TARGETING REWARD DYSFUNCTION AS A MECHANISM TO IMPROVE SMOKING CESSATION

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COVID Amendment
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DESIGN AND PROCEDURES

Explanation

Restrictions imposed by the COVID-19 pandemic have required amending the procedures in this study. We have created this protocol amendment specifically for the sections requiring these procedural changes. The changes minimize participant contact and reduce risk of exposure but still allow for collection of the important outcome and safety measures necessary to address the specific aims of this NIH grant. Only sections of the original protocol that will be modified during COVID-19 restrictions are listed below. Otherwise the protocol and procedures will remain the same as the currently-approved protocol.

Screening Session. The screening visit will be split into two portions: remote and in-person. The remote session will be conducted first. A duke approved video meeting platform (i.e. Zoom) will be scheduled for the screening session. Participants will be required to first present a valid photo ID prior to obtaining informed e-consent to confirm age and identity. During remote screening, all aspects of the study will be described to subjects and informed consent will be acquired through electronic consent. Measures of smoking history, nicotine dependence, and mood will be collected (see Table 1 below for key measures acquired at each visit). In addition, computerized psychiatric screening measure and depression measure survey link will be emailed to subjects and a follow-up interview will be done to assess current and past psychiatric disorders. During the in-person portion of the screening visit, breath and urine samples will be collected in order to verify smoking status and assess recent drug use; vitals such as heart rate and blood pressure will also be measured. For staff and participant safety, the subject will be alone in a designated ventilated study room and will be taught over video how to collect the breath sample and vitals. They will either verbally report or show the results to the camera. A urine sample will be obtained in order to screen for illicit drug use and to assess pregnancy status.

As the K-BIT2 is an in-person measure requiring up to 30 minutes of face to face contact to administer, we will be substituting it with the word reading subtest of the WRAT during the remote portion of screening. Subjects who meet all entry criteria will be provided with the option to continue with the training session on the same day as in-person screening.

Interviewer-Administered forms

The following questionnaires will now be completed as an interview during the video session.

1) Basic Demographics
2) MR Screening Form
3) Brief Medical History
4) Respiratory Health Questionnaire
5) Side Effects Form (screening)

Web-based data collection completed by the participant via survey link:

The following questionnaires will now be completed via REDCap survey link:

1) BDI
2) Barriers to Participation

Changes to Inclusion/Exclusion Criteria

Inclusion criteria:

3) Removing KBIT-2 inclusion criteria, changing it to WRAT score ≥ 70
9) Access to a smartphone, tablet or computer with functioning camera, adequate data, and/or internet access for conducting remote visits and completing online surveys in REDCap

Exclusion criteria:

23) Removing breath alcohol level > 0.0
32) Refusal to abide by safety standards

Training Session. Participants will complete the training session on the same day as the in-person screening session, unless there are concerns about information collected that day (e.g. high blood pressure).BAL and weight are no longer collected. If there are no concerns, the subject will remain alone in the private testing room and will be interviewed over video. MR screening form will be reviewed and signed by participant. Participants will then be scheduled for their first fMRI session. REDCap questionnaires will be set up for them on an iPad or computer.

Participants will then be moved to a room containing a mock scanner. They will have the opportunity to experience the mock MRI scanner and will be trained on the rewarded guessing task and behavioral incentive delay task from a distance. Instead of staying in the scanner for 5 minutes, they will be in the scanner for 10 minutes with a mask on to confirm ability to scan.

Interviewer-Administered forms

The following interviews will be conducted over video instead of face to face.

1) Health Changes Questionnaire
2) Timeline Follow-Back

fMRI Sessions. MRI procedures will remain the same with key exceptions:

1. Initial CO will be collected by subject, outside, with RA a minimum of 6 feet away with appropriate safety material (e.g. N95 mask, gloves)
2. Subject will be alone in testing rooms to complete questionnaires. Any questions will be answered via video or phone
3. Removing the EEfRT task (to reduce contact)
4. Removing second and third CO collection (to reduce contact)

Interviewer-Administered forms

The following interviews will be conducted via video instead of face to face.

1) Health Changes Questionnaire

2) Side Effects Form (From last visit)

Web-based data collection completed by the participant via survey link:

The following questionnaires will now be completed via REDCap survey link:

1) Caffeine and Alcohol Intake

Treatment Sessions. Treatment will remain identical with the exception that they will be conducted remotely over video or phone.

Web-based data collection completed by the participant via survey link:

The following questionnaires will now be completed via REDCap survey link:

1) WAI
2) Treatment Evaluation Form (treatment 8 only)

Assessment Sessions. Assessment procedures will be changed to reduce contact and duration in lab as much as possible. During the first, second, and third assessment, subjects will enter the lab to complete procedures. Vitals are essential to monitor for adverse events while using the study cigarettes. BAL and weight are no longer collected though, as these are not necessary for participant safety. They will be in a private room for the duration of the visit. All study interviews and questionnaires will be conducted via video call and/or Redcap survey link. After the third assessment, (when investigational cigarettes are no longer provided), we will be introducing a curbside exchange/drop-off. Subjects will complete the interview and questionnaires remotely and then have until the next day to return product. Subjects may meet up outside to complete the CO and exchange product, with staff wearing appropriate protective gear. All other vitals will stop being collected after assessment 3.

Interviewer-Administered forms

The following questionnaires will be completed as an interview during the video or phone session.

1) Health Changes Questionnaire
2) Timeline Follow-Back
3) Respiratory Health Questionnaire
4) Side Effects Form (From last visit)

Web-based data collection completed by the participant via survey link:

The following questionnaires will now be completed via REDCap survey link:

1) BDI

RISK/BENEFIT ASSESSMENT

COVID-19

We have made attempts to protect participants and staff from covid-19. There is still some risk as we are asking subjects to come to our laboratory and to BIAC for fMRI scanning. There is additional risk if subjects choose to come by public transportation. This will be addressed to them during the consent process.

PARTICIPANTRECRUITMENT ANDCOMPENSATION

Participants will receive $40 for screening only if they pass the remote screening procedures and attend the in-person visit. As before, participants must pass the drug screen and CO to receive payment.

DATA SAFETY AND MONITORING PLAN

In addition to the data safety and monitoring plan, we will be adding this withdrawal criteria.

Withdrawal of Participants and Medical Monitoring

For safety concerns, participants will be withdrawn immediately from the study if any of the following occur:

5) Positive Covid-19 test