e-Motivación: Developing and Pilot Testing an App to Improve Latinos' Screening Colonoscopy Rates
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Mount Sinai *The Tisch Cancer Institute*

e-Motivación: Developing and Pilot Testing an App to Improve Latinos' Screening Colonoscopy Rates [Aim III, RCT]

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

Principal Investigator (PI) Name: Sarah Miller

PI Sign [redacted]

Date: July 11, 2022

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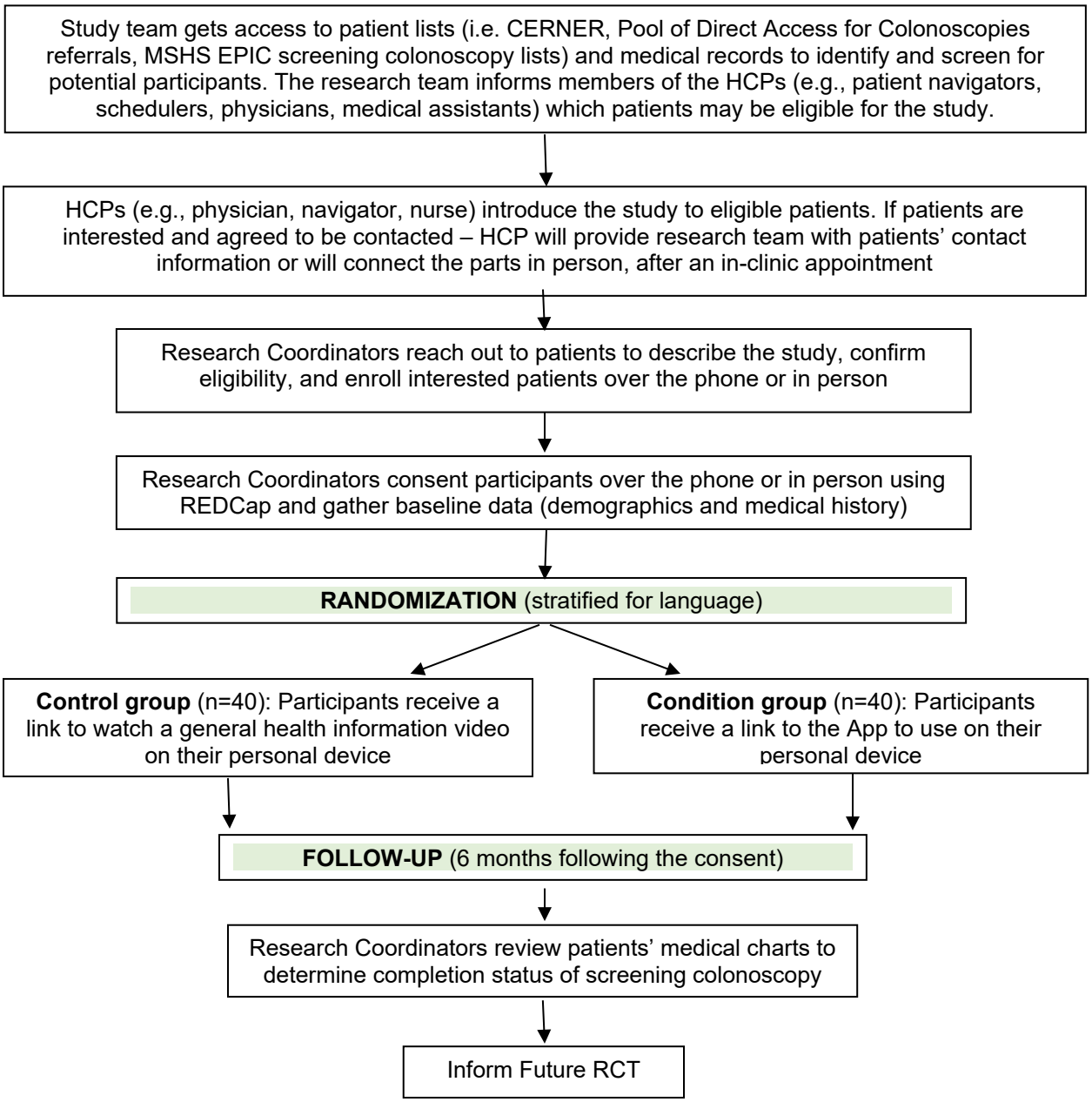
LIST OF ABBREVIATIONS

