Aim-3: Alzheimer's Disease and Related Dementias Prevention Messaging to Increase Smoking Cessation Attempts in Older Adult Smokers

Protocol and Statistical Analysis Plan

Principal Investigator:

Adrienne L. Johnson, PhD
(she/her/hers)
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Center for Tobacco Research and Intervention
Department of Medicine
University of Wisconsin School of Medicine and Public Health

Study Sponsor:

DHHS, PHS, NATIONAL INSTITUTES OF HEALTH

Protocol Number:

NCT05194917

Version Number and Date:

Version 7; 02/05/2025

Contact Information:

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IRB Approval:

IRB Approval Number: 2023-0650
Approval Date: 05/22/2023

University of Wisconsin-Madison MR IRB Application

Study # : 2023-0650

Principal Investigator: Adrienne Johnson

Basic Study Information

1. Formal Title

This is the title that will appear in correspondence.

* Provide the full, formal study title.

> Motivating Change in Aging Smokers (MCAS 3)

2. Transferred Study

Answer Yes to this question only if:

a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and,

b) they plan to open a study here that is already IRB-approved at their previous institution.

* Is this study being transferred from another institution?

○ Yes ◉ **No**

3. Principal Investigator

* Identify the Principal Investigator.

Adrienne Johnson

Type of Research Application

1. Type of Research Application

* Select one of the following: Full review

PI Appointment

1. Principal Investigator

PI: Adrienne Johnson

2. Primary Appointment

* Choose the appointment under which you will be conducting this research. Note, most UW-Madison employees with clinical appointments at UW Health conduct ALL their research under their UW-Madison appointment. Only choose option 2 (UW Hospital and Clinics) if the scope of your UW-Madison appointment does NOT include research.

UW-Madison

3. UW-Madison Appointment

3.1. Appointment Details

* Identify the appointment under which the PI will conduct this research.

	Title	Type	UDDS	Department Combined Name
◉	**Assistant Professor**	**FA**	**A534253**	**SMPH/MEDICINE/GEN INT MD**

3.2. Appointment Not Found

Check if the appointment is not listed above. ☐

4. Investigator-Initiated Study

* Is this an investigator-initiated study?

◉ **Yes** ○ No

Study Team

1. Points of Contact Selection

Points of contact can edit the application and will receive email notifications about this submission.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

If the PI is serving as the only study point of contact, indicate that here.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

* Identify the points of contact for this study (limit of four).

Name	Email
Sarah Jarvis	sjarvis3@wisc.edu
Adrienne Johnson	aljohnson43@ctri.wisc.edu
Mark Zehner	mark.zehner@ctri.wisc.edu

2. All Other Study Team Personnel

List ONLY UW-Madison, UW Health, or Madison VA personnel. External personnel will be listed elsewhere in the application.

Please do not use personal email addresses (e.g., Gmail, Hotmail, etc.). A campus business email can be changed following the instructions here.

Study team members listed below will have read-access only and will not be able to edit the application. They also will not receive email notifications.

Can't find someone in the chooser? See this FAQ for help.

To register a NetID, click here.

List all the other members of the study team (not including the PI or points of contact).

Name	Email
Brooke Anderson	brooke.anderson@ctri.wisc.edu
Todd Hayes-Birchler	hayesbirchle@ctri.wisc.edu
Hannah Hayward	hahayward@ctri.wisc.edu
Chris Hollenback	ch3@ctri.wisc.edu
Kate Kobinsky	ks6@ctri.wisc.edu

Name	Email
Danielle McCarthy	demccarthy@ctri.wisc.edu
Adam Nunez	adam.nunez@wisc.edu
Thomas Piasecki	tpiasecki@wisc.edu
Megan Piper	mep@ctri.wisc.edu
Lisa Rogers	lmrogers@ctri.wisc.edu
Julia Sales Leite	jsleite@outlook.com
Jonah Stankovsky	jstankov@ctri.wisc.edu

Study Team Roles

1. Primary POC

If the PI is serving as the primary point of contact, indicate that here.

* Identify the primary point of contact for this study.
Adrienne Johnson

2. Human Subject Involvement

* Does this study involve recruiting, consenting, or interacting with human subjects?

(●) **Yes** ( ) No

2.1. Study Team Details

For each study team member below, click the button and check the boxes to indicate that study team member's roles for this study. Note: Some study team members may not have any roles listed below.

Tell us which study team members will: recruit human subjects, obtain informed consent from human subjects, interact with human subjects, or perform cognitive assessments on human subjects.

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Brooke Anderson			
Todd Hayes-Birchler			
Hannah Hayward			
Chris Hollenback			
Sarah Jarvis	yes	yes	yes
Adrienne Johnson	yes	yes	yes
Kate Kobinsky	yes	yes	yes
Danielle McCarthy			
Adam Nunez			
Thomas Piasecki			
Megan Piper			
Lisa Rogers			

Study Team Member	Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Julia Sales Leite	yes	yes	yes
Jonah Stankovsky			
Mark Zehner			

Funding

1. Funding Administered by UW Madison

Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

* Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

(●) **Yes** ( ) No

1.1. Funding Sources

For **federal funds**, pending sources may be listed if the grant has received a highly meritorious score. For example, an impact score of <30 is an indication of a highly meritorious NIH grant proposal. Receipt of a request for Just In Time (JIT) documentation is another indication of a highly meritorious proposal.

