Protocol NX-21270

Cover Sheet

Official Title: Boost Study 21270 (Cognition)

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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 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. In this study mHealth-based exercises are provided to healthy individuals to inform design of optimal interventions for OUD.

2. Protocol and Procedures

This study consists of a feasibility study of the mHealth platform for cognitive training completion in two configurations.

Participants in the beta test (see SAP for subjects recruitment targets) will be invited to participate by investigators, in a remote study coordinated by the investigator institution.

IRB approval will be obtained by the local host institution prior to any human subjects activities.
If no waiver of written consent is granted under IRB oversight, subjects will provide informed consent in writing before enrollment. There is no more than minimal risk expected to participants in the study.

The experiments will be completed online and users will be required supply their own standard electronic mobile device to complete the study.

Participants will be recruited to engage with the application for a recommended period of 150 minutes per week for 8 weeks total, with enrollment as detailed in Section 3. During the study period, we will evaluate application feasibility by gathering optional open-ended and closed-ended feedback along with required measures of user adherence to the intervention and requested measures of task performance as delivered on a numerical score basis by the mHealth application.

3. Recruitment and Enrollment

Recruitment will proceed through two stages. First, participants will be pre-screened for their eligibility for the second stage and their baseline rates will be determined, in addition to an optional survey relating to health behaviors, as the selection of the site investigator and subject to remote platform screening acceptance. Second, participants meeting eligibility criteria below and who occupy the upper 25% quartile of scored choices will be invited to an 8-week long follow-up study. Compensation for participation will be set at a rate of $5 per hr (or as adjusted based on prevalent remuneration rates at the time of study execution).

Subjects will only be tracked by an assigned numeric ID that is unassociated with an individual's personally-identifiable information.

Inclusion Criteria are as follows:

Age 18 years and above

Fluent in English
Resides in the United States
Score on prescreen task is in 25% quartile
Familiar with smartphone device app installation and device usage
Possesses a compatible smartphone

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 Samples

None will be collected or analyzed.