20-3115: Overcoming barriers to the uptake of cascade screening for Lynch Syndrome

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Master Protocol – Summary of changes from previous version

Version	V. Date	Revision summary	PRC status	IRB status
1.0	03/01/2021	n/a – Initial submission	accrual tracking only, PRC not required.	Approved on 06/14/2021
2.0	6/22/2021	The patient recruitment process has been updated. Patient records will be accessed by genetic counselors to identify potential participants to be contacted about the study opportunity. A partial waiver of HIPAA authorization is being requested, and the data sources, recruitment questions, and study protocol have been updated to reflect the revised recruitment plan. The verbal consent scripts have been revised to emphasize that the enrollment call is related to the study opportunity previously shared with the participant. The information sheets have been updated to identify OSU as a collaborator.	accrual tracking only, PRC not required.	Approved on 9/1/2021
3.0	11/3/2021	Modifications to the recruitment and informed consent process for participants, informed consent will be gathered from patients and genetic counselors who wish to provide feedback on using the workbook before conducting a follow up interview and survey. Patients and genetic counselors will still be contacted by email to introduce the study opportunity. However, the email will only discuss providing feedback about the workbook as part of the simplified consent process that does not disrupt genetic counselor workflow.	accrual tracking only, PRC not required.	Approved on 1/13/2022
4.0	2/1/2022	Ohio State University was added as a second site and study was updated to a multi-site study.	accrual tracking only, PRC not required.	Approved on 2/28/2022

5.0	3/28/2023	The recruitment strategy was expanded. In addition to patients with Lynch Syndrome being recruited through genetic counselors at Ohio State University and UNC Chapel Hill, newly diagnosed patients will also be recruited through the Lynch Syndrome International (LSI) Facebook community due to personnel changes and recruitment delays at OSU. An advertisement will be posted on the LSI Facebook page to share the study opportunity, and patients with Lynch Syndrome who see the advertisement will be able to email to join the study. Verbal consent will be collected for patients recruited through LSI using an updated verbal consent script that accounts for this modification.	accrual tracking only, PRC not required.	Approved on 5/12/2023
6.0	6/20/2023	The eligibility criteria were changed. Instead of calling patients to assess initial eligibility, an online survey link (using REDCap) will be sent in response to their interest email, which includes eligibility criteria (see attached Eligibility Screener). Additionally, sociodemographic items will be included in this survey to meet enrollment goals and ensure representative enrollment by race, ethnicity, and gender. Once eligibility has been determined, follow-up will be conducted by the research assistant via email to schedule a call with the eligible participant to complete informed consent or to inform them that they are not eligible to participate in the study.	accrual tracking only, PRC not required.	Approved on 6/28/2023

7.0	5/29/2025	Several updates were made to the protocol to reflect changes in the recruitment approach: (1) the analysis software was changed from Atlas.ti to NVivo (2) the language was revised to refer only to patients, removing references to genetic counselors given that recruitment approaches changed (3) Section 7.2 was updated to list only the UNC IRB as the IRB of record. These changes were necessary due to earlier modifications in the recruitment strategy. No patients were recruited from Ohio State University due to personnel changes and recruitment delays. As a result, recruitment through the Lynch Syndrome International (LSI) Facebook community was prioritized over recruitment through genetic counselors.	accrual tracking only, PRC not required.	6/06/2025

Protocol Amendment (v7. 06062025)
Summary of Changes:

- Recruitment procedures were updated to include Lynch Syndrome International's social media page as a recruitment site.
- Participants were recruited through Lynch Syndrome International.

- Recruitment through Lynch Syndrome International was prioritize over genetic counselors' recruitment.
- No patients were recruited from OSU due to personnel changes and recruitment delays.

Consents:

- Updated verbal consent script for patients recruited through LSI.