For **non-federal funds**, pending sources may be listed if you have confirmation from the sponsor that funding will be awarded due to merit AND the sponsor has a peer-review process.

For **industry**, do not select industry sponsors who are only providing drug/device OR only limited support for the study.

* Use this chooser to select each funding source administered through UW-Madison that will support this study or project.

Funding Source Details

View

PI Name	Johnson,Adrienne
Proposal ID	MSN242995
Award ID	MSN242995
Funding Title	ADRD Prevention Messaging to Increase Smoking Cessation Attempts in Older Adult Smokers
Project ID	*No Value Entered*
Sponsor (Source)	DHHS, PHS, NATIONAL INSTITUTES OF HEALTH
Sponsor Reference Number	1K23AG067929-01A1
Primary Sponsor	*No Value Entered*

Funding Source Details

Primary Sponsor Reference Number	*No Value Entered*
Federal	Yes
Status	Active
Start Date	5/1/2021
End Date	2/28/2026

2. Other Funding

* Do you have pending or approved funding NOT listed on this page?

○ Yes ◉ **No**

Conflict Of Interest

Please review the study team member Outside Activities Report (OAR) and managed entities data below before answering the questions on this page.

The following study team members have not completed their OAR for the year:

Brooke Anderson, Sarah Jarvis, Danielle McCarthy, Julia Sales Leite, Jonah Stankovsky

NOTE: Per campus policy all study team members must submit an OAR every year and keep it up to date.

No study team members have any managed entities at this time.

1. Intellectual Property

* Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

○ Yes ◉ **No**

2. Other Entities

* Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

○ Yes ◉ **No**

3. Incentives

* Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

- ( ) Yes
- (•) **No**

VA Status

All studies that fall under Madison VA purview must be reviewed and approved by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences IRB. For information about the VA R&D Committee review process, please contact **VHAMADRDCoordinator@va.gov**.

1. VA Status

* Does this study involve the Madison VA (Wm. S. Middleton VA Hospital); e.g., funding from the VA, conducted under VA appointment, use of VA facility, recruitment of veterans or use of their data or samples at the Madison VA?

○ Yes ◉ **No**

Scientific Review: PRMC & CRU

1. Cancer Related

* Is the scientific question of the protocol cancer related?

○ Yes ◉ **No**

2. Targeting Cancer Patients

* Are you specifically targeting cancer patients for enrollment in this study?

○ Yes ◉ **No**

3. Use of Cancer Data or Images

* Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

○ Yes ◉ **No**

4. Use of CRU

If the answer to this question is Yes, you must upload a copy of the CRU application to the Submit activity form.

* Will this study use the Clinical Research Unit (CRU)?

○ Yes ○ No

UROC Determination

Submission of research studies that meet certain criteria must be reviewed by either Protocol Review and Monitoring Committee (PRMC) or UW Health/SMPH Research Operations Committee (UROC) prior to review by the IRB. The UROC Endorsement Letter, if review is required, must be uploaded prior to submission of your protocol to the IRB. For more information about UROC review, visit the **UROC KB Page**.

1. Criteria for UROC Review

* Select all the criteria below that apply to your study.

None of the above apply or the study was approved by the IRB prior to July 1, 2024.

ClinicalTrials.gov Information

This page is designed to aid in identifying ClinicalTrials.gov registration requirements. Registration may be required by the FDA, NIH, or if you are planning to publish in a journal that follows International Committee of Medical Journal Editors (ICMJE) guidance. Please answer each question carefully.

UW-Madison has a free service available to assist you in registering your record with ClinicalTrials.gov. Contact **CT.gov_Help@clinicaltrials.wisc.edu** for more information.

For information on registration and results reporting requirements see our **KnowledgeBase page** or contact the Office of Research Compliance at **ClinicalTrials.gov_Support@research.wisc.edu**.

1. Study Intervention(s)

Prospective assignment means enrolling study subjects and collecting data on them in the future. It is a study not solely reliant on existing or retrospective data. It is not a requirement to have multiple groups or arms for a study to be considered prospectively assigned.

An **intervention** is any manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Any study that is not observational (where participants may receive a drug, device, medical procedure, or behavioral intervention as part of their standard clinical care) should be considered interventional. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

A **health-related biomedical or behavioral outcome** is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical status, behavioral status, or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

* Are subjects prospectively assigned by the protocol to any intervention(s) that are being evaluated for any health-related

biomedical or behavioral outcomes?

(●) **Yes** ( ) No

2. ClinicalTrials.gov Determinants

* Check the box(es) that apply to this study:

NIH funded, when registration is a required condition of the grant (consult your award letter or with your NIH Program Officer if unsure)

3. FDA or NIH Requirement

* Based on your responses, registration with ClinicalTrials.gov may be required by the FDA or NIH. Will UW-Madison (study team or service line support staff) register the study with ClinicalTrials.gov?

