Official Title: Mind to Quit Trial: Comparing Two Behavioral Approaches to Quitting Smoking in Mental Health Settings

NCT05030272

IRB Approval Date: 02/04/2025

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**Consent to Participate in a Research Study**
**ADULT**

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**KEY INFORMATION SUMMARY**

The purpose of this study is to evaluate the advantages and disadvantages of two approaches for quitting smoking among people with serious mental illness (SMI). You will participate in a 24-week (~6-month) study where you will be assigned to one of two behavioral approaches to quitting smoking. Regardless of the group you are assigned to, you will also receive a combination of nicotine replacement therapy (patches and gums) that have been shown to be effective in assisting people quit smoking.

You will be required to complete five online video call visits. Each visit will last approximately 1-2.5 hours. All visits will be conducted on Zoom video calling. Depending on the group you are randomized to, you will be asked to complete questionnaires, attend brief advice or download an app, use nicotine replacement therapy (NRT), and possibly asked to provide breath and saliva samples to test the carbon monoxide and nicotine.

The biggest risks of this study are side effects from NRT such as skin irritation, nausea, and lightheadedness and the risk of loss of confidentiality of your personal information. Other risks include withdrawal symptoms from quitting smoking cigarettes such as craving for cigarettes, headaches, difficulty concentrating, irritable mood, and increased appetite.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this study because you are a smoker with a diagnosis of a serious mental illness or SMI (schizophrenia, schizoaffective disorder, bipolar disorder, or recurrent major depression). Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will

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discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institute on Drug Abuse (NIDA) will sponsor this study. Portions of Dr. Paolo Mannelli's, Dr. Roger Vilardaga's, and his research team's salary will be paid by this grant.

**Who will be my doctor on this study?**
If you decide to participate, Dr. Roger Vilardaga and Dr. Paolo Mannelli will be your doctors for the study. Dr. Roger Vilardaga is the lead study doctor who is responsible for the research team and monitoring your safety. Dr. Paolo Mannelli will assist with the safety monitoring. They will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

If you decide to participate, we will also require that you sign a Release of Information (ROI) so that we may speak with your provider, and gain access to your medical records if necessary. We will only do so in order to ensure your safety, and the integrity of the research.

**Why is this study being done?**
The purpose of this study is to learn more about the advantages and disadvantages of two brief quitting smoking approaches that could be cost-effective in assisting individuals who suffer from serious mental illness.

The first approach is brief advice combined with the use of nicotine gum and patches. The second approach uses an app on your smartphone combined with the

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use of nicotine gums and patches. This app is an investigational device. The word "investigational" means the study drug or device or biologic is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA). These approaches to quitting smoking have been developed by Dr. Roger Vilardaga, the Principal Investigator, and by previous research funded by the National Institute of Health.

We will be comparing these two ways of quitting smoking to help us understand the unique advantages or disadvantages of each for people with serious mental illness who are trying to quit smoking. Findings from this research may be used to increase access to behavioral treatments for quitting smoking in people with mental illness.

Up to 200 people will take part in this study at Wake Forest University and up to 675 people will take part in total from all the participating sites.

**What is involved in the study?**
All five visits will be done over Zoom video calling. We will provide you with a link to the Zoom call prior to each of your study visits. At the beginning of each visit, we will verify your identity by taking a photo of you via zoom. We ask that during your scheduled visit you find a quiet, private place to talk with us, as we will discuss some personal topics. You may be asked to provide a breath sample and saliva sample to measure the carbon monoxide and nicotine levels.

***Screening Visit***
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Completing a Release of Information (ROI) to communicate with your treatment providers
- Obtaining your contact information
- Completing questionnaires about your medical history, smoking and tobacco use history, past and current substance use, and mental health

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- You will be asked to provide us with a photo ID so that we may verify your identity and age

Once this screening visit is finished, we will review your information to determine whether you can participate in the study. We will contact you once we determine this. If you are still eligible to continue with the study, we will schedule your next visit where you will be assigned to one of the two quit smoking approaches.

***Baseline Visit***
During the baseline visit, we will have you complete some more tests and questionnaires:

- Asking about any changes to your physical or mental health
- Questionnaires about your smoking status and your experience with technology
- Completing a cognitive test

Once the questionnaires are completed, you will be randomly assigned (like the flip of a coin) to receive one of the two behavioral approaches to quitting smoking. You have a 1 in 2 (50%) chance of receiving either approach. One of the approaches requires that you own a smartphone device. If you do not own a smartphone, we will mail one to you to use during your participation in the study but will request that you return it at study completion.

