Research Proposal: The Lived Experience of Patients with Chronic Gastrointestinal Disorders

By

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Abstract

Living with a chronic gastrointestinal disorder can have a significant impact on the person's quality of life. No studies have been identified that explore the experience of living with a chronic gastrointestinal disorder from the perspective of the patient. The proposed study will use Van Manen's phenomenological method to explore the experiences of up to 25 participants who are living with a chronic gastrointestinal disorder. Interviews will be recorded and transcribed. Data will be analyzed using coding for themes. Personal identifying information will be protected by the use of participant ID numbers and locking all research materials at the home of the principal investigator. The study is expected to contribute to the knowledge of the experience of living with a chronic gastrointestinal disorder and how the disorder impacts quality of life.

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Approximately 60-70 million Americans are affected by digestive diseases (Peery, Dellon, Lund, Crockett, McGowan, Bulsiewicz, Gangarosa, Thiny, Stizenberg, Morgan, Ringel, Kim, DiBonaventura, Carroll, Allen, Cook, Sandler, Kappelman, & Shaheen, 2013). No research to date has presented an in-depth look at the impact of having a chronic gastrointestinal disorder from the perspective of the patient.

For the purpose of this proposal, the term chronic is used to indicate a condition of length as greater than 3 months. Gastrointestinal disorders studied could include diagnoses such as Inflammatory Bowel Disease, Irritable Bowel Syndrome (IBS), Crohn's disease, Gastroesophageal Reflux Disease (GERD) and Dyspepsia, Diverticulosis and Diverticulitis, and ulcerative colitis. Additionally, gastrointestinal disorders are classified as either structural or functional. Structural disorders include disorders include tumors and Crohn's disease, where there is an identifiable structural cause to the symptoms. Functional disorders are those that present with persistent GI symptoms that are part of abnormal functioning, but not caused by structural issues (UNC School of Medicine, 2017).

Purpose of the Study

The purpose of the proposed study is to examine the lived experiences of adults with chronic gastrointestinal disorders from their perspective. The study will:

1. Explore what it is like to have a chronic gastrointestinal disorder.
2. Reveal the methods that participants use to manage their condition.

Significance to Health Care

Chronic gastrointestinal disorders have a serious impact on the welfare and productivity of Americans. For example, Perry, et al, (2013) reports that the symptom of abdominal pain prompted 15.9 million visits to U.S. clinics in 2012. Gastroesophageal reflux alone prompted 8.9 million clinic visits, and there were over 2 million visits for each of the following symptoms: nausea, diarrhea, constipation, and vomiting (Peery, et al, 2013). Johanson & Kralstein (2007) studied 557 patients with chronic constipation; 69% of the study's participants reported some form of work or school impairment due to symptoms, and 12% reported missing time from work or school because of constipation.

The presence of a gastrointestinal disorder affects the life of the patient, but to date no studies have explored the experience of living with a chronic gastrointestinal disorder. A qualitative approach is needed to explore this experience from the perspective of the patient. Results of such a study may identify aspects of gastrointestinal disorders that are currently not being addressed in nursing treatment plans, such as quality of life issues. Targeting resolutions for these aspects may improve quality of life and lead to fewer clinic visits and costs for gastrointestinal disease care.

Background

There are many studies that discuss quality of life of patients with various chronic gastrointestinal disorders. For example, Johanson and Kralstein (2007) found that symptoms of chronic constipation affected quality of life in 52% of their survey respondents. Participants in their study rated symptoms of abdominal discomfort, infrequent bowel movements, feeling of incomplete evacuation after bowel movement, hard stool, and straining in terms of how bothersome it is and level of severity. Moreover, 69% the participants reported some level of work or school impairment. Koloski, Talley,

& Boyce's (2000) study of 2910 participants in Australia used a quality of life measure which revealed that having a gastrointestinal disorder was significantly associated with impairments in mental and physical functioning. Hahn, Kirchdoefer, and Mayer (1997) studied 126 patients with IBS and found that quality of life was associated with perceived symptom severity. The authors note, "as IBS severity increased, psychological symptom severity as part of a global measure increased" (p. 555).