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Signature Page

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

Principal Investigator (PI) Name: Megan Roberts

PI Signature: 

1. BACKGROUND AND RATIONALE

1.1. Study Synopsis

We will trial an educational workbook on family cascade screening for individuals diagnosed with Lynch Syndrome, a genetic predisposition for certain types of cancer. Up to 5 genetic counselors at Ohio State University (OSU) and the University of North Carolina at Chapel Hill (UNC Chapel Hill) as well as 15 patients at OSU, University of North Carolina at Chapel Hill (UNC Chapel Hill), and Lynch Syndrome International (LSI) will pilot test the workbook and we will conduct surveys and qualitative interviews to understand the feasibility, acceptability, practicality, and economic impact of the workbook. The research team developed the workbook in a previous project using implementation science strategies to identify and develop an intervention for barrier and facilitators to family screening for Lynch Syndrome.

1.2. Background

An estimated 1 million people in the US have Lynch Syndrome (LS), a genetic disorder that increases lifetime risk for several cancers including up to 82% for colorectal cancer (CRC) and 60% for endometrial cancers (compared to 4% and 3% in the general population, respectively). Universal testing of all CRC and endometrial cancer patients for LS is an effective approach for identifying affected individuals and reducing their risk of subsequent cancers through enhanced screening and primary prevention strategies. The cost effectiveness of universal testing for LS hinges on cascade screening, the systematic identification and testing of family members of affected individuals. Unfortunately, many family members of patients with LS do not receive cascade screening. In previous research, we identified barriers to cascade screening including low knowledge, skills, and self-efficacy and perceived barriers such as family dynamics, cost, and fear of discrimination. We also identified facilitators including expectations of positive outcomes from communicating with family members and options for free family member testing. We used intervention mapping to identify an intervention that targets actionable barriers and facilitators to improve cascade screening uptake for LS.

1.3. Purpose and Rationale

The objective of this project is to test the feasibility and implementation of our intervention, an educational workbook on the importance of cascade screening for Lynch Syndrome families. Fifteen patients diagnosed with Lynch Syndrome will test the workbook. We will assess the success of the workbook as a tool to improve cascade screening through post-intervention surveys and a qualitative interview. This feasibility study will provide foundational knowledge on the usefulness and acceptability of the workbook to inform an R01 to test if the intervention can improve cascade screening uptake when

used in the clinical environment.

2. STUDY OBJECTIVES AND ENDPOINTS

2.1. Primary Objective

The primary research question is: Is Let's Talk, an educational workbook on cascade screening for individuals diagnosed with Lynch Syndrome, a feasible intervention for health professionals to improve family testing for Lynch Syndrome?

2.2. Secondary Objectives

There are no secondary objectives in this study.

3. PATIENT ELIGIBILITY

3.1. Inclusion Criteria

3.1.1. Participants must meet all of the following inclusion criteria to participate in the study.

3.1.2. Patients must have been diagnosed with Lynch Syndrome within the last 365 days.

3.1.3. Patients must be age 18 or older.

3.1.4. Patients must be receiving care from genetic counselors at UNC Health System OR OSU OR be a part of the Lynch Syndrome International advocacy group Facebook page.

3.1.5. Patients must be able to speak and read in English.

3.1.6. Patients must review informed consent documents and provide verbal consent to participate in the follow up interview and survey.

3.2. Exclusion Criteria

3.2.1. There are no exclusion criteria for study participants.

4. STUDY PLAN

4.1. Study Design

This is a nonrandomized, multi-center, interventional feasibility study on the use of an educational workbook to improve cascade screening among individuals diagnosed with Lynch Syndrome. The study is a single arm, interventional trial of 15 patients diagnosed with Lynch Syndrome who are (1) patients of genetic counselors at Ohio State University Comprehensive Cancer Center or UNC Health System or (2) are member of the LSI Facebook page and up to 5 genetic counselors at Ohio State University Comprehensive Cancer Center or UNC Health System. The primary purpose of this study is to evaluate the feasibility of an educational workbook for Lynch Syndrome patients to improve family genetic testing. We anticipate study enrollment will take approximately 24 months, cumulative patient active participation will last approximately 10 months, and genetic counselor active participation will last

approximately 24 months. Individual patient participation duration will be approximately 1 month. The feasibility of the intervention workbook will be assessed through template analysis[2] of qualitative interviews guided by CFIR[1] and quantitative survey design by the research team with scales to assess the costs of workbook use, knowledge, perceived knowledge, acceptability[3], and self-efficacy[4].

