“Effects of a Sexual Health Education Serious Game Intervention on Sexual Health Among Emerging Adult Men: A Quasi-Experimental Study”

Study Protocol with Statistical Analysis Plan and Informed Consent Form

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Part I. Study Protocol

1. **Background:** Sexual health is an important health issue among young people. Healthy sexual relationships require mutual respect, sexual consent, and safer sexual practices. However, sexual health issues differ by gender, and research focusing on sexual consent among emerging adult men remains limited. In addition, the contextual factors associated with safer and risky sexual behaviors among emerging adult men are complex. Therefore, strengthening sexual health education and providing gender-responsive interventions that promote sexual consent and safer sexual decision-making are important for improving sexual health among emerging adult men.
2. **Aims:** To examine the effects of a serious game intervention on emerging adult men's sexual knowledge, sexual consent, and theory of planned behavior variables related to safer sexual behaviors, including attitudes, subjective norms, perceived behavioral control, and behavioral intentions.
3. **Study design:** This study will use a quasi-experimental design with intervention and control groups.
4. **Inclusion criteria of participants:** (1) Men aged 18–24 years (2) Have access to a smartphone and mobile internet services and regularly use LINE.
5. **Exclusion criteria of participants:** (1) Individuals who identify as gay (2) Individuals who are unsure of their sexual orientation.
6. **Intervention:** A serious game for sexual health education.
7. **Outcome Measures:** Outcome measures will include sexual knowledge, sexual consent, and theory of planned behavior variables related to safer sexual behaviors. The theory of planned behavior outcomes will include attitudes, subjective norms, perceived behavioral control, and behavioral intentions related to condom use.
8. **Data collection:** Participants will be recruited from universities, online social media platforms, and community settings using convenience and snowball sampling. Data will be collected at three time points: baseline, immediately after the 6-week intervention, and 4 weeks after the first post-test.
9. **Ethical Considerations:** This study was approved by the Institutional Review Board of Kaohsiung Medical University Hospital (Approval No. KMUHIRB-SV(II)-20210130).

Part II. Statistical Analysis Plan

1. **Sample Size Calculation:** The sample size was estimated using G*Power for an independent-samples *t*-test comparing two independent groups. The effect size was set at 0.50, representing a medium effect, with a statistical power of .80 and a significance level (α) of .05.
2. **Analysis Population:** The analysis will include participants who complete the pre-test and both post-tests.
3. **Baseline Characteristics:** Baseline characteristics will include demographic characteristics and research variables measured at the pre-test.
4. **Outcome Analysis:** Differences in demographic characteristics and baseline research variables between the two groups will be assessed using chi-square tests and independent-samples *t*-tests. Generalized estimating equations will be used to evaluate the effectiveness of the intervention.
5. **Missing Data:** Cases with missing data will be excluded from the analysis.
6. **Statistical Significance:** All statistical tests will be two-sided, and a p value < .05 will be considered statistically significant. For the generalized estimating equations analyses, 95% confidence intervals will be reported for the estimated effects..
7. **Statistical Software:** Data will be analyzed using IBM SPSS Statistics version 21.0.

Part III. Informed Consent Form

1. **Purpose of the Study:** This study aims to examine the effects of a serious game intervention on emerging adult men's sexual knowledge, sexual consent, and theory of planned behavior variables related to safer sexual behaviors.
2. **Procedures:** The study will last 10 weeks. You will be asked to complete an online questionnaire at three time points: before the intervention, immediately after the 6-week intervention, and 4 weeks after the intervention ends. The questionnaires will collect demographic information and assess sexual knowledge, sexual consent, and theory of planned behavior variables related to safer sexual behaviors.
3. **Voluntary Participation:** Participation in this study is entirely voluntary. You may choose whether to participate and may withdraw at any time, for any reason, without penalty.
4. **Risks and Responses:** Because sexual consent and sexual behavior are sensitive topics, your privacy and confidentiality will be protected. Research data will be coded and securely stored by the research team. If you do not wish to ask sensitive questions publicly in the discussion area, you may contact the research team through anonymous private messages or anonymous email inquiries. The research team will respond to these inquiries.
5. **Potential benefits:** The intervention may improve your sexual knowledge, promote sexual consent, and encourage safer sexual behaviors.
6. **Confidentiality:** After the information you provide has been entered into a computer and coded, it will be securely stored on a password-protected hard drive or computer.
7. **Compensation:** If you complete the entire study, you will receive a gift or monetary payment commensurate with your contribution as compensation.
8. **Contact Information:**

   Principal Investigator: Ying-Hua Tseng

   Email: yhtseng@kmu.edu.tw
9. Signatures: Signature of Subject _____.

Approval of Clinical Trials/Research (Continuing reviews)

Protocol Title: *The effect of serious game on sex consent and safer sex behavior among male youths:From development to evaluation*
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See the back of this page for the procedures for reporting unanticipated problems, or drug serious adverse reactions, or interim, and other important notes.

Hsueh-Wei Yen

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