AE	Adverse Event
CRC	Colorectal Cancer
DHHS	Department of Health and Human Services
DSMB	Data and Safety Monitoring Board
FDA	US Food & Drug Administration
GCP	Good Clinical Practice
HCP	Healthcare Provider
IRB	Institutional Review Board
ISMMS	Icahn School of Medicine at Mount Sinai
MI	Motivational Interviewing
NIH	National Institute of Health
PPHS	Program for the Protection of Human Subjects
RCT	Randomized Control Study
SAE	Serious Adverse Event
UPR/UPIRSO	Unanticipated Problems Involving Risk to Subjects or Others

STUDY SCHEMA



STUDY SUMMARY

Title	e-Motivación: Developing and Pilot Testing an App to Improve Latinos' Screening Colonoscopy Rates: Aim III
Short Title	N/A
Protocol Number	IRB-18-00344
Phase	N/A
Methodology	Pilot Randomized Control Trial
Study Duration	9 months to conduct pilot study, 6 months to analyze pilot study data and disseminate results.
Study Center(s)	Single-center
Objectives	To begin to examine the efficacy of the e-Motivación app for improving screening colonoscopy uptake among Latinos (results of the pilot study will inform power calculations for a future randomized clinical trial that will formally test the efficacy of the app).
Number of Subjects	80 subjects total (N=40 in control group, N=40 in condition group)
Diagnosis and Main Inclusion Criteria	1. Self-identified as Latino,a,x 2. English or Spanish-speaking 3. Received a physician referral for a screening colonoscopy 4. Has access to a tablet, smartphone, or computer with working internet
Study Product(s), Dose, Route, Regimen	N/A
Duration of administration	N/A
Reference therapy	N/A
Statistical Methodology	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. Effect size estimate: Logistic regression analyses will be used to evaluate an estimate of the efficacy. The model will include any covariates that differentiate the intervention and control groups. The effect size of the treatment group will be used as an indicator to inform power calculations for a future RCT. The power calculations will inform the appropriate sample size needed for the RCT.

1.0 BACKGROUND AND RATIONALE

1.1 Disease Background

Colorectal Cancer and Aging. The risk of developing colorectal cancer (CRC) directly increases with age, with 89% of all CRC occurring in individuals over the age of 50.[1] The median age of a colon cancer diagnosis is 68 in men and 72 in women; the median age for rectal cancer is 63 in both men and women.[1] Given the link between age and CRC, the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology recommend that average risk people begin screening for CRC at the age of 50 and continue until at least the age of 75.[2] Of the recommended CRC screening tests, a colonoscopy is considered the gold standard because it allows for both the detection and removal of precancerous and cancerous growths.[3,4] Epidemiological research has found an association between increased screening colonoscopy rates and reduced mortality rates.[5]

Colorectal Cancer and Latinos. Among Latinos, a fast growing population, CRC remains the third leading cause of cancer death in the U.S. Compared to non-Latino whites, Latinos are less likely to be diagnosed with localized CRC and more likely to be diagnosed with advanced stage disease.[1] Given this disparity, it is critical to increase this population's participation in CRC prevention efforts. Although screening colonoscopies can detect and prevent CRC, more than half of Latinos have not received a screening colonoscopy within the recommended time frame (one colonoscopy per ten years).[6] Among uninsured Latinos, only a staggering 11% have received any type of recent CRC screening.[7] It is critical to increase Latinos' screening colonoscopy rates in order to the unequal burden of CRC in the Latino community.

Motivational Interviewing. Motivational Interviewing (MI), a brief client-centered behavioral intervention, may improve Latinos' screening colonoscopy uptake. Drawing from Self-Determination Theory (SDT),[8-10] MI helps increase competence, autonomy, and relatedness in order to promote behavioral change. MI involves four sequential processes: (1) *engaging* the patient in the intervention; (2) *focusing* the goal of the intervention; (3) *evoking* motivations for change; and, (4) *planning* for change.[11] Within this framework, MI implements techniques (e.g., decisional balance) to support behavior change.[12] MI was originally developed to treat substance use, and extensive research supports its efficacy for treating drug, alcohol, and nicotine use.[13-16] More recently, MI has proven efficacious for improving health behaviors such as diet,[17-19] exercise,[17] and medication adherence.[20] A meta-analysis found that MI had a significant, moderate effect (d=0.53) for improving health behaviors when compared to a no treatment/placebo control group.[21] Moreover, research has found that the effects of MI are long-lasting (>2 year follow up).[21] Extensive evidence supports the use of MI with Latinos. For example, research with exclusively or predominantly Latinos/Hispanic samples have found MI efficacious for managing diabetes,[22] decreasing drug use/needle sharing,[23,24] quitting smoking,[25] and decreasing alcohol use.[26] In fact, a 2005 review found MI to yield larger effect sizes with minorities, compared to non-minority whites.[15]

