Official Title: The United States Health Living Study

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UFIRB 02 – Social & Behavioral Research Protocol Submission Form			
THIS FORM MUST BE TYPED. DO NOT STAPLE. Send this form and the supporting documents to IRB02, PO Box 112250, Gainesville, FL 32611. Should you have questions about completing this form, call 352-392-0433.			
Title of Protocol:	**The United States Health Living Study (IRB201801473)**		
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Degree / Title:		**Mailing Address:** (If on campus provide PO Box address):	**Email :**
Department:			**Telephone #:**
Dates of Proposed Research:	**TBD**		
Source of Funding *(A copy of the grant proposal must be submitted with this protocol if funding is involved):*	N/A		

Describe the Scientific Purpose of the Study:
The purpose of this study is to pilot test the efficacy of a patient-centered, tailored message intervention delivered via virtual human technology for increasing colorectal cancer (CRC) screening within guidelines. Although we are not limiting participation to these groups, we are particularly interested in the feasibility of the intervention for reaching racial/ethnic minority and rural patients.

Background

In an attempt to reduce colorectal cancer (CRC) mortality by nearly 50%, as well as reduce incidence by nearly 80%, Healthy People 2020 and the National Colorectal Cancer Roundtable have made increasing CRC screening rates a primary goal. To enhance the likelihood of attaining this goal, researchers have begun to utilize strategic message design to augment patent outreach efforts and create highly-customized, culturally-sensitive, and patient-specific behavioral interventions for patients who are out-of-guidelines for CRC screening.

To date, limited efforts have examined the benefits of delivering such patient-tailored CRC screening messages highlighting fecal immunochemical testing (FIT) for average-risk patients. Screening using FIT (as opposed to colonoscopy) provides both patient and healthcare system benefits. For patients, it is less expensive, non-invasive, and can be done at home. This reduces barriers associated with CRC screening such as cost, travel time (which can be particularly burdensome for rural patients), the necessity of undergoing anesthesia, and discomfort and embarrassment. For healthcare systems, it reduces costs and helps prioritize patients at higher risk for CRC (those with family history of CRC, history of cancer, positive FIT results, etc.) for colonoscopy.

Additionally, prior research suggests that demographic concordance (i.e. a patient is seen by a provider his or her same race and gender) increases positive outcomes in healthcare across a variety of measures. Patients are more satisfied with their care when their provider shares their demographic characteristics and are more likely to follow recommendations. This study aims to reduce racial disparities in CRC screening by delivering tailored messages to patients using virtual human technology (VHT) that can be matched with them to provide demographic concordance.

In addition to the ability to be demographically customized, studies suggest that VHT is useful in discussing stigmatized issues with patients, who may be more likely to reveal information with a virtual

character than with a human doctor. VHT is well-suited for this type of intervention, then, because of the embarrassment often associated with CRC screening.

As such, using tailored messaging to encourage patients to screen for CRC with FIT has multiple potential benefits. However, there remains a dearth of research on the theoretical and practical implications of providing personalized messages to supplement and improve upon the goals of tailored messaging interventions to increase screening for FIT among patients who are at average risk and out-of-guidelines. This study aims to address this problem.

Study Aims

The primary goal of the study is to reduce colorectal cancer (CRC) morbidity and mortality by increasing CRC screening rates among the at-risk patient community and to reduce racial and geographic (rural vs. urban) disparities in CRC screening and mortality rates. To accomplish this long-term goal, this study aims to develop and test precision messaging tailored to target audiences through development and evaluation of culturally sensitive, interactive messages about CRC screening delivered using VHT. The study will investigate whether interactive, tailored messages contribute to an overall enhancement of knowledge of CRC and screening options by eliciting positive attitudes and behaviors toward FIT screening.

Specifically, this study focuses on the effectiveness of messages employing visual field (close vs. far), racial concordance (demographically matching or mismatching), and modality (visual vs. text) to develop strategic messages about CRC screening.

To date, there is no other study that has looked to partner specific message strategies and colorectal cancer screening with an emphasis on racial concordance and modality. As such, the researchers hope to shed new light on how, as health communicators, we can more successfully engage target audiences to change attitudes and/or behaviors towards getting screened for colorectal cancer.

Describe the Research Methodology in Non-Technical Language: ***(Explain what will be done with or to the research participant.)***

The pilot study will include 1,500 participants. All participants will be between the ages of 50 and 73 and will be out-of-guidelines for CRC screening (>10 years for colonoscopy, >3 years for Cologuard, >1 year for FIT).

Patients will either see a racially concordant virtual human message, a racially discordant virtual human message, a racially concordant text-based message, a racially discordant text-based message, or an attention control message. All patients exposed to a VHT or text-based message will be matched to the character based on gender (as per their response to a screener question). The patients seeing virtual human messages will either see a near or far visual field image of the virtual character. The patients seeing the control message will receive information about nutrition and cancer delivered by a cartoon computer without an identifiable race or gender.

