Study Protocol

A Colorectal Cancer Educational Intervention in the Latino Community Assessing the Feasibility of Recruitment & Retention via a Church-Based Approach: Identification of Novel Barriers to Cancer Clinical Trial Enrollment

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PROTOCOL TEMPLATE: INTERVENTIONAL STUDY

Complete Title: A Colorectal Cancer Educational Intervention in the Latino Community Assessing the Feasibility of Recruitment & Retention via a Church-Based Approach: Identification of Novel Barriers to Cancer Clinical Trial Enrollment

Short Title: PeLear CCC: Proyecto Latino Contra Cáncer Colorrectal

Drug or Device Name(s): N/A

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Sponsor: José G. Guillem

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Amendment 3 Date:

Amendment 4 Date:

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Version Date: November 21, 2024

I confirm that I have read this protocol and understand it.

Principal Investigator Name: _____

Principal Investigator Signature: _____

Date: _____

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Abbreviations and Definitions of Terms

Abbreviation	Definition
NCTraCS	North Carolina Clinical and Translational Science Institute
US	United States
CRC	Colorectal Cancer
CCT	Cancer Clinical Trial
STM	Saint Thomas More
LCRB	Latine Community Review Board
CHW	Community Health Workers
IRB	Institutional Review Board
PHI	Private Health Information
RCMU	Research Coordination & Management Unit
UNC	University of North Carolina
PI	Primary Investigator
RIS	Research Information Sheet
CTS	Clinical Translational Science

PROTOCOL SYNOPSIS

Study Title	A Colorectal Cancer Educational Intervention in the Latino Community Assessing the Feasibility of Recruitment & Retention via a Church-Based Approach: Identification of Novel Barriers to Cancer Clinical Trial Enrollment
Funder	NCTraCS
Clinical Phase	N/A
Study Rationale	Cancer is the leading cause of death in the US Latino community, with CRC accounting for 10% of overall Latino mortality. Although Latino individuals are among the largest and fastest growing communities of color in the US, currently comprising 18.7%, their representation in CCTs remains low. This is of concern because: 1) advances arising from trials with limited Latino representation may not be applicable to the Latino population, and 2) decreased Latino participation in CCTs may delay Latino access to novel therapies. We believe that low cancer-specific health knowledge may be impacting Latino representation and willingness to participate in CCTs and can be addressed through culturally and linguistically appropriate community-based educational interventions. Since Latino CCT underrepresentation is likely to be a multifaceted phenomenon with potential contributing barriers at the physician-, healthcare system-, and patient-level, understanding the multiple driving forces and barriers is essential to identifying potential targets for improvement and addressing our CTS roadblock of Latino underrepresentation in CCTs.
Study Objective(s)	1. To identify novel Latino-perceived barriers to participation in CCTs. 2. To assess the impact that CRC educational videos in Spanish have on participants' CRC knowledge. 3. To assess the potential relationship between an increase in health knowledge of a specific cancer via educational videos in Spanish and willingness to participate in CCTs.
Test Article	The intervention in this study entails three CRC educational videos in Spanish.
Study Design	To achieve our goals, Spanish speaking Latino individuals will be recruited to participate in an educational intervention that will take place at STM Church. On Study Day 1, participants will be given the *CRC Knowledge Survey* in Spanish before watching three CRC educational videos. After watching the videos, participants will be given the *Post Video CRC Knowledge Survey*. After 30 +/- 7 days, participants will be asked to return to the Church for Study Day 2 in order to complete the *30 Day Follow Up CRC Knowledge Survey*,

