Quit for Life Protocol

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Statistical Analysis Plan see Section 2.4

1. PURPOSE

The purpose of this MOP is to guide the study's conduct and operations. It will help to facilitate consistency in recruitment, screening, enrollment, randomization, intervention procedures and follow-up procedures, data collection methods, data flow, surveys conducted at different time points and quality control procedures. This guide will supplement the study IRB protocol.

User/audience

- Principal Investigators, Co-Investigators
- Counselor
- Research Assistants (RA)

2. PROCEDURES

Description of responsibilities for study personnel as well as the steps and processes to be followed when conducting the study.

2.1.1 Pre-launching

- Before launching the study, the study research assistant will:
    - Approach individuals who attend the HIV clinic at GMU and conduct face-to-face interviews to screen them for eligibility.
    - Get notified by physicians at the clinic of potentially eligible/interested participants so that the RA can conduct face-to-face interviews to screen them for eligibility
    - Get trained on conducting follow-up counseling sessions according to the counseling guide
    - Prepare baseline and follow-up surveys in the same format across participants (via computer, WeChat, in-person etc.)
    - Ensure paper data forms are finalized and computer data entry systems are ready for data entry (EpiData) so that computer-generated spreadsheets of data can be generated
    - The RA will prepare self-help manual and NRT gum for every participant
    - Purchase the CO monitor, train users how to use it for biochemical verification of quitting at 12-month follow-up assessment
    - Train the counselor using the counseling guide that is established to conduct counseling sessions. Counselors should be familiar with the content and procedures of the guide to communicate with participants
    - Counselor should be familiar with referral services around the area/online for smoking cessation

2.1.2 Study visits

- **Pre-study visit procedures**
    - Prior to conducting study visits, the RA will ensure that appropriate materials are in place to help in the smooth running of the clinical research study activities. The materials needed to begin the trial is listed in Section 2.4. Below are the procedures needed to be done to begin the trial:
        - Train counselors according to the counseling guide to prepare for the counseling sessions

        - Prepare the brief screening agreement, baseline survey, 8-week follow-up survey, and 12-week follow-up survey
        - Prepare informed consent form (one form for the study participant to keep, one form to be collected by the RA)
        - Set up EpiData system and be ready to enter participant data once the screening process starts
        - Prepare approximately 110 envelopes for randomization
        - Create a storage location to list participants' phone number
        - Create a list to keep track of what messages have been sent to each participant
        - Create a WeChat account for the study and for sending text messages
        - The RA should be accustomed to accessing the WeChat account and sending the messages to each participant
        - Print the self-help manual for each participant (110 copies)
        - Purchase and prepare NRT gums to give out to participants (gums will be given out 8 week dosage at a time to all participants)
        - Familiarize the usage instructions for the NRT gums to explain to participants
        - Obtain usage instruction of the NRT gums to hand out to participants
        - Training on using the CO monitor and filters (at least 100)
- **Study visit procedures**
    - The RA will conduct face-to-face interviews with potential participants and ask the screening questions (Refer to document 1: brief screening agreement)
        - If eligible: Make a note in tracking system that an individual was screened and was eligible, and the criteria for which they were eligible. Answers will not be retained.
        - If not eligible: Make a note in tracking system that an individual was screened and was ineligible, and note the criteria for which they were ineligible. Answers will not be retained.
    - The RA will collect and verify all signed informed consent documents and place them in participants' study folders (labeled by ID number).
    - Participants will receive a signed copy of the informed consent form
    - The RA will add participants' WeChat contact after participants have signed the informed consent form and are randomized into the intervention group
    - The RA will record participants' phone number for follow-up counseling sessions (Refer to document 11: tracking spreadsheet)
    - Record survey completion status for each participant

2.1.3 Randomization

- Study statistician will produce a randomization scheme that is unknown to the RAs and produce 110 envelopes for randomization. Half of the envelopes indicate that participants are assigned to the control group, half of the envelopes indicate that participants are assigned to the intervention group
- After the completion of baseline questionnaire, RA is going to randomly open up an envelope to assign participants to either the control or the intervention group

- The RA is going to input participants' ID number and their assigned group into the data storage system (EpiData)

2.1.4 Monitoring

- The principal investigators will periodically monitor the trial progression to ensure aspects of the protocol are followed
- Study and source documentation will be reviewed for verification of data collected. Check the source documentation at visits
- Review the participants' study folders to ensure it is complete and current
- Create a tracking spreadsheet to keep track of participant activities, such as enrollment progress, phone numbers, WeChat account names, text message schedule for each participant, and NRT usage (Refer to document 11: tracking spreadsheet)
- Meeting with the study coordinator approximately once a week to review any issues found during screening, enrollment and any other study activities

2.2 Research Assistant

Step 1: Identifying Subjects, Screening and Eligibility, and Enrollment

- Recruitment will occur via physician referral and approaching individuals who are seeking care at the HIV clinic
- Individuals will be screened for eligibility (Refer to brief screening agreement)

Step 2: Informed Consent Process

- RA must have enough copies of the consent documentation (Refer to document 2: adult informed consent form)
- The RA will conduct the consent process in a private location, hand out the printed consent form and review the form with the participant
- If the participant provides consent to participate, the adult informed consent form should be maintained in the participant's study file
- A copy of the signed consent document will be provided to the participant to keep
- RA will submit the signed participant informed consent forms to the study coordinator to be saved in the participant study file