MI for Colonoscopy. Preliminary research has found MI to be efficacious for improving screenings for HIV,[27,28] breast cancer,[29,30] skin cancer,[31] and cervical cancer.[29] A recently published study examining the efficacy of MI to improve CRC screening uptake produced promising results, though non-significant (OR=1.6, CI=0.9, 3.0). Notable problems with this study may have limited the effects of MI. Most critical, not all MI interventionists were proficient in MI in the beginning stages of the study. Additionally, the intervention implemented techniques (e.g., discussing ambivalence when it was not clinically indicated) that may have been counterproductive.[32] A systematic review of the literature yielded that

MI shows strong promise for improving health screening behaviors, including several cancer screenings. [33]

1.2 Study Agent(s) Background and Associated Known Toxicities

N/A

1.3 Other Agents

N/A

1.4 Rationale

MI as an E-Health Intervention. Traditionally, MI is delivered live, where individuals meet with a professional either in person or over the telephone. Although efficacious, live-MI is not without limitations. Of greatest concern, live-MI requires staffing and economic resources, limiting its potential for wide dissemination. As such, many studies have examined the efficacy of e-MI, that is MI interventions delivered via electronic media (e.g., smartphone). This line of research began with the "Drinker's Checkup", an e-MI intervention designed to reduce alcohol use in problem drinkers. Extensive research supports the efficacy of this intervention[34,35] and it is currently listed in the Substance Abuse and Mental Health Administration (SAMSHA)'s National Registry of Evidenced-based Protocols and Programs (NREPP). Due to its proven efficacy, the Drinker's Checkup can be accessed online for clinical use and it has been widely disseminated both nationally and internationally.[36]

Although e-MI cannot replicate the nuances of live-MI, with advancing technology (e.g., algorithm based tailoring), e-MI is able to capture many of the essential components of live-MI, thus contributing to its widely proven efficacy.

Advantages of e-MI versus live-MI. There are both clinical and research advantages to using e-Health interventions, such as e-MI, as compared to live interventions. The *clinical* advantages of e-Health interventions include: **(1) High Technology Use:** E-health interventions are timely given the ubiquity of technology use in the U.S. According to a recent report from the U.S. Census, in 2015, 78% of households had a computer and 75% had a handheld computer (e.g., smartphone).[46] The PEW Internet & American Life Project's 2015 statistics reported that 84% of Latino adults use the Internet and 80% of Latino adults access the Internet via smartphone or tablet.[47] In recent years, the digital divide between Latinos and non-Latino whites has significantly narrowed, largely due to the increases in Internet use among immigrant Latinos and Spanish-speaking dominant Latinos. In fact, from 2009 to 2015, the rate of immigrant Latinos who use the Internet increased from 51% to 78% and the rate of Spanish-speaking dominant Latinos who use the Internet increased from 36% to 74%.[48] **(2) High Reach:** E-Health interventions have the potential for wide dissemination because they can be accessed from multiple locations and at convenient times, thus overcoming common barriers to receiving health interventions (e.g., limited transportation). E-Health interventions may be particularly useful for individuals of low socioeconomic status as they are often confronted with access barriers such as having limited transportation.[49] **(3) Privacy:** E-Health interventions can be accessed in private locations, maximizing anonymity and privacy. Research has found that individuals are more willing to disclose personal information when interacting with a computerized device versus a person.[50-52] Privacy may be particularly important with regard to potentially embarrassing health content, such as that surrounding a colonoscopy. **(4) Low Cost:** E-Health interventions do not require the hiring or training of staff thus reducing costs.[53] The *research* advantages to e-Health interventions include: **(1) Standardization:** E-Health interventions are highly standardized, thereby minimizing variance and maximizing internal validity.[53] **(2) Storage and Backup:** E-Health interventions can be linked to secure online databases that are regularly backed up thereby

eliminating errors in data entry and maximizing data security.[53] **(3) Tailored by Language:** E-health interventions can be programmed to be offered in multiple languages (e.g., Spanish and English) to address a wide range of patient populations.

e-MI to Improve Latinos' Screening Colonoscopy Uptake. Despite the strong promise of MI for improving screening colonoscopy uptake, and the advantages of e-MI, no study to date has examined the efficacy of e-MI to improve Latinos' screening colonoscopy uptake. This study pilot tests an e-MI intervention, e-Motivación (e-Motivation), to help improve Latinos' screening colonoscopy uptake. This line of research will increase our understanding of efficacious interventions to improve Latinos' CRC screening rates. It will also provide power calculations for a future RCT that will formally examine the efficacy of the e-Motivación app for improving Latinos' screening colonoscopy uptake. This program of research can help increase Latinos' colonoscopy uptake and, in doing so, reduce CRC screening disparities.