	consisting of the original survey plus an open-ended question regarding barriers to participation in CCTs. Subsequently, 20 participants will be invited to participate in one-on-one qualitative interviews aimed at gaining further insight on Latino-perceived barriers to CCT participation. (Study Day 3)
Subject Population Key Criteria for Inclusion and Exclusion:	Participants should: 1. Self-identify as Hispanic/Latino. 2. Be Spanish speakers. 3. Be 18 years or older. Participants will be excluded if they: 1. Do not identify as Hispanic/Latino. 2. Are not Spanish speakers. 3. Are younger than 18 years old.
Number Of Participants	60
Study Duration	Every participant's involvement will require at least two and a half hours over a 4-month period (two hours to take the *CRC Knowledge Survey*, watch the videos and take the *Post Video CRC Knowledge Survey* and thirty minutes to complete the *30 Day Follow Up CRC Knowledge Survey*). Participants willing to take part in a qualitative one-on-one interview will be asked to participate for an additional hour, totaling three and a half hours over a 6-month period. The entire study is expected to last 12 months.
Study Phases A. Educational Video i. Screening ii. Study Intervention iii. Follow-Up B. Identification of Barriers Preventing Latinos from participating in CCTs	A. <u>Educational Video:</u> (i) Screening: Spanish speaking attendees at STM Church will be screened for study eligibility. (ii) Intervention (Study Day 1): Consented participants will complete the *CRC Knowledge Survey*, watch three CRC educational videos and complete the *Post Video CRC Knowledge Survey*. Both surveys will be administered on paper form. (ii) Follow up (Study Day 2): In order to assess retention of knowledge, participants will return to STM Church 30 +/- 7 days after Study Day 1 to complete the *30 Day Follow Up CRC Knowledge Survey* on paper form. B. <u>Identification of Barriers for Latino Participation in CCTs:</u> (Study Day 3): 20 of the participants will be asked to participate in a qualitative one-on-one interview aimed at identifying barriers preventing Latinos from participating in CCTs.
Efficacy Evaluations	Participants' knowledge on CRC symptoms, risk factors, and general CRC facts will be assessed using questions from the "Bowel Cancer Awareness Measure" and from the "Colorectal Cancer Screening Decision Quality Instrument (CRC-DQI)".

Safety Evaluations	N/A, this study imposes minimal risk.
Statistical And Analytic Plan	A. Identification of Barriers: The top 2 conceptual themes within each section of the interview (attitudes regarding general clinical trials, attitudes regarding CCTs, and perception of the Hispanic/Latino community) and the top 3 higher-level, holistic themes across the sections will be reported in terms of percentage of participants. B. Assessment of the potential impact of the educational videos in Spanish on CRC knowledge: Use of repeated measures ANOVA with appropriate follow-up contrasts to compare total number of correct responses within three time points (baseline vs post-video; baseline vs 30 +/- 7 days follow up; post-video vs 30 +/- 7 days follow-up) accounting for multiple observations within participants. C. Exploration of the potential relationship between an increase in health knowledge of a specific cancer via educational videos in Spanish and willingness to participate in CCTs: Since questionnaires will be completed pre- and post-video, we will explore, in a preliminary fashion, the association between watching the video (X) and willingness to participate in CCTs (Y) using repeated-measures/mixed-effects logistic regression on the paired responses of participants. The mediating effect of Study Day 1 post-video health knowledge levels (M) on the relationship between X and Y (established in the preliminary step above) will be explored. Using a structural equation modeling approach, two mixed-effects generalized linear models will be carried out: one model uses both X and M to predict Y, while another uses only X to predict M. The two models will be compared and tested using the algorithm introduced by Imai and colleagues. The estimated average causal mediation effect (from X to Y, through M) will be tested using the bootstrapping method with 1,000 replications, and the proportion of the effect being mediated will be reported as the effect size. Lastly, in order to explore an adjusted approach, the same steps used for the mediation model will be replicated, while incorporating demographic variables as covariates.
DATA AND SAFETY MONITORING PLAN	Monitoring of quality data entry will be performed by our collaborators at the RCMU and members of the study team after the initial 5 registrants and then after every 10. The PI will be responsible for data monitoring. To minimize the risk of breach of confidentiality, all PHI will be stored in a password protected server accessible only by members of the study team. To minimize the risk of emotional distress, participants will be reassured that they will not have to answer any questions that make them feel uncomfortable and may stop completing the questionnaires at any point.

