Study Protocol with Statistical Analysis Plan and Inform Consent Form

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Part I. Study Protocol

1. **Background**: Adolescence is a critical period for learning and the cultivation of intimate relationships. Sexual communication and safe sexual practices are closely linked to relationship satisfaction and stability; however, discussing sexual topics is often a sensitive and embarrassing experience for adolescents. In particular, the socialization process often conditions young women to feel unable to assertively express their sexual desires and relationship preferences, making it crucial to equip them with the communication and negotiation skills necessary to promote their sexual health.

2. **Aims:** To examine the effect of a mobile application on adolescent girls' sexual communication self-efficacy and sexual health outcomes.

3. **Study design:** A quasi-experimental study with non-equivalent comparison groups.

4. **Inclusion criteria of participants:** (1) anyone using a smartphone or mobile Internet; (2) female aged 18–25.

5. **Exclusion criteria of participants:** anyone who identified as lesbian, or with uncertainty about sexual orientation, or individuals with a mental disability.

6. **Intervention**: sexual communication program

7. **Outcome Measures:** Sexual Communication Self-Efficacy, safer sex knowledge, TPB variables of condom use with relationship partners, and TPB variables for casual sex.

8. **Data collection:** This study recruited participants through schools, online social media, and snowball sampling methods. Data were collected included three time points: before the intervention, after six weeks of intervention, and four weeks

after the end of intervention.

9. Ethical Considerations: This study was approved by the Institutional Review Board of National Chen Kung University Governance Framework for Human Research Ethics (Approval No. 108-370-2).

Part II. Statistical Analysis Plan

1. **Sample Size Calculation**: The statistical power was set as .80, and the significance level (α) as .05. The effect size is based on prior research on sexual communication.
2. **Analysis Population**: Participants completed the pre-test and both post-tests.
3. **Baseline Characteristics**: Pre-test variables
4. **Outcome Analysis:** Differences in demographic and baseline research variables between the two groups were evaluated with χ^2 and an independent t-test. generalized estimating equations (GEEs) analyses to evaluate the effectiveness of the intervention. The model included group, time, and group-by-time interaction as fixed effects, with baseline characteristics considered as covariates where appropriate.
5. **Missing Data**: Cases with missing data were excluded.
6. **Statistical Significance**: A two-sided significance level of $\alpha = .05$ was used for all statistical tests. Statistical significance was defined as $p < .05$. For the GEE analyses, 95% confidence intervals (CIs) were also reported for the estimated effects.
7. **Statistical Software**: IBM SPSS Statistics version 26.0.

Part III. Informed Consent Form

1. **Purpose of the Study**: This study aimed to examine the impact of a mobile application on adolescent girls' sexual communication self-efficacy and sexual health outcomes.

2. **Procedures**: The study lasts 10 weeks and requires participants to complete an online questionnaire at three time points: before the intervention (baseline questionnaire), after six weeks of intervention (post-test 1), and four weeks after the intervention ends (post-test 2). Outcome Measures included demographic data, **s**exual communication self-efficacy, safer sex knowledge, TPB variables of condom use.

3. **Voluntary Participation**: Participation in this study is entirely voluntary. You may choose whether to take part and may withdraw at any time, for any reason, without penalty.

4. **Risks and Responses**: Because some questionnaire items addressed sensitive topics, participants could submit anonymous email inquiries, which the research team answered. The intervention lasted 10 weeks. Participants could withdraw at any time; if they did, their decision was respected and their cloud-stored questionnaire data was deleted.

5. **Potential benefits**: The intervention in this study can promote adolescent girls' sexual communication self-efficacy, sexual knowledge, and safer sexual behaviors.

6. **Confidentiality**: Once the data you provided has been entered into the computer and coded, we will securely store it on a password-protected hard drive or computer.

7. **Compensation**: Participants who complete the entire study will receive a gift or

monetary payment commensurate with their contribution as compensation. For those who do not complete the study and withdraw midway, compensation will be provided on a pro-rata basis.

8. **Contact Information**: Principal investigator was Tseng, ying-hua, email address: yhtseng@kmu.edu.tw
9. Signatures: Signature of Subject _____

國立成功大學人類研究倫理審查委員會
National Cheng Kung University Human Research Ethics Committee
網址：http://rec.chass.ncku.edu.tw/ E-mail：em51020@email.ncku.edu.tw
70101台南市大學路1號光復校區雲平大樓東棟北側4樓
電話：886-6-2757575-51020 , 886-6-2756831

Approval No. NCKU HREC-F-108-370-2
Project Title: The effect of "Girls" mobile application on sex communication among adolescent girls: From development to evaluation
Principal Investigator: Tseng, ying-hua
Affiliation: Kaohsiung Medical University
Current REC Approval Period: Nov.09.2019 to Jul.31.2021
Due Date of Progress Report: May.08.2020
Nov.08.2020
May.08.2021
Due Date of Final Report: Jul.31.2021

Dear Applicant Dr. Tseng, ying-hua,

Human Research Ethics Committee at National Cheng Kung University (NCKU HREC), authorized by the Ministry of Education, has reviewed the project "The effect of "Girls" mobile application on sex communication among adolescent girls: From development to evaluation". The project and your response to our review comments have been determined by our committee to be in conformity with the ethical guidelines for ensuring that the rights and welfare of research participants are adequately protected. Within the mandate for ethical review, the NCKU HREC hereby approves the implementation of your project.

If the documents reviewed need revision, or if any unexpected event which would affect participants' rights and welfare should occur, please inform the NCKU HREC during the approval period. Please also notify the NCKU HREC when the project is not being conducted for any particular reason.

If you have any questions regarding this approval, please contact the NCKU HREC office at +886-6-2757575-51020. The NCKU HREC appreciates your commitment towards the ethical conduct of human research.

Yours sincerely,

Shu-Chin Grace Kuo

Date: Nov.09.2019

Shu-Chin Grace Kuo, S.J.D.
Professor of Law
Chair, Human Research Ethics Committee
National Cheng Kung University
TAIWAN

National Cheng Kung University Human Research Ethics Committee