1.5 Correlative Studies

N/A

2.0 STUDY OBJECTIVES

2.1 Primary Objectives

2.1.1 To obtain an estimate of the efficacy of the e-Motivación app for improving screening colonoscopy uptake among Latinos
[For details, please see section 5.2.2; a detailed flowchart of the App is attached – please see Appendix B]

2.2 Secondary Objectives

N/A

2.3 Exploratory Objectives

N/A

2.4 Endpoints

2.4.1 Screening colonoscopy completion status in medical charts six months after t participants complete the consent for the study will be used as a proxy for *efficacy* of the e-Motivación app in improving screening colonoscopy uptake among Latinos. In our previous study with a similar sample, less than 10 of 900+ participants reported completing the colonoscopy at a different hospital. As such, for the proposed project, if the medical chart does not report that a colonoscopy was completed, the colonoscopy will be documented as "not completed".

3.0 PATIENT ELIGIBILITY

Eligibility waivers are not permitted. Subjects must meet all of the inclusion and exclusion criteria to be registered to the study. Study treatment may not begin until a subject is registered.

3.1 Inclusion Criteria

3.1.1 Self-identified as Latino,a,x

3.1.2 English or Spanish-speaking

3.1.3 Received a physician referral for a screening colonoscopy

3.1.4 Has access to a tablet, smartphone, or computer with working Internet

3.2 Exclusion Criteria

3.2.1 Hearing or vision impaired

3.2.2 Aim 1 or 2 participant

4.0 TREATMENT PLAN

4.1 Administration

Participants will be randomly assigned to one of two groups: e-Motivación (N=40) or control group (N=40). Participants assigned to the e-Motivación condition will complete the e-Motivación app on a personal device of their choice (for details, please see section 5.2.2; a detailed flowchart of the App is attached – please see Appendix B). Participants assigned to the control group will watch a general health video on a personal device of their choice.

4.2 Toxicities and Dosing Delays/Dose Modifications

N/A

4.3 Concomitant Medications/Treatments

N/A

4.4 Other Modalities or Procedures

N/A

4.5 Duration of Therapy

N/A

4.6 Duration of Follow Up

Six months following the consent to take part into the study, medical charts will be reviewed to determine colonoscopy completion status.

4.7 Removal of Patients from Protocol Therapy

Patients can be taken off the study at any time at their own request, or they may be withdrawn at the discretion of the investigator for safety, behavioral or administrative reasons. The reason(s) for discontinuation will be documented and may include:

4.7.1 Patient voluntarily withdraws from the study (follow-up permitted);

4.7.2 Patient withdraws consent (termination of treatment and follow-up);

4.7.3 Patient is unable to comply with protocol requirements;

4.7.4 Continuation on the study would not be in the patient's best interest based on the judgement of the treating physician, study PI, study doctor, sponsor or study institutions

4.8 Patient Replacement

N/A

5.0 STUDY PROCEDURES

5.1 Screening/Baseline Procedures

A HIPAA waiver will be requested to access patient lists and medical records to screen for study eligibility. Patients' lists (i.e. CERNER, Pool of Direct Access for Colonoscopies referrals, MSHS EPIC screening colonoscopy lists) and medical records will be obtained to identify and screen for potential participants. A member of the research team will inform members of the healthcare team (e.g., patient navigators, schedulers, physicians, medical assistants) which patients may be eligible for the study.

Members of the healthcare team, including patient navigators and primary care providers, will introduce the study to eligible patients (e.g., identify as Latino, received a primary care referral for a screening colonoscopy). If patients are interested in learning more about the study, and agree to be contacted, the member of the healthcare team will provide the research staff with the patient's contact information. If patients are being recruited in person, the member of the healthcare team will introduce the patient to the member of the research team, in person, after an in-clinic appointment.

The research staff will then contact (via email/over the phone/in person) the eligible patient to provide the patient with more details about the study. If the patient is interested in participating in the study and meets eligibility criteria, the patient will complete the consent form on RedCAP (emailed/texted/shown on the device of the person obtaining consent).