If you are in the group using the app to quit smoking, you will be instructed how to download it and we will give you a brief overview of the app and its main functions. You will be free to ask any questions you have about your app during this explanation. During this part of the visit, we will ask you to register with a unique ID that we will use to track your app usage (e.g., how often you use the app, what features you use, how long you use the app for). We will **not** track any other activity on your smartphone besides your use of the study app.

If you are in the group that receives brief advice to quit smoking, we will discuss key strategies and techniques to quitting smoking and to manage urges to smoke. You will be free to ask any questions you have during this explanation. We will

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also send you a handout that you can take with you as a reminder of the key strategies and techniques discussed during this brief session.

After the baseline visit is completed, we will mail you NRT patches and gum. We will ask that you contact us when you get your NRT in the mail, and then we will go over the instructions on how to use the NRT patches and gum properly. You will be given an 8-week supply of NRT patches and a 5-10 week supply of NRT gum. You will be responsible for keeping track of all of your NRT use:

- NRT patches: We will ask you to keep your used patches for counting at each follow-up visit. At the follow-up visits, we will count both the used and unused patches to see how many you have used since your last visit.
- NRT gum: We will ask you to keep the packages that the gum comes in to count how many pieces of gum you have used since your last visit.

We will review these procedures in greater detail during the baseline visit.

***Follow-Up Visits***

There are three follow-up visits during this study: 1 Month Follow-Up (FU1), 3 Month Follow-Up (FU2), and a 6 Month Follow-Up (FU3). During these visits, you will be asked to complete the following procedures:

- Asking about any changes in your physical or mental health
- Questionnaires about your smoking status and use of the NRT
- Questions about your experience using the smartphone app (if you are in this group)
- Completing a carbon monoxide (CO) breath test and saliva nicotine test if you indicate that you quit smoking

If you reported to the staff that you have quit smoking at or prior to the FU2 or FU3 visit you will be asked to provide a breath sample by breathing into a small device that measures the amount of CO in your lungs. In addition, we will provide a test strip that will test for nicotine in your saliva.
We will provide detailed instructions on how to do each test.

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Please remember that participation is always voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If at any point during this visit or any other study visit you want to stop and no longer participate, please let a research staff member know.

**How long will I be in this study?**
In this study, there are five visits which will take place over the course of 24 weeks (or about 6 months). You can choose to stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

**What are the risks of the study?**
As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

**Physical Side Effects:** As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

**Nicotine Replacement Therapy (NRT):**
NRT patches may cause some, all, or none of the side effects listed below:

More likely:
- Itchy or irritated skin where the patch is placed
- Indigestion/heartburn, nausea

Less likely:
- Insomnia, vivid dreams
- Dizziness, lightheadedness
- Rapid heart rate, increased blood pressure

NRT gum may cause some, all, or none of the side effects listed below:

More likely:

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- Indigestion/heartburn, nausea
- Oral irritation

Less likely:

- Rapid heart rate, increased blood pressure
- Dizziness
- Insomnia
- Irritability
- Loss of appetite
- Hiccups
- Increased salivation
- Cough
- Gas
- Sore throat
- Dental:
  - Pain
  - May loosen inlays/fillings
  - Stick to dentures
  - Damage to oral mucosa and teeth
  - Temporal mandibular joint (TMJ) dysfunction and pain with excessive chewing

**Nicotine Withdrawal Symptoms:** Quitting smoking cigarettes may also cause mild symptoms called withdrawal symptoms. Though these feelings can be uncomfortable, they are of minimal risk. Common withdrawal symptoms include:

- Cravings for cigarettes
- Feeling irritable, on edge, or grouchy
- Having trouble concentrating
- Feeling down or sad
- Restlessness
- Feeling hungrier than usual

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We will be monitoring these symptoms throughout your participation in the study. If we think that participating in the study is putting your health at risk, we may have to withdraw you from the study.

**Reproductive Risks:**
**If YOU Could Possibly Become Pregnant:** Smoking is associated with an increased risk of bad outcomes in pregnancy, including miscarriage, preterm birth, and stillbirth. Although nicotine replacement therapy is sometimes used to help pregnant smokers quit, the changes your body undergoes during pregnancy could affect your response to the other treatments in the study. Women who are pregnant or planning a pregnancy during the next 6 months are not allowed to participate in the study.

You and your partner should use effective methods of contraception to avoid pregnancy during the study. These methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices, (d) barrier methods (condoms, diaphragms, cervical caps) plus spermicide, or (e) hormonal methods (birth control pills, implants, injections, patches, vaginal rings). Depending on your age and other medications you may be taking, some of these methods may not be appropriate. Your study doctor will review your birth control method with you to make sure it is appropriate and meets the requirements of this study. Because no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant.