4.2. Study Recruitment and Activities

The recruitment goal for genetic counselors is up to 5 genetic counselors. The recruitment goal for patients with Lynch Syndrome is 15 total patients between OSU, UNC, and LSI. There is no minimum or maximum number of patients that can be enrolled at each site up to the goal of 15 patients total.

At OSU and UNC, the co-PI or another member of the research team will contact genetic counselors who work with Lynch Syndrome patients via email and notify them of the study opportunity and provide an information sheet. Interested genetic counselors will use the workbook with their Lynch Syndrome patients as a support tool for their standard cascade screening. The genetic counselors will provide the workbook to patients likely to test positive for Lynch syndrome or patients who have already been confirmed to have Lynch syndrome. If the patient is positive for Lynch syndrome, during a counseling call/appointment, the genetic counselor will complete the first prompt of the workbook to identify family members with the patient and explain the other sections of the workbook. Patients will complete the other sections of the work independently. The genetic counselor will notify the patient that the workbook creators are interested in hearing feedback on the workbook use and if the patient is interested, the genetic counselor will send the name, phone number, and email address of the patient to the UNC research team via secure email.

Through the LSI Facebook page, the study team will post an advertisement for patients recently diagnosed with Lynch Syndrome. Interested patients will reach out to the UNC research team by emailing the address posted in the study advertisement.

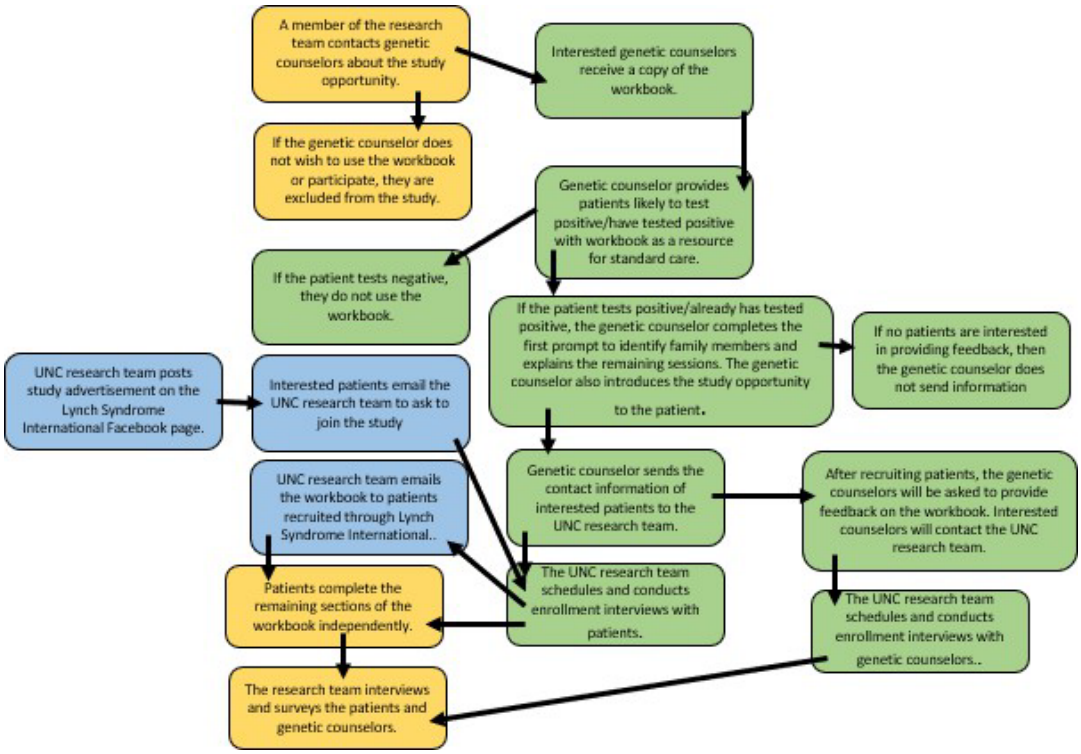
For all patients referred by a genetic counselor or self-referred, the UNC research team will schedule and complete a study enrollment call to answer questions, confirm eligibility, and document informed consent to participate in a follow up interview and survey. For patients directed to the study from the LSI Facebook page advertisement, the UNC research team will provide the workbook following the enrollment call and the participant will complete the activities in the workbook independently.