The screening procedures include:

5.1.1 ***Obtaining Informed Consent***

5.1.2 ***Reviewing Subject Eligibility Criteria***

5.1.3 ***Collecting Demographics***

[Age;; Length of permanence in the US; Ethnicity; Race; Preferred language; Territory of identity; Gender; Highest level of education; Marital Status; Estimated total income for the household for the past year]

5.1.4 ***Collecting Medical History***

[Referral for a screening colonoscopy (Yes/No); Previous experience of colonoscopy before (Yes/No) - If yes: year of last colonoscopy; Diagnosis of colorectal cancer (Yes/No); Diagnosis of a gastrointestinal disease (Yes/No); Family history of colorectal cancer (Yes/No) - If yes: Mother, Father, Brother, Sister, Child, Other; PRIMARY type of health insurance]

5.2 Procedures During Treatment

Consented participants will first complete a demographics questionnaire administered over the phone or in-person. Then, the participant will be randomly assigned to either the intervention condition (e-motivacion) or the control condition (general health video). The

participants will be emailed or texted a hyperlink. The hyperlink will either direct the participants to the app or to a general health video (see Appendices A and B, for details).

5.2.1 ***Completing an interviewer-administered baseline questionnaire***

[Age; Length of permanence in the US; Ethnicity; Race; Preferred language; Territory of identity; Referral for a screening colonoscopy (Yes/No); Previous experience of colonoscopy before (Yes/No) - If yes: year of last colonoscopy; Diagnosis of colorectal cancer (Yes/No); Diagnosis of a gastrointestinal disease (Yes/No); Family history of colorectal cancer (Yes/No) - If yes: Mother, Father, Brother, Sister, Child, Other; Gender; Highest level of education; PRIMARY type of health insurance; Marital Status; Estimated total income for the household for the past year, before taxes]

5.2.2 ***Interacting with the App (condition group)***

The app is designed to be used in English or Spanish, based on participant preference. The content of the app is drawn from our preliminary studies and the current MI literature, with particular emphasis on the most recently published MI guidelines (MI-III).[11,15,81-83] The e-Motivación app is designed to be user-friendly and to require low computer literacy. Consistent with the published MI guidelines, the e-Motivación app involves four sequential phases: **(1) Engaging:** During the *engaging phase*, participants will watch a video welcoming them to the intervention. Drawing from other e-MI interventions,[42] a live video coach will be used. **(2) Focusing:** During the *focusing phase,* participants will reaffirm their willingness to discuss the decision to have a screening colonoscopy. Then, using the "elicit-provide-elicit" MI technique, through touch screen multiple-choice questions, participants' knowledge about CRC prevention will be assessed. If participants lack knowledge regarding certain aspects of the colonoscopy or CRC in general, they will be given the option to view information videos (e.g., how to prepare for a screening colonoscopy). **(3) Evoking**: During the *evoking phase* of the intervention, participants will rate their perceived importance of having a colonoscopy and their level of confidence in their ability to complete the procedure. Based on their responses, participants will complete interactive MI exercises (e.g., decisional balance, values clarification) to help improve their perceived importance and confidence. **(4) Planning:** During the *planning phase* of the intervention, participants will be offered the option to watch a video designed to orient them to complete an action plan (e.g., scheduling the colonoscopy, planning for an escort).

[A detailed flowchart of the App is attached – please see Appendix B]

5.2.3 **The study team will have access to back end information that will allow authorized members to know which parts of the App were utilized by the user and how. That information will be linked to each participant by the ID that users are required to enter to log into the app.** ***Watching a General Health Information Video (control group)***

For the control group, the investigators will not be able to know if the video was watched by the participant or not.

5.3 Follow-up Procedures

5.3.1 Reviewing Medical Charts to Determine Colonoscopy Completion Status and relevant medical information [Screening colonoscopy referral and scheduling date; Screening colonoscopy completion (yes/no); Screening colonoscopy completion date; bowel prep quality; number of cancelations and no-shows;

Received patient navigation/care coordination(yes/no); reasons for not completion (if applicable)]

6 months following consent to participate in the study

5.4 Time and Events Table

Research Timeline [Aim III]	Months 1-3	Months 4-6	Months 7-9	Months 10-12	Months 13-15
Recruitment	X	X	X		
Informed Consent	X	X	X		
Baseline data (demographics & medical history)	X	X	X		
Review of medical charts (colonoscopy completion status)			X	X	X
Analyze pilot study data					X
Disseminate results					X

5.5 Removal of Subjects from Study

Patients can be taken off the study at any time at their own request, or they may be withdrawn at the discretion of the investigator for safety, behavioral or administrative reasons. The reasons for discontinuation will be documented and may include:

5.5.1 Patient voluntarily withdraws from the study (follow-up permitted);

5.5.2 Patient withdraws consent (termination of treatment and follow-up);

5.5.3 Patient is unable to comply with protocol requirements;

5.5.4 Continuation on the study would not be in the patient's best interest based on the judgement of the treating physician, study PI, study doctor, sponsor or study institution

6.0 Measurement of Effect

Screening colonoscopy completion status (in medical charts) six months after the patient expressed informed consent to participate in the study will be the proxy for efficacy of the e-Motivación app in improving screening colonoscopy uptake among Latinos. If the medical chart does not report that a colonoscopy was completed, the colonoscopy will be documented as "not completed". This decision is informed by a study that we have conducted with a similar sample, where less than 10 out of 900+ participants reported completing the colonoscopy at a different hospital.