BACKGROUND AND RATIONALE

1.1 Introduction

Cancer is the leading cause of death in the US Latino community, with CRC accounting for 10% of this overall mortality.[1] Although Latino individuals are among the largest and fastest growing communities of color in the US, currently comprising 18.7%,[2] their representation in CCTs remains low.[3–5] This is of concern because: 1) advances arising from trials with limited Latino representation may not be applicable to the Latino population,[6] and 2) decreased Latino participation in CCTs may delay Latino access to novel therapies.

We believe that low cancer-specific health knowledge may be impacting Latino representation and willingness to participate in CCTs and that this can be addressed through culturally and linguistically appropriate community-based educational interventions.[7,8] Since Latino CCT underrepresentation is likely to be a multifaceted phenomenon with potential contributing barriers at the physician-, healthcare system-, and patient-level, understanding the multiple driving forces and barriers is essential to identifying potential targets for improvement and addressing our CTS roadblock of Latino underrepresentation in CCTs.

1.2 Name and Description of Investigational Product or Intervention

This study will assess the impact of three educational videos in Spanish on participants' CRC knowledge and willingness to participate in CCTs.

1.3 Non-Clinical and Clinical Study Findings

Potential benefits from participation in this study may include improvement in participants' knowledge of CRC, a major healthcare problem for the Latino community. The pre- (*CRC Knowledge Survey)* and post-educational video (*Post Video CRC Knowledge Survey)* questionnaires will allow us to determine the impact of the educational videos on CRC knowledge and retainment as well as allow us to explore the potential relationship between an increase in knowledge on a specific cancer and willingness to participate in CCTs. The follow-up questionnaire (*30 Day Follow Up CRC Knowledge Survey*) will assess retention of information at 30 +/- 7 days. In addition, through the conduct of qualitative one-on-one interviews, Latino-perceived barriers to CCT participation may be identified. The study requires completion of three questionnaires and a potential one-on-one interview. It will be conducted in a familiar location (namely, STM Church), and we do not anticipate any adverse events. There is minimal risk of emotional distress from answering questions related to CRC. However,

participants will be encouraged to not answer any questions that make them feel uncomfortable and to stop the questionnaires at any point. Participants will be asked to provide contact information in order to schedule interviews. Efforts are in place to minimize any potential breach of confidentiality. Overall, the potential risks from participating in our study are minimal while the knowledge to be gleamed, including Latino-specific barriers to CCT participation, will be significant.

1.4 Relevant Literature and Data

Use of the Church-based Approach: Approximately 75% of Foreign- and 55% of US-born Latino identify as Christian, respectively[9] and 74% of Latinos attend Church at least 1-2 times a month.[10] As a testament to the important role that the Church plays in the Latino community, several interventions have been evaluated in the Church setting[11–25] including: breast cancer prevention;[16,17,19] diabetes mellitus;[14,23,24] cancer screening promotion;[13,15] physical exercise promotion;[18,21] HIV stigma reduction;[20] stroke prevention;[22] organ donation promotion;[25] and cardiovascular risk reduction.[11,12] With the exception of a recent study limited to Latino men,[26] we are not aware of any Church-based educational interventions that have: 1) educated Latinos on CRC or 2) reported strategies for their recruitment and retention. We believe that our approach, if successful, may have broad applicability for the recruitment of other ethnic minority groups with high religious beliefs across a multitude of denominations (e.g. 68% of Asians attend Church at least 1-2/month[10]).

Education of the general population/non-cancer afflicted individuals: Most CCT educational interventions target individuals afflicted with the disease.[27–33] While only a handful target the non-affected general population,[34–37] this approach may be uniquely suited for recruitment of Latinos in CCTs since in the Latino community the decision to enroll in a CCT is likely to be multifactorial and heavily influenced by input from family members.[38] In fact, a core value of Latino culture is *familismo*: "the concept of a broad network of familial support that extends beyond the nuclear family".[39] Since lack of family support may act as a barrier to Latino CCT participation,[40,41] we believe that: (1) educating the general population and non-cancer afflicted Latino individuals and families will facilitate Latino CCT participation and (2) the Church setting, given the multiple familial generations attending mass, is a viable venue for educating the Latino general population.

