Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

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Project Title: Using a Virtual Health Insurance Navigation Program to Understand and Improve Health Insurance Coverage

Version Date: 1/29/25

For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.

1. Background and Significance

Colorectal Cancer in the United States

Rates of colorectal cancer, particularly for those under the age of 50 have been increasing.[1] This trend will likely lead to an increase in the number of survivors of colorectal cancer, due to relatively high survival rates.[2] Interventions are needed to ensure the health and wellbeing of this growing population, particularly around the areas of health insurance, financial burden, and cancer surveillance and follow-up care.

Health Insurance Specifics and Financial Burden Among Cancer Survivors. Cancer survivors experience a high degree of financial burden related to medical care, particularly in relation to health insurance. Such financial burden impacts the health-related quality of life of cancer survivors.[3] Cancer survivors with high deductible insurance plans, for instance, tend to postpone or go without medical care, have higher financial barriers to care access, and skipping or taking less medication.[4-7] Additionally, survivors and their partners often make employment decisions that are motivated by the need to maintain health insurance, pointing to the importance of the relationship between medical cost, financial burden, and health insurance in this population.[8]

Financial Burden and Health Insurance Among Survivors of Colorectal Cancer. Patients diagnosed with colorectal cancer have a higher risk of experiencing financial burden related to health care costs when compared to patients diagnosed with other typed of cancer.[9] While many cancer survivors report experiencing financial burden[3,8], financial burden is particularly acute among survivors of colorectal cancer.[10,11] Outcomes of financial burden among colorectal cancer survivors include lower health related quality of life, employment concerns, and delay or lack of engagement in needed surveillance and follow-up care.[10-12] Type of health insurance, which may be related to offsetting of burdensome medical costs, has been shown to be related to engagement in follow-up and surveillance care among colorectal cancer survivors.[13] Private health insurance, for instance, has been shown to be a protective factor for receipt of surveillance care among colorectal cancer survivors. Low health insurance literacy has also been linked with a higher degree of financial burden among colorectal cancer survivors.[14] This obligates practitioners and interventions to target health insurance literacy among this population to reduce financial burden and improve adherence to needed cancer surveillance and follow-up care.

Previous Study
In 2018, the American Cancer Society funded a project to develop and pilot a health insurance navigation intervention with childhood cancer survivors from the Childhood Cancer Survivor Study (Protocol # 2018P003088- "Understanding and Improving the Health Insurance Coverage Among Long Term Follow-up Study Cohort Participants". The present study builds on the project to adapt the intervention for adult survivors of colorectal cancer.

Rationale of Proposed Research
Health care reform under the Patient Protection and Affordable Care Act (ACA) offers considerable opportunities for colorectal cancer survivors to obtain coverage and improve access to needed care. However, in the general population, many people have low understanding of available insurance benefits and resources and have limited health insurance literacy (i.e. perceived knowledge, ability, and confidence to make informed decisions about choosing and using health insurance).[15] Misperceptions about which services require out-of-pocket costs may lead some enrollees to avoid services that are in fact exempt from cost sharing. For colorectal cancer survivors are particularly vulnerable to financial burden related to low health insurance literacy.[14] For colorectal cancer survivors, having a proficient understanding of health insurance is necessary for obtaining adequate health insurance to meet follow-up and surveillance needs without experiencing a significant degree of financial burden

2. Specific Aims and Objectives

Aim 1: To conduct an open pilot of a videoconferencing-based randomized trial of the health insurance navigation tools program with approximately 5 colorectal cancer survivors.
A1a: To assess the preliminary feasibility and acceptability of the HINT intervention via the measures and methods described below
A1b: To utilize open pilot feasibility and acceptability data to inform Aim 2 (RCT) methodology

Aim 2: To conduct a videoconferencing-based randomized trial of the health insurance navigation tools program (HINT) (n= approximately 60).
A2a: To assess the feasibility (number of eligible enrolled and sessions completed) and acceptability (satisfaction, perceived support) of participants undergoing a health insurance navigation tools program (HINT).
A2b: At 3-month post-program follow-up, to assess the efficacy of the HINT to assist participants with accessing and utilizing coverage and managing costs. Primary outcomes are 1) health insurance literacy and 2) financial distress related to medical costs. *A2b Hypothesis*: The HINT, compared to enhanced usual care, will improve participants' health insurance literacy and decrease financial distress.

3. General Description of Study Design

Open Pilot Design: We will recruit approximately 5 colorectal cancer survivors from Massachusetts General Hospital via the Research Patient Data Registry (RDPR) to take part in a health insurance navigation intervention. Recruitment, consent, and intervention approach for the pilot will mirror the trial design, as described below. The purpose of the open pilot is to inform any changes in the trial and program approach prior to implementing the randomized pilot trial.