6.1 Antitumor Effect- Solid Tumors

N/A

6.2 Antitumor Effect- Hematologic Tumors

N/A

6.3 Safety/tolerability

N/A

7.0 ADVERSE EVENTS

7.1 Experimental Therapy

N/A

7.2 Adverse Event Monitoring

Adverse event data collection and reporting, which are required as part of every clinical trial, are done to ensure the safety of Subjects enrolled in the studies as well as those who will enroll in future studies. Adverse events are reported in a routine manner at scheduled times during a trial. Additionally, certain adverse events must be reported in an expedited manner to allow for optimal monitoring of patient safety and care.

All patients experiencing an adverse event, regardless of its relationship to the study, will be monitored until:

- the adverse event resolves or the symptoms or signs that constitute the adverse event return to baseline;
- any abnormal laboratory values have returned to baseline;
- there is a satisfactory explanation other than the study for the changes observed; or
- death.

7.3 Definitions

7.3.1 Definition of Adverse Event

An adverse event (AE) is any untoward medical occurrence in a patient receiving study treatment and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an experimental intervention, whether or not related to the intervention.

7.3.2 Severity of Adverse Events

The severity of an AE is graded as follows:

Mild (grade 1): the event causes discomfort without disruption of normal daily activities.
Moderate (grade 2): the event causes discomfort that affects normal daily activities.
Severe (grade 3): the event makes the patient unable to perform normal daily activities or significantly affects his/her clinical status.
Life-threatening (grade 4): the patient was at risk of death at the time of the event.
Fatal (grade 5): the event caused death.

7.3.3 Serious Adverse Events

A “serious” adverse event is defined in regulatory terminology as any untoward medical occurrence that:

7.3.3.1 Results in death.

If death results from (progression of) the disease, the disease should be reported as event (SAE) itself.

7.3.3.2 Is life-threatening.

(the patient was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe).

7.3.3.3 Requires in-patient hospitalization or prolongation of existing hospitalization for ≥ 24 hours.

7.3.3.4 Results in persistent or significant disability or incapacity.

7.3.3.5 Is an important medical event

Any event that does not meet the above criteria, but that in the judgment of the investigator jeopardizes the patient, may be considered for reporting as a serious adverse event. The event may require medical or surgical intervention to prevent one of the outcomes listed in the definition of "Serious Adverse Event".

7.4 Steps to Determine If an Adverse Event Requires Expedited Reporting

Step 1: Identify the type of adverse event using the aforementioned scale (7.3.2).

Step 2: Grade the adverse event using the aforementioned scale (7.3.2).

Step 3: Determine whether the adverse event is related to the study protocol
Attribution categories are as follows:

- Definite – The AE *is clearly related* to the study.
- Probable – The AE *is likely related* to the study.
- Possible – The AE *may be related* to the study.
- Unrelated – The AE is clearly NOT related to the study.

Note: This includes all events that occur within 30 days of the last participation of patient in the study. Any event that occurs more than 30 days after the last participation and is attributed (possibly, probably, or definitely) to the agent(s) must also be reported accordingly.

Step 4: Determine the prior experience of the adverse event.
Expected events are those that have been previously identified as resulting from administration of the intervention.

7.5 Reporting Requirements for Adverse Events

7.5.1 Expedited Reporting

- The Principal Investigator must be notified within 24 hours of learning of any serious adverse events, regardless of attribution, occurring during the study or within 30 days of the last participation of patient in the study.
- The IRB/PPHS must be notified within 5 business days of "any unanticipated problems involving risk to subjects or others" (UPR/UPIRSO).

  The following events meet the definition of UPR

  a. Any new information that indicates a new or increased risk, or safety issue (e.g., interim analysis, safety monitoring report, publication, updated sponsor safety report), that indicates an unexpected change to the risk/benefit ratio for the research.

b. Protocol deviation or violation that harmed subjects or others or that indicated subjects or others might be at increased risk of harm.

c. Complaint of subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm

d. Any breach in confidentiality that may involve risk to the subject or others.

e. Any harm experienced by a subject or other individual that in the opinion of the investigator is unexpected and at least probably related to the research procedures.

7.5.2 Routine Reporting

All other adverse events- such as those that are expected, or are unlikely or definitely not related to the study participation- are to be reported annually as part of regular data submission.

7.6 Unblinding Procedures

N/A

7.7 Stopping Rules

N/A

8.0 DRUG INFORMATION

8.1 N/A

9.0 CORRELATIVES/SPECIAL STUDIES

9.1 Sample Collection Guidelines

N/A

9.2 Assay Methodology

N/A

9.3 Specimen Banking

N/A

10.0 STATISTICAL CONSIDERATIONS

10.1 Study Design/Study Endpoints

This pilot study is a behavioral research Randomized Control Trial. A previously used English/Spanish questionnaire[90, 91] is administered to assess demographics and medical history of participants. Stratified randomization (per language, English or Spanish) assigns participants to either the e-Motivación condition arm or control arm.
Participants in both groups will be asked to complete their respective tasks on their personal device of choice (going through the e-Motivación App or watching the general health informative video). To determine colonoscopy completion status, patients' medical charts are to be reviewed six months following patient's consent to participate in the study.

10.2 Sample Size and Accrual

The sample includes 80 participants: 40 in the e-Motivación condition arm and 40 in the control arm. Based on previous studies, this sample will provide a large enough sample to determine the effect of the intervention. We also expect the ratio of male to female participation to be 4 to 6.

10.3 Data Analyses Plans

Analyses of covariates: Due to the use of randomization, significant baseline differences (e.g., gender, age) between condition and control groups are not expected. However, contingency tables and t-tests will be performed to determine any differences between the two arms. 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.

Effect size estimate: Logistic regression analyses will be used to evaluate an estimate of the efficacy. The model will include any covariates that differentiate the intervention and control groups. The effect size of the treatment group will be used as an indicator to inform power calculations for a future RCT. The power calculations will inform the appropriate sample size needed for the RCT.

Missing data: The e-Motivación app is a one-time intervention and the questionnaire to assess demographics and medical history of participants will be conducted as an interview. Therefore, we anticipate minimal missing data.

11.0 STUDY MANAGEMENT

11.1 Conflict of Interest

Any research personnel who has a conflict of interest with this study (patent ownership, intellectual property, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must declare their conflict of interest to the appropriate institutional review bodies. Local institutional conflict of interest policies will be followed for all research personnel associated with the research project.

11.2 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated (in person or electronic via RedCAP) by the patient and by the person who conducted the informed consent discussion.

11.3 Required Documentation

N/A

11.4 Registration Procedures

All patients must be enrolled onto trial through the Cancer Clinical Trials Office Central Registration process. Prior to registration, a member of the study staff must scan and email the following documents as individual PDF files to the Central Registration Mailbox (central.registration@mssm.edu) with a cc to the Central Registrars.

- Signed Informed Consent(s)
- Signed CCTO Registration Form
- Signed Eligibility Checklist
- Additional supporting documentation (i.e. lab/scan reports) may be included at the study teams' discretion.

The designated Central Registrar will review all received documents for consistency and completeness.

- If there is any concern or discrepancy noted, the study staff member who originated the central registration request will be contacted immediately for clarification.

If the patient is deemed eligible for study enrollment based on a thorough review by the Central Registrar, the patient will be entered into the CTMS system and a Registration Confirmation Letter is generated and sent to the following individuals:

- Study team
- Treating Physician
- Research Infusion Nurse designee
- Research Pharmacy

11.5 Data Management and Monitoring/Auditing

11.5.1 Elements of a Data and Safety Monitoring Plan

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

ISMMS Principal Monitor:
Principal Investigator

Last Name: Miller
First Name: Sarah
Academic Title:
Department: Oncological Sciences
Mailing Address: 1 Gustave L. Levy Place, Box 1130
Phone: 212.824.7783
E-mail: Sarah.miller@mssm.edu

ISMMS Additional Monitor:
Team Member

Last Name: Jandorf
First Name: Lina
Academic Title: MA
Department: Population Health Science and Policy, Oncological Sciences
Mailing Address: 1425 Madison Ave, New York, NY 10029
Phone: 212-659-5506
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.*

Participants could experience mild to moderate emotional discomfort from 1) failed attempts to use the App, 2) engaging with an App that is focused on colorectal cancer 3) breach in confidentiality. In the event a patient requires a higher level of care or assistance than provided in this study, a Licensed Clinical Psychologist (Dr. Sarah Miller, PI) will be consulted and the participant will be referred to the appropriate level of care. If additional intervention is necessary, Dr. Miller will coordinate with Mount Sinai's Psychiatry Department.

