CLINICAL STUDY PROTOCOL

Leveraging Social Media to Increase Lung Cancer Screening Awareness, Knowledge and Uptake in High-Risk Populations

Protocol Version

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Version 2

1.

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Icahn School of Medicine at Mount Sinai, New York, NY **

GO2 Foundation for Lung Cancer, Washington, DC **

** *Please note that this is a national study using Facebook advertisement to recruit and intervene with an educational intervention. The 3 research locations listed above reflect the institutions of the collaborators/co-investigators involved with the study and represent personnel only. There are no research recruitment, enrollment, or data collection activities occurring at these locations.*

Abbreviations

Abbreviation	Explanation
ACS	American Cancer Society
FB	Facebook
FBTA	Facebook-targeted Advertisement
LCS	Lung Cancer Screening
LDCT	Low dose computed tomography
USPSTF	U. S. Preventive Services Task Force

Revision History :

Revision #	Version Date	Summary of Changes	Consent Change?

Summary

Study Title	**Leveraging Social Media to Increase Lung Cancer Screening Awareness, Knowledge, and Uptake in High-Risk Populations**
Study Design	Randomized Controlled Trial
Primary Objective	**Aim 1.** Examine the use of a social media platform (i.e., Facebook) to reach high-risk individuals eligible for lung screening. **Aim 2.** Compare the effectiveness of a computer-tailored health communication and decision support tool (*LungTalk*) to a non-tailored ACS Lung Screening Informational Video on lung screening: 1) knowledge; 2) health beliefs (perceived risk, perceived benefits, perceived barriers, self-efficacy); 3) occurrence of a patient-clinician discussion about lung screening; and 4) uptake and completion. **Aim 3.** Explore the sustainability of a social media-based approach among key stakeholders to increase lung screening awareness, knowledge, adoption, and uptake among screening-eligible individuals.
Secondary Objective(s)	n/a
Research Intervention(s)	1) *LungTalk* (computer-tailored health communication and decision support tool) 2) Non-tailored educational video (Go2 Foundation's 'Screening Saves Lives! Learn More About Low Dose CT Lung Cancer Screening)

Study Population	Adults aged 55-80 years who currently smoke or quit within the past 15 years with a 30 pack-year tobacco smoking history
Sample Size	500
Study Duration for individual participants	6 months

1 – Introduction

While lung screening is recommended by the U.S. Preventive Services Task Force (USPSTF),[1,2] has the potential to detect lung cancer at earlier, more treatable stages, has a 20% lung cancer-related mortality reduction in long-term smokers[3,4] and is covered by Medicare and other health insurers,[5] population uptake has been abysmal. It has been 9 years since the USPSTF released its recommendation, yet less than 5% of screening-eligible Americans have been screened.[6] Screening-eligible individuals are generally unaware of early detection of lung cancer.[7-9] Given that high-risk individuals are not aware that lung screening exists, it is essential to employ novel community-focused strategies to increase awareness about lung screening so as to reach high-risk, screening-eligible individuals. Social media offers untapped opportunities to address the lack of awareness and knowledge that stymie lung screening uptake. Because Facebook (FB) has the ability to target advertisements to individual users by key demographic and interest areas within their profile, Facebook-targeted advertisement (FBTA) offers an ideal platform to target and deliver a public-facing, tailored health communication and decision support intervention to increase awareness of, and knowledge about, lung screening among those most at risk. To facilitate both awareness of the option to screen and meaningful patient-clinician discussions about screening, effective communication strategies are needed to prepare patients to initiate (“Ask your doctor”) and to have these important discussions with their primary care clinician. To foster both, our team has developed LungTalk,[10] a novel computer-tailored health communication and decision support tool to (1) increase awareness and knowledge about lung screening; (2) decrease perceived barriers to screening based upon misinformation; and (3) increase screening rates among individuals whose decision after a shared decision-making discussion with their primary care clinician is to screen. LungTalk currently tailors on smoking status because our prior research revealed individuals who used to smoke feel further stigmatized when messaging is crafted as if they still smoke. The current version of LungTalk has been pilot tested and indicated that tailored information for lung screening more than doubled total knowledge scores regarding lung cancer risk and screening compared to a non-tailored lung screening information sheet. In addition, our prior work also revealed the top barriers screening-eligible individuals face when considering lung screening. Therefore, during the first 9 months of the study (prior to any participants being enrolled), refinements to the master content library of LungTalk will be undertaken with our internal IT team at MSK to insert video testimonials for perceived barriers to lung screening and algorithms for the perceived barriers

content.

2 – Background

2.1. Background/literature review (make sure you provide references)

2.1.a. Scientific Background

Lung cancer kills more people than colorectal, breast, prostate and cervical cancers combined. Lung screening with annual low-dose computed tomography (LDCT) reduces lung cancer-related mortality by identifying lung cancer at earlier, more treatable stages.[3,4,12] However, population-level screening efforts are only effective when appropriate, high risk individuals are aware and engaged. In 2015, the Centers for Medicare and Medicaid agreed to cover lung screening in response to the 2013 USPSTF Grade B recommendation for individuals aged 55 to 80 years with a 30-pack-year smoking history who currently smoke or have quit within the past 15 years.[5,12,13] In response to new scientific evidence, recent updated recommendations have decreased the minimum screening eligible age to 50 and pack-year history to 20.[14] As part of Medicare's coverage decision, in order for lung screening to be reimbursed, a shared decision-making and counseling visit must be conducted with one or more patient decision aids.[5] Medicare's unprecedented policy fostered an environment conducive to advancing understanding of the shared decision-making process for lung screening. However, one of the greatest barriers to effective lung screening implementation and uptake is lack of awareness.[7,9,15] New and novel ways to increase awareness, knowledge about lung screening and adoption – in high-risk populations – are essential to support effective population-based lung screening implementation. It is likely the majority of screening-eligible individuals are not highly engaged consumers of the healthcare system. So how do we raise awareness about lung screening? Solutions must be community-based, engaging and readily accessible from the information ecosystem in which the general public consumes health and other information in the 21st century.