Randomized Trial Design: We will recruit and randomize approximately 60 colorectal cancer survivors from Massachusetts General Hospital via the Research Patient Data Registry (RDPR) to a health insurance navigation intervention or to enhanced usual care (Please see Sections III and IV for information on subject selection and consenting procedures). We have selected this sample size of approximately 40 per arm to enable evaluation of feasibility and acceptability goals as well as explore meaningful differences in the outcomes.[78] Surveys will be conducted at baseline and 3-month post program completion follow-up via REDCap or mail. All participants will be asked to complete a follow-up survey approximately 3-months after the HINT intervention period (in other words approximately 5-months post pilot trial enrollment). Participants will be remunerated $20 for each survey.

Study Arms

Enhanced Usual Care
Enhanced usual care will consist of a mailed or emailed copy of a health insurance booklet.

Navigation Intervention
The intervention will be delivered via synchronous videoconferencing (real-time delivery and communication between the navigator and the participant) by a trained patient navigator (See Intervention Fidelity in Section VI) and will consist of 5, approximately 30-minute sessions delivered every week or two, over the span of approximately one month (See Table 1: Proposed HINP Intervention). The sessions will occur one-on-one between the navigator and the participant and will be interactive (i.e. participants will be able to ask questions and respond to content throughout the sessions). The proposed program content was informed by the following: 1) aforementioned research on the associations between financial burden and health insurance literacy among colorectal cancer survivors, 2) CCSS health insurance survey, 3) ACA provisions that are relevant to survivors (e.g., prevention services exempted from cost sharing, sources of available coverage and eligibility, benefits policies that have cost-related implications like OOP costs, and essential health benefits such as prescription medications), and 4) an ongoing randomized pilot trial of the program with survivors of childhood cancer. The navigation intervention group will also receive a mailed copy of the health insurance booklet given to the enhanced usual care arm.

Table 1: Proposed HINT Intervention
Session One: Learning About Survivorship Healthcare Needs
Sessions Two: Learning About Your Plan in Relation to Policy
Session Three: Navigating One's Own Plan
Session Four: Managing Care Costs

4. Subject Selection

Participants: Inclusion and Exclusion Criteria
Study participants will be identified via the online query tool of the RDPR for both the open pilot and randomized trial. Patients who are 1) approximately 6 months to 5 years posttreatment for stages I-III colon or rectal cancer or 2) approximately more than 3 months post-diagnosis for stage IV colon or rectal cancer at the time of screening will be eligible. We will constrain records to patients who have (a) had a medical visit at a MGH Cancer Center (ie. MGH Boston, Danvers, Waltham or Mass General Cancer Center at Newton-Wellesley) in the past two years, (b) an ICD diagnostic code of colorectal cancer (i.e.,

malignant neoplasm of the colon, rectum, or rectosigmoid junction), and (c) a pathology report with the terms “stage I”, “stage one”, “stage II, “stage two”, “stage III” or “stage three”.

Records include patient’s medical record numbers, demographic characteristics, diagnoses (code and encounter date), inpatient and outpatient encounters, and other medical care. Approximately 65 (5 for the open pilot, 60 for the RCT) participants meeting these criteria will be identified and recruited. We will exclude participants who: (1) do not speak English, (2) do not have health insurance, (3) are under the age of 18, (4) are over the age of 65, (5) are unable to give informed consent due to psychiatric, cognitive, or medical (ie. Patient in hospice at end of life) impairment as determined in consultation with study PI, patient navigator, or oncology social worker, and (6) do not have access to a smartphone, computer or tablet with internet access. The rationale for the third exclusion criterion is that an intervention with a large number of Medicaid-eligible survivors would be outside the scope of the current intervention. The rationale for the fifth exclusion criterion is that the health insurance navigation intervention is delivered via an MGB-approved video-conferencing system (ie. Zoom).

A member of the research team will review the electronic medical record (i.e., EPIC) to ensure that identified patients are eligible for the study before proceeding with outreach. A team member will confirm that the patient is alive and has not been hospitalized within the past year due to psychiatric reasons.

Sources of Subjects and Recruitment Methods

The Research Patient Data Registry is a centralized clinical data registry that stores and gathers patient information from across the Mass General Brigham system. It provides clinical researchers the ability to perform population queries and identify target subpopulations for research studies. Research Options Direct to You [RODY] patients and self-referred within the RDPR will be contacted about the study.