As per ISMMS PPHS policies, the PI is required to notify PPHS of any unanticipated problems involving risks to participants or others that occur. If an adverse event is due to the intervention and is unexpected, the PI will draft a safety report and send a copy to PPHS. The PPHS committee will serve as an objective review mechanism. This policy/procedure means that any potential conflict of interest inherent in the PI being the sole reviewer of serious adverse advents is avoided.

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

- Informed Consent
- Subject compliance with the protocol
- Research Staff compliance with the protocol
- Adverse Events
- Drop outs

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.*

The PI will monitor the progress of the trial and the safety of participants on an ongoing basis. The procedures of this study, such as regular meetings with research staff and the entire study team, will ensure prompt discussion and reporting of all study conduct issues, including adverse events. During these meetings, the PI will focus on participant safety by reviewing adverse events, study progress (e.g. recruitment, retention, protocol adherence), data integrity and study outcomes. Additionally, we anticipate that risk-benefit ratio will remain favorable throughout the study. However, if at any point it is not, we will stop the study and re-evaluate study procedures in order to ensure a positive risk-benefit ratio for participants.

The table below describes each data monitoring activity, responsible staff person, and frequency of review. Tracking forms will be developed to document the occurrence of all reviews. The PI will review all reports as they are generated.

Activity	**Report**	**Timing of review**
Informed Consent	Quality control of each new consent by Research Coordinators	PI reviews all consents upon receipt
Protocol Adherence (both Subjects and Research Staff)	Weekly report generated by Research Coordinators	Weekly PI review

Adverse Events	Weekly report generated by Research Coordinators	Weekly PI review
Study Retention	Weekly report generated by Research Coordinators	Weekly PI review
Review of Medical Charts to Assess Colonoscopy Completion Status	Weekly report generated by Research Coordinators	Weekly PI review
Self-Report Information	PI and other study staff will review all self-report materials and complete fidelity checklist	PI will review data weekly for completeness and accurate entry into a database for analysis

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).*

The severity of an adverse event is graded as follows:

- Mild (grade 1): the event causes discomfort without disruption of normal daily activities.
- Moderate (grade 2): the event causes discomfort that affects normal daily activities.
- Severe (grade 3): the event makes the patient unable to perform normal daily activities or significantly affects his/her clinical status.
- Life-threatening (grade 4): the patient was at risk of death at the time of the event.
- Fatal (grade 5): the event caused death.

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

Study data will be entered by a Research Coordinator trained to enter data into a password-protected, secure database on REDCap. To ensure the validity and integrity of study data, the PI will oversee all data management responsibilities. Data entry, level of accuracy and percentage of error in data entry will be discussed with the study team on a regular basis. Monthly meetings (either in person or via video/telephone conference) will be held with the entire study team.

Thorough training of Research Coordinators is also designed to ensure adequate protection of human subjects. All Research Coordinators will receive all required training and certification in Mount Sinai's human subjects in research. Research Coordinators will be required to participate in a training program designed to ensure that they administer the interviews and evaluate participant responses in a sensitive manner. Research Coordinators will be trained to speak clearly and audibly and let participants determine the pace of the interview.

Protocol compliance will be monitored at the weekly research staff meetings. The PI will meet with the study staff on a weekly basis to train and ensure adherence to the intended protocol. The PI will be responsible for updating all investigators regarding any study related issues that arise of that need to be addressed.

The medical chart abstraction will be conducted by a research team member. A second research team member will review 20% of the medical charts to confirm accuracy.

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?*

IRB and Program Officer of the National Institute On Aging/NIH/DHHS

11.5.2 Data Monitoring Committee/Data Safety Monitoring Board (DMC/DSMB)

N/A

11.6 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

11.6.1 Emergency Modifications

Investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB approval.

11.6.2 Other Reportable New Information and Protocol Deviations/Violations

In accordance with local IRB requirements, the following information must be reported within five (5) business days.

- Non-compliance with federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance
- Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- Breach of confidentiality
- Premature suspension or termination of the research by the sponsor or investigator.

11.7 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to the IRB for approval prior to implementation.

11.8 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that the study investigator must retain all study documentation pertaining to the conduct of a clinical trial. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

11.9 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator at each institution or site will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

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13.0 APPENDICES

A. Shortlisted General Health Information Videos

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- Acabe con los microbios. ¡Lávese las manos! [Spanish version]
- Fight Germs. Wash Your Hands [English version]

Note: The shortlisted videos are CDC's materials; If approved by the IRB, the research team will make sure to follow the Agency's requirements to utilize CDC's public domain content. .

B. App Flowchart - Field Testing II