Study Title: Mobile Technology for Reducing and Preventing Adolescent Suicide

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Statistical Analysis Plan

for

[0766] 2020-Oui-001

Oui Therapeutics, Inc.

Mobile Technology for Reducing and Preventing Adolescent Suicide

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Study Objectives and Endpoints

1.1 Study Objectives

1.1.1 Primary Objective

The primary objective of this study is to collect descriptive data to support feasibility, acceptability, safety, and potential for effectiveness.

- The potential for effectiveness is determined by examining participants' pre-test and post-test scores for SI and depression.
- The study will also collect data to guide refinements to the product and the workflow for product use.
- Participants will complete 12 sessions over approximately 12 weeks.
- Participants will complete assessments at baseline and weeks 1, 4, 8, and 12.
- Acceptability is determined from rates of session completion, rolling retention rate (percentage of participants who use the app on or after a set timeframe), and the system usability scale (SUS; Bangor et al., 2008), which indicates the extent to which participants found Oui's app usable.
- We will also conduct semi-structured user-feedback interviews.

2 Sample Size

As proposed in the Phase 1 study, we will enroll 20 participants.

3 General Issues for Statistical Analysis

The study will use a frequentist approach to statistical analysis. Descriptive statistics will be used to generate an overall summary of the baseline participant characteristics, and participant disposition. The following summary statistics will be presented unless otherwise stated: Numerical variables will be summarized with sample size, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized with frequency and percentages.

4 Demographics and Other Baseline Characteristics

4.1 Demographics

All demographics will be summarized, and a listing will be generated, unless otherwise specified. Demographics will include age, gender, race/ethnicity, and sexual orientation,

4.2 Concomitant Medications/Psychotherapy

All concomitant medications and participation in outpatient psychotherapy will be recorded at the Baseline Visit. The use of ongoing and any new medications will then be noted at each following study visit.

4.3 Baseline Medical History

Medical history, the status of each comorbidity (ongoing/resolved), and treatment will be collected by body system (dermatological, cardiovascular, pulmonary, musculoskeletal, abdomen/gastrointestinal, neurological, lymphatic, psychiatric/behavioral, endocrine/metabolic, blood/lymphatic, respiratory, renal, genitourinary, hematological, allergies/drug sensitivities, substance abuse, and other).

5 Adverse Events

All adverse events (AEs) will be coded using the standardized Medical Dictionary for Regulatory Activities (MedDRA) central coding dictionary, version 24.1 or greater. AEs will be summarized in the safety population.

5.1 All Adverse Events

Summaries of incidence rates of individual AEs by System Organ Class (SOC) and Preferred Term (PT) will be prepared. Because a participant may experience more than one AE, summaries will provide both the number of participants experiencing at least one event and the number of events within a reporting period.

5.2 Serious Adverse Events

Summaries of incidence rates and relationship to the investigational device of individual SAEs by SOC and PT will be prepared. Summaries will provide both the number of participants and the number of events within a reporting period. Percentages provided will be the percent of participants experiencing one or more serious adverse events.

6 Other Planned Analyses

6.1 Other Analyses

6.1.1 System Usability Scale (SUS)

The SUS is a 10-item instrument used to measure device usability and results in an overall score. Scores will be presented in a table using means, standard deviations, medians, minimums, and maximums over time: at week 4, week 8, and week 12.

6.1.2 Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS is a rater-based interview to assess the severity and intensity of suicidal ideation and behaviors. Results will be presented for each question and within each of four constructs using counts and percentages over time: at week 4, week 8, and week 12.

7 Reporting Conventions

All reporting will meet the standards of SOP-68 AS Data Analysis Reporting and SOP-83 AS Programming Standards.

8 References

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