Education on a specific cancer & willingness to participate in CCTs: Unlike other studies aimed at increasing willingness to participate in CCTs solely through general education about CCTs, our study focuses primarily on education on a specific cancer.[27–37,42] Since education on CRC has been shown to

increase willingness to participate in CRC screening,[43] we anticipate it could similarly increase willingness to participate in CCTs. This can be achieved by increasing awareness of CRC and its treatment options ultimately leading to improved decision-making.[27]

***Questionnaire*:** Knowledge on CRC and willingness to participate in CCTs will be assessed using 3 subscales from 2 CRC knowledge questionnaires previously validated in English. Dr. Perreira and Jessica Grant from the Odum Institute combined the 3 subscales[44–46] to form our Pilot Study Questionnaire. This Pilot Study Questionnaire has been translated into Spanish by Language Line Solutions, hired through the UNC Clinical Research Support Office (CRSO), and revised, using an iterative process with input from the LCRB, for linguistic and cultural relevance and accuracy. The resultant Pilot Study Questionnaire consists of 29 items that assess health knowledge levels and 1 that assesses willingness to participate in CCTs (30 total questions). General knowledge on CRC will be assessed using the prompted 9-item "Awareness of warning signs'' (Yes/No) and the prompted 11-item "Awareness of risk factors'' (5 point Likert agreement scale) subscales of the "Bowel/CRC Cancer Awareness Measure (Bowel/CRC CAM)".[45] Specific knowledge on CRC screening will be assessed using the 9-item "Knowledge on CRC screening" (mixed types of response options) subscale from the CRC Screening Decision Quality Instrument (CRC-DQI).[46] Our outcome variable, *willingness to participate in CCTs*, will be assessed using a "Yes/No" item.[28,36,42] Our Pilot Study Questionnaire is used in all three surveys, namely the *CRC Knowledge Survey; Post Video CRC Knowledge Survey and 30 Day Follow Up CRC Knowledge Survey.* Additionally, the *CRC Knowledge Survey,* administered pre-video, includes seventeen questions capturing demographic information (47 total questions), while the *30 Day Follow Up CRC Knowledge Survey* contains in addition to the pilot study Questionnaire, an open-ended question aimed at capturing barriers preventing Latinos from participating in CCTs (31 total questions).

Video: Previous studies demonstrate the superiority of a video-based approach compared to other educational tools in terms of knowledge acquisition and acceptance within the Latino population.[42,43,47,48] Based upon strong recommendation from the UNC's Audio and Video Production Team, we contracted DWALT Media, which has filmed videos for UNC Medical Center and worked with local churches, for the production of our Spanish educational videos. Filming occurred at UNC Medical Center and included animations, figures and 3D models. The videos will educate the participants on CRC symptoms, risk factors, screening and CRC facts. In addition, the third video will contain some information regarding CCTs. Since Latinos consider physicians a trustworthy source of

medical information,[49] our PI, a member of the STM Latino community, will present some of the educational material.

1 STUDY OBJECTIVES

1.4 Primary Objective

The Primary Objective of this study is to identify novel Latino-perceived barriers to participation in CCTs.

1.5 Secondary Objectives

1. Assess the impact that CRC educational videos in Spanish may have on participants' CRC knowledge.
2. Assess the potential relationship between an increase in health knowledge of a specific cancer via educational videos in Spanish and willingness to participate in CCTs.