(●) **Yes** ( ) No

External Collaborations

1. Outside UW Activities

* Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA: subject recruitment, obtaining informed consent, or interacting or intervening with subjects?

○ Yes ◉ **No**

2. Requesting UW Serve as IRB

Please note that you must consult with RELIANT before you submit a request for the UW to serve as the reviewing IRB for external sites or individuals. A consultation may be requested here.

* Are you requesting that UW Madison serve as the reviewing IRB for any external sites or individuals?

○ Yes ◉ **No**

Sharing Data Outside UW

1. Sharing Data Outside UW Madison

* Will subject data, images, or specimens be shared outside the UW Madison?

( ) Yes (•) **No**

Study Procedures and Special Populations

1. Study Procedures Involved

Select "Review or use of information from health care records"

* If your study involves any of the following special procedures or considerations, additional information may be needed. Select all that apply. If none apply, check Not Applicable.

- [ ] Creation of audio or video recordings or photographs
- [ ] Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)

2. Special Populations

If you will collect data points identifying individuals as any of the following, select the corresponding box(es).

* Is the research designed to include any of the following populations? Select “Not Applicable” if the research will not include any of the populations below. NOTE: If enrolling pregnant women, children, or prisoners, and you can identify them as such, check the box.

- [ ] Poor/uninsured, elderly/aged, or educationally disadvantaged

Research Design and Procedures

1. Overall Purpose

Describe the research questions or gap in knowledge the study proposes to address or contribute to in language that someone who is educated but not an expert in the field can understand.

* What is the overall purpose and aim of this project or study?

> The purpose of this research is to evaluate messages that motivate older smokers to make quit attempts using evidence based smoking treatments (EBSTs).

2. Pre-Existing Information/Background Knowledge

* What prior information or knowledge exists to support the conduct of this project or study?

> An estimated 5.8 million people have Alzheimer's disease and related dementias (ADRD) in the U.S., costing $290 billion per year. The incidence of ADRD is expected to triple by 2050, costing an estimated $1.1 trillion per year. Due to the rapid growth and tremendous impact of this disease, focus has shifted towards targeting modifiable risk factors to prevent and slow the development of ADRD, potentially preventing approximately 40% of ADRD cases. A candidate risk factor, cigarette smoking, is the leading preventable cause of death and disability in the U.S., resulting in 480,000 deaths and costing over $300 billion each year. Epidemiological studies show that cigarette smoking is prospectively associated with a 70% increased risk of Alzheimer's disease (AD) dementia onset, accounting for at least 13.9% of ADRD cases. Smoking directly increases the likelihood and severity of at least five risk factors for ADRD onset (i.e., diabetes, hypertension, stroke, heart disease, and high cholesterol). Smoking cessation can lower these risk factors, even among an aging population.
>
> Regardless of genetic risk, healthy lifestyle modifications such as smoking cessation can cut the risk of ADRD in half. Due to the known relations between smoking, other ADRD risk factors, and ADRD, the World Health Organization, Institute of Medicine, and Alzheimer's Association state that smoking cessation is among the top priorities for reducing cognitive decline and preventing onset of dementia. Fortunately, evidence-based smoking treatments (EBSTs) exist that can double or triple cessation success. Older adult smokers are at especially high risk for ADRD. Currently, there are 19 million smokers ages 45 and older. Given the predicted doubling of older adults in the next 25 years, helping older smokers quit is a vital public health priority. Unfortunately, older smokers are half as likely to attempt to quit smoking compared to younger adults. Lower cessation efforts in older smokers may be a function of both clinician inaction and dysfunctional beliefs/motivational deficits of older smokers. Compared to younger adults, older smokers are less likely to receive advice to quit or be offered EBSTs (e.g., pharmacotherapy, counseling) by healthcare professionals. Moreover, older smokers' doubts about the benefits of quitting later in life and the efficacy of smoking cessation interventions may reduce older smokers' motivation to quit13. Importantly, older smokers who do attempt to quit are more likely to maintain abstinence than younger smokers when using EBSTs. The chief obstacle to reducing smoking among older adults does not appear to be treatment efficacy, but rather failing to motivate this underserved population to make quit attempts using EBSTs.

According to the Health Belief Model, impactful motivational messages for older smokers should focus on threats they perceive as important and personally relevant and messages should be offered with a feasible, effective course of action to address the health threat. Older adults' greatest aging-related fear is cognitive decline and developing dementia; it is both important and relevant. The link between smoking and ADRD risk factors and the availability of EBSTs offers an effective strategy to respond to this threat. Unfortunately, the indirect relation between smoking and ADRD risk expressed via known ADRD risk factors has not been clearly articulated to the general or medical community, and is not used as a motivator for smoking cessation. Building novel interventions for translation will facilitate more rapid dissemination and subsequent impact on public health. The overarching objective of this proposal is to test a readily translatable Stage 1 motivational intervention for smoking cessation in older adults consisting of: (1) a novel patient-informed motivational message promoting smoking cessation; and (2) ready access to EBSTs for smoking cessation. This responds to two of NIA's goals: (1) develop effective interventions to maintain health, well-being, and function and prevent age-related diseases/disabilities; and (2) disseminate information to the public, medical, and scientific communities. This project will evaluate the motivational impact of a message packages developed from a previous study (IRB# 2020-1429).