The UNC research team will complete the follow up interview and survey with patients approximately 4 weeks after they received the workbook from their genetic counselor.

All patient information will be tracked in a project in UNC's REDCap. All follow up interviews for patients will be conducted via Zoom. All follow up surveys for patients will be conducted electronically in REDCap.

For questions specifically related to genetic counseling or care management, patient participants should contact their site-specific genetic counselor or personal healthcare provider. For all other questions and concerns at any point in the study, participants recruited from OSU or UNC should contact the UNC research team. Questions about study eligibility and responsibilities should be directed to the UNC research team. If participants have questions or concerns about their rights as a research subject, or if they would like to obtain information or offer input, they can also contact the UNC Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

4.3. Schemas



4.4. Duration of Study

The duration of the study is anticipated to be approximately 24 months. We anticipate study enrollment will take approximately 20 months, individual patient active participation will last approximately 3 months, and genetic counselor active participation will last approximately 9 months. We expect patient participants to spend approximately 8 hours engaged in study activities

over the approximately 3 months of their enrollment. Hours of patient participation may vary by patient's use of the workbook and particular family situation. We expect genetic counselor participants to spend approximately 4 to 20 hours engaged in study activities over the approximately 9 months of enrollment. Genetic counselor time will vary by the number of patients a genetic counselor has enrolled into the study.

4.5. Intervention Description

The educational workbook is in a PDF format. The workbook contains a series of lessons and exercises on the following topics:

What is Lynch Syndrome?
Why should I tell my family members about Lynch Syndrome?
Who is at risk for Lynch Syndrome and who should I reach out to?
Create a list of first-degree relatives at risk for inheriting Lynch Syndrome
What should I tell my family members about Lynch Syndrome?
Create a script for discussing Lynch Syndrome with family
What are common concerns family members might express?
How should I tell my family members about Lynch Syndrome?
Create a plan to reach out to each family member
Create goals for talking to family members
What if my conversation with family didn't go well?
What are common terms and questions about Lynch Syndrome?
How can I manage having Lynch Syndrome?
Where can I find additional information about living with Lynch Syndrome

4.6. Follow Up

After a genetic counselor has provided the contact information of an interested patients or the patient has directly contacted the research team by email, the UNC research team will reach out to the patient in approximately 1 weeks to gather informed consent and will conduct a follow up interview and survey after approximately 4 weeks.

All interviews will be completed through Zoom using a semi-structured interview guide developed by the research team based on the Consolidated Framework for Implementation Research.[1] The interviews will be conducted by the research assistant and a trained interviewer and recorded. The recordings will be transcribed for qualitative template analysis to identify major themes.[2]

During the follow-up session, participants will also complete an electronic survey to assess the following feasibility concepts: acceptability of workbook[3], self-efficacy[4], Lynch Syndrome knowledge, Lynch Syndrome perceived knowledge, cost of workbook use.

4.7. Statistical Considerations

4.7.1. Sample Size and Accrual

With up to five genetic counselors across sites or through LSI, we will enroll 15 Lynch Syndrome patients. The study personnel have conducted previous qualitative research on genetic testing for cancer care, including Lynch Syndrome. Thematic saturation in those studies was reached through 15 interviews with patients and providers. Thus, we expect to reach thematic saturation on the feasibility of the workbook for patients in the template analysis process by enrolling approximately 15 patients in the pilot study. Because we are working with a small number of patients for a rare disease, we anticipate working with a small number of genetic counselors. We expect general feasibility feedback from providers on the workbook.