The Hahn, et al (1997) study was one of many studies that found an association between gastrointestinal disease and psychological symptoms or mental illness. Irwin, Falsetti, Lydiard, Ballenger, Brock, and Bener (1996) studied 50 patients with IBS and revealed that 54% met criteria for at least one psychiatric illness in their lifetime, including Post-Traumatic Stress Disorder (PTSD), Major Depressive Disorder, or Substance abuse. Savas, White, Wieman, Dacis, Fitgerald, Smith, Tan, Graham, Cully, & El-Serag (2008) found that female veteran participants with IBS and dyspepsia reported significantly higher levels of anxiety and depression than the women without GI disorders. Additionally, Drossman, Leserman, Nachan, Li, Gluck, Toomey, & Mitchell, (1990) saw two hundred and six women participants in a gastroenterology practice, and 44% of participants reported a history of physical or sexual abuse, which are also known to be connected to psychological disorders such as depression and PTSD.

Studies have revealed some interesting findings about the psychosocial aspects of functional gastrointestinal disorders. Locke, Weaver, Melton, and Talley (2004) found that functional gastrointestinal disorders are linked to more psychological distress, higher interpersonal sensitivity, and greater numbers of life stress events. Some studies have found that antidepressants, such as paroxetine (Tabas, Beaves, Wang, Friday, Mardini, &

Arnold, 2004), desipramine (Drossman, Toner, Whitehead, Diamant, Dalton, Duncan, Emmott, Proffitt, Akman, Frusciante, Le, Meyer, Bradshaw, Mukula, Morris, Blackman, Hu, Jia, Li, Koch, & Bangdiwala, 2003), and tricyclic antidepressants (Jackson, O'Malley, Tomkins, Balden, Santoro, & Kroenke, 2000), have been effective in treating functional gastrointestinal disorders (Jackson et al, 2000; Drossman et al, 2003; Tabas et al, 2004).

Findings of several studies show an impact on quality of life and an increase in psychiatric illness in patients with gastrointestinal disorders. However, data in each of these studies has been abstracted using surveys, questionnaires, and other quantitative methods. One review used looked at multiple studies in an attempt to determine the patient's perspective on functional gastrointestinal disorders and concluded that how the patient is able to function in their day-to-day lives is what matters most to the patient (Chang, Toner, Fukudo, Guthrie, Locke, Norton, & Sperber, 2006). A qualitative, phenomenological study exploring the lived experience of living with a chronic GI disorder might close the gap in the research and provide information to enhance future research and treatment goals.

Research Question

The research question is "What is the lived experience of individuals with chronic gastrointestinal disease?" The study will aim to explore all aspects of living with a chronic GI condition, such as symptoms, the diagnostic process, treatment, lifestyle changes, day-to-day functioning, and much more. The goal of the study is to derive rich data about living with a chronic gastrointestinal disorder from the participants' own stories and perspective.

Methodology

Design

The study design will follow Van Manen's method of hermeneutical phenomenology. Van Manen & Van Manen state that this method involves "reflecting on experience while abstaining from theoretical, polemical, suppositional, and emotional intoxications" (Van Manen & Van Manen, 2014). This method is most appropriate for this study because the principal investigator is proposing to study the phenomenon of the lived experience of having a chronic gastrointestinal disorder. The procedural steps will follow those delineated by Van Manen:

1. Turning to the Phenomenon – This involves orienting oneself to the phenomenon, formulating the research question, and becoming aware of one's assumptions and pre-understandings.
2. Investigating experience as we live it – This involves obtaining experiential descriptions from others, interviewing, observing, and reviewing experiential descriptions in the literature.
3. Engage in phenomenological reflection – This involves conducting a thematic analysis, interpretation through conversation, and determining essential themes.
4. Engage in phenomenological writing – This involves reflecting on the anecdotal evidence and writing conclusions to pass on the value of the evidence (Van Manen, 2007).