5. Subject Enrollment

Methods of Enrollment

Potential participants will be identified via the Mass General Brigham RDPR. Patients among the Research Options Direct to You (RODY) designation within the RDPR will receive an opt-out letter from the study team. This letter (See Recruitment Letters) will describe the study procedures and ask patients to contact the study team within 3 days if they would not like to be contacted further about the study. Those who do not opt-out will be contacted via encrypted email or by phone by the PI or by a trained and CITI-certified research staff member, and they will be read or sent a brief description of the study (See Study Description Documents).

Patients may also express interest in the study by contacting the research team directly.

Patients who are interested will be screened for eligibility, and those who are eligible will undergo informed consent. Specifically, eligible and interested patients will be asked to review the study fact sheet by phone with a study team member. Once that is completed, the study fact sheet will be sent to participants in an encrypted / unencrypted email, depending on their preference (see HINT C Short Consent). This method of obtaining consent has been used in other IRB-approved trials, like 2018P000539). Following consent, enrollees will be assigned a unique study identification number and will complete a baseline assessment. Patients who consent and complete the baseline assessment will then be randomized into the intervention or control arm.

The study interventionist will contact consented participants randomized to the intervention via unencrypted or encrypted email to schedule the HINT sessions, again depending on patient preference. To facilitate communication with the oncology team, the interventionist will complete a summary documentation note within EPIC informing clinicians of the patients' participation in the program. We will send reminder notices via calls, emails, mail, and Patient Gateway for participants who have not completed the baseline survey or for those in the intervention arm who have not scheduled their sessions, as needed (see "HINT C Difficult to Reach Letter").

Privacy protection: To address security issues related to email communication, participants will be informed about security in the opt-out letter itself via inclusion of the following text:

"Please note that emails sent to the study staff from your personal email address may not be secure and could result in the unauthorized use or disclosure of your information. If you want to email the study team despite these risks, Partners HealthCare will not be held responsible. If you do not want to email the study team, you may instead call [XXX RA's phone number]".

For any emails sent by the study team, they will be encrypted using Send Secure unless patients verbally agree to receive unencrypted email, which we will document. Patients will receive the following information:

"The Partners HealthCare standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to research studies for emails sent to you from research staff in this study. If you wish to communicate with other research staff at Partners regarding additional studies, your preference will have to be documented with each research group."

Informed Consent

Eligible and interested patients will be asked to review the study fact sheet by phone with a study team member. Once that is completed, the study fact sheet will be sent to participants in an encrypted / unencrypted email, depending on their preference (see HINT C Short Consent). This method of obtaining consent has been used in other IRB-approved trials, like 2018P000539).

Intervention Assignment and Randomization

Using the RDPR, MGH staff will outreach to patients meeting the eligibility criteria and query terms. For the randomized pilot trial, the 60 participants will be randomized to either enhanced usual care (n=40), or the health insurance navigation intervention (n=40). Randomization will employ a random plan generator, with consented patients being randomly assigned to either the enhanced usual care or the health insurance navigation intervention, stratified by age (18-39 and 40-65).

6. Study Procedures

Navigation Intervention

After baseline survey completion, consented intervention arm participants will be contacted by the health insurance navigator to schedule their health insurance navigation sessions. The sessions will occur weekly or every other week, depending on participant availability. The health insurance navigator will utilize encrypted email (unless the participant agrees to communicate via unencrypted email) and phone calls to schedule health insurance navigation sessions. The navigator may also use a Partners approved text messaging service to contact patients who have agreed to be sent text messages during the consent process, which will be utilized for session reminders.

Upon completion of the intervention, the interventionist will document within EPIC the number of sessions a participant attended so that the clinicians may be aware of their patients' participation.

Data Management, Collection, and Transfer

Recruitment

The RDPR allows for HIPAA-compliant recruitment and contact of potential research subjects. Participants will be contacted securely via encrypted recruitment emails. If patients consent to enroll in the study, the patient's RDPR information (e.g., demographics, health insurance type) will be imported into a REDCap database, which is a secure-web based portal housed within the Mass General Brigham fire wall. Other information pertaining participant recruitment will be stored on password-protected excel spreadsheets within Secure File Areas, which will only be accessible to study team members.

Assessments

All study participants will complete a baseline survey and a follow up survey approximately 3 months post-program completion. Participants will be remunerated $20 for the completion of each survey. MGH extracted medical record data will provide information on sociodemographics and cancer history (e.g., cancer diagnosis, age at diagnosis, and type of treatment). These data will be extracted from EPIC records by CITI and EPIC-trained study staff after participant consent.