2 INVESTIGATIONAL PLAN

2.1 Study Design

Type of Design: Single-arm intervention study

Brief Overview of Study Phases: Following completion of the Hispanic Masses at STM Church on Saturday and Sunday, attendees will be approached by members of our study team and CHWs. They will be screened for their eligibility to participate in our study through an Intake Form which they will be able to complete either in-person while they are at the Church, or through the project website. Those deemed eligible will be prompted to complete the RIS online, in-person, or via the phone. Those that complete the RIS and enroll in the study will be scheduled to come to STM Church on future *Study Days*. During *Study Day 1*, participants will complete the *CRC Knowledge Survey*, watch three CRC educational videos in Spanish and then complete the *Post Video CRC Knowledge Survey*. On *Study Day 2* (30 +/- 7 days after their participation in *Study Day 1*), participants will return to STM Church in order to complete the *30 Day Follow Up CRC Knowledge Survey.* Subsequently, on *Study Day* 3, 20 of the 60 participants will participate in a one-on-one qualitative interview aimed at identifying barriers preventing Latinos from participating in CCTs.

2.2 Study Duration, Enrollment and Number of Participants

Participant commitment will consist of at least two and a half hours over a 4-month period (two hours to take the *CRC Knowledge Survey*, watch the videos and take the *Post Video CRC Knowledge Survey* and thirty minutes to complete the *30 Day Follow Up CRC Knowledge Survey*). Participants willing to take part in a qualitative one-on-one interview will commit an additional hour, totaling three and a half hours over a 6-month period. The entire study is expected to last 12 months. We intend to enroll a total of 60 participants. However, in order to recruit the necessary 20 for the qualitative interview, we may need to enroll more than 60 since not everyone participating in *Study Days 1 and 2* will choose to participate in *Study Day 3.*

2.3 Study Population

Participants should:

(1) Self-identify as Hispanic/Latino.
(2) Be Spanish speakers.
(3) Be 18 years or older.

Participants will be excluded if they:

(1) Do not identify as Hispanic/Latino.
(2) Are not Spanish speakers.
(3) Are younger than 18 years.

3 STUDY PROCEDURES

3.1 Screening/Baseline Visit procedures

Interested participants will be asked to complete an Intake Form in Spanish which captures name and contact information as well as determines study eligibility as listed above. Those deemed eligible will be prompted to complete the RIS. In addition to in-person recruitment, interested participants will have the opportunity to complete the Intake Form using our study website, which will be readily accessible via a QR code found on the Study Flyer.

3.2 Intervention/Treatment procedures

Study Day 1: Consented participants come to STM Church. During *Study Day 1*, they will be asked to complete the *CRC Knowledge Survey*, watch three CRC educational videos in Spanish and subsequently complete the *Post Video CRC Knowledge Survey* in Spanish. Both surveys will be administered on paper form.

3.3 Follow- up procedures

Study Day 2: The participants return to STM Church 30 +/- 7 days after their participation in *Study Day 1*. During *Study Day 2*, they will complete the *30 Day Follow Up CRC Knowledge Survey* on paper form.
Study Day 3: A random subset of participants from *Study Days 1* and *2* will be invited to participate in qualitative one-on-one interviews aimed at identifying barriers preventing Latinos from participating in CCTs.

3.4 Subject Completion/ Withdrawal procedures

At the completion of *Study Day* 2, participants will receive a $100 gift card and a study T-shirt from either our research assistant or one of the volunteers, all of whom will be Tango trained and enlisted on the study's IRB. Participants interested in participating in qualitative one-on-one interviews aimed at identifying barriers preventing Latinos from participating in CCTs will be invited to participate in *Study Day 3*. Following completion of *Study Day 3*, these participants will receive an additional $50 gift card for their participation in the qualitative one-on-one interviews. Participants choosing to withdraw from the study may do so at any point by notifying the PI via email.

3.5 Screen failure procedures

At the beginning of each educational session, eligibility requirements (age $\geq$ 18 years of age; identifying as Hispanic/Latino and being Spanish speaker) will be confirmed for each registered individual. In the unlikely event that an ineligible individual had been registered, this will be noted and the involved parties reminded of the eligibility requirements and their inability to participate in the study.