**Exacerbation of Psychiatric Symptoms:** It is possible that quitting smoking could cause psychiatric symptoms to worsen or cause new symptoms to appear. If you feel like you are experiencing new or worsening psychiatric symptoms, please contact the study team and/or your personal doctor as soon as possible.

**Loss of Privacy/Confidentiality:** The research team will be taking very careful steps to ensure your information remains strictly confidential. All study files are kept in locked filing cabinets in locked offices. All digital data is stored on secured Duke School of Medicine servers. However, there is always the possibility there may be an unauthorized disclosure of your personal information.

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**Uncomfortable or Embarrassing Tasks:** You may be asked to answer questions and do tasks that may cause some discomfort or embarrassment including:

- Answering questions about your medical history, psychiatric symptoms, and smoking history
- Answering questions about your familiarity with technology
- Using a smartphone and app, which could be embarrassing if you are not familiar with this technology

You may skip any question you do not wish to answer; however, not answering certain questions could affect your eligibility to participate in the study. You may stop the interview at any time, and you may do so without penalty.

**Drug and Food Interactions**: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

**Mobile Phone Risks**: If you are randomized to the group that uses a smarphone app combined with nicotine gum and patches, we will instruct you in downloading an app onto your personal smartphone. We will track how often you use the app during your enrollment in the study. Your app use data will be linked to your unique subject ID that will be assigned to you. Personal identifiers are not collected or tracked in this app. We will not track any other activity on your smartphone besides your use of the study app.

**Study Related Apps:** Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these

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mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

If you are in the group that uses a smartphone app combined with nicotine gum and patches, at the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.
As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

**If Loaned a Cellphone:** If you are loaned a Duke Phone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized

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persons. The device will be preset with security settings. Please do not alter these during the course of the study. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

**Are there benefits to taking part in the study?**
If you agree to take part in this study, there may be direct medical benefit to you. The behavioral approaches and medication (NRT) you will receive in this study may assist you in quitting smoking, which could have positive effects on your physical and mental health. Study treatments are provided at no charge to you. In addition, the information gathered in this study may help other people with serious mental illness quit smoking.

**Will my study data be shared?**
If you choose to be in this study, data collected from you that can be used for future research will be stored long-term in a repository following the completion of the study. Any personal information that could identify you will be removed or changed before files are stored in this repository for use by other researchers or results are made public. The removal of this information allows your data to be used without anyone knowing which person in the study it comes from.

**What other choices are there to being in this study?**
You do not need to participate in this study to get help with quitting smoking. If you decide that you do not wish to be a part of the study, the research team will assist you in finding other services or resources that may be available to you. This may include other popular quitting smoking smartphone apps, and recommendations for NRT use.

Please talk to your doctor about these and perhaps other options.
**Will my information be kept confidential?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot

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guarantee total confidentiality. Your personal information will be accessible by research staff working on this study from Wake Forest University, Duke University, and University at Buffalo. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with the National Institutes on Drug Abuse and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives from the Food and Drug Administration,
- representatives and affiliates of National Institutes on Drug Abuse,
- the Duke University Health System Institutional Review Board,
- and others as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

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Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

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Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

**Will it cost me anything to be in the study?**
If you agree to be in the study, there are no direct costs to you. However, smartphone usage may use some of your cellular data if you are not on WiFi while using the app. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused study drug.

**Will I be paid to be in the study?**
You will be reimbursed up to $150 for your expenses related to your participation. Below is the payment schedule for completing each visit. If you withdraw from the study, you will be compensated for the visits that you do complete.

| Assessment Time Point | Compensation Amount |
|---|---|
| Screening | $20 |
| Baseline | $30 |
| Week 4 (FU1) | $20 |
| Week 12 (FU2) | $30 |
| Week 24 (FU3) | $50 |
| **Total** | **$150** |

**What about research related injuries?**
Immediate necessary medical care is available at Atrium Health Wake Forest Baptist in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Wake Forest University School of Medicine, the North Carolina Baptist Hospitals , Inc., or your Atrium

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physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Roger Vilardaga at [redacted] during regular business hours and after hours and on weekends and holidays.

**What if I want to withdraw from the study?**
If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern is an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care. If you do decide to withdraw, we ask that you contact the research team to let them know that you wish to withdraw from the study. You will be asked to complete a termination visit where we will ask you to send back any unused NRT, and (if applicable) instruct you on deleting the app off your phone.

The study doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if they determine that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified, and your study doctor will discuss other options with you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**Whom should I call if I have questions or problems?**
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr**.** Vilardaga at [redacted] during regular business hours and after hours and on weekends and holidays.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

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**STATEMENT OF CONSENT**

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

| _____ | _____ | _____ |
|---|---|---|
| Signature of Participant | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |