Internet-based Motivational Interviewing for Colonoscopy in African Americans

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Mount Sinai	Protocol Name:	Internet-based Motivational Interviewing for Colonoscopy in African Americans
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HRP-503 PROTOCOL TEMPLATE

Brief Summary of Research (250-400 words):

Colorectal cancer (CRC), a largely preventable disease, remains the second cause of cancer death in the United States in men and women combined. Compared to other racial groups, Black/African Americans have the highest CRC morbidity and mortality rates. Given these disparities, it is critical to increase Black/African Americans' participation in CRC prevention efforts.

A motivational interviewing (MI) intervention can help improve Black/African Americans' screening colonoscopy uptake. MI is a brief patient-centered intervention that increases perceived competence, autonomy, and relatedness in order to promote behavioral change. Extensive research supports the efficacy of MI to promote preventive health screening uptake (e.g., increase HIV testing) and MI has proven efficacious with Black/African Americans across a wide range of diseases. There is strong support for the use of MI to improve Black/African Americans' screening colonoscopy uptake.

Traditionally, MI is delivered live, where individuals meet with a professional for a one-on-one intervention. Although efficacious, live-MI is not without limitations. Of greatest concern, live-MI requires both staffing and economic resources, limiting its ability to be widely disseminated. A motivational interviewing based app (called e-Motivate) may overcome these limitations. By eliminating the need for an on-site professional, e-Motivate is a high reach, low cost intervention with the potential to have a significant public health impact. Research with other health behaviors supports the efficacy of electronically delivered MI. Yet, no research to date has examined the efficacy of e-Motivate to increase screening colonoscopy uptake in Black/African American patients.

The primary goal of this project is to develop e-Motivate and conduct a randomized clinical trial (RCT) that examines its efficacy for improving African Americans' screening colonoscopy uptake.

1) Objectives

Primary objective: To conduct an RCT that examines the efficacy of e-Motivate versus a control condition for increasing screening colonoscopy uptake in Black/African Americans. Black/African American patients referred for a screening colonoscopy will be recruited to the RCT. Participants (N=200) will be randomly assigned to an e-Motivate group (N=100) or a control group (N=100). Participants in e-Motivate group will receive usual care and will also complete a one-time, 20-minute e-Motivate app on a tablet immediately following the primary care appointment in which they received a referral for a screening colonoscopy. Participants in the control group will receive usual care (e.g., print handout, patient navigation). It is hypothesized that participants in e-Motivate condition will be more likely to complete the recommended screening colonoscopy.

Exploratory Aim 2a. To explore the efficacy of e-Motivate for improving a secondary adherence outcome (e.g., bowel prep quality).
Exploratory Aim 2b. To explore mediators and moderators of e-Motivate. As a part of the RCT, potential mediators (i.e., competence, autonomy, relatedness) and moderators (i.e., demographics, Internet fluency/use) will be explored.

2) Background

Colorectal cancer (CRC), a largely preventable disease, remains the second cause of cancer death in the United States in men and women combined. Compared to other racial groups, Black/African Americans have the highest CRC morbidity and mortality rates. Given these disparities, it is critical to increase Black/African Americans' participation in CRC prevention efforts.

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3) Setting of the Human Research

The research will be conducted at Mount Sinai Hospital (IMA and GI clinic) and Mount Sinai Doctors West 147th Street. Patients will be recruited immediately following their primary care or GI appointment in which they received a referral for screening colonoscopy.

4) Resources Available to Conduct the Human Research

The IMA clinic sees over 25,000 unique clients annually of whom, 37.3% are African American. The total target population of 240 is therefore feasible. Mount Sinai Doctors West 147th street is located in Harlem and treats a predominantly racial/ethnic minority patient population.

As a part of the agreement to abide by regulations set forth by the Mount Sinai Institutional Review Board all members of the research team have been trained in all aspects of the protocol, Human Subjects Protection and HIPAA requirements.

5) Study Design

a) Recruitment Methods

Patients will be recruited from the Mount Sinai Hospital (IMA and GI clinic) and Mount Sinai Doctors West 147th Street immediately following an appointment with their physician. The physician or patient navigator will provide a brief description of the study to the patient. If the patient is interested in learning more about the study, he/she will meet with the Research Assistant (RA) in a private room immediately following their GI or PCP appointment to review the study and complete the consent form.

If the patient is interested in participating in the study, but unable to complete the study after the clinic visit (e.g., time constraints, first contact with patient navigator is over the telephone, RA is not on site), the patient can provide the healthcare professional (physician or patient navigator) with permission to be contacted by the study research team. The healthcare provider (e.g., patient navigator or physician) will then give the research staff the patient's preferred contact information. The research staff members will then contact the patient to arrange for a convenient time to meet to complete the consent and intervention.

b) Inclusion and Exclusion Criteria

Eligibility criteria include: 1) self-identify as Black/African American; 2) received a referral for a screening colonoscopy; and 3) English speaking

Healthcare providers (e.g., primary care physicians and gastroenterologists) will determine whether the patent is medically eligible for a screening colonoscopy (e.g., age eligible for a screening colonoscopy based on published guidelines).

Exclusion include: 1) hearing or vision impaired; 2) Phase I participant

c) Number of Subjects

200 participants (100 per condition)

d) Study Timelines

The total study duration is 5 years (September 2015-October 2020).

Years 1-2: Create and field test e-Motivate

Years 3-4: Enroll participants in RCT (Phase II)

Years 4-5: Conduct follow up medical chart reviews. Conduct qualitative follow up interviews. Conduct all data analyses.

e) Endpoints

Participants in the RCT will have their medical charts reviewed, six months following the initial referral, to determine if the colonoscopy has been completed. Secondary outcomes (e.g., bowel prep quality, number of cancellations) will also be recorded. Participants will also complete a demographics assessment and a questionnaire that assesses mediators (autonomy, competence, relatedness).

There are no events/results that would cause a study subject's participation to end due to safety.

f) Procedures Involved in the Human Research

The e-Motivate app will be administered on a touchscreen tablet, which the RA will provide to the participant. Depending on the participants responses to prompts in the app, the app could take up to 20 minutes to complete.

Description of the Intervention:

Demonstration video: brief video explaining to the users how to use the app (e.g., "press next to go to the next page")

Introduction video: brief video welcoming participants to the app and providing a brief overview of the app

Education: True/False questions about CRC prevention (e.g., "colorectal cancer is one of the leading causes of cancer death in the US). Optional educational text and videos (adapted from mentors' previous work).

Motivational Interviewing Exercises: Decisional balance (pros/cons), reviewing previous success video, looking forward/looking backward, reviewing social support, reviewing personal strengths. All of the motivational interviewing exercises are designed to resolve ambivalence, improve participants' self-efficacy of having a screening colonoscopy, and motivate participants to get screened.

Action Plan Video: Participants will view a brief video that will review the steps they need to take in order to complete the colonoscopy (e.g., 1. Schedule procedure, 2. Follow doctor's instructions for completing the prep. 3. Identify someone to take them home after the procedure).

RCT Procedures:

200 participants will be enrolled in an RCT that examines the efficacy of e-Motivate for improving screening colonoscopy uptake among Black/African American patients. A HIPAA waiver was requested in order for the study team to review the information provided on CERNER and EMR to assess for eligibility. In particular, at the beginning of

each recruitment day, the RAs will use the CERNER list and EMR to review patients' race, age, and previous colonoscopy history. RAs will alert healthcare providers (e.g., physicians and patient navigators) daily of patients who may be eligible for a screening colonoscopy referral. If a patient is eligible for the study (e.g., self-identifies as black/African American, age-eligible for CRC screening, and received a referral for a screening colonoscopy), the physician or patent navigator will briefly introduce the study to the patients at the end of the primary care or GI appointment. Patients who are interested in participating in the study will meet with an RA in a private exam room immediately following their appointment to review and complete the consent form.

If the patient is interested in participating in the study, but unable to complete the study after the clinic visit (e.g., time constraints, first contact with patient navigator is over the telephone, RA is not on site), the patient can provide the healthcare professional (physician or patient navigator) with permission to be contacted by the study research team. The healthcare provider (patient navigator or physician) will then give the research staff the patient's preferred contact information. The research coordinator will then contact the potential participant and schedule a date/time to complete the consent form.

Consented participants will complete a verbally administered baseline questionnaire. Participants will then be assigned to one of two groups: e-Motivate (N=100) or control group (N=100). Participants assigned to e-Motivate condition will receive usual care and will also complete the 20 minute e-Motivate app. Immediately after completing the e-Motivate app, the RA will verbally administer a post-intervention questionnaire that assesses the hypothesized mediators. Participants in the control group will receive usual care (e.g., patient navigation, print materials). Participants will receive $20 gift card to Target as compensation. Six months following the initial referral, medical charts will be reviewed to determine whether the colonoscopy was completed, the quality of the bowel prep, and process variables (e.g., number of cancellations/rescheduled appointments/no-shows)

g) Specimen Banking

N/A

h) Data Management and Confidentiality

Survey Data:

Throughout the study, quantitative survey data will be collected. The survey data will be scanned and uploaded on our Department's secure internet server (J drive). The hard copies of the surveys will be stored in a locked filing cabinet in the CAM building. Each participant's data will be de-identified and assigned an anonymous ID number. A "cross-over" file matching ID number with participant identifying information (name, address and phone number) will be maintained and stored separately on our department's secured and encrypted intranet server. Only study personnel will have access to the crossover file.

CERNER Data:

In addition, as part of the RCT, we will first obtain the CERNER list to identify the Black/African American patients who are age eligible or CRC screening and are scheduled for a primary care or GI appointment that day. We will then access EMR to identify whether the patient may be eligible for a screening colonoscopy (has not had a recent screening colonoscopy procedure in the EMR). We have requested a HIPAA waiver. We will then alert the physicians and patient navigators of the patients who may be eligible or our study. The CERNER list will be destroyed at the end of each recruitment shift.

App Engagement Data:

We will record participants' engagement with e-Motivate. The e-Motivate will be linked to an electronic database that will be entirely anonymous and will only record the participants' overall engagement (e.g. responses to the exercises, amount of time spent on each exercise, etc.). The database will initially be stored on the AppLab's encrypted server. The anonymous dataset will then be sent to the Mount Sinai investigative team.

Outcome Data:

Six months following the initial visit, we will check the medical records of all consented participants in Phase II to obtain outcome data (e.g., colonoscopy completion status, prep quality, # of cancellations/rescheduled appointments/no-shows, receipt of PN/care coordination). The medical information will be de-identified and stored on a password protected file on Mount Sinai's intranet server.

DATA ANALYSES

Missing data: The e-Motivate is a one-time intervention and thus we anticipate minimal missing data. *Analyses of covariates*: Participants will be randomly assigned to treatment condition and therefore significant baseline differences are not expected. However, contingency tables and t-tests will be performed to determine any differences between the two groups. Using a p value of ≤ 0.15, any consistent pattern of correlation for any of the covariates would suggest their inclusion in the primary data analysis model.

Analysis of Primary Outcome: The primary outcome (screening uptake) will be assessed with a logistic regression model. The hypothesized moderators will be evaluated individually. The final logistic model will contain the main effect for the treatment group, any identified covariates, and any significant moderators.

Analysis of Secondary Outcome: If bowel prep quality is normally distributed, a t-test will be used to compare the two treatment groups.

Exploration of Mediation: In the mediation analyses, we will first show that treatment predicts the primary outcome. We will next evaluate the extent to which the treatment affects the mediators using a linear mixed model with repeated measures. Time will be entered into the model first followed by any covariates. Next, the binary treatment vector will be introduced as a main effect followed by interaction with time. Since there are three

correlated mediators, the p-values will be adjusted using the Sidak correction for multiple comparisons. Only the mediators that are predicted by the treatment main effect or the time by treatment interaction will be retained. Each mediator will then be introduced into the logistic model predicting the primary outcome. To establish mediation, the indirect paths from treatment to mediators and from mediators to outcomes will be assessed using 1000 bootstrap samples following the procedures.

Analysis of Power: We are proposing a sample of 200 participants (100 in each treatment arm) and setting alpha equal to 0.05. In our pilot study, the MI condition was associated with 71.4% (20/28) screening uptake compared to 52.0% (13/25) for the control condition. Based on these results, we are hypothesizing that approximately 71.4% of participants in e-Motivate condition will complete the colonoscopy, compared to approximately 52% of the participants in the control condition. Based on these projections, power is equal to 0.83. Of note, for the proposed study, the control condition will be a print brochure. Previous research suggests that a print brochure produces comparable CRC screening rates (52.0%-53.5%) to our pilot study's attention control condition (52.0%).

i) Provisions to Monitor the Data to Ensure the Safety of Subjects

Part I: Elements of a Data and Safety Monitoring Plan

1. List the name(s) of the individual(s) at the Mount Sinai School of Medicine (MSSM) who will be responsible for data and safety monitoring of this study. For each individual, indicate their role, name, title, and department information.