4.7.2. Statistical Analysis Plan Data Analysis Plans

The transcribed qualitative interviews will be double coded using template analysis2 in NVIVO, a qualitative data analysis tool, by the research assistant and another investigator. Expected themes (practicality, integration, demand, and reach) will be a prior coded in the transcripts, but the themes will be modified, removed, or additional themes will be coded as identified to create a codebook. A final codebook will be created and used to double code all interview transcripts. We will compile the major themes and subthemes identified regarding the workbook feasibility.

During the follow-up session, participants will complete an electronic survey to assess the following feasibility concepts. Acceptability of workbook[3] will be measured through 7 questions for patients rated with a scale 1 (very unacceptable) to 5 (very acceptable). A score of over 80% suggests an acceptable intervention. Self-efficacy in communicating about Lynch Syndrome and the importance of family testing[4] will be measured through 5 questions rated with a scale 1 (very low confidence) to 5 (very high confidence). A score of 15 or higher suggests moderate to high self-efficacy. Lynch Syndrome knowledge will be measured by 7 multiple-choice questions and a score of 4/7 or higher suggests moderate to high knowledge of workbook users. Lynch Syndrome perceived knowledge will be measured by 7 questions rates with a scale 1 (very low confidence) to 5 (very high confidence) and a score of 21 or higher suggests moderate to high perceived knowledge. The cost of workbook use will be measured through 19 questions on implementation, intervention, and downstream costs of completing the workbook exercises.

One-sample Wilcoxon signed rank tests will be used to compare

average acceptability, self-efficacy, knowledge, and perceived knowledge levels to the comparison threshold levels to understand feasibility of the workbook.

4.8. Expected Risks

The risks to use of the workbook are minimal. A diagnosis of Lynch Syndrome and the task of communicating with family members could be an emotional and mental challenge to process and manage. The workbook is specifically designed to allow flexible timing so the patient can shape the workbook use to fit their emotional and mental needs.

Participant contact and identifying information will be stored in a REDCap project in the UNC REDCap environment and will be accessible only to the research team to reduce the risk of a breach of confidentiality. Genetic counselors will have access to contact and identifying information for their patients from the recruitment process and to facilitate study activities.

There is a low risk of economic harm. The Genetic Information Nondiscrimination Act of 2008 prohibits discrimination on the basis of genetic information in aspects of employment and health coverage.

4.9. Removal of Patients from Protocol

Any patient or genetic counselor who indicates they no longer wish to use the workbook or provide feedback on the workbook for any reason can notify the Principal Investigator at the UNC or the co-PI at OSU or another member of the research team who will inform the site PI and the participant will be removed from the study.

5. TIME AND EVENTS TABLE

Genetic Counselor Introduction to Study
Guided Exercise at Counseling Appointment
Patient Independent Use
Patient Informed Consent
Patient semi-structured qualitative interview/electronic survey

6. UNANTICIPATED PROBLEMS

6.1. Definition

As defined by UNC's IRB, unanticipated problems involving risks to study subjects or others (UPIRSO) refers to any incident, experience, or outcome:

Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

Is related or possibly related to a subject's participation in the research; and Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

6.2. Reporting

Any UPIRSO that occurs during the conduct of this study and that meets all three criteria listed in 6.1 must be reported to the UNC IRB using the IRB's web-based reporting system.

7. STUDY MANAGEMENT

7.1. Data Management/Audit

Qualitative interviews will be conducted via Zoom and recorded using Zoom. Video will not be used through Zoom interviews. The recording will be downloaded, transcribed and deidentified, and stored on a secure network drive. The research assistant will also take notes during the interviews and the notes will be stored on a secure network drive. The final codebook of themes and subthemes identified in the interviews will be stored in a Microsoft Word document.

The electronic survey will be administered through REDCap and the collected data will be stored in the REDCap system. The survey results will be exported and loaded into STATA for statistical analysis. Exported data files will be stored on a secure network drive.

The research will receive a limited waiver of HIPAA authorization to allow genetic counselors and the research team to access PHI necessary for the recruitment of Lynch Syndrome patients. Specifically, the waiver will approve access to patient names, patient ID numbers for UNC patients, telephone numbers, email addresses, ages, diagnoses, and dates of diagnosis. Participant contact and enrollment information will be collected and stored in REDCap. Contact and identifying information for all patients who are referred to the UNC research team by their genetic counselor will be collected and stored in REDCap. The data for patients who decline to participate or are found ineligible during enrollment or withdraw from the study at a later point will remain stored in REDCap. The names and contact information of participants

and patients who were contacted but not enrolled or withdrew from the study, along with linkage codes, will be destroyed by the PI after the study is complete.