3. Study Procedures and Interventions

Provide an overview of the types of records that will be reviewed, what information from these records will be collected, and the kinds of analyses that will be performed on the study data. If data from multiple sources will be used describe this here (e.g., medical record information connected to imaging or billing information or data from multiple institutions collated).

* Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved. Do not include information on recruitment or consent.

Participants will be randomized to one of four messaging interventions; 1) active control (CDC TIPS from former smokers campaign), 2) active control (American Lung Association campaign), 3) treatment condition including message package focused on the link between smoking and dementia, 4) no intervention control. The messaging intervention will be delivered via mail, which will include a QR code link that will allow participants to view associated motivational video. Participants will then complete the first of 2 telephone survey assessments (lasting ~30 minutes). Participants will then receive three mailers over the next couple of months and will schedule their follow-up call approximately 2.5 months later. At one to two weeks, one month, and two months after this call they will be mailed the corresponding message to their group (no intervention group will not be sent a message package). Follow up telephone assessments will occur within approximately 1-2 weeks following intervention exposure marked by date the intervention mailer was sent.

Up to 20 participants randomized to the intervention condition will complete an additional brief qualitative interview following their second telephone survey assessment (lasting ~20 minutes). The qualitative interview will focus on the perceived impact of the message, preferred number of message exposures, preferred modality of message receipt, and suggested improvement to message content. Health Believe Model (HBM) constructs assessed include: perceived severity, perceived benefits (i.e., efficacy of EBSTs; impact of quitting on ADRD risk), perceived barriers (i.e., knowledge of how to access EBSTs in healthcare setting), and self-efficacy (i.e., confidence in ability to quit in the next 30 days).

4.
Incidental or Adventitious Findings

* Will any study procedures produce incidental or adventitious findings (e.g., imaging scans, laboratory blood tests, depression screening questionnaires, etc.)?

- ○ Yes
- ◉ **No**

5. Instruments/Technology Involved (Includes AI/ML Algorithms)

This question is intended to identify projects involving the development or use of medical devices. This does not apply to surveys, questionnaires, or statistical analysis software.

* Are there instruments or technology of any kind, including software, tests run on samples, and algorithms, used or developed in the study?

- ○ Yes
- ◉ **No**

Subject Identification: Medical Records

1. Medical Record Use

* Will medical records be used to identify subjects or records?

○ Yes ◉ **No**

Risks and Benefits

1. Direct Benefits Intended

For this type of research there are generally no direct benefits to subjects. The response to this question, "There are no direct benefits to subjects", would be acceptable.

* Are any of the research activities intended to directly benefit subjects?

○ Yes ◉ **No**

2. Potential Benefits to Society

Describe how the research might help future patients.

* Describe the importance of the knowledge reasonably to be gained from this study and what benefit the research may provide to society.

> The knowledge gained from this study will identify the most impactful motivational message to promote smoking cessation and the use of evidence-based cessation treatment in older adult smokers. This population of smokers are particularly at risk for all of the known health effects of smoking, including dementia.

3. Direct Physical Intervention

A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject's body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Does this study involve direct physical intervention with subjects?

○ Yes ◉ **No**

4. Potential Psychosocial Risks

For this type of research the risks to subjects are generally limited to the risk of breach of confidentiality. The response to this question, "There is a risk of breach of confidentiality", would be acceptable.

* Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation,

economic risks, and legal risks).

> There is a risk of a confidentiality breach.
>
> Participants may become upset or experience discomfort.

5. Procedures to Minimize Risks

The response to this question should address how the risk of breach of confidentiality will be minimized. For example, it could be described that the study team has several measures in place to protect against a breach of confidentiality, such as limiting the number of people who view identifiable information, coding study instruments, storing study data in restricted areas and on computers that are password-protected, only transmitting coded data outside the institution (if data will be shared), and using a secure web-interface to transmit data off-site (if data will be shared).

* Describe the procedures in place to minimize risks from all interventions performed for research purposes. This should include activities in place to identify, monitor, mitigate, and eliminate risks to the degree possible.

> Data will be stored securely according to campus policy.
>
> Participants will be informed of the approximate length of study activities during the consent process and will be offered the opportunity to take breaks during the study activities if needed.
>
> Participants will be informed about all aspects of the study during consent and have the option to skip or withdraw from any activities that make them upset or uncomfortable.

Subject Population

1. Total Subjects

You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

* Provide the number of subjects that will be enrolled at sites for which UW Madison is serving as the reviewing IRB.

> 220

2. Inclusion Criteria

* Describe the main inclusion criteria.

> - Adults between the ages of 50-80
> - Self-reported current smoker
> - Do not hold a current diagnosis of dementia or Mild Cognitive Impairment (MCI)
> - Can read/write in English

3. Exclusion Criteria

* Describe the main exclusion criteria.

