPV vaccination programme will also be provided.

(4) Self-Efficacy:

There will be three 5-minute narrative stories on STIs and HPV infection based on different scenarios that are relevant to college students' situations. There will be questions to lead the participants to have decision about condom use in the videos with different scenarios. They will be able to assess their own values and be given feedback on their choices. Moreover, there will be a page designed to summarise the participants' individual factors for facilitating their decision-making about consistent condom use in the future sexual activities. There will be questions asking the participants to rate their level of self-efficacy in terms of knowledge, skills, clarity of information, and perceived support and advice on a scale of 1-5. If their level of self-efficacy is low (rating of 1-3), they will be directed to relevant information again by hyperlinks.

In addition, a discussion forum will be created to handle questions from the participants. Also, there will be an email address for enquiries if the participants need any support or if they want to seek further enquiry/ clarification after reading the web-based information.

For the control group, all participants will receive minimal intervention with a one-page online information about procedures and tips of condom use. The site for control group will have similar graphic design as that for intervention group. However, there will be no self-assessment materials or online quiz questions. The time spent on the web information will approximately be 30 minutes for intervention group and 10 minutes for control group.

It is hypothesized that female students in the intervention group will have consistent condom use at 3- and 6-month follow-up compared to students in the control group. It is expected that the intervention will provide participants with increased knowledge,

attitude, norms, self-efficacy towards condom use, sexual consent and sexual coercion.

Measurements

The following measurements will be conducted at 3 time points: baseline (T1); 3-month post intervention (T2); and 6-month post intervention (T3), which consist of the same set of measurements. The individual characteristics will also be assessed at T1 and questions related to feasibility of the programme will be asked only at T3.

Primary outcomes

1. Change from Consistency in condom use with every partner: It will be assessed by using percentage of male condom protected sex with every partner according to the recommended guidelines from the systematic review of 56 studies.[22] Other behavioural items will also be asked, for examples, condom use at last sex and description of sexual partners (dating partner vs casual partner) at last sex.

Secondary outcomes:

- 2. Knowledge, attitude, norms and self-efficacy of condom use:** It will be assessed by 25-item MCAS[23] which contains assessment on five subscales: reliability and effectiveness of condoms, sexual pleasure associated with condom use, stigma associated with people proposing or using condoms, embarrassment about negotiating and using of condoms, and embarrassment about purchasing condoms. The measurement can be used with participants who do and do not have personal experience with condoms. The items are answered by a 7-point Likert-scale and total scores are ranged from 7 to 175. The higher the score, the more positive is the knowledge, attitude, norms, and self-efficacy of condom use.
- 3. Knowledge, attitude, norms and self-efficacy of sexual coercion and sexual consent:** It will be assessed by 39-item SCS-R.[24] It contains four attitudinal subscales (positive attitude towards establishing consent, lack of perceived behavioral control, relationship length norms, and (pro) assuming consent) and two behavioral subscales (indirect consent behaviors and awareness of consent). It is suitable for both participants who do and do not have personal

experience with sexual consent. The items are answered by a 7-point Likert-scale and total scores are ranged from 39 to 273. The higher the score, the more positive is the attitude, norms, and perceived behavioural control of sexual consent.

4. **Sexual coercion:** It will be measured by 7-item subscale from Revised Conflict Tactic Scale.[25] The responses will be on a dichotomous scale for assessing sexual coercion. All items will be rated on a 7-point Likert scale indicating how often the behaviour occurred. The higher the score, the greater the frequency.
5. **Self-efficacy in sexual communication:** It will be assessed by 20-item SCSES.[26] It contains five domains (contraceptive communication, positive sexual messages, negative sexual messages, sexual history, and condom negotiation). The items are answered by a 4-point Likert-scale and total scores are ranged from 20 to 80. The higher the score, the more the self-efficacy in sexual communication.
6. **Retention of the participant:** It will be evaluated by recording retention of the participants at 6-month post intervention.
7. **Engagement time of the participants:** It will be evaluated by recording the total time spent on the website at 6-month post intervention.
8. **Incidence of adverse events of the intervention:** It will be evaluated by recording the adverse events of the intervention at 6-month post intervention.
9. **Overall satisfaction of the intervention:** It will be evaluated by recording overall satisfaction of the intervention in a scale of 0-10 and overall perception of the intervention with a 5-Likert-scale. Also, participants will be asked whether they will recommend the intervention to friends and “yes” will be scored 1 point. The higher the score, the higher overall satisfaction of the intervention.
10. **Total pages of the website each participant visited:** It will be evaluated by recording the total pages of the website each participant visited.
11. **Percentage of performance on the interactive tasks:** It will be evaluated by recording each participant’s performance on the interactive tasks.
12. **Incidence of searching more information about safe sex practice:** Participants will be asked whether they searched for more information about safe sex practice during the last three months.
13. **Demographics:** It includes items such as gender, age, year of study, and dating

relationships status. Also, the participants will be asked for history of childhood sexual coercion. The item is extracted from Adverse Childhood Experiences questionnaire[27] — “Did an adult or person at least 5 years older than you ever touch or fondle you or have you touch their body in a sexual way? Or attempt or actually have oral, anal, or vaginal intercourse with you?” Also, the information regarding individual risks on STIs and cervical cancer will be collected at baseline (including age, age at first sexual intercourse, number of sexual partners during one's lifetime, frequency of condom use, history of ever being diagnosed with an STI, smoking status, history of giving birth, and history of having pap smear test).