7.2. Institutional Review Board (IRB) Approval and Consent

The IRB for UNC will be the IRB of record and have primary oversight for this study. Future references to the IRB refer to UNC's IRB. It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB will approve the consent form and protocol.

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

Before providing informed consent to give feedback on the workbook after use, the participants will be given a full explanation of the study and will be given the opportunity to review the information sheet. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give verbal consent in a telephone enrollment call. Verbal consent will be documented by the UNC research team in REDCap.

Patients recruited from OSU and UNC should contact the UNC IRB with any questions.

7.3. Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol. UNC investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior UNC IRB approval. For any such emergency modification implemented, a UNC IRB modification form must be completed by UNC Research Personnel within five (5) business days of making the change.

Eligibility single subject exceptions are not permitted for Lineberger Comprehensive Cancer Center Investigator Initiated Trials under any circumstances. Other types of single subject exceptions may be allowed if proper regulatory review has been completed in accordance with Lineberger Comprehensive Cancer Center's Single Subject Exceptions Policy.

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that (1)Is generally noted or recognized after it occurs, (2) Has no substantive effect on the risks to research participants, (3)

Has no substantive effect on the scientific integrity of the research plan or the value of the data collected, (4) Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria: (1)Has harmed or increased the risk of harm to one or more research participants, (2) Has damaged the scientific integrity of the data collected for the study, (3) Results from willful or knowing misconduct on the part of the investigator(s), (4) Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs please follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore® (or other appropriate database set up for the study), and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report UPIRSO.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO: Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB (see section 6.1) must be reported by the Study Coordinator using the IRB's web-based reporting system.

7.4. Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required. The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation.

7.5. Record Retention

Study documentation includes email correspondence, interview notes, recordings, and transcripts, REDCap projects, forms, surveys, and exported files to statistical/analysis software, planning documents, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by

the study investigator. Study documents should be kept on file until three years after the completion and final study report of this investigational study.

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

8. REFERENCES

(1) Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50
(2) King N. Template analysis In: GCS, ed. Qualitative methods and analysis in organizational research: A practical guide. Thousand Oaks: Sage; 1998:118-134
(3) Tariman JD, Berry DL, Halpenny B, Wolpin S, Schepp K. Validation and testing of the Acceptability E-scale for web-based patient-reported outcomes in cancer care. Appl Nurs Res. 2011;24(1):53-58.
(4) Carroll JC, Rideout AL, Wilson BJ, et al. Genetic education for primary care providers: improving attitudes, knowledge, and confidence. Can Fam Physician. 2009;55(12):e92-99.

9. APPENDICES

9.1. Patient Qualitative Semi-Structured Interview Guide

Theme #1: Practicality
Focus A: Understand Let's Talk complexity
Interview Questions:

1. Now that you have used the workbook, what did you think about it?
    a. What did you like?
    b. What did you dislike?
2. How complex or easy did you find it was to use "Let's Talk"?
3. How long did it take you to complete the exercises in the workbook?
    a. For patients recruited through LSI: The first prompt covered identifying your first-degree relatives. How did identifying your relatives go? Could anything have improved the process of identifying relatives to contact?

4. How did you feel about the length of the workbook? (too long, too short, just right?)
5. Did you seek help from anyone when you used the workbook?
6. Was the organization of the exercises logical?
    a. Would you change the order of the workbook sections?
7. Was there any part of the workbook you found difficult to understand or complete? Please explain.

Focus B: Understand how Let's Talk format impacts ease of use

Introduction: Now I'm interested in learning more about how easy or difficult it was to use the workbook as a "paper"/PDF format, as well as any suggestions you have for improving its design.