> History of Mild Cognitive Impairment (MCI) or dementia.

4. Targeted Populations

Populations could be racial/ethnic, sex, or gender (this also applies to gender identity, or lack thereof).

* Will this study target or exclude specific populations?

(●) **Yes** ( ) No

4.1. Targeted Population Justification

* Describe the population that will be targeted or excluded and provide justification.

> This study will target an elderly population (ages 50 to 80 years old). Given the intervention being tested is intended for older adult smokers, it is necessary that we recruit individuals from this age group. This population of smokers are particularly at risk for all of the known health effects of smoking, including dementia. Participants with self-reported history of MCI or dementia will be excluded to ensure ability to provide consent.

Special Populations Justification

1. Justification

If more than one special population is enrolled, separate justifications should be provided for each unique population.

* What is the justification for the inclusion of these subjects?

> Older adults/elderly are the main focus of this study and therefore required to be included.

2. Safeguards

Include the measures that will be taken to minimize any potential coercion or undue influence in recruitment and ongoing participation in the study.

* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

> We will only include participants with the cognitive capacity to consent as defined by lack of MCI or dementia diagnosis.

Recruitment Methods

1. Recruitment Plan

This description should address what methods will be used, when and how often they will be used, and how many times potential subjects will be contacted.

* Describe the recruitment plan for this study.

> Participants will be recruited nationally (within the United States) primarily via social media advertisements. Should these efforts fail, we will use flyers, web banners, and television advertisements. If television advertisements are used, we will upload a TV ad script with a COP at that time. The English translation of the La Communidad web banner ad is as follows: "Are you 50 to 80 years old and smoke? Get paid up to $75 for sharing your opinions on smoking in English for a University of Wisconsin research study via phone. You do NOT need to quit smoking. Click here!" Those interested in participating in the study will complete the online qualtrics screener or call the provided contact information to enroll in the study directly with UW-CTRI staff. Upon contacting UW-CTRI we will confirm their location via their provided address.

2. Recruitment Material Upload

Upload recruitment materials such as recruitment emails, letters, phone scripts, brochures, or advertisements.

- facebook ad_v3(0.04)
- LaCommunidad-Ad_v1(0.01)
- MCAS_TVadscript_v1_09_13_2023(0.01)
- recruitment flyer_v3(0.04)

3. Approved Recruitment Database Usage

* Are you using an IRB approved recruitment database to disseminate recruitment materials or to contact subjects?

○ Yes ◉ **No**

Subject Screening

1. Preliminary Eligibility Screen

* Will subjects undergo a preliminary screen to determine basic eligibility?

(●) **Yes** ( ) No

1.1. Screening Materials

* Upload a copy of the screening questionnaire.

Phone Screen v4(0.05)

qualtrics screen_v4(0.04)

1.2. Data Retention

If you are retaining screen data, the previously uploaded questionnaire/script should address this and include authorization language for maintaining PHI if HIPAA applies.

* Will you be retaining screen data from subjects who do not enroll in the study?

(●) **Yes** ( ) No

1.2.1. Retention Justification

Describe the purpose of retaining the screen data.

> Phone screen data will be maintained separately from the participant database once these data are not needed for study operations.

1.2.2. Data Storage and Maintenance

Describe where the screen data will be maintained. If these data will be retained in a recruitment database, indicate whether the development of a recruitment

database is the purpose of this study OR provide the IRB protocol number of the database.

> All phone screen data for those who do not consent to participate in the study will be maintained in HIPAA-de-identified form until the end of the study and then destroyed.

2. Planned Study Procedures Before Obtaining Consent

Examples include fasting, discontinuing medications, etc.

* Will there be any procedures performed before informed consent is obtained from subjects (apart from screening)?

- ○ Yes
- ◉ **No**

Remuneration and Costs

1. Payment

* Will subjects be compensated to participate in the study?

(●) **Yes** ( ) No

1.1. Travel and Other Expenses

* Is payment limited to covering travel expenses and other costs incurred by subjects as a result of study participation?

( ) Yes (●) **No**

1.2. Payment Plan

Include the amount of payment(s), proration, multiple payment schedules, etc. Payments to research participants must adhere to campus policy. Questions about payment methods can be directed to Business Services.

* Describe the payment plan.

> Participants will be paid $35 for their time and effort for the first phone interview and $40 for the second interview (max. possible/person=$75). Additionally, up to 20 participants will be invited to participate in a brief qualitative interview following the second survey interview. Those who participate in this optional additional interview will be paid $25 more for their additional time and effort.

1.3. Child/Parent Payment

* Are any payments being offered to child subjects?

( ) Yes (●) **No**

1.4. Nonmonetary Compensation

* Will nonmonetary compensation be offered?

( ) Yes (●) **No**

2. Costs

* Will subjects incur any costs as a result of study participation (pharmacy preparation fees, payment for a device, billing of study procedures to subjects insurance)?

- ( ) Yes
- (•) **No**

Privacy and Confidentiality

1. Privacy Plan

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

* Explain how the subjects' privacy will be protected. (e.g., research intervention is conducted in a private room).