4 STUDY EVALUATIONS AND MEASUREMENTS

4.1 Efficacy Evaluation

To assess the impact of the CRC educational videos in Spanish on participant's knowledge of CRC symptoms, risk factors, screening, and facts, this study will utilize questions obtained from 3 subscales from 2 questionnaires previously validated in English.

1. Participants' knowledge on CRC symptoms will be assessed using the "Knowledge of Warning Signs" questions from the "Bowel Cancer Awareness Measure". Potential answers to these questions include "Yes", "No" and "Don't Know". The overall score will range from 0 to 9 and it is anticipated that average scores will increase after the intervention. Higher scores imply greater knowledge of symptoms.
2. Participant's knowledge on CRC risk factors will be assessed using the "Knowledge of Risk Factors" questions from the "Bowel Cancer Awareness Measure". This scale is measured using a Likert 1-5 scale with "1" corresponding to "Strongly Disagree" and "5" corresponding to "Strongly Agree". The overall score will range from 11 to 55 and it is anticipated that the average scores will increase after the intervention. Higher scores imply greater knowledge of risk factors.
3. Participant's knowledge on CRC screening and general facts will be assessed using nine questions from the "Colorectal Cancer Screening Decision Quality Instrument (CRC-DQI)". The overall score will range from 0 to 9 and it is anticipated that average scores will increase after the intervention. Higher scores imply greater knowledge of general facts.

STATISTICAL CONSIDERATIONS

4.2 Primary Endpoint

Identify novel Latino-perceived barriers to participation in CCTs.

4.3 Secondary Endpoints

The Secondary Endpoints of our study are to assess the association of:

1. Educational videos on knowledge of CRC symptoms.
2. Educational videos on knowledge of CRC risk factors.
3. Educational videos on knowledge on CRC screening and facts.
4. Watching the videos and willingness to participate in CCTs.

4.4 Methods

Primary Endpoint: Twenty enrolled participants will participate in qualitative, semi-structured, one-on-one interviews that will be performed in Spanish. The interviews will be recorded and transcribed. ATLAS.ti software will be used for the transcript analysis. The top 2 conceptual themes within each section of the interview (attitudes regarding general clinical trials, attitudes regarding CCTs, and perception of the Hispanic/Latino community) and the top 3 higher-level, holistic themes across the sections will be reported in terms of percentage of participants.

Secondary Endpoint 1: Use of repeated measures ANOVA with appropriate follow-up contrasts to compare total number of correct responses within three time points (baseline vs post-video; baseline vs 30 +/- 7 days follow-up; post-video vs 30 +/- 7 days follow-up) accounting for multiple observations within participants. Knowledge pertaining to CRC symptoms will be assessed using the "Knowledge of Warning Signs" questions from the "Bowel Cancer Awareness Measure". Potential answers include "Yes", "No" and "Don't Know". The overall score will range from 0 to 9 and it is anticipated that average scores will increase after the intervention. Higher scores imply a greater knowledge of symptoms.

Secondary Endpoint 2: Use of repeated measures ANOVA with appropriate follow-up contrasts to compare total number of correct responses within three time points (baseline vs post-video; baseline vs 30 +/- 7 days follow-up; post-video vs 30 +/- 7 days follow-up) accounting for multiple observations within participants. Knowledge pertaining to CRC risk factors will be assessed using the "Knowledge of Risk Factors" questions from the "Bowel Cancer Awareness Measure". This scale is measured using a Likert 1-5 scale with "1" corresponding to "Strongly Disagree" and "5" corresponding to "Strongly Agree". The overall score will range from 11 to 55 and it is anticipated that the average scores will increase after the intervention. Higher scores imply higher knowledge of risk factors.

Secondary Endpoint 3: Use of repeated measures ANOVA with appropriate follow-up contrasts to compare total number of correct responses within three time points (baseline vs post-video; baseline vs 30 +/- 7 days follow-up; post-video vs 30 +/- 7 days follow-up) accounting for multiple observations within participants. Knowledge of CRC screening and general facts will be assessed using nine questions from the "Colorectal Cancer Decision Quality Instrument (CRC-DQI)". The overall score will range from 0 to 9 and it is anticipated that average scores will increase after the intervention. Higher scores imply greater knowledge of screening and facts.