MSSM Principal Monitor:
Check One: PI:☒ Team Member: ☐ Independent:☐
Last Name: Miller
First Name: Sarah
Academic Title: Instructor
Department: Oncological Sciences
Mailing Address: One Gustave L. Levy Place, Box 1130
Phone: 212.824.7783
Fax: 212.849.2566
E-mail: Sarah.Miller@mssm.edu

MSSM Additional Monitor:
Check One: PI: ☐ Team Member: ☒ Independent: ☐
Last Name: Jandorf
First Name: Lina
Academic Title: Professor
Department: Oncological Sciences
Mailing Address: One Gustave L. Levy Place, Box 1130
Phone: 212-659-5506

Fax: 212.849.2566
E-mail: Lina.Jandorf@mssm.edu

2. Justify your choice of principal monitor in terms of the assessed risk to the research subject's health and wellbeing. In high risk studies when the principal monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and the rationale for selection.

The PI Sarah Miller, will oversee all aspects of the project. Miller is an Assistant Professor in the Department of Population Health Science and Policy at ISMMS. Her primary research interests lie in identifying factors that contribute to CRC disparities and testing interventions designed to reduce those disparities. As a clinical health psychologist, her research interests stem from her clinical and community work with racially diverse, underserved populations.

3. List the specific items that will be monitored for safety (e.g., adverse events, subject compliance with the protocol, drop outs, etc.).

The following items will be monitored for safety:

- Patient safety (e.g., adverse events)
- Protocol compliance
- Data management (e.g., missing data)
- Recruitment rates
- Screen failures (e.g., ineligibility)

4. Indicate the frequency at which **ACCUMULATED** safety and data information (items listed in number 3 above and interim analysis of efficacy outcomes) will be reviewed by the monitor(s) or the Data Monitoring Committee (DMC). Although this information must be reviewed at least annually, the higher the study risks, the more frequently reviews must be scheduled.

All data will be reviewed at least annually.

5. Where applicable, describe rules which will guide interruption or alteration of the study design.

N/A

6. Where applicable, indicate dose selection procedures that will be used to minimize toxicity.

N/A

7. List any specialized grading system that will be used to evaluate adverse events (e.g., National Cancer Institute Common Toxicity Criteria).

N/A

8. Describe procedures that will be used to assure data accuracy and completeness.

All survey data will be administered via interview. This method will ensure that participants will varying levels of literacy can accurately complete the assessments. All data will be entered into SPSS twice and then cleaned for accuracy. Any discrepancies in the data will be corrected based on the original assessments.

9. Should a temporary or permanent suspension of your study occur, in addition to the PPHS, to whom (NIH, FDA, sponsor, IRB) will you report the occurrence?

The proposed research is a low-risk behavioral study. The ISMMS's Program for the Protection of Human Subjects (PPHS) requires the PI to notify the PPHS promptly of any unanticipated problems involving risks to study participants or others that occur. The PI and research team will monitor the progress of the trial and safety of participants on an ongoing basis. The procedures of this study, such as regular meetings with the research team, will ensure that that all outcomes and adverse events are discussed and reported. If an adverse event is due to the study and is unexpected, the PI will send a safety report to ISMMS's PPHS. The PPHS committee will serve as an objective review mechanism. This policy means that any potential conflict of interest inherent in the PI being the sole reviewer of a serious adverse event is avoided.

All serious adverse events that occur during the study, regardless of the relation to the research, will be reported to ISMMS's PPHS by telephone, e-mail, or FAX within 24 hours of the investigator's awareness of the occurrence of the event. The PI will report serious adverse events to ISMMS's PPHS and will disseminate information to other agencies as necessary. These initial reports will be followed by a safety report which is a written account of the serious adverse event determined by a sponsor/investigator to be both related to the treatment under investigation and unexpected in nature. Serious adverse events will be summarized annually in the PPHS application for continuation or termination of the research.

All expected non-serious adverse events that occur at a greater frequency or severity than anticipated and all unexpected non-serious adverse events will be reported to the PPHS within 20 working days of the investigator becoming aware of the event. These adverse events are also summarized annually in the PPHS application for continuation or termination of the research.

Ms. Jessica Moise, Director, Grants and Contracts Office at ISMMS, will provide prompt written notification of any action resulting in a temporary or permanent suspension of this protocol to the NCI grant program director responsible for the grant.

The study PI and research team will follow the procedures outlined above, which serve as part of the quality control procedure. The PI and the study team will meet on a regular basis (see budget justification) to ensure data accuracy and protocol compliance. These ongoing meetings (in person and via conference call) with the entire study team will also ensure protocol adherence. To ensure the validity and integrity of study data, the PI will also oversee all data management responsibilities (e.g., data entry and data checking). The PI will discuss all data management issues with the research team.