1. Would you prefer an online version of the workbook? Why or why not?
2. What additional materials, if any, would enhance your use of the workbook?
3. Does the format (e.g. paper-based) of the work workbook create any barriers to its use?
4. Will the format (e.g. paper-based) of the workbook affect your ability to use the workbook?

Theme #2: Demand
Focus A: Understand Let's Talk value to patients

Introduction: I'm also interested in hearing about how the workbook was valuable to you, if it was, and how it impacted the process of communicating with your family members.

Interview Questions:

1. Is the workbook effective in enhancing your knowledge of cascade screening (the process of testing family members for Lynch syndrome)?
2. What positive or negative effects have you experienced in using the workbook?
3. Would you recommend the workbook to other patients? Why or why not?

Theme #3: Reach

Measure #1: Intention to Discuss Lynch Syndrome

Question: On a scale of 1 to 5, 1 being extremely weak and 5 being extremely strong, choose the number that represents your intention to discuss Lynch Syndrome with your relatives. Explain how you arrived at your chosen number.

OR

Measure #2A: Number of Relatives Contacted

Question: How many relatives have you contacted regarding your Lynch Syndrome diagnosis after using the workbook?

Measure #2B: What was your overall impression of the conversation with your relative? What went well and what could have gone better?

Measure #3: Number of Relatives Who Sought Genetic Testing

Question: Of the relatives you contacted, how many have sought genetic testing?

Conclusion: Is there anything else you'd like to share before we wrap up today?

9.2. Patient Acceptability Electronic Survey Segment

Acceptability: Please rate how much you agree with the following statements (1 – Strongly disagree to 5 – Strongly agree)

The workbook was easy to use.
The workbook exercises were understandable.
I enjoyed using the workbook.
The workbook was helpful in understanding Lynch Syndrome and the importance of family genetic testing.
The workbook was helpful in communicating my diagnosis and information about genetic testing with relatives.
Completing the workbook exercises took an acceptable amount of time.
Overall, I am satisfied with the workbook.

9.3. Patient Self-Efficacy Electronic Survey Segment

Self-Efficacy: Please rate how confident you are in your ability to do the following tasks.

Identify relatives that are good candidates for genetic testing for Lynch Syndrome.
Plan strategies to communicate with relatives about Lynch Syndrome.
Share your Lynch Syndrome diagnosis with a relative.
Explain what Lynch Syndrome is and the associated risk of cancer.
Explain the benefits and risks of genetic testing for Lynch Syndrome to relatives.

9.4. Patient Knowledge and Perceived Knowledge Electronic Survey Segment

Please answer the following questions about Lynch Syndrome. Then please rate your confidence that you chose the correct answer for each question. The scale for confidence is Very Sure, Somewhat Sure, Neither Sure nor Unsure, Somewhat Unsure, and Very Unsure.

(1) Having Lynch Syndrome means you have a _____ of developing certain types of cancer compared to people who don't have Lynch Syndrome.
Higher risk
Lower risk
Equal risk

(2) Lynch Syndrome is a genetic condition which means:
All members of a family will have Lynch Syndrome.
Lynch Syndrome can be passed down between generations of a family.
Other family members are not at risk for Lynch Syndrome if a family member is diagnosed with Lynch Syndrome.

(3) What are the most common types of cancer associated with Lynch Syndrome?
Skin and bone cancer
Brain and stomach cancer
Colorectal and endometrial/uterine cancer

(4) What family members should I discuss my Lynch Syndrome diagnosis with?
No family members. I should only discuss my diagnosis with my doctors.
My nieces, nephews, aunts, uncles, and cousins
My parents, children, brothers, and sisters

(5) The best way to manage the risk of cancer after a Lynch Syndrome diagnosis is:
Talk to your doctor about screening for cancer at a younger age and possible surgical options to prevent cancer.
There is nothing I can do to prevent getting cancer if I have Lynch Syndrome.
Continue with my usual care and bring up my Lynch Syndrome diagnosis if I get diagnosed with cancer.

(6) Why should people diagnosed with Lynch Syndrome talk to their relatives about their diagnosis?
So their relatives can start increased screening for Lynch Syndrome related cancers.
So their relatives can teach other people about what Lynch Syndrome is
So their relatives can seek genetic testing to learn their own Lynch Syndrome

status and make the best choices for their health.