Quantitative Data

MGH study staff will oversee the scheduling participants to health insurance navigation sessions and will ensure completion of the baseline survey and follow-up surveys. Survey data will be collected via a secure web-based portal (REDCap). Research Electronic Data Capture (REDCap) is a web-based platform that allows for HIPAA-compliant storage of protected health information.[16] RCT participants will complete the study measures.

Intervention Fidelity

The patient navigator (PN) will undergo training by the Co-investigators and pilot sessions. The NCI, with support from the ACS, established the Patient Navigation Research Program (PNRP) to implement and evaluate patient navigator programs. The PNRP developed a navigation performance checklist with 3 quality indicators of care:[17,18] 1) participant interaction (e.g., established rapport), 2) care management (assessed subjects' understanding), and 3) intervention delivery (e.g., relevant information provided on insurance options, cost savings). Study investigators will review approximately 15% of patient navigation encounters using these quality indicator criteria. Navigation sessions will be recorded following patient assent to facilitate these fidelity assessments. The recordings will be audio and not video.

Measures

To evaluate the pilot, we will use a mixed methods data collection approach, using both quantitative survey items and open-ended questions.[26] Most study measures will come from survey questions repeated from the 2011-2012 CCSS health insurance survey (see Appendix); some new questions will be added and are indicated as such. Survey development included modifications and inclusions of national survey questions[26-32] and a cognitive testing phase. Using data collected previously by the RDPR via abstraction of medical records, data will be used to provide information on cancer diagnosis, age at diagnosis, and cancer treatment. Data from the RDPR will provide information on sociodemographic and medical history since cancer treatment, and presence of a medical late effects and chronic health conditions including second cancers. The measures will include the following:

Participant Characteristic Measures (From RPDR and/or study surveys)
Characteristics: Age, Gender, Education, Race/Ethnicity, Partnership/Marital Status
Enabling Characteristics: Zip Code, Familiarity with ACA Policies
Health Insurance Literacy: Likert scale assessments of- Confidence in Understanding of Terms (e.g. Coinsurance), Confidence in Choosing, Comparing, and Using Insurance, Household and Personal Income
Cancer Diagnosis, Treatment Type

Outcome Measures
Primary Outcomes: Feasibility and Acceptability.
1. Feasibility: Number of eligible enrollees and number of sessions completed. 2. Acceptability: 4-point scales of satisfaction with navigation services (To what extent has this program met your needs? Did you get the kind of health insurance assistance that you wanted? How helpful has this program been for you?) and perceived support (emotional/informational scale of the Medical Outcomes Study social support survey, an 8-item scale widely used with cancer patients).20-24

Secondary Outcomes: Efficacy.
The ACS's National Patient Navigator Leadership Summit recommend patient-navigation outcome measures, which include: perceived knowledge, perceived confidence in overcoming barriers to care, and satisfaction with patient navigation services. Accordingly, we will measure: 1) health insurance literacy, 2) financial distress related to medical costs, 3) familiarity with healthcare reform policies, 4) insurance status (among those insured at study enrollment), and 5) discussion with providers about health care costs24 and preventive services among those having a visit during this interval (2-item y/n questions).

Secondary Outcomes: Program Satisfaction.
Program satisfaction outcomes will include Likert scale (very poor, poor, average, good, excellent) on items including communication with the navigator, scheduling convenience, number of sessions, length of sessions, the health insurance booklet, the overall quality of the program. Satisfaction with the virtual format delivery of the program will also be assessed on a Likert scale, and will include items on the MGB-approved video-conferencing system (ie. Zoom) and the material presented via PowerPoint during the navigation sessions. We will also assess likelihood of program recommendation for other colorectal cancer survivors (definitely would recommend, probably would recommend, neutral, probably would not recommend, definitely would not recommend). Program helpfulness will be assessed on a 1-10 scale. Lastly, open ended questions will be asked about helpfulness of the program and aspects of improve upon. Program satisfaction questions will be asked only of intervention arm participants.

7. Risks and Discomforts

Psychological Risks

Individuals may find it stressful to answer questions about their experiences with health insurance coverage and care. The risks associated with these discussions are minimal, and do not rise above the level of harm encountered during daily activities.

The potential risks to subject include: 1) Answering questions about or discussing health insurance coverage and care and participating in a program to discuss these issues with the navigator and the patient navigator has the potential for increasing psychological vulnerability.

