

**Me & You-Tech: A Socio-Ecological Solution to Teen Dating Violence for the Digital Age**

**NCT05225727**

**Version Date: 12/08/2023**

## PHASE 2. Efficacy Trial of Me & You Tech

Purpose – To conduct efficacy trial of MYTech in schools and online

Who – Protocols for the study investigators and research staff.

When – Months 25-38 of the 38 month study. Pending Institutional Review Board (IRB) approval.

Where - The procedures below will be conducted in two ways depending on the COVID-19 situation, UTHealth policies and participants' comfort level with in person testing. We will have a few options for participants to choose from and these options can be combined depending on changes in the comfort level of participants.

**OPTION A)** We will be conducting the efficacy trial in participating schools; **OPTION B)** entirely online study for participants and remote technical assistance from project staff.

Materials needed - Informed consent form (verbal and in-person), assent form (verbal and in-person), MYT program, on-line (REDCap) baseline and two follow up surveys including psychosocial and behavioral surveys and usability ratings scale.

### Procedures:

1. *Study participants:* We will conduct the efficacy trial with five to six 6th-grade schools (n=300 students total), their parents (n=150) to determine the efficacy of MYTech in the school and home. We will also evaluate the school staff module with school staff indicated by the school (n=25). We will also administer efficacy study protocols to determine that MYTech and study surveys can be accessed and operated as designed.
2. We will recruit five to six schools to participate in this efficacy trial. Recruitment procedures will mirror those described in approved Protocol 1.2. Youth and parents will work through MYTech in a concatenated timeline.
3. *Informed consent:* **OPTION A:** The testing will be held in the school classrooms. Active parental and student consent will be obtained. Youth will be informed that they have a right to refuse to participate and can withdraw at any time. Parent consent and youth assent will be secured prior to administration of the baseline survey. We will also obtain active consent from school staff that are participating in the program. **OPTION B:** Project staff will read the verbal consent aloud to the parents and school staff prior to testing. The youth will be read the verbal assent prior to the testing. All participants will be informed that they have the right to refuse to participate and can withdraw at any time.
4. *Program Implementation:* Students will receive the 13 lessons for Me & You Tech. Research staff will work with school personnel to identify subjects for MYTech program delivery. Prior to implementation, parents will receive information about MYTech and be provided with a parental consent form for program participation (students will be provided with assent). Times will be scheduled for parents to preview program material and to discuss any concerns if necessary. Students will access the program via their own device or via school-provided computer resources per out previous studies. Parents will receive six corresponding modules to the 13 student lessons. School staff will receive three training modules prior to implementation of student program.
5. *Process Evaluation.* To monitor the extent and fidelity of MYTech implementation, we will collect process data throughout implementation. Student exposure to and familiarity with MYTech activities, and any other DV prevention activities, will be assessed with process questions in the student assessment for both conditions. We will also inquire from teachers from both conditions to assess whether any other DV or health programs were implemented. Further, youth, parent, and school personnel-exposure to MYT will be

measured via web analytics, e.g., resource accesses, session length, time on individual task, navigation, user preferences, and completed PEP talks.

6. *Pre-test (Baseline).* **OPTION A:** The youth, parents and school staff will individually complete the on-line survey privately in school (for students and school staff) or privately from their location (parents) **OPTION B:** The youth, parents and school staff will individually complete the online survey privately from their location.
7. *Post-test.* Youth participants will complete the two follow-up surveys: one after completing thirteen online lessons from the Me & You Tech program and another at 9-12 months follow up. Parents and school staff will complete a follow up survey after the completion of the program. **OPTION C:** Youth, parents and school staff will be offered the option to complete follow up surveys via phone if they are unable to complete it via Option A or Option B above. This will be conducted in line with other projects by contacting the participant with phone numbers received from the participant or school. The participant will be given the option to complete over the phone. If they select this, a staff member will complete the survey and log completion on the excel file with their initials.
8. *Data Collection Procedures and Incentives:* All surveys will be completed via web-based CASI surveys (e.g., REDcap) hosted on secure UTHealth servers to ensure standardization of data collection procedures. Prior to participation, all participants will receive information about the study and how confidentiality will be protected. If they choose to participate, students will complete an assent form (parental permission will have been obtained). Data collection will be conducted in schools using school computers during class time as done successfully in previous studies (IYG-Tech, Me & You). For parents, we will offer the option of technical assistance through online video conferencing as needed for both surveys and curriculum access as used in our previously approved Usability Testing Protocol.
9. *Incentives.* Electronic gift cards will be provided parents (\$50) and school personnel (\$50). Students will receive physical gift cards in a total of \$25.00: \$5.00 gift card for returning completed consent, \$5.00 gift card for completing baseline survey, \$5.00 gift card for completing second survey and \$10.00 gift card for completing the third survey. The study will take approximately 8 hours of the student's time, and 4 hours of the parent's and school personnel's time to complete. We will also include a \$25.00 gift card for teachers of classes that have an 80% return rate of consent forms for students. We have used this process in other studies and it has been found to be a successful recruitment strategy to increase return rates. We will also include a classroom wide incentives (e.g. pizza party or something else) as we have used this process in other studies and it has been found to be a successful recruitment strategy to increase return rates.
10. *Identifiers.* Participants will be assigned a unique identification number and no personal identifiers will be linked with the surveys or documentation.
11. *Data security.* Completed surveys will be stored on the UTHealth server on REDCap. It will be downloaded into a secure study database in the UTSPH server separate from the REDCap data which will not have personal identifiers.