(7) How do relatives benefit from receiving genetic testing for Lynch Syndrome?
They will know if they should talk with their providers about ways to manage Lynch Syndrome and if they should talk to their family members about Lynch Syndrome risks.
They will know when they should start receiving treatment for cancer.
They will know if they should start annual screenings for all types of cancer.

9.5. Patient Workbook Costs Electronic Survey Segment

We are interested in understanding what time and resources are necessary to use the workbook. The next set of questions are intended to evaluate the time and resources needed to use this workbook starting from the genetic counseling appointment when you first received the workbook.

(1) Your genetic counseling appointment took place virtually. Did you have to purchase any new tools or resources to access your appointment? If yes, please describe.

(2) How far away do you live from your genetic counselor's physical office? Please estimate the distance in miles and the time it would have taken you to travel to and from your genetic counselor's physical office.

(3) How long did you use the workbook with your genetic counselor? (Please round your answer to the nearest 15 minutes.)

(4) Did you have to take time off work to talk with your genetic counselor?

(5) How many hours, if any, did you take off work to meet with your genetic counselor to learn about the workbook?

(6) After your genetic counseling appointment, how long did it take you to go through the workbook exercises? (Please round your answer to the nearest 15 minutes.)

(7) Did you take any time off work to use the workbook?

(8) How many hours, if any, did you take off work to use the workbook?

(9) Did you use the workbook in a virtual format (e.g. using a computer, tablet or phone) or did you print the workbook and fill it out by hand?

(10) Which pages of the workbook did you print? Please describe (e.g. all pages, pages 1-5, etc.)

(11) After using the workbook, did you spend any additional time using other resources for Lynch Syndrome that were mentioned in the workbook?

(12) How long did you spend using the extra resources mentioned in the workbook? (Please round your answer to the nearest 15 minutes.)

(13) How many first-degree relatives did you communicate with after using the workbook?

(14) Did you take any time off work to communicate with your relatives?

(15) How many hours, if any, did you take off work to communicate with your relatives?

(16) For each relative that you contacted, please list (1) how you communicated with them and (2) how long the entire communication process took from initial contact to follow up. Please consider time spent planning, communicating, and following up with relatives.

Planning time refers to time spent coordinating/preparing for communication with your relatives including activities such as arranging time for a phone call or traveling to see a family member.

Communication time refers to time spent telling your family member about your Lynch Syndrome diagnosis. Time might be spent talking to your relative over the phone or through a video chat.

Follow up time refers to additional time spent assisting your relatives after your initial conversation informing them of your diagnosis. For example, you might have spent time sending them additional resources about Lynch Syndrome or connecting them to a genetic counselor.

Example Scenario: I spent 10 minutes texting my sister to arrange a time to talk on the phone. I called her and we talked for 45 minutes during which I told her about my Lynch Syndrome diagnosis and explained why she should get tested. She asked for additional materials to learn about Lynch Syndrome, so after the call, I spent 20 minutes emailing additional resources to her. In the text box, I would list Text/Phone Call/Email as the method of communication, 10 minutes of planning time, 45 minutes of communication time, and 20 minutes of follow up time.

(17) For each relative that you contacted, please describe your use (if any) of the following resources: (1) transportation, (2) Supplies, (3) Food & Drink, (4) Other.

Example: For my parent, I drove 30 miles total to and from my parent's house.

I also printed out 3 sheets of information on Lynch Syndrome to give to my parent.

(18) What was your preferred method of communication with your family members and why?

(19) If there were any unexpected costs that you had to pay in using the workbook, please describe in the text box.

How old are you?
__ 18-25 years old
__ 26-35 years old
__ 36-45 years old
__ 46-55 years old
__ 56 years old or older

What is your sex?
__ Male
__ Female
__ Other, please specify_____

What is your annual income?
__ Less than $20,000
__ $20,000 - $34,999
__ $35,000 - $49,999
__ $50,000 - $64,999
__ $65,000 - $79,999
__ $80,000 or greater