These risks will be described by the patient navigator and be clearly outlined in the consent form. Participants will be encouraged to discuss any concerns with the patient navigator. In the event of a psychiatric emergency, confidentiality may be suspended. If the patient navigator notes severe distress, Dr. Park will contact the participant to assess for safety and report concerns as soon as possible to the MGB IRB.

Procedures for Minimizing Risk

Every effort will be made to minimize the study burden. The time commitment will be explained to all participants prior to the focus groups and pilot trial study consent. Every effort will be made to minimize the length and maximize the convenience or the pilot surveys completion.

Maintaining Confidentiality

There is a low risk that protected health information could be impermissibly disclosed or that the confidentiality of patient information may be breached. Stringent guidelines are established in order to assure the confidentiality of study subjects. A unique study identification number will serve as the primary identifier for study participants. Personal identifiers will not be part of the computerized data record. Names and addresses will be maintained in a password protected restricted data file accessible only to the principal investigator, study coordinator and designated study personnel. Similarly, names will be removed from all RDPR abstracted information. Study participants are informed of the potential risks and benefits regarding the security of their personal information. Utilizing an MGB-approved video-conferencing system (ie. Zoom) enables connection through virtual HIPAA-compliant videoconferencing technology. The virtual visits will be conducted via MGB-approved video-conferencing system (ie. Zoom).

8. Benefits

The consent form states that there may be no direct benefit to the participants from study participation. Participants in both groups will be given information that could improve their ability to access affordable coverage. Participants in the intervention group will also receive navigation support, for up to 5 video-based sessions. As an alternative to the intervention, participants may explore health insurance support options at their current primary care center.

9. Statistical Analysis

Dr. Kirchhoff, and the study team at University of Utah will complete the analyses. The team will be blinded to treatment allocation until trial analyses completion. Dr. Kirchhoff's team will receive de-identified study data.

Open Pilot

Pilot data is meant to inform and test the function of the study procedures, so no formal analyses will be performed. We will use preliminary feasibility and acceptability data (as outlined below) to inform necessary changes to our approach.

Randomized Trial

Quantitative Data

We will use descriptive statistics to report on the following endpoints: intervention feasibility (percent of participants enrolled), acceptability (satisfaction, perceived support) and efficacy (e.g., ACA familiarity, health insurance literacy, intention to adhere to recommended survivorship care, provider communication, and coverage status). Descriptive statistics will examine group differences at baseline; any imbalances will be adjusted. We will use chi square and independent t-tests to compare end-of-intervention changes in preliminary efficacy outcomes between the two groups. Although a 3-month post intervention follow-up period is brief, we will also conduct exploratory comparisons with other study outcomes to see if trends change in the expected direction. We will compare pre/end-of-treatment, within groups, with paired t-tests. In addition, we will use bivariate statistics to examine sociodemographic and cancer-related factors (e.g., type of diagnosis, age at diagnosis, cancer treatment[18], cancer treatment (e.g., cranial radiation yes/no, anthracycline exposure yes/no) associated with feasibility, acceptability and preliminary efficacy outcomes.

10. Monitoring and Quality Assurance

Training of all Study Personnel in the Responsible Conduct of Human Studies

Prior to recruiting subjects or handling study data, all study personnel will be required to pass an NIH-approved course that reviews regulatory and informational documents on human subject protection and the responsible conduct of human studies. In addition, all study personnel will sign a statement of commitment to the protection of the rights and welfare of human subjects participating in research. In addition, all study staff must complete and submit Conflict of Interest (COI) Disclosure forms to their respective institutions.

Data Monitoring Plan

Survey data will be collected via Dr. Park's study team at the Health Policy Research Center. Data will be collected via mailed/phone-based survey and through a secure web-based portal (REDCap). Electronic participant tracking databases will be stored on a secure server (Shared File Area) accessible only by IRB-approved members of Dr. Park's study staff. Data quality (including sessions participated in for the intervention group, data missingness, and recruitment rates) will be monitored monthly. Interim data analysis will be conducted throughout the trial and results will be reported in the annual ACS progress report.

Adverse Events Reporting

Serious adverse events will be reported to Dr. Park by study staff immediately. Dr. Park will be responsible for the reporting of any adverse events to the Massachusetts General Hospital Institutional Review Board. The MGH IRB requires that serious adverse events are to be reported to the IRB as soon as possible, but no later than 10 working days from the date on which the investigator became aware of the event. Non-serious adverse events are to be reported within 20 working days

11. Select the Privacy and Confidentiality measures that apply to this research:

☒ Study procedures will be conducted in a private setting
☒ Only data and/or specimens necessary for the conduct of the study will be collected
☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
☐ Additional privacy and/or confidentiality protections

Describe below:

12. References

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