Step one, turning to the phenomenon will involve a thorough review of current gastrointestinal disorders and the related research on the topic of living with a

gastrointestinal disorder. Step two will involve data collection which will take place in the form of up to two unstructured interviews with each participant. The principal investigator will follow an interview guide (Appendix D), and each interview will last no more than 90 minutes. Each interview will be audio recorded and transcribed. The principal investigator will self-review the transcripts for accuracy. During step three, engaging in phenomenological reflection, the principle investigator will employ naïve and interpretive reading sessions after transcription of the interviews, in order to reach a concluding interpretation of the whole. Member-check will also be done during this step, which will involve conversations with the participants, gathering their thoughts on the principal investigator's conclusions and interpretations. Step four will involve writing the research report for submission to publication (Van Manen, 2007).

Sample

A sample of up to twenty-five participants will be recruited for the study, using the method of purposeful sampling and the principle of saturation. Participants must have been diagnosed with a chronic (greater than three months) gastrointestinal disorder, be willing to commit to up to two interviews, speak English fluently, and be over age eighteen. People with gastrointestinal disorders that are acute and who are symptomatic but have no official diagnosis, are unwilling to be interviewed, do not speak English fluently, and are 18 years or younger will be excluded from the study. There will be no exclusion based on gender or ethnicity.

Recruitment

Recruitment will begin after University of Texas Medical Branch (UTMB) Institutional Review Board (IRB) approval. Participants will be recruited through flyers (Appendix A) and referrals from other participants. Flyers will be placed in public places such as libraries, parks, fitness centers, and businesses with community bulletin boards. The flyer asks potential participants to contact the principal investigator by phone or email. If contacted by email, the principle investigator will request to set up a short phone conversation with the potential participant. During phone contact, the principle investigator will explain the study's purpose and protocols and determine whether the potential participant meets inclusion criteria. Participants will be selected among those who will be able to provide data that is relevant to the research purpose. Recruitment will continue until data saturation is achieved. Saturation is reached when no new information is gathered from the interviews.

Setting

Data collection will take place by phone, through videoconferencing, or in-person. The participant should be located in a place that is comfortable for the participant and which allows for privacy and minimal interruptions. If interviewing by phone or videoconferencing, this may be the participant's home. If in person, this will require renting a private room at a local library, to allow for privacy.

Data Collection

When a potential participant contacts the principal investigator and before data collection begins, participants will be given information about the study's purpose and protocols. They will be informed of institutional review board approval and their rights as a participant in the study, which include the right to withdraw at any time, and that they may choose not to answer any specific questions during the interview. During the initial contact period, potential participants will also be screened for inclusion and exclusion

criteria. If they meet study criteria and are willing to participate, then the principal investigator will arrange a separate time to complete the first interview.

On the day of the interview, the principal investigator will review the study protocols and the informed consent with the participant. Participants will sign the informed consent (Appendix B) if they choose to participate in the study. If the participant does not wish to sign the informed consent, then the interview will be immediately ended.

Study data will consist of demographic data, interviews, and field notes. Participant demographics, including their specific gastrointestinal diagnosis, will be recorded on a paper demographic form (Appendix C). In-person interviews will be tape recorded and phone and videoconference interviews will be recorded on the same electronic device. All interviews will be transcribed by the principal investigator. The principal investigator will take field notes during the session, noting the environment and participant's body language. All documents and recordings will be tagged with an individual code for each participant in order to protect personal information. Master list of participant IDs and original recordings will be locked at the home of the principal investigator.

Interviews will be unstructured, with the researcher following a general interview guide (Appendix D). Participants will be asked two main questions: "What it is like to have a chronic gastrointestinal disorder?" and "What kinds of changes in your life do you anticipate and/or experience as a result of your chronic gastrointestinal disorder?" The principal investigator will use follow-up questions and probes as needed to enrich the data collection.

If additional questions arise, the principal investigator will phone or email the participant to arrange a follow-up interview. There will be no more than two interviews for each participant. After completion of data collection, the participants will be mailed a gift card in the value of ten dollars.

