**Study Protocol and Statistical Analysis Plan**

**Brief Title:** Study of an Online Program to Help Parents Talk with Their Tween Children About Health, Gender, Body-Image, and Relationships

**Protocol ID:** TweenHealthStudy-R21-23-006-01

**ClinicalTrials.gov ID:** NCT06408818

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**Study Protocol**

The purpose of this project is to assess a self-paced online program, *Media Aware Parent: Tween* (*MAP: Tween*), designed to provide parents with knowledge about preadolescent development, media mediation skills, and practice in high-quality parent-child communication about body image, sexual development, gender stereotypes, and romantic relationships. The program will help parents of preadolescents (9-12 years of age) have effective conversations with their child about these topics and enhance media literacy skills to counter unhealthy media messages.

Study participants will contribute to the evaluation of a web-based application that will act as a resource for parents to have informed high-quality conversations with their preadolescent child about body image, sexual development, gender stereotypes, and romantic relationships. Through their participation, parents and children in the study may also acquire an increased knowledge about these topics and media literacy.

Preadolescence is a critical stage of development as youth transition from childhood into adolescence, and the *MAP: Tween* program may help improve communication between parents and children. High-quality parent-child communication has been shown to positively impact youth decision-making and health outcomes; therefore, this program has the potential to benefit society by resulting in an evidence-based program to enhance parent-child communication.

The procedure that will be used for conducting the research study is as follows:

1. We will aim to recruit a diverse sample of 300 parent-tween pairs (youth aged 9-12) to participate in this study. We will aim to have the sample consist of at least 40% fathers or male guardians and no more than 60% non-Hispanic/Latinx white adult participants. Parent-child pairs will be stratified by parent's gender and race/ethnicity prior to randomization to ensure diversity across groups.
2. A recruitment website will be available. Interested parents can complete an online screener found on the website. If eligible, parents will be directed to a place where parents and their children can complete the online informed consent process.
3. On the parent permission and consent form, participants will be asked for their preferred email address to receive study communications over the study period. Before receiving communications at this address, they will need to verify that they can receive emails at this address by clicking a link that is emailed to them. Parents will also be asked on the permission and consent form to agree to receiving study communication via text. Before receiving text communications at their phone number, they will need to verify that they can receive texts at their number by clicking on the verification link that is sent via SMS message. Finally, parents will also be asked to verify their name and address either through uploading on the permission-consent form an image of some form of document that includes their name and address (e.g., license; electric bill) or showing the document to a study team member through a live web conferencing call (e.g., Zoom call). [Modification: Due to concerns of people uploading images of documentation that was photoshopped, during the study the verification protocol was modified (and approved by the IRB) so that all participants were asked in the screener survey to indicate the school district where their

child attended school and then this was checked against our list of schools that distributed our flyer. Only parents that listed a school district where our flyer was distributed, were enrolled.]

4. The study team will enroll eligible, consented, and verified pairs based on whether there is room in the study according to gender and race/ethnicity stratification. If there is space in the study, parent-child pairs will be randomly assigned to either the Intervention condition (receiving the *MAP: Tween* program) or the Active Control condition (i.e., receiving medically-accurate information from sources like the CDC about topics such as preadolescent development, body-image, gender, and relationship health).
5. Pretest questionnaires for parents and their children will be distributed to enrolled parents in two separate emails/texts containing a link to complete their respective questionnaires. Participants will have one week to complete their questionnaires. If both the parent and child complete their questionnaire, they will be eligible for a $30 gift card.
6. Parents will receive a reminder (email, phone call, or text) to complete the pretest questionnaires if both are not completed in the first two business days. If both questionnaires are not completed, the parent will receive a final reminder around the 6$^{th}$ day.
7. Once pretests questionnaires are completed, parents will receive a link to access their randomly assigned resource (i.e., *MAP: Tween* OR medically-accurate information from sources like the CDC). The resources could take up to a total of 2 hours to review over the course of 3 weeks. Parents who complete the program within 3 weeks will be eligible to take the parent feedback questionnaire. Completion of the feedback questionnaire may take up to 15 minutes. If the parent completes the questionnaire, they will be eligible for a $40 gift card.
8. About four weeks after pretest questionnaire completion, parents will receive two emails/texts – one with a link to their posttest questionnaire and one with a link to their child's posttest questionnaire. Participants will have one week to complete their questionnaires. If both the parent and child complete their questionnaire, they will be eligible for a $45 gift card. Parents will receive a reminder (email, phone call, or text) to complete the posttest questionnaires if both are not completed in the first two business days. If both questionnaires are not completed, the parent will receive a final reminder around the 6th day.
9. Incentives will take the form of gift cards. Participants will be emailed the appropriate Amazon.com electronic gift card after completing the study questionnaires.

**Statistical Analysis Plan**

Preliminary Analyses. Psychometric analyses will be conducted to study the reliability, validity, and distributions of key variables. These analyses will be conducted by first assessing the internal consistency (i.e., Cronbach's alphas) of outcomes with Likert-type scales. If the alpha for an outcome is unacceptable (i.e., less than 0.70), then items that do not correlate strongly with the total scale will be removed, one-at-a-time, until the alpha for the scale is acceptable. Once items are averaged together to create the scale, outcome distributions will be assessed using univariate analyses to examine skewness and kurtosis, providing preliminary inside into potential deviations from normality prior to model fitting. If outcomes are unacceptably skewed or kurtotic, then outcomes scales will be modified (via re-scaling or dichotomizing) or eliminated

from analysis. The impact of random assignment on producing equivalent groups will be assessed on pretest demographic and background characteristics in a series of t-tests and $\chi^2$ analyses. If we establish that the groups are not equivalent on any pre-specified variables, these variables will be used as covariates in the analyses of intervention effects. For continuous outcomes, normality assumptions will be tested using the Shapiro-Wilk test, Q-Q plots, and histogram of the residual distributions, via linear regression analyses of raw data, with all covariates included in the model. If the Shapiro-Wilk test is significant (p-value of w <.05), the histogram of residuals deviates substantially from a bell curve, and the Q-Q plot includes a pronounced S-curve (deviates substantially from the line), then the outcome scale will be transformed (via re-scaling or dichotomizing) or eliminated from analyses. Finally, we will use multiple imputation to handle missing data and analyses will be conducted on each imputed dataset, with resulting estimates and standard errors pooled using Rubin's Rules.

Main Analyses. Analyses will examine the effects of the program on attitudes, cognitions, and behaviors, which will provide information on program feasibility. We will use a series of linear regressions for outcomes with continuous distributions and logistic regressions for dichotomous (yes/no) outcomes in intent-to-treat analyses. Posttest scores will be regressed onto pretest scores, covariates, and the intervention effect. Covariates will include those that were non-equivalent between groups at pretest, parent sex, child sex, socioeconomic status, and parent- and child-reported supportive parenting. The Benjamini-Hochberg procedure will be employed to control for the False Discovery Rate (FDR).