> All communications regarding research activities will be directly with the consented participant and from a location where privacy can be maintained. Participant study data will be collected by research personnel and will be stored on secure, password protected servers. Data will be accessible only to assigned study staff for their study function; computer workstations will be password-protected, and thus secured from unauthorized use. A Certificate of Confidentiality will be issued for the study.

2. Level of Identifiability

* Select how subjects are identified in the data. Check all that apply.

Directly: Direct Identifiers stored on data (e.g., name, initials, phone number, SSN, or medical record number, stored on data)

2.1. Necessity of Data

* Explain the necessity of collecting or maintaining data linked to subjects’ identities.

> This will allow for study payments to be sent to participants and to contact participants for follow up assessments. Data will be stored in a password protected file on a secure departmental server.

2.2. Retaining Data

* How long will data linked to subjects’ identities be retained?

> Subject identify will be linked to data until data collection is complete.

At that time, participants information will be deidentified.

3. Data Protection Plan

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

The study team should describe how data confidentiality will be protected. Some measures that are often used and acceptable to the IRB are: using codes so that no direct subject identifiers are recorded on data collection sheets; creating codes for data that are not based on subject identifiers (i.e., avoiding codes that include subject initials or are based on birth dates); and destroying the link to the code as soon as possible.

* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss, or destruction? Include how and where the data and/or specimens will be stored.

> Video and/or audio files will be recorded using a secure device and will be stored in a restricted access folder on the department server. Audio files are for transcription purposes only and will be permanently destroyed as soon as transcription is complete. If names or identifiable information are revealed during the recordings, this information will not recorded in the transcription. Electronic files will be stored on a secure department server.
>
> Servers at the UW-CTRI Madison office are physically secured in a locked room. Data backups are created nightly and stored in a locked safe. Significant safeguards have been implemented to protect data including virus and adware protection, firewall, access controls and encryption when appropriate such as wireless and remote access. All UW-CTRI staff members have completed HIPAA and human subjects training and are aware of the sensitivity of study-related data. The UW-SMPH has developed school-wide data security policies and procedures. UW-CTRI data security policies and procedures conform to those of the UW-SMPH. No publications or presentations resulting from this research program will contain any identifying information about individual participants. Following cleaning and verification of data at the conclusion of the study, all research data will be placed in a de-identified data set at UW-CTRI.

4. Certificate of Confidentiality

If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes".

* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research?

(●) **Yes** ( ) No

4.1. CoC Details

* Select the answer that applies to your CoC.

- (●) **I will rely on a CoC that is included as part of current NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award.**
- ( ) I will apply for a CoC (there is no NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award).
- ( ) I have obtained a CoC.

Retention of Data and or Specimens

1. Future Research Plans

* Will data and/or specimens collected for this study be banked for future research outside the scope of the current project?

○ Yes ◉ **No**

Consent: General

1. Obtaining Consent/Assent

* Will you obtain consent or assent from some or all participants?

(●) **Yes** ( ) No

1.1. Signed Consent/Assent

* Will you obtain signed consent or assent from all participants?

( ) Yes (●) **No**

1.2. Altering Required Elements

* Are you proposing to alter required elements of consent or assent (e.g. required information will not be disclosed, or the research involves deception)?

( ) Yes (●) **No**

1.3. No Consent/Assent

* Are there some participants from whom you will not obtain consent or assent?

( ) Yes (●) **No**

Waiver of Signed Consent

1. Waiver of Signed Consent Process

* Are you requesting a waiver of signed consent for all components of the study?

(●) **Yes** ( ) No

2. Criteria

* Under which of the following criteria does this research qualify for waiver of signed consent? The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3. Criteria Justification

* Provide a justification for the criterion selected above.

> The research is a benign behavioral intervention that will be of minimal risk to the participants. Data security measures minimize the risk of breach of confidentiality, and the study activities do not normally require written consent outside the research context.

Consent Overview

1. Consent Process

* Describe the consent process, including when and where it will occur and how the consent process will be conducted (e.g., face to face, phone or video discussion) and how consent information will be provided to participants (e.g., in person, mailed/emailed).

> Consenting will be done over the phone. After completing the Phone Screen, study staff will use the Study Information Sheet (see uploaded Study Information Sheet) to discuss study procedures and all elements of informed consent including:
>
> • Study sponsor
> • Invitation/Summary
> • Study purpose
> • Study participation, including assessments, schedule of study contacts, and treatment overview
> • Risks, Benefits, and Costs
> • Payment for participation
> • How to revoke authorization
> • Confidentiality
> • How to contact study staff
>
> We will provide a text copy of the the information sheet to the participants by mail after the initial call. Due to the screening and initial survey assessment occurring in the same call it is not feasible to provide the information to the participants prior to the first call. We will offer to email participants the information sheet if they explicitly ask for it, otherwise it will be mailed to participants.

2. Special Populations Involved

* Will the study enroll participants with limited English proficiency, who are illiterate/low-literacy, or have visual/hearing impairments?