Additional questions:

In order to strengthen the process evaluation of the study, three specific questions will be asked at 3- and 6-month follow-up for both intervention and control groups:

- (1) Have you ever searched for more additional health information after joining this study? (Yes/ No)
- (2) If yes, what is the information you got? (abuse and violence/ condom use/ HPV vaccine/ STI/ STI testing/ mental health/ others)
- (3) Also, where did you get the information? (Internet/ government materials/ consult health care providers/ others)”

All measurement tools have been validated and the Chinese version is available.

Procedures

Recruitment of participants will be conducted by using bulk electronic mails, promotional brochures, posters and campus booths. An invitation card with a QR code of the web-based intervention will be used for inviting female university students to enrol the study. Online enrolment will be done for screening participants for eligibility. From our past experience in recruiting university students, we shall be able to reach over 30,000 female university students in five Universities.

Participants will be asked to complete the web-based baseline survey at enrolment. The *web-based questionnaire* will be set up under an online platform. Participants may use their mobile devices including laptop computers and smartphones to complete the questionnaire. Participation is entirely voluntary. Written informed consent will be obtained via the web-based platform before completing the baseline questionnaire.

After completion of the questionnaire, the recruited students will then be randomized to either intervention group or control group, according to a list prepared by blocked randomization of a size decided by a *randomizer*. The block size and order of allocation will be kept securely in the randomizer to avoid selection bias. Allocation concealment will be done at the online platform according to the participants' enrolment sequence. The participant will then be guided to a web-page according to their group allocation.

At 3-month and 6-month after the entry of the study, participants will receive a link through their e-mail to complete a follow-up questionnaire (T2). Three months later, another e-mail link will be sent to participants for completing the last follow-up questionnaire (T3). If no response from a participant, a follow up telephone text-message and/or telephone call will be sent after 1 week as a reminder.

6. Treatment of Subjects

Not applicable

7. Assessment of Efficacy

Not applicable

8. Assessment of Safety

There is no question designed to provoke a strong or emotional reaction. If the participants find the intervention stressful or discomfort or having anxious physiological responses (for example, trembling, shaking, sweating, facial flushing, severe headache, shortness of breath, palpitations, severe pain or crying uncontrollably), they will be given the opportunity to decide whether to continue or to terminate the intervention and withdraw from the study.

9. Statistics

To assess the efficacy of ICBI in increasing consistency of condom use, a linear mixed effects model will be adopted with intervention group and baseline consistency of condom use as the covariates. The group by time interaction shall be assessed for changes of ICBI effects over time. The mixed effects model was to take account of the extra covariance of repeated measurements at 3 and 6 months. The intention-to-treat principle will be adopted and all study subjects will be included in the analysis. Missing values at 3- and 6-month follow-up will be replaced by the last observed value and multiple imputation. The analysis will be repeated on the per-protocol set comprising individuals without missing values.

For secondary outcomes that were assessed approximately on a continuous scale, the same analysis approach as mentioned above will be adopted. For those assessed on a dichotomous scale, e.g. sexual coercion, similar approach by a non-linear mixed effects model with a logit link will be used.

The analysis will be performed by using the IBM SPSS (IBM Corp, Armonk, NY, USA). Each estimated effect will be accompanied by a 95% confidence interval and 5% level of significance.

10. Direct Access to Source Data/ Documents

The investigators and the research assistants of the research team are responsible for data collection and they will be permitted to access to source data and study record.

11. Quality Control and Quality Assurance

Daily logs will be recorded by the research assistants to monitor the study progress including the number of respondents approached, interviews completed or refused and incomplete interviews. All data entered in the database will be verified and cleaned. After completion of data entry, computer logic checks will be run for consistency of related code. Necessary corrections will be made to the database.

12. Ethics

The protocol will be submitted to the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster for approval. The conduct of the study will be complied to the “Declaration of Helsinki”. Participation in the study is voluntary. An information sheet is provided and a written consent is required from the participant for each individual study.

13. Data Handling and Record Keeping

The completed questionnaires and records will be kept by the Principal Investigator for 10 years. The computerized data will be kept for planning of future studies.

14. Financing and Insurance

The proposed study is supported by the University of Hong Kong.

15. Publication Policy

The dissemination of research findings will be done by publication in international peer reviewed journals and presentation in local or international conferences.

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