This study builds upon rigorous preliminary research conducted by our team.[7-10,14-17] We have repeatedly successfully leveraged social media to recruit large numbers of lung screening-eligible individuals nationwide,[17,18] developed and psychometrically validated scales to measure lung cancer screening health beliefs,[16] and developed *LungTalk*.[10,14]

As noted, this study uses a social media-based platform to target high-risk, screening-eligible individuals in the community to deliver a tailored health communication and decision support intervention. This strategy is based upon our prior highly successful experience with recruitment via FBTA. Because the age demographic of FB specifically has increased over the past decade, this makes FB the ideal social media platform for this work. Of the 226 million FB users in the U.S., 30.8% of those are aged 50 years and older.[19] The age demographic of the average FB user has increased over the past decade, and our prior studies have repeatedly demonstrated the success of recruiting lung screening-eligible individuals using FBTA.[14,16-18] Historically low levels of public trust in expert entities such as the government,

the news media, and the healthcare system as well as growing awareness of the new cancer information ecosystem led us to consider social media as a novel cancer communication platform. FBTA functions to provide "precision marketing", sending the right content to the right person at the right time via the right channel.

Our first study to recruit lung screening-eligible individuals (aged 55-77 years, individuals who currently smoke or quit within the past 15 years, and have a 30 pack-year history or more) in 2015 was not only efficient and cost effective,[17,18] but also established our teams' ability to recruit a lung screening-eligible sample that is varied socioeconomically and educationally. In this initial study, an 18-day FBTA campaign costing $500 yielded a national sample of 331 lung screening-eligible individuals. During the 18 day period, 1,121 unique FB users clicked the recruitment ad and were redirected to our secure online survey platform and completed the screening survey. Of those, 423 were eligible and of those, 331 enrolled and completed the survey study yielding a 78.3% participation rate.[18] Since 2015, we have had repeated success using FBTA to recruit lung screening-eligible individuals into our subsequent studies,[9,14,17] including a study where we manipulated the targeting criteria (including zip codes) to recruit a diverse lung screening-eligible sample in Indiana.[9] Given our prior successful work with FBTA, we do not anticipate problems using this social media platform to target screening-eligible individuals in the community to recruit and then deliver a tailored health communication and decision support intervention to increase awareness and knowledge about lung screening.

Frandsen and colleagues (2014) demonstrated that participants recruited to smoking cessation randomized controlled trials with FBTA did not differ from those recruited by traditional methods on smoking characteristics or demographics.[20] Our team extended Fransden's work by demonstrating that participants age 55 years and older recruited to a web-based survey study about lung screening did not differ sociodemographically from those recruited by traditional methods further supporting the ability and feasibility to reach lung screening-eligible individuals in the community **before** they engage with the healthcare system.[18] FBTA has well-established utility to reach young adults who smoke,[21-23] and our team has clearly demonstrated FB's effectiveness for recruiting older individuals who smoke long-term.[18] FB is popular with 69% of American adult users and has grown in use among older individuals.[24,25]

Tailored health communication interventions have been used to promote health behavior change, are more effective compared to non-tailored ones,[26-29] and have been shown to improve knowledge and change health beliefs regarding colorectal [30,31] and breast cancer screening.[32-34] Our teams' preliminary work indicated that tailored information for lung screening more than doubled total knowledge scores regarding lung cancer risk and screening compared to a non-tailored lung screening information sheet.[14] Tailored messages provide customized information that is more likely to be viewed as personally relevant and,

as a result, increase engagement in important healthcare options such as prevention and early detection efforts. Individuals eligible for lung screening may experience stigma or feelings of blame and shame secondary to their history of smoking.[7] Therefore, it is critical that public facing health communication and decision support interventions educate and decrease perceived barriers to screening but do so in a way that does not increase stigma. Early health communication tools and decision aids about lung screening have primarily focused on calculating personal risk for the development of lung cancer and subsequent recommendations to screen based upon calculated risk.[35-37] These tools range in level of complexity and delivery including pamphlets and brochures, videos, educational scripts, and computer programs.[36-40] These tools can also be deployed in multiple formats such as by mail, telephone, in person and via the internet. Although the state of the science is still early for a comprehensive systematic review, there are a number of early reports of patient-facing health communication tool and decision aid development, feasibility and efficacy.[38-41]

Volk and colleagues developed the video, *Lung Cancer Screening: Is It Right for Me?* This 6-minute video provides information about risk factors for lung cancer and harms and benefits of lung screening as well as vignettes depicting trade-offs between harms and benefits to clarify values. Initial feasibility showed this decision aid increased knowledge ($p < 0.01$) and supported readiness to make a decision to screen as reflected in values clarity scores.[38] Lau and colleagues developed a web-based decision aid available publicly at the website, www.shouldiscreen.com, using an established prediction model to compute baseline lung cancer risk and an individual's chance of benefiting from, and risk of being harmed by, screening.[5] Knowledge of lung cancer and screening increased ($p < 0.001$) and decisional conflict decreased ($p < 0.001$) in initial feasibility testing.[35] Other commercially-developed lung screening decision aids and tools focus on calculating personal risk for the development of lung cancer with subsequent screening recommendations based upon the calculated risk. [36,37] Dharod and colleagues (2019) examined the feasibility of a digital health outreach strategy via patient portal.[40] Of the 1,000 portal invitations they sent, 86% read the invitation and 40% (n=404) of those visited the interactive website which then accessed screening eligibility. Similar to other patient decision aids, the mPATH Lung Interactive website calculates risk for lung cancer, but does not tailor beyond personalized risk and development of this tool is atheoretical. McDonnell and colleagues (2018) developed and tested the feasibility of a patient decision aid for use during a clinic consultation and is theoretically grounded in Conflict Theory.[41] Four clinicians and 20 patients found the decision aid helpful.[42] The ACS developed the web-based video, Lung Screening Informational Video (LSIV), as an educational tool to assist with patient decision-making regarding lung screening.[43] The video reviews benefits and risks of screening, how screening is performed with an LDCT, and to discuss screening with a primary care clinician. However, lung screening is a complex decision; current tools are not tailored to the individual and do

not address issues that may be personally relevant to the individual weighing the decision to screen, or not, for lung cancer.