Note: If a participant is withdrawn after enrollment, the consent form should still be maintained and not destroyed

- The study team obtaining the consent must also sign and date the consent form
- Record date the ICF has been signed on a tracking spreadsheet (Refer to document 11: tracking spreadsheet)
- The RA will record participant's contact information including WeChat name and telephone number (Refer to document 11: tracking spreadsheet)

Step 3: Survey Administration and Randomization

- After participants sign the informed consent document, RA will administer the baseline survey, baseline demographics, smoking habits, and other information will be surveyed (Refer to document 3: baseline survey)
- For accurate baseline measurements, the protocol below will be followed:
    - The RA will conduct face-to-face baseline surveying process to all participants

    - After participants complete the baseline survey, RA will make sure participant ID is written on the survey
    - Participant's identifiers are going to be removed from the survey and gets stored in another location separated from the survey answers. Survey responses are going to match participants' ID number in EpiData
    - The RA will enter the participant's ID and responses into EpiData
- The RA is going to conduct the randomization process after baseline surveys are completed. Corresponding participant ID and assigned group should be entered into EpiData

Step 4: Intervention group (Counseling Sessions and Text Messages)

- The RA will give each participant in the intervention group a self-help manual and 8-week dosage of NRT gum
- The text messages are going to be sent by the RA following the pre-determined schedule with pre-determined content (Refer to document 6: text messages)
- RA should keep a record of the messages that are sent and have not been sent to each participant (Refer to document 11: tracking spreadsheet)
- RA should keep a record of whether each participant is accepted the NRT gum (Refer to document 11: tracking spreadsheet)

Step 5: Control group

- The RA is going to give out a self-help manual and 8-week dosage of NRT gum to participants who are assigned to the control group
- RA should keep a record of whether each participant is accepted the NRT gum (Refer to document 11: tracking spreadsheet)

Step 6: Follow-up Visits

- The RA is going to administer the follow-up survey at 8-week and 12-week (Refer to document 4: 8-week survey and document 5: 12-week survey)
- RA has the flexibility to administer the surveys over WeChat or phone if in-person administration is not possible
- The RA is going to make sure that surveys are completed by the participants and have participants' ID number on each survey
- The RA is going to enter ID numbers and responses into EpiData

Step 7: CO2 Measurement

- At 12-week, the amount of carbon monoxide in the exhaled air for all participants using a CO monitor (Refer to document 5: 12-week follow-up survey)
- The RA will prepare the CO monitor and make sure that there are enough filters (100 filters) for all participants to get measured
- The RA will learn the method of measuring carbon monoxide in the exhaled air
- The RA will record the CO2 measurement results into EpiData along with participant's ID number and other follow-up results

2.2 COUNSELOR

Step 1: Preparation for Counseling Sessions

- The counselor will train with experts according to the counseling guide (Refer to document 7: counseling guide)
- The counselor will be notified by the RA when there are new intervention participants joining the study (once an ICF has been signed)

Step 2: Follow-up Counseling Sessions

- The counselor will provide counseling sessions at participants' follow-up appointments at the HIV clinic
- The initial counseling session will be face-to-face (20 minutes)
- The next three counseling sessions will be face-to-face ideally, but can be switched to telephone if appropriate (15 minutes each)

Step 3: Quality Assurance

- Counselor will record 10% of all calls for the counseling sessions, these recordings will be transcribed and translated
- The counselor will record any feedback or issues during the sessions and should meet regularly with supervisor for troubleshooting

2.3 MATERIALS

1. Brief screen agreement
2. Adult consent form
3. Baseline survey
4. 8-week follow-up survey
5. 12-week follow-up survey
6. Text messages
7. Counseling guide
8. Self-help manual
9. CO monitor
10. 100 filters for the monitor
11. Tracking spreadsheet
    a. Spreadsheet with enrollment progress (date and ICF)
    b. Spreadsheet with contact information (WeChat account names, phone numbers)
    c. Spreadsheet with text message schedule for each participant
    d. Spreadsheet of NRT gum usage

2.4 STATISTICAL ANALYSIS

1. Generate mean and standard deviation for demographic variables at baseline (or N and percentage). Run chi-square tests and t-tests for the variables and compare if there is a difference between treatment groups for each of the variables. Variables that are significantly associated with treatment group will be covariates in future analyses.
2. Analyze primary outcome: PPM (CO level) at 12-week. PPM will be a binary outcome: participants have either a PPM level that is less than 8 (success in cessation), or a PPM level of

equal or greater than 8 (no success in cessation). Run an unadjusted logistic regression with 12-week PPM as the outcome and treatment group as the predictor. Run an adjusted logistic regression adjusting covariates

3. Analyze secondary outcomes: 7-day point prevalence abstinence at 8- and 12-week. Run an unadjusted logistic model with 8-week PPA as the outcome and treatment group as the predictor. Run the same logistic model as above but with 12-week PPA. Run an unadjusted logistic model with 8-week PPA as the outcome and treatment group asthe predictor, adjusting for covariates. Run the same logistic model as above but with 12-week PPA, adjusting for covariates
4. Analyze other secondary outcomes: quality-of-life, ART adherence, change in smoking quantity, quit attempts.