Secondary Endpoint 4: Since questionnaires will be completed pre and post video, we will explore, in a preliminary fashion, the association between watching the video (X) and willingness to participate in CCTs (Y) using repeated-measures/mixed-effects logistic regression on the paired responses of participants. The mediating effect of *Study Day 1* post-video health knowledge levels (M) on the relationship between X and Y (established in the preliminary step above) will be explored. Using a structural equation modeling approach, two mixed-effects generalized linear models will be carried out: one model uses both X and M to predict Y, while another uses only X to predict M. The two

models will be compared and tested using the algorithm introduced by Imai and colleagues[50,51] The estimated average causal mediation effect (from X to Y, through M) will be tested using the bootstrapping method with 1,000 replications, and the proportion of the effect being mediated will be reported as the effect size. Lastly, in order to explore an adjusted approach, the same steps used for the mediation model will be replicated, while incorporating demographic variables as covariates.

4.5 Sample Size and Power

A traditional "power analysis" is not directly applicable to the primary endpoint of the study which is qualitative in nature. Based on published methodologies to assess the adequate sample to reach "saturation",[52–54] we chose to invite 20 participants for qualitative interviews.

For our quantitative, secondary endpoints, a traditional "power analysis" was performed. A total of 60 participants will be recruited into the study. If in our study population the mean difference is 0.4, which as defined by Cohen is a small to medium difference, and the pre- to post- correlation is 0.5, then the power to reject the null hypothesis will be over 80%. If the differences in our study population are more extreme, our sample size will have even more power to reject the null hypothesis.

5 STUDY INTERVENTION (DEVICE, DRUG, OR OTHER INTERVENTION)

The study intervention consists of three CRC educational videos in Spanish. The aim is to assess the potential impact of the intervention on participants' CRC knowledge and willingness to participate in CCTs.

6 STUDY INTERVENTION ADMINISTRATION

This is a single arm study with consecutive enrollment of eligible participants as noted above.

7. SAFETY MANAGEMENT

A possible inherit study risk for participants, although low, is a potential breach of confidentiality. To minimize this risk, all PHI and study data will be stored in password protected servers that only members of the study team will have access to. (e.g. secure drive on the UNC network, UNC SharePoint/OneDrive/Teams, REDCap). Intake information obtained on paper form will be initially stored in the file tote, transcribed into REDCap, and subsequently stored in a secure file cabinet in the

PI's academic office. In addition, every participant will be assigned a unique deidentified study number that will be used during *Study Days 1* and *2* (completion of questionnaires) as well as during *Study Day 3* (performance of qualitative one-on-one interview). In addition, there is minimal risk of emotional distress from answering questions related to CRC. Participants will be informed that they do not have to answer any questions that make them feel uncomfortable and may stop completing the questionnaires at any point.

7.1. Adverse Events and Serious Adverse Event Collection and Reporting

In case of a breach of confidentiality, the PI will immediately notify the IRB at UNC Chapel Hill. No serious adverse events are anticipated. However, any unanticipated problems will be reported to our IRB in a timely fashion.

7.2. Entity Responsible for Monitoring

The PI in collaboration with the RCMU will be responsible for data monitoring.

7.3. Data Monitoring

Monitoring of data quality entry will be performed by our collaborators at RCMU and members of the study team after the initial 5 registrants and then after every 10. In order to assure accuracy in transcription of information from paper form to REDCap, a member of the study team other than the individual initially entering the data into REDCap, will confirm the accuracy of the entered data into REDCap by using the paper form to compare data on the initial 5 registrants. On subsequent data monitoring efforts (every 10 subsequent registrations), data entered into REDCap on 5 randomly selected registrants will be similarly evaluated for accuracy.