3 – Rationale, Objectives and Hypothesis

3.1. Study Rationale/Problem Statement/Research question or Study significance

LungTalk and leveraging FBTA addresses the call to develop and test multi-level, cancer communication interventions using innovative methods and designs. Our long term goal is to increase lung cancer screening uptake among appropriate, high-risk individuals nationwide.

3.2. Hypothesis (if applicable)

1) Leveraging Facebook targeted advertisement will increase reach to screening-eligible individuals at the community level.

2) A tailored communication intervention will result in increased lung cancer screening uptake compared to a non-tailored communication intervention.

3.3. Primary Objective

Our overall objective in this application is to test the effectiveness of: 1) leveraging a well-established, social media-based platform to target screening-eligible individuals in the community and 2) a novel, tailored health communication and decision support intervention related to lung screening (LungTalk).

3.4. Primary Outcome Variable(s)

a) patient-perceived lung cancer screening decision quality; b) screening completion among patients deciding to screen; and c) stage of readiness for smoking cessation among current smokers

4 - Study Design

4.1 General Design

Using a randomized controlled trial design, we will randomize 500 screening-eligible individuals recruited through Facebook from diverse zip codes nationwide to receive either a tailored health communication intervention (*LungTalk*) or non-tailored American Cancer Society (ACS) Lung Screening Informational Video. We do recognize that individuals on FB who have identified smoking as an interest in their profile may differ from individuals who qualify for lung screening but have not identified smoking interest in their profile. Future research will explore these potential differences and alternative methods of reaching screening-eligible individuals in the community for the purpose of increasing knowledge and awareness about this screening option.

Finally, we will also use qualitative methodology to conduct key informant interviews with stakeholders to explore the sustainability of a social media-based approach to increase lung

screening awareness, knowledge, and uptake in the community. We will recruit key stakeholders (N=20) representing administrators (healthcare system and screening centers), key screening center personnel, advocacy organizations (i.e., LUNGevity, Dusty Joy Foundation), and national organizations (American Cancer Society, American Lung Association, GO_2 Foundation for Lung Cancer). As members of the National Lung Cancer Roundtable, Drs. Carter-Bawa (PI) and Ostroff (Co-I) have well-established relationships with key stakeholders involved in the national implementation of lung screening and will leverage these relationships to recruit key stakeholders for the individual interview component of the study.

4.1.1 Study Duration (if applicable)

Total study duration = 5 years (2022 – 2027).

Participants are enrolled in the study and have one follow-up time point in the study at 6 months post intervention

4.1.2 Number of Study Sites

N/A – national social media-based recruitment, enrollment, and intervention

4.2 Study Population

4.2.2. Eligibility Criteria

a. Inclusion criteria

6.1 Participant Inclusion Criteria for Intervention (Aim 2)

- Age 50-80 years;
- ≥20-pack-year smoking history;
- Individuals who currently smoke or quit smoking within the past 15 years;

6.2 Participant Exclusion Criteria for Intervention (Aim 2)

- Previously undergone LDCT for early detection of lung cancer, have a lung nodule or nodules that are currently being followed
- Has ever been diagnosed with lung cancer
- Individuals with impaired decision-making (because our primary outcome is decision-making, we will not include individuals with impaired decision-making)

- **6.3 Participant Inclusion Criteria for Key Stakeholders (Aim 3)**

  - Age 18 or older
  - Employed in a capacity that has an interest in lung cancer screening such as, but not limited to, administrators (healthcare system, screening centers), key screening center personnel, advocacy organizations (i.e., LUNGevity, Dusty Joy Foundation), national organizations (American Cancer Society, American Lung Association, GO_2 Foundation for Lung Cancer).

4.2.3. Vulnerable populations (if applicable). Vulnerable populations include children, prisoners, cognitively impaired individuals, economically or educationally disadvantaged individuals, employees, students. When vulnerable populations are included, indicate what safeguards are in place to minimize coercion or undue influence to participate.

n/a

4.2.4. Withdrawal criteria (as applicable)

n/a

4.3. Study procedures

4.3.a. Subject Identification

REDCap will be used to identify and determine the eligibility of the participants who are redirected from the Facebook targeted advertisement (see 4.3.c. for description of Facebook targeted advertisement). REDCap will also be utilized for the consent process and to randomize the participants. Once the participant is randomized, the study team will register the participant in CTMS.

4.3.b. Data for Identification

A screening form to confirm eligibility will be completed prior to completion of the baseline survey and randomization to intervention arm. The screening survey will assess:

- Age 50-80 years;
- ≥20-pack-year smoking history;
- Individuals who currently smoke or quit smoking within the past 15 years;
- Previous LDCT for early detection of lung cancer, lung nodule or nodules that are currently being followed
- Has ever been diagnosed with lung cancer

4.3.c. Screening and Recruitment Process

We will use a highly successful recruitment strategy via FB Targeted Advertisement (FBTA)[18] to recruit screening-eligible individuals from Indiana, Kentucky, Pennsylvania, Oklahoma, and Oregon. We chose geographically-diverse states with a 15.9% or greater adult smoking rate representing all regions of the U.S. making the plausibility of screening-eligible individuals in the area high in addition to offering racial and ethnic diversity. We have chosen FB as our social media platform for recruitment in part because, as of 2021, individuals aged 65 and older are the fastest growing demographic group on Facebook (FB). FB use in individuals born in 1945 or earlier has nearly doubled in the past three years. Further, out of the 2.7 billion FB users, over 32 million are age 50 and older – the age for lung screening eligibility.

FB has the ability to “target” an advertisement by demographics and keywords listed in each individual FB user’s profile or interest list. The FB user’s interest list includes a wide range of details a user can indicate when setting up and/or maintaining their profile that they have an

interest in such as groups, hobbies, lifestyle choices, behaviors, points of view, specific organizations and more. This allows us to purposively sample people who are age 50 years and older, indicate smoking as an interest and reside in a particular state, city, or zip code. Using this approach, as we have in prior studies,[9,14,17,18] we can target our advertisement on FB using the following keywords: cigarette, tobacco, nicotine replacement therapy, nicotine gum, electronic cigarette, smoking. Guided by the safety and monitoring guidelines for researchers using social media,[48] our approach includes design and close monitoring of the FBTA to ensure all methodologic and ethical standards are upheld.

We are partnering with the GO_2 Foundation to identify Lung Cancer Screening Centers of Excellence (as certified by the GO_2 Foundation)[49] to identify primary care networks to connect individuals who seek a screening referral request but do not have a primary care clinician. There are more than 600 Screening Centers of Excellence nationwide. There are 126 Screening Centers of Excellence in the 5 states in which we will conduct the proposed study. These centers are well-established, well-connected, and strong collaborators with their local primary care networks making them the ideal national partner to connect participants without a primary care clinician to one for the patient-clinician discussion about screening prior to referral. They also can link individuals to care regardless of insurance status through federally qualified health centers and community health centers fostering access to high quality screening for low income and other vulnerable subpopulations.

A screening form to confirm eligibility and baseline assessment will be completed prior to receiving the intervention.

Assessment or Measure	Screening	Baseline (T1)
Screening/eligibility Assessment	X	
Demographic and Health Status Characteristics		X
Knowledge: Lung Cancer Screening		X
Perceived Risk of Lung Cancer Scale[16]		X
Perceived Benefits of Lung Cancer Screening Scale[16]		X
Perceived Barriers to Lung Cancer Screening Scale[16]		X
Self-Efficacy for Lung Cancer Screening Scale[16]		X
Self-report of Occurrence of a Patient-Clinician Discussion about Lung Cancer Screening		X
Self-report via the stages of adoption algorithm for screening with verification process		X
Self-report of upcoming visit with primary care provider scheduled		X

4.3.1. Study discontinuation (if applicable) N/A

4.3.2. Concomitant medication (if applicable) N/A

4.4. Risks and Benefits

There should be minimal side effects or discomfort associated with participating in this research study. One potential risk of participation for participants is loss of confidentiality

and privacy. However, when we collect identifying data, unique code numbers will always replace patient names in the research database. Locked file cabinets will be used to store materials with identifying information. Participants may refuse any part of study participation.

Cognizant of the potential risks to privacy in social media research, we will follow methodological and ethical considerations for recruitment and intervention delivery published by thought leaders including Dr. Carter-Harris.[55] The present trial will follow the formal safety and monitoring guidelines for researchers using social media outlined by Russomanno and colleagues (2019)[48] through protocols defining FB page administration, notification settings and monitoring, recruitment cycle duration, inclusion and exclusion terms, and public page settings and moderation.[48] These guidelines are described below:

Defining Facebook Page Administration. The FBTA will be posted through publicly accessible Facebook pages associated with the study PI's research lab. To ensure adequate monitoring of the FBTA, at least 2 research team members (Dr. Lisa Carter-Bawa, PI and Ms. Zulfia Pathan, Research Project Associate) will be assigned as administrators of the page and advertisement settings.

Notifications. To assure continuous monitoring, all page and advertisement administrators will have the Facebook app downloaded to their mobile phones prior to beginning study recruitment and ensure that all notifications and interactions with the recruitment advertisement are being monitored.

Recruitment Cycle Duration. Advertisements should be posted for, at maximum, 7 days per cycle to minimize burnout to research study staff during recruitment.

Inclusion and Exclusion Terms. To target the Facebook advertisements to the study population of interest, researchers should use inclusion and exclusion terms based on study criteria.

Public Page Settings and Moderation. Researchers may restrict who can post directly to the public Facebook page by turning off the Visitor Posts feature in order to ensure only page administrators can post directly to the public site.

An additional side effect considered to be minimal and far outweighed by the potential benefits of participating in this study is participants may find it stressful to answer questions regarding their smoking history and behaviors especially in the context of lung cancer screening. If an individual reports significant distress, an appropriate referral will be made.

We do not expect any adverse events because of this intervention.

5 – Methods

5.3. Study intervention (including schedule of events and study visits)

Participants randomized to *LungTalk* or non-tailored video will watch the web-based online videos and then complete study assessments as per the schedule of assessments in Section 5.5. Please see below for a full description of the study intervention.

LungTalk **(**https://www.lungtalkhmh.org/)is a 10-15 minute long computer-tailored health communication and decision-making tool that is theoretically grounded in the Conceptual Model on Lung Cancer Screening Participation.[41] This model links the Health Belief Model to the Precaution Adoption Process Model and includes key psychological variables (e.g., stigma, mistrust, fatalism, fear and worry) as factors that may influence an individuals' decision to screen, or not, for lung cancer.[41] The tool as a whole serves as a cue to action for a screening-eligible individual to engage in a discussion with their primary care clinician about the option to screen, or not, for lung cancer. *LungTalk* is an interactive computer program that includes audio, video, and animation segments with tailoring algorithms for scripts presented from a master content library.[10] *LungTalk* tailors initially on smoking status. Our prior research revealed individuals who used to smoke feel further stigmatized when messaging is crafted as if they still smoke. Early in the program, the user is asked to indicate if they currently smoke or if they quit smoking and the content has been adjusted to respect an individuals' current smoking status. In addition, during the study start-up phase (prior to participants being enrolled), *LungTalk*'s master content library will be enhanced to tailor content based upon personal barriers to lung screening. The top 5 barriers (*cost, worry, lack of symptoms, time, stigma)* have been identified in our recently completed study testing the Conceptual Model on Lung Cancer Screening from the perspective of the individual (R15 CA208543). Using a similar process as performed in prior studies of which Dr. Carter-Bawa was Co-I (R01CA196243; MPIs: Paskett/Champion; PCORI IHS-1507-31333; PI: Rawl), Drs. Carter-Bawa, Banerjee, and Rawl will create brief video clip testimonials with dedicated in-house resources using MSK Information Technology who manage and maintain *LungTalk* programming and servers to address each barrier. These short (~2-3 min) video clips will be embedded into the master content library and tailoring algorithms added to the master programming of *LungTalk.* After the lung scan video, a brief modified version of the Perceived Barriers to Lung Cancer Screening Scale will be administered on screen. Based upon the users' identification of personal barriers (i.e., cost, worry about finding something, lack of symptoms or current lung issues, lack of knowledge about the screening process, stigma), *LungTalk* will tailor to those specific barriers with the brief video clip testimonials from the master content library. Following this component, *LungTalk* concludes by offering the option of saving or printing a tailored print-out at the end for individuals to use as a discussion prompt with their primary care clinician.[10] This print-out highlights key points related to lung health and screening tailored by smoking status, offers question prompts the user can use to initiate a discussion with their primary care clinician, and tailors based upon questions that remain important to the user that they wish to discuss further with their primary care clinician.[10] Messaging in *LungTalk* is presented at an 8th grade level, and in

consideration of different ways people like to learn, the content is presented via narration as well as key text on screen.[10]

GO² Foundation for Lung Cancer Lung Screening Informational Video (ADD LINK) is a non-tailored educational brochure and link to the video, *Screening Saves Lives! Learn More About Low Dose CT Lung Cancer Screening* produced by the GO² Foundation for Lung Cancer that will be delivered via emailed or texted link to the participant.

5.4. Assignment / randomization (if applicable)

After eligibility is confirmed in REDCap, participants will be registered in the CTMS system. Upon completion of baseline assessment, participants will be randomized using the REDCap randomization module to one of the two arms (i.e., LungTalk or non-tailored GO² video) using a stratified block design stratifying by smoking status (current vs former). Stratified random assignment will ensure the two groups are comparable in distribution on smoking status, a salient variable for lung screening behavior noted in our prior work.[9,17,41] Consolidated Reporting of Randomized Clinical Trials (CONSORT) guidelines for RCTs will be followed.

5.5. Section of instruments (to include for all studies with a social behavioral intervention)

Table 1. Measures and Timepoints of Assessment

Constructs	Assessment or Measure	# of Items	Time to Complete (min)	Validated?	Baseline (T1)	1 Wk Follow-Up (T2)
Eligbility	Screening Survey	3	1	N		
Demographics	Demographic and Health Status Characteristics	20	5	N	X	
Knowledge	Knowledge: Lung Cancer Screening	9	5	N	X	X
Perceived Risk	Perceived Risk of Lung Cancer Scale[16]	3	1	Y	X	X
Perceived Benefits	Perceived Benefits of Lung Cancer Screening Scale[16]	6	3	Y	X	X
Perceived Barriers	Perceived Barriers to Lung Cancer Screening Scale[16]	17	10	Y	X	X
Self-Efficacy	Self-Efficacy for Lung Cancer Screening Scale[16]	9	5	Y	X	X
Occurrence of a Patient-Clinician Discussion	Self-report of Occurrence of a Patient-Clinician Discussion about Lung Cancer Screening	1	1	N	X	X
Screening Uptake	Self-report via the stages of adoption algorithm for screening with verification process	1	1	N	X	X
Upcoming PCP Visit	Self-report of upcoming visit with	1	1	N	X	X

	primary care provider scheduled					
TOTAL TIME					32 minutes	27 minutes

1. **Screening Survey** will be used to determine eligibility. See Section 4.3.b above for details.

2. **Demographic and Health Status Characteristics** will be assessed using items we have used in prior studies. These include age, gender, race/ethnicity, education level, income level, perceived financial status, insurance status, marital status, employment status, smoking status (if former, how long since quit in months), and family history of lung cancer.

3. **Total Knowledge of Lung Cancer Screening** will be assessed with a 9-item multi-dimensional scale used in our preliminary study adapted from literature specific to lung cancer.[16] Several aspects will be assessed, including knowledge of lung cancer, risk, and screening. The range of scores is 0 to 9.

4. **Lung Cancer Screening Health Belief Scales** described in the preliminary studies section will be used to measure perceived risk, perceived benefits, perceived barriers, and self-efficacy. Content and construct validity have been established. Internal consistency reliability was established by our team with a sample of 497 screening-eligible long-term smokers:

   i. *Perceived Risk of Lung Cancer* is a 3-item scale with Likert-type responses. The range of scores is 3 to 12 (higher perceived risk of lung cancer). Cronbach's α was 0.88 in our preliminary study.[16]
   ii. *Perceived Benefits of Lung Cancer Screening* is a 6-item scale with responses ranging from 1=*strongly disagree* to 4=*strongly agree*. The range of scores is 6 to 24 (higher perceived benefits) with a Cronbach's α of 0.76 in our preliminary study.[16]
   iii. *Perceived Barriers to Lung Cancer Screening*. This scale has 17 items with four-point Likert responses where 1=*strongly disagree* and 4=*strongly agree.* The range of scores is 17 to 68 (higher perceived barriers) with a Cronbach's α of 0.87 in our preliminary psychometric study.[16]
   iv. *Self-Efficacy for Lung Cancer Screening*. This scale has 9 items with a four-point Likert response option to assess individual beliefs about ability to arrange and complete an LDCT to screen for lung cancer. The range of scores is 9 to 36 (higher levels of self-efficacy) with a Cronbach's α of 0.92 in our preliminary psychometric study.[16]

5. **Occurrence of a Patient-Clinician Discussion about Lung Cancer Screening** will be assessed with a single item requiring dichotomous (Y/N) response: Have you had a discussion with your primary care clinician about lung cancer screening?

6. **Lung Cancer Screening Uptake** is the primary outcome and will be assessed via self-report via the stages of adoption algorithm for lung screening. The algorithm for collecting this item presents additional questions conditional on responses (see Appendix D). There are seven stages (*unaware, aware but unengaged, undecided*, *decided not to act, decided to act, action, and maintenance*). This will help to understand screening behavior more robustly by understanding the stages of decision-making and adoption (i.e., uptake) of the behavior. Please note that screening uptake is considered stages 6 and 7 (action and maintenance).

The description of lung cancer screening with LDCT of the chest developed in our preliminary studies includes a picture and a written description of an LDCT. This description is embedded in the follow up surveys (Appendix C) prior to the self-reported question to ensure participants understand the question. Using the same successful procedure as in our prior pilot RCT for *LungTalk*,[45] we will verify screening for individuals who self-report completing an LDCT of the chest to screen for lung cancer by mailing an authorization form to be signed and mailed back to the research office. Trained research staff will verify the screening LDCT scan using the information and signed authorization form by contacting the facility directly to request confirmation.

7. **Upcoming Primary Care Provider Visit** will be measured with one item: Do you have an appointment already scheduled to follow-up with your primary care provider? If yes, when?

In order to generate a robust semi-structured interview guide about the sustainability of a social media-based approach to increasing lung screening awareness and uptake, key stakeholder participants representing administrators (healthcare system and screening centers), key screening center personnel, advocacy organizations (i.e., LUNGevity, Dusty Joy Foundation), and national organizations (American Cancer Society, American Lung Association, GO_2 Foundation for Lung Cancer) will be conducted. We will begin the Key Stakeholder participant recruitment no earlier than Year 3 of the study. These stakeholder participants will complete one semi-structured interview that will take 45-60 minutes to complete. We will amend the protocol to include the semi-structured interview guide that will be informed and created from the quantitative data collected from the participants.

FB Analytics. Using the FB analytics component[46] of our FBTA, our assessment plan will measure the total reach of the FBTA to increase awareness of the option to screen for lung cancer among screening-eligible individuals.[47] Quantitative data collected from FB analytics during the recruitment campaign will assess reach by detailing: 1) reach; 2) link clicks; and 3) impressions.[46] Reach in FB analytics is defined as the number of people who saw the FBTA at least once.[46] This can be further analyzed by hour, day, specific number of days, week, and campaign length. In addition, reach can be further stratified by specific location (i.e., state, city, town, county, zip code).[46] Table 1 defines key Facebook analytics for this study. In addition, Facebook will provide the number of people who meet the target profile, within each location.

Table 1. Key Facebook Analytics to Assess Reach

Facebook Analytic	Definition
Reach [46]	Total # of people who saw the FBTA at least once.
Link Clicks [46]	Total # of clicks on the link within the FBTA that led to the REDCap survey platform of the study.
Impressions[46]	Total # of times the FBTA was on screen (may include multiple views of the ad by the same person/people).

5.6. Data management (data collection, source, and storage)

Data collected for this study will be entered into and managed via a secure REDCap Database. REDCap, Research Electronic Data Capture, is an open-source platform that allows for the collection of research data in a secure manner over a web-based interface. Usage of the platform is contingent on an open-source license. The platform was developed by Vanderbilt University which HMH has a standing agreement with to allow the usage of REDCap for academic/research purposes.

For this protocol, electronic REDCap data entry forms will be completed online by the participant. They will be auto sent survey invitations when their surveys are due. Participant responses will be recorded directly in REDCap. All connections to REDCap utilize encrypted (SSL-based) connections to ensure data is protected.

User access to the data is contingent on those a part of the study team and data sharing agreements in place with third party entities, if applicable. Project managers are responsible for regularly auditing these permissions to ensure changes in staff are reflected appropriately.

REDCap has the ability maintain an audit trail of changes to the database providing a timestamp as well as the user making the update. In addition, a data resolution module offers the ability of opening and closing queries optionally requiring justification when data is being updated. Permission roles for data resolution are integrated in REDCap. Comprehensive system logs are also maintained of user activity and when changes to the database are made.

Final data sets for publication are required to be locked and stored centrally for potential future access requests from outside entities.

Audio recorded data from the key stakeholder interviews will be stored on an CDI/HMH passphrase-protected server until transcribed. Audio recorded data from stakeholder participants will not include any identifying information and will be used to produce a de-identified verbatim transcript and erased after transcribed.

5.7. Follow-up and end-of study (if applicable) n/a

5.8. Statistical Method

This behavioral intervention study will randomize 500 screening-eligible individuals in a 1:1 ratio into the *LungTalk* intervention or the non-tailored video intervention condition. We will use descriptive statistics such as means, standard deviations, and frequency distributions/distributional assumptions to examine data quality, identify patterns of missing and out-of-range values, and evaluate parametric assumptions. Remediation of normal distribution assumption violations will be accomplished using the Box-Cox procedure for transformations. We will apply the intention-to-treat (ITT) principle in handling missing data on screening uptake; a study participant will be coded as 'no screening uptake' unless otherwise verified by our participation sites. We will examine violations of the missing-at-random assumption for secondary outcomes. If missingness is associated with any

observed characteristics, then covariates associated with missingness will be incorporated into a sensitivity analysis to minimize bias.

Aim 1. Examine the use of a social media platform (i.e., Facebook) to reach high-risk individuals eligible for lung screening. We will describe and compare the following measures and metrics using a mixture of data from FB analytics and study data from REDCap.

Goal	Analytic Plan
Estimate the number and percentage of individuals aged 50 and older who currently or formerly smoke in the population that the advertisement is marketed.	Numerator = # of Facebook members age 50+ who currently or formerly smoke in target markets Denominator = total # of Facebook members in target markets Both numerator and denominator provided by FB Analytics.
Estimate the approximate percent of this population to which this advertisement is marketed are eligible for lung screening according to the USPSTF guidelines.	Numerator = # of eligible participants, among those screened. Denominator = total number screened. Data from screening survey.
Record the percent of eligible participants who agree to participate in the study.	Numerator = total number consented Denominator = # of eligible participants
Compare differences between those participating and those not participating on smoking status (i.e., current vs. former), age, gender, geography, and other key variables collected on the screening survey.	Descriptive tables along with a series of independent samples t-tests and Chi-square tests.
Record reasons that participants refuse to participate in the study.	Descriptive analysis from screening survey data.
Estimate attrition at 1 week and 6-month follow-up time periods.	Numerator = # of baseline participants - # of participants who complete the follow-up assessment (either 1 week or 6 month) Denominator = # of baseline participants Completion at follow-up defined as completing, at the least, the screening/stage of adoption item.
Compare differences between those completing and those not completing the study on sociodemographic and health status variables, geography, baseline scores on knowledge, lung cancer screening health beliefs, and stage of adoption for lung cancer screening.	Descriptive tables along with a series of independent samples t-tests and Chi-square tests. Completion of the study is defined as completing the screening uptake item for the 6-month assessment.

Aim 2. Compare the effectiveness of a computer-tailored health communication and decision support tool (LungTalk) to a non-tailored Lung Screening Informational Video on lung screening: 1)

knowledge; 2) health beliefs (perceived risk, perceived benefits, perceived barriers, self-efficacy); 3) occurrence of a patient-clinician discussion about lung screening; and 4) uptake and completion (primary outcome). Total knowledge scale scores and Lung Cancer Screening Health Beliefs (total scale scores for perceived risk, perceived benefits, perceived barriers, self-efficacy) are continuous variables. Occurrence of patient-clinician discussion and screening uptake are dichotomous variables. Prior to group comparisons, measures will be described by timepoint, both overall and by group. Within-group changes will be assessed using standardized effect sizes. The primary outcome is screening uptake at 6-month follow-up. For between-group comparisons, generalized linear models will be used with adjustment for smoking status; appropriate link functions for each outcome will be determined based on distributions (e.g., for dichotomous outcome variables we will use a logit link). In the case of differential attrition, as noted above, a sensitivity analysis will be conducted such that regression models will also include baseline covariates that differ significantly between participants who do and do not complete follow-up assessments.

Aim 3 (Qualitative). Explore the sustainability of a social media-based approach among key stakeholders to increase lung screening awareness, knowledge, adoption and uptake among screening-eligible individuals. (Note: Sustainability is defined as the extent an evidence-based intervention can deliver its intended benefits over an extended period of time within practice based upon the Dynamic Sustainability Framework.11). Audio recordings will be transcribed verbatim. Dr. Carter-Bawa will read and verify each transcript. Drs. Carter-Bawa and Ostroff will analyze the transcripts with the aid of QRS International's NVivo10, a qualitative data analysis program, using conventional content analysis techniques. Each text unit (meaningful phrase, sentence, or story relevant to the study aims) will be extracted and coded with a short phrase reflecting its essence. Codes will be displayed on a case-by-variable matrix as described by Miles, Huberman, and Saldaña. Using data from the in-depth interviews, the research team will first categorize codes in each column and provide a description of each category. This will yield an in-depth description of factors that contribute to sustainability. All transcribed interviews will be validated for accuracy by Dr. Carter-Bawa. Because the initial coding of the data involves a low level of interpretation, a clinical research coordinator will code the data and place each code in the relevant cell of the data display table. Dr. Carter-Bawa will verify the coding. Coding will be further verified by the investigators during a data analytic team meeting. Disagreements about code labels or placement will be resolved by a reevaluation of transcript data and team discussion until consensus is reached. The categorization of the data in each column, which involves a higher degree of interpretation, will be done by team discussion to reach consensus. Because the findings will be produced in an evolving and iterative process, inter-coder reliability indices are not feasible; however, a detailed and systematic plan to ensure negotiated consensual validity at each stage of analysis will ensure credibility of the findings, and a detailed audit trail will be maintained that chronicles all analytic decisions. All digital recordings will be saved on a passphrase protected HMH server and deleted 7 days after verification of the transcript for accuracy. Only the PI and Research Project Associate will have access to the digital recordings.

5.8.1. Sample size calculation and justification

With a sample size of n=250 per group and up to 20% missing assessment data (n=200 available for analysis) on total knowledge scale and total perceived risk scale scores (secondary outcomes), we will have an 80% statistical power if the difference is d=0.28 (in standardized effect size units, or Cohen d), in an independent-sample t-test with a two-sided type-I error rate of 5%. A 0.25 effect is what Cohen considered a 'small' effect size in psychology research, thus a conservative estimate of the statistical evidence that can be supported in our study design.

5.8.2. Statistical Analysis Plan

With a sample size of n=250 per intervention group, and using an ITT analysis (default is no screening uptake unless otherwise verified, thus no "missing" outcome data), we will be able to detect a difference between the *LungTalk* and non-tailored educational video groups with an 80% statistical power if the difference in lung screening uptake at 6-month follow-up (primary outcome) is 25% in the *LungTalk* group compared to 15% in the non-tailored educational video groups, in a test of independent proportions and a two-sided type-I error rate of 5%. This 25% vs. 15% comparison is a conservative estimate, as 31% vs. 10% difference was observed in preliminary data testing *LungTalk* in a sample of community-based screening-eligible individuals in Indiana in 2018 using the same ITT procedure.[16]

6 - Trial Administration

6.1. Ethical Considerations - Institutional Review Board (IRB) Review

The study will be conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), the Declaration of Helsinki, Institutional Review Boards (IRB) and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

6.2. Institutional Review Board (IRB) Review (list the IRB of record)

Hackensack Meridian Health

6.3. Confidentiality

HMH may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. The use and disclosure of protected health information will be limited to the individuals/entities described in the Research Authorization form. A Research Authorization form must be approved by the IRB.

The consent indicates that individualized, de-identified information collected for the purposes of this study may be shared with other qualified researchers. Only researchers who have received approval from HMH will be allowed to access this information, which will not include protected health information such as the participant's name, except for dates.

6.4. Informed consent

All participants (N=500) (except stakeholders) will sign an e-consent in REDCap.

The consent form/research authorization meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of HMH. The consent form will include the following:

1. The nature, objectives, potential risks, and benefits of the intended study.
2. The length of study, what it entails, and the likely follow-up required.
3. Alternatives to the proposed study.
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.
6. How the participants' data will be protected, who will have access to their PHI, and what data will be disclosed for research purposes.

Prior to inclusion in the study and before protocol-specified procedures are carried out, potential participants will be able to read the full details of the protocol as outlined in the consent and research authorization. Participants will have the ability to contact the investigator if there are any questions prior to consenting electronically. Participants will also be informed that they are free to withdraw from the study at any time.

All participants must electronically sign an IRB-approved consent form via REDCap indicating their consent to participate. A consenting professional signature is not required as noted in IRB SOP IC-706. The participant will be offered to receive a copy of the signed informed consent form either by email or by mail.

Key stakeholder participants (N=20) will be consented over the phone using a verbal consent.

The verbal informed consent/research authorization meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of HMH. The consent/research authorization script will include the following:

1. The nature, objectives, potential risks, and benefits of the intended study.
2. The length of study, what it entails, and the likely follow-up required.
3. Alternatives to the proposed study.
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.
6. How the participants' data will be protected, who will have access to their PHI, and what data will be disclosed for research purposes.

Prior to inclusion in the study and before protocol-specified procedures are carried out, consenting professionals will explain the details of the protocol to participants. Participants

will also be informed that they are free to withdraw from the study at any time. The consent discussion will occur remotely via teleconference, telephone, or videoconference.

6.5. Data Quality Assurance (if applicable)

Online processes and platform (REDCap) will be monitored daily by the study team/project manager to assess intervention delivery issues and any unusual events. Modifications will be made as necessary and recorded to ensure appropriate intervention delivery and maintenance of protocol integrity. In addition, any problems identified will be discussed at team meetings and corrected.

6.6. Study Records (retention etc.)

Final data sets for publication are required to be locked and stored centrally for potential future access requests from outside entities.

Audio recorded data from the key stakeholder interviews will be stored on an CDI/HMH passphrase-protected server until transcribed. Audio recorded data from stakeholder participants will not include any identifying information and will be used to produce a de-identified verbatim transcript and erased after transcribed.

6.7. Compensation for Research-Related Injury (if applicable)

n/a

6.8. Economic Burden to Subjects (if applicable)

n/a

6.9. Credentials, Training

All research personnel will be up-to-date with required CITI training.

6.10. Financing and Insurance (if applicable)

n/a

6.11. Publication Plan (if applicable)

n/a

7- Resources Available

7.1. Describe the resources available to conduct the research:

The **Cancer Prevention Precision Control Institute** is led by the applicant. The primary office space for senior investigators, fellows, data managers and research support staff consists of 10,000 sq feet. Access to the research office, which houses study data, is limited to study

personnel and is kept locked at all times. The space is well equipped with individual offices, cubicles, and several multipurpose rooms for conducting interviews and convening research team meetings, journal clubs, and didactic seminars. Faculty all have office space, computer workstations, locked filing cabinets, and onsite access to videoconference facilities.

Computer The PI and research team have designated computer workstations that are networked to the various secure campus-wide hospital systems. CDI has a well-maintained computing environment that includes frequent software updates, proper hardware maintenance schedules, and 24/7/365 help desk and network administration support. CDI has an institutional site license for many software programs including Microsoft Office Suite, Adobe Acrobat, SAS, and SPSS. The computers are also equipped with the statistical program R, and bibliographic manager software (EndNote). The CDI has its own web and database servers based on Microsoft platform to streamline data collection and maintain data integrities. The department also has full-time in-house software developers and project managers to build and manage all the research IT related activities.

Administrative Support: The CDI and HMH provide full supportive services for all research projects including a full time Sponsored Programs Manager to help investigators comply with all relevant regulations and policies and managing grants. A financial analyst supports financial needs in sponsored research, cost analysis, procurement, and budgeting. The Research Department also has comprehensive administrative support for all researchers.

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