Protocol NX-31380

Cover Sheet

Official Title: Boost Study 31380 (mHealth)

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Practices Statement

This study is to be performed in full compliance with the protocol and applicable oversight body and regulatory requirements. All required study documentation and data will be archived in accordance with preauthorized policies and procedures.

1. Background

Opioid use disorder (OUD) affects an estimated 1.9 million people in the United States (2014) with an estimated 586,000 of cases related to heroin use, and with all patients suffering harms as a result of this chronic condition. The economic impact of illicit prescription opioid abuse alone is estimated to be $53-$72 billion, imposing high costs to society as a whole. In previous work, NXTech developed an mHealth application derived from cognitive science findings to assist in symptom management for OUD. In this study we provide mHealth-based exercises to individuals diagnosed and in treatment for opioid use disorder to inform design of optimal mHealth (mobile healthcare) interventions for OUD.

2. Protocol and Procedures

This study consists of a feasibility study of the mHealth platform for cognitive training completion in a single-arm study of individuals in supervised treatment at the site of recruitment, under the care of an independent clinical provider.

Participants in this study of the mHealth platform (see SAP for recruitment targets) will be invited to participate by study investigators, in a local study of 8 week duration, with an optional extension of up to 8 additional weeks upon participant election.

IRB approval will be obtained by the local host institution prior to any human participants activities. Procedures are intended to adhere to the Good Clinical Practices Consolidated Guideline and the Declaration of Helsinki. Monitoring data and safety of participants will be performed by the Principal Investigator and an applicable human participants Institutional Review Board (IRB) with authorized recognition of the IRB by the study site. All participants must provide informed consent in writing before enrollment and will be informed that they may disenroll at any time. There is no more than minimal risk expected to participants in the study.

In this study, participants are requested engage with mHealth platform interactions for the duration of the study period of at least 8 weeks, in addition to completing weekly assessments. Enrollment criteria are provided in Section 3. Participants supply their own standard electronic mobile device to complete the study or may receive a loaner device. All mobile devices used in this study will be standard commercial units.

After completion of the final day of participation by the final participant, full analysis of recorded data will be completed. During the study period, intervention feasibility will be assessed using measures of utilization, in addition to structured and open-ended user feedback. Primary outcome measures are user acceptability of the and secondarily for treatment-related effects of the mHealth application as an addition to usual care.

3. Recruitment and Enrollment

Recruitment will proceed under the supervision of a local site investigator, such that participants will be offered study participation after provision of written informed consent. Participants will only be tracked by an assigned numeric ID that is unassociated with an individual's personally-identifiable information.

Patient enrollment will follow, over an up to 4 month period and participants will continue into the study in rolling fashion. Individuals will be remunerated for their participation at a rate of up to $50 per week for the primary study period of 8 weeks (or as adjusted based on prevalent rates at the time of study execution).

Demography of enrolled participants will be collected for review during the analysis phase.

Inclusion Criteria are as follows, in addition to concurrent enrollment in a clinician-supervised treatment program:

Age 18-65 years
Diagnosis of opioid use disorder
Experiencing symptoms multiple times per week
Familiar with smartphone usage

Exclusion Criteria: None if qualified under Inclusion Criteria

4. Compliance Procedures

This study will be performed in accordance with Protocol requirements and applicable oversight body policies.

Data collection will be primarily in electronic format. All required study documentation and data records will be archived in accordance with preauthorized policies and procedures. Investigators will assure that either a wavier of consent is granted under IRB approval, or that informed consent is obtained prior to performing any research procedures. Investigators will ensure that all participants meet eligibility requirements, and that the study is conducted according to the IRB-approve research plan and in accordance with the Federalwide Assurance certification of the site.

Adverse events and serious adverse events are not expected but will be recorded and addressed under institutional procedures.

Documentation and data will be stored and archived in a secure format for at least 2 years and for the duration required by the Sponsor and collaborating sites.

5. Biological Specimens

None are expected to be collected specifically under the Protocol.