Part II. Data Monitoring Committee/Data Safety Monitoring Board (DMC/DSMB)
When appropriate, attach a description of the DMC. Provide the number of members of the DMC, their names and area of professional expertise. DMC reports must be made available to the local PI and the TCI's DSMC. The report need not contain specifics of the study or data, but there must be assurance that subject safety is not being compromised and that the results of treatment do not warrant early termination of the study.

As a minimal risk study, we will follow the minimum DSMP standards of the PPHS. Enrollment numbers will be reported to the Cancer Clinical Trials Office.

j) Withdrawal of Subjects

Taking part in this study is voluntary and subjects can withdraw at any point during Phase I/Phase II/Phase III.

6) Risks to Subjects

There are no physical risks posed by this study. Participants may become uncomfortable when answering questions about CRC. Participants will have the option to skip any questions they do not choose to answer. All study participants will be encouraged to contact the PI, a licensed clinical psychologist, if they have any questions, concerns or distress related to study participation.

7) Provisions for Research Related Harm/Injury

If, at any point during the study, patients express distress, they will be referred to speak with the Dr. Miller, a licensed clinical psychologist.

8) Potential Benefits to Subjects

Participants will likely not benefit from participating in the study. Participants may benefit from learning more about their health. Given the minimal risk involved in the study, the risk/benefits ratio is reasonable**.**

9) Provisions to Protect the Privacy Interests of Subjects

Patients will learn about this study from a member of their healthcare team after receiving a referral for a screening colonoscopy. Potential patients who agree to participate will meet in a private room, with an RA who will review the consent document with each patient. If patients agree to participate, they will consent to the study and be given a copy of the consent document. The RA will explain the structure of the study and answer all questions the participants may have. We will assure participants that all aspects of the study are confidential and voluntary

The RA will only approach the patient once they have indicated that they are interested in participating in the study. Consented participants will participate in the study in a private clinic exam room with the RA present.

10) Economic Impact on Subjects

There are no foreseeable economic impacts on the participants.

11) Payments to Subjects

Participants will receive a $20 gift card to Target as compensation for participation.

12) Consent Process

The enrollment process is conducted in accordance with good clinical practice and the research staff is following the "SOP HRP-090 Informed Consent Process for Research". In Phases I & II, the consent process will take place immediately before completing the study procedures.

The consent document will be administered by the RA, in a private clinic exam room, to each participant individually. The informed consent will be fully explained page by page and any questions will be answered at that time. The RA will provide as much time as needed to answer any of the questions the participant may have. The RA will remain impartial throughout the consent process and will not coerce the participants. All information provided to participants is in terms that they can fully understand. The potential participant will then be asked to summarize their understanding of the study and what they will be required to do by participating.

Written consent will be obtained using the standard PPHS consent form. The key elements of the informed consent procedure which will be explained to the participants are: 1) a description of the study; 2) the lack of foreseeable risks and benefits; 3) an explanation of confidentiality; 4) the voluntary nature of the study; 5) the lack of consequences regarding the decision to consent or refuse to participate (including the lack of consequences to patients' medical care offered at Mount Sinai); 6) the lack of consequences related to withdrawing from the study or opting to skip/miss questions; 7) the approximate

number of patients to be enrolled; and 8) a description of compensation for participating in the study (i.e., $20 gift card).

Non-English Speaking Subjects

This study is exclusively enrolling English speaking, Black/African American patients due to the high CRC morbidity and mortality rates experienced by this racial group. Potential participants who do not speak English will be excluded from the study. All consent documents will be in English.

13) Process to Document Consent in Writing

The RA will review the consent document in a private clinic room with the patient. The consent form will be reviewed and signed before the onset of study. The study will be utilizing the standard PPHS consent form to obtain consent.

14) Vulnerable Populations

Participation is voluntary. All participants will be treated equally.

Some economically or educationally disadvantaged persons may be recruited. In order to ensure voluntary consent for vulnerable participants the following precautions will be taken: (1) a consent document will be written in the English language that the potential subject can understand; (2) Efforts will be taken to ensure the participant's understanding of the consent (e.g., we will ask patients to state in their own words the potential risks of the study); (3) vulnerable participants will not be preferentially enrolled; (4) information will be provided to participants in terms that they can fully understand; and (5) no overt or covert coercion will be exerted.

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
	X	*Pregnant women*
	X	*Prisoners*

15) Multi-Site Human Research (Coordinating Center)

N/A

16) Community-Based Participatory Research

N/A

17) Sharing of Results with Subjects

If participants request information about the study results, they will be provided with a copy of the publication detailing this information.

18) External IRB Review History

N/A

19) Control of Drugs, Biologics, or Devices

N/A