After completing informed consent and passing initial screening questions (appropriate age range, out-of-guidelines for CRC screening, etc.), patients will be instructed to view the message as if they were a patient at UF Health. Following an attention check to ensure they viewed the message, patients fill out

a questionnaire containing items designed to measure attitudes towards CRC and screening, attitudes towards the intervention, health literacy, and other factors suggested to influence screening behaviors. Finally, participants will be given the option to learn more about CRC screening and to click a link to Amazon.com where they can view home stool tests (outcome measures).

Planned Analyses
The primary outcome of the study is intentions of the patients to talk to their doctor about CRC screening. Intentions will be measured using a 5-point Likert scale. Analyses will be conducted using R, version 4.0.1. The model will contain the main effects of the attention control condition, animated VHA intervention, and static VHA intervention. For pairwise testing, *p*-values will be corrected for multiple comparisons testing using the multivariate *t*-distribution method. Sociodemographic variables will be included as controls.

Describe Potential Benefits:

There are no direct benefits from participating in this study. However, participants may garner valuable information on their individual risk of developing colorectal cancer. They will also learn how to screen for colorectal cancer.

Describe Potential Risks: (*If risk of physical, psychological or economic harm may be involved, describe the steps taken to protect participant.)*

As with any behavioral intervention that tests the efficacy of specific communication strategies, there is the possibility of minimal emotional discomfort from being presented with individual risk factors for a disease. However, the probability of any physical, psychological, or social harm is minimal to none.

Describe How Participant(s) Will Be Recruited:

Participants will be recruited via online Qualtrics recruitment panels. Qualtrics maintains a proprietary opt-in online panel comprised of U.S. residents who have agreed to participate in its web surveys. When people are recruited into the panel, age and geographic information are collected to aid in constructing samples. I am paying Qualtrics to have access to their web panel, in the same manner if we were purchasing a list of phone numbers to conduct a phone survey. Subjects will be randomly selected and notified of the opportunity to participate in the study through an invitation email (included as first page of questionnaire).

Eligibility Criteria

Patients are eligible for this study if they meet the demographic characteristics: age between 50 and 73 years, reside within the United States but outside of Florida, speak English, and are of either black or white racial background. Patients also must be out of guidelines for colorectal cancer screening.

Date safety: The subject's participation is completely voluntary. There is a minimal risk that security of any online data may be breached, but since no identifying information will be collected, and the online host (Qualtrics) uses several forms of encryption and other protections, it is unlikely that a security breach of the online data will result in any adverse consequences for participants. For further information, please see Qualtrics Privacy Policy: http://www.qualtrics.com/privacy-statement/

Maximum Number of Participants (to be approached with consent)	**1500**	**Age Range of Participants:**	**50-73**	**Amount of Compensation/ course credit:**	Qualtrics will reward the participants for their survey participation. They will receive a cash value reward for completing the survey that will be credited to their member account on the site. Once their account value exceeds $10, they may redeem their credit for either an Amazon.com gift certificate, a Payoneer prepaid debit card, or a gift certificate for a local restaurant through Restaurants.com.

Describe the Informed Consent Process. (See Following Page for Informed Consent Document)

Participants receive an email from Qualtrics inviting them to participate in the study. When they click the link, they are taken to a Qualtrics survey. The first page of the survey is the informed consent form. Participants are informed of their rights as research participants and asked whether they consent to take part in the study. Participants who agree enter the study; participants who do not agree are thanked and the study terminated for them.

Informed Consent

Please read this consent document carefully before you decide to participate in this study.

Welcome to a health and wellness survey. We are conducting a brief survey to understand how people make decisions about their health.

Time required: 15-20 minutes.

Risks and Benefits: There are no direct benefits to you for participating in the study. There will be no potential risk for physical, psychological or economic harm.

Compensation: You will receive compensation for your participation. The panel company you are working with will arrange payment once you have finished the survey.

Confidentiality: There is a minimal risk that security of any online data may be breached, but since no identifying information will be collected, and the online host (Qualtrics) uses several forms of encryption and other protections, it is unlikely that a security breach of the online data will result in any adverse consequence for you. For further information, please see Qualtrics Privacy Policy: http://www.qualtrics.com/privacy-statement/

Voluntary participation: Your participation in this study is completely voluntary. There is no penalty for not participating, and you do not have to answer any question you do not wish to answer.

Right to withdraw from the study: You have the right to withdraw from the study at any time without consequence.

Whom to contact if you have questions about the study:
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2024 Weimer Hall, University of Florida
P.O. Box 118400
Gainesville, FL 32611-8400
(352) 273-0240
janicekrieger@ufl.edu

Whom to contact about your rights as a research participant in the study:
IRB02 Office
Box 112250
University of Florida
Gainesville, FL 32611-2250
352-392-0433

QUESTION: Do you consent to participate in this study?

Yes (clicking this option allows participate to continue to questionnaire)
No (terminates questionnaire)