8. DATA COLLECTION AND MANAGEMENT

Every participant will be assigned a unique deidentified study number upon enrollment. When a participant arrives at STM Church and before they get seated, members of the study team will verify their name and DOB and subsequently enter their unique deidentified study number on their survey form.

At the beginning of *Study Day 1*, members of the study team will distribute paper surveys with deidentified study numbers to the corresponding participants pre- and post-video projection. In order to ensure privacy, adequate seating space between participant will be created. Upon completion of the surveys, members of the study team will perform a visual review of the survey to identify any quality control items such as illegible responses or stray marks across response bubbles. All completed surveys

with a corresponding unique, deidentified study number will be placed into a portable file tote to assure privacy. Within 72 hours of collection, pre- and post-video survey responses for each participant will be uploaded to REDCap. Paper surveys will be stored in a secure file cabinet in the PI's academic office. Similar procedures will be followed for the paper surveys collected during *Study Day 2*.

On *Study Day 3* (one-on-one qualitative interview), the audio of the interview will be recorded using a recording device and transcribed by GMR Transcription. ATLAS.ti software will be used for the analysis of the 20 deidentified transcripts. The deidentified transcripts will be stored in a secure file cabinet in the PI's academic office.

9. RECRUITMENT STRATEGY

Participants will be recruited in-person on the premises of STM Church. Members of the study team along with CHW from El Centro Hispano and UNC-Chapel Hill students that are members of the Carolina Latinx Center or Comprehensive Advanced Medical Program of Spanish (CAMPOS) will be present at STM every Saturday and Sunday for 3 months totaling an initial 24 recruitment attempts. During the in-person recruitment, Study Flyers will be handed out to Church attendees as they exit the mass. Interested individuals will complete the study Intake Form with the assistance of either a member of the study team or a CHW. Once eligibility for study participation has been determined, eligible individuals will have the option to enroll while on the premises of STM Church by completing the RIS with the assistance of eligible study team members or CHWs.

In addition to in-person recruitment, interested participants will have the opportunity to enroll via our study website, which will be readily accessible via a QR code found on the Study Flyer. While on the study website, participants will be prompted to fill out the Intake Form, which captures demographics, preferred mode of communication (phone/text or email), contact information, and assesses eligibility.

Eligible participants indicating that their preferred mode of communication is the phone will be contacted by our study Research Assistant who will walk them through the telephonic version of the RIS. If they indicate that their preferred mode of communication is email, our study Research Assistant will email them a link leading to the electronic version of the RIS.

In order to facilitate our recruitment efforts, the Study Flyer along with the study QR will be posted on the STM Bulletin. In addition, the STM Deacon has agreed to make announcements following the

Hispanic masses on Saturday and Sunday introducing the study and its importance to the Hispanic community.

10. CONSENT PROCESS

Eligible participants will have the option to consent by completing the RIS in three different scenarios: (1) in-person at STM Church; (2) online or (3) via the phone. Those that wish to complete the RIS form in-person will be guided by eligible members of the study team or El Centro Hispano CHWs. Participants completing the Intake Form online using the study website, will have the opportunity to indicate their preferred mode of communication. Eligible participants indicating the phone as their preferred mode of communication will be contacted by our study Research Assistant who will walk them through the telephonic version of the RIS. If they indicate that their preferred mode of communication is email, our study Research Assistant will email them a link leading to the online version of the RIS. It should be noted that all three versions of the RIS (in-person, online, telephonic) explain the study procedures in detail as well as the potential risks and benefits. Those that opt for either the in-person or the telephonic consent will be guided through the RIS by members of the study team. Those that indicate they would prefer to complete the RIS on their own will be advised to contact the study team via phone with any questions regarding the online consenting process.

11. PLANS FOR PUBLICATION

Our study is designed to capture novel data in multiple fields of research including the identification of barriers preventing Latinos from participating in CCTs as well as the mediating effect that an increase in CRC knowledge may have on the willingness to participate in CCTs. We envision publishing multiple impactful papers.

12. REFERENCES

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APPENDIX