○ Yes ◉ **No**

3. Qualification Affirmation

* Do you confirm that all study personnel responsible for obtaining informed consent have the following qualifications: 1) are familiar with the details of the study; 2) will ensure subjects are provided with sufficient information to make an informed and voluntary decision about study participation; 3) are familiar with UW-Madison policies regarding

informed consent?

- (●) **Yes**
- ( ) No

Consent and Authorization Upload

1. Consent/Assent Documentation

• E.g., information sheet, consent form, assent form, translated consent documents.
• Please use IRBs informed consent templates to develop consent processes and documents for non-exempt studies.
• For educational and social-behavioral studies, you can use the Consent Form Wizard. The Wizard does not include HIPAA authorization language.

* Upload all consent authorization, and/or assent documents.

consent process_v2(0.02)

Study information sheet_v4(0.06)

HIPAA

1. Identifiable Information

* Will the research involve identifiable health information for any reason?

(●) **Yes** ( ) No

1.1. UW Madison Health Care Component or Madison VA

The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; and Waisman Center (clinical units only). Ensure the PI or any study team members are covered under HIPAA Privacy Rule regulations as part of their appointment.

* Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) and/or Affiliated Covered Entity (ACE) or the Madison VA?

(●) **Yes** ( ) No

1.2. HIPAA Authorization

* Will HIPAA authorization for access to the PHI be obtained for all or some subjects, or for only some uses?

( ) Yes, always: HIPAA authorization will be obtained from all subjects with signed documentation.

(●) **Yes, sometimes or without signed documentation: HIPAA authorization will not be obtained from some subjects/uses or may be obtained without a signature.**

( ) No: HIPAA authorization will not be obtained from any subjects.

1.3. External PHI Access

* Will you access or obtain fully identifiable health information from a health care provider that is not UW or UW Health or the Madison VA, such as Meriter or ACHC, without first obtaining

patient permission or authorization?

- ○ Yes
- ◉ **No**

Authorization and Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. HIPAA Requirement Fulfillment

* Please select which option(s) will be applied to fulfill HIPAA requirements.

- [ ] Request Partial Waiver or Altered Authorization

2. Applicable HIPAA Identifiers

Select which of following identifiers will be associated with the health information you propose to collect for study purposes. Check all that apply to your study. If none of these identifiers will be collected for you study, select 'None of the Above'.

- [ ] Names
- [ ] Geographic subdivisions smaller than a state
- [ ] All elements of dates (except year) related to an individual including:
*Dates of admission, discharge, or service
*Dates of birth or death
- [ ] Telephone numbers
- [ ] Electronic mail addresses

Request for Authorization/Waivers

When sharing fully identifiable health information outside of UW or UW Health or obtaining it from a covered entity that is not UW or UW Health (e.g. bringing PHI from Meriter to a UW workstation to contact for phone screening or to recruit), you may need a partial waiver of authorization and accounting for disclosures may be required. Please consult with the **HIPAA Privacy Officer** and consult the Accounting for Disclosures Guidance found **here**.

1. Altered Authorization

HIPAA authorization for research must be project-specific. Standard clinical consent and authorization does not cover research use. If you will not obtain authorization in writing or seek to significantly modify the standard HIPAA authorization language, an altered authorization is necessary.

* Are you requesting an altered authorization?

(●) **Yes** ( ) No

1.1. Altered Authorization - Details

Please describe how authorization will be altered.

> Verbal authorization

2. Partial Waiver of Authorization

If you will not obtain authorization from any subjects, a full waiver is required.

* Are you requesting a partial waiver of authorization?

( ) Yes (●) **No**

3. Type of PHI Records

* Identify the PHI to be used. Select all that apply.

Demographic information

4. Confirm Policy for Sharing PHI Externally

For help, see HIPAA – Privacy & Security Coordinators. Examples of directly identifiable data is data that includes name, MRN, narrative text fields, or a rare condition that can be traced back to an individual.

If you disclose directly identifiable PHI outside the HIPAA covered entity under which you are conducting the study, confirm you will contact the UW Madison HIPAA Privacy Officer or the Madison VA Privacy Officer.

(●) **Yes** ( ) No

5. PHI Protection Plan

* Describe your plan to protect PHI form unauthorized use or disclosure.

> Paper files will be stored in a secure campus location and destroyed after data has been entered electronically.
>
> Electronic files will be stored on a secure department server.
>
> Only approved personnel will have access to study data.

6. PHI Destruction Plan

* Describe your plan for destroying identifiers at the earliest possible opportunity.

> Identifiers will be destroyed at study closure.

7. Waiver/Alteration Justification

* Explain why the study cannot practicably be conducted without the waiver of authorization or altered authorization.

> Signed consent will not be obtained in the interest of limiting the number of study documents with the participant's name and participation in the study activities

indicates consent and authorization.

Only the minimum necessary PHI needed will be collected.

8. Limitations Confirmation

* Federal law prohibits the re-use or disclosure of PHI in connection with this research to any person or entity other than those authorized to receive it, except: (1) as required by law; (2) for authorized oversight of the research; or (3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed. Do you agree to abide by these limitations in order to obtain a waiver of authorization?

(●) **Yes** ( ) No

Audio/Video Recordings and Photographs

1. Recordings Collected

* Select which of the following will be collected for this study. Check all that apply.

- [x] **Audio recordings**
- [ ] Video recordings
- [ ] Photographs

2. Identifiable Recordings

E.g., full face photo/video, audio recording of first and last name, or other individually identifiable information.

* Will the subject be identifiable in the audio/video recording or photograph?

○ Yes ◉ **No**

3. Retain Recordings

* Will the audio/video recordings or photographs be retained beyond the conclusion of this study?

○ Yes ◉ **No**

4. External Transcription

* Will anyone outside the study team transcribe audio recordings?

◉ **Yes** ○ No

4.1. Transcriber Details

* Indicate who will perform the transcription.

> Transcription will be done by a professional transcription service.

Interviews, Focus Groups, Surveys, Questionnaires

1. Tool Details

* Describe the interview tools, questionnaires, or surveys that will be used. Click the add button to provide information about each tool to be used.

View

Tool Description	Optional Qualitative Interview
Tool Standardized	No
File name	Outline of Qualitative Interviews_V1_2023.10.13.docx
Tool Manner	Telephone
Tool Manner Other	*No Value Entered*
Date Modified	10/20/2023

View

Tool Description	Follow Up Survey
Tool Standardized	No
File name	MCAS Aim 3 3 Month Follow Up Questionnaire_V2_10_20_23_trackedchanges.docx
Tool Manner	Telephone
Tool Manner Other	*No Value Entered*
Date Modified	10/20/2023

View

Tool Description	Baseline Survey
Tool Standardized	No
File name	MCAS Aim 3 Baseline Questionnaire_V5
Tool Manner	Telephone

Tool Manner Other	*No Value Entered*
Date Modified	9/13/2023

2. Cognitive or Psychological Assessment

* Are any of the uploaded instruments used to assess cognitive or psychological status or function?

( ) Yes (•) **No**

Interviews, Focus Groups, Surveys, Questionnaires Cont.

1. Focus Group

* Will the study involve conducting focus groups?

○ Yes ◉ **No**

2. In-Home Visit

* Does the study involve in-home visits?

○ Yes ◉ **No**

Supplemental Information

1. Additional Documents

Provide any additional relevant documents (e.g., data sharing agreements, letters of support, MOUs, site permission letters), if applicable.

- active control flyer 1(0.01)
- active control flyer 2(0.01)
- active control flyer 3(0.01)
- active control videos(0.01)
- fear flyer(0.01)
- fear video(0.01)
- MCAS Mailing 1 Cover Letter Active Control and Treatment Condition (Groups 1, 2, 4)_v2(0.02)
- MCAS Mailing 1 Cover Letter No Treatment Condition (Group 3)_v2(0.02)
- MCAS Mailing 2 Cover Letter Active Control and Treatment Condition (Groups 1, 2, 4)_v2(0.02)
- MCAS Mailing 3 Cover Letter Active Control and Treatment Condition (Groups 1, 2, 4)_v2(0.02)
- MCAS Mailing for Follow-up Payment v1_11_8_23.docx(0.01)
- MCAS Video Group 1 Email 1.docx(0.01)
- MCAS Video Group 1 Email 2.docx(0.01)
- MCAS Video Group 1 Email 3.docx(0.01)
- MCAS Video Group 1 Email 3_V2_10_20_23_trackedchanges.docx(0.01)
- MCAS Video Group 2 Email 1.docx(0.01)
- MCAS Video Group 2 Email 2.docx(0.01)
- MCAS Video Group 2 Email 3.docx(0.01)
- MCAS Video Group 2 Email 3_V2_10_20_23_trackedchanges.docx(0.01)
- MCAS Video Group 4 Email 1.docx(0.01)

MCAS Video Group 4 Email 2.docx(0.01)

MCAS Video Group 4 Email 3.docx(0.01)

MCAS Video Group 4 Email 3_V2_10_20_23_trackedchanges.docx(0.01)

1.1. Describe Documents

Describe what additional documents were added in 1.

> We have added a cover letter to be included with the participants' final study payment.

Final Page

1. Assurance

- The information presented in this application is accurate;
- If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
- The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Do you certify the above statements?

(●) **Yes** ( ) No

2. Complete and Submit Application Instructions

To complete and submit this application to the IRB office, please follow the steps below:

- Select 'Finish' or 'Exit' on this page to be directed to the application workspace.
- In the application workspace, click the Submit activity to send the application to the IRB office. NOTE: The Submit activity is only available to certain study team members.

Statistical Analysis Plan

Dr. Johnson will use SPSS to examine differences in changes in motivation (primary), number of 24 hour quit attempts (secondary), and use of evidence-based treatment (secondary) between groups. Specifically, she will examine differences in mean scores from baseline and follow up between the treatment group and three control groups. Given the pilot nature of this study, we will not be statistically powered to conduct regression analyses. Therefore, descriptive analyses will be the primary analytic method.