Data Management

The researcher will make a duplicate of each interview audio recording. One file will be locked in the filing cabinet while the other file is being transcribed. Data will be transcribed by a professional transcriptionist. Accuracy will be checked at random by comparing sections of transcript with audio recordings. The transcriptionist will return audio file to the researcher.

All data will be de-identified and labeled with a participant number. Data such as demographic sheet, audio files, and transcripts will be stored in a locked filing cabinet. Participant list with identifying information will be stored in a separate locked cabinet.

Data Analysis

Data analysis will follow Van Manen's (2007) process of phenomenological reflection. This involves seeking meaning from the participant's words. The process begins by isolating potential thematic statements, which are rich data and lead to identifying themes. Each interview will be coded, which highlights key data pieces. These sections will be transferred to a separate document and grouped by potential themes. Some data pieces might fit multiple thematic categories. As each interview is added, these themes will change. Data analysis will begin at the completion of the first interview and will proceed through the end of the study. Based on multiple readings of each interview, the essential themes will be discovered.

Trustworthiness

To establish trustworthiness, the researcher will use Richards (2015) method of keeping a log trail. The steps of this method are:

1. Note the exact actions taken
2. At each step, record why it happened
3. Record relevant alternatives and why they were rejected
4. Record likely results and implications of the step

By keeping a detailed log trail, other researchers will be able to follow the logic of the process step by step. Readers will be able to determine if the researcher's conclusions in the research report are reasonably true.

Human Subject Protection

In order to protect the participants, the study will not proceed without Institutional Review Board approval from the University of Texas Medical Branch. Procedures to protect the safety of the human subjects include a detailed informed consent, with which the participants will be presented before each interview may begin. The informed consent will educate participants on the purpose and procedures of the study, the risks and benefits of participating or not participating, and the alternatives to not participating. Additionally, it will include information on the protection of their privacy. Risks include potential loss of confidentiality and risk of emotional distress during interviews.

Participant's privacy will be protected by using unique participant ID numbers for each human subject. No personal identifying information will be used on research materials. All audiotapes, transcripts, field notes, and demographic forms, will be coded with the individual participant ID number. Only the principal investigator will have

access to the list of participant names and coordinating ID number. Direct quotes used in the research report will be accredited to the participant ID number and will not use the participant's name. All research materials will be locked at the home of the principal investigator.

Implications

The proposed study is the first of its kind. To date, it is the only study that will review the lived experience of adults with chronic gastrointestinal disorders. This study has the potential to contribute greatly to the existing literature. It is expected that the research will reveal insights into the daily habits and coping skills that are used by adults with chronic gastrointestinal disorders. Additionally, the study is expected to show changes that this population has made to their lifestyle due to their condition and their treatment experience.

The study has implications for millions of adults around the worth who are living with chronic gastrointestinal disorders. Insights revealed may lead to new areas of research on potential treatments. At a minimum, the research will provide health care providers with a better understanding of the lived experience of chronic gastrointestinal disorders, which they can use to provide more empathetic care to their patients.

Strengths

The strength of this study is the psychiatric specialty background of the researching nurse. This training allows the nurse to provide attentive listening and appropriate probing questions, potentially gathering more detailed information than someone without this background. This broader perspective will allow the researcher to

interpret the data not only from the physical symptomology aspects, but also from the emotional, mental health features that accompany chronic gastrointestinal disorders.

Limitations

This study is limited by the small sample size yet large age and range of potential chronic gastrointestinal disorders. Results can be generalized to adults in the United States with chronic gastrointestinal disorders. However, it would be difficult to generalize results further to more specific groups.

Suggestions for Future Study

Based on the stated limitations, it is suggested that future research focus on subpopulations of adults with chronic gastrointestinal disorders. For example, studies should be done that center only on Crohn's disease or Irritable Bowel Syndrome. There should be studies with the population more focused on ages, such as the lived experience of adults age 20-29 or geriatric adults age 65 and older. It is expected that the lived experience of any chronic gastrointestinal disorder would be different in someone age twenty verses a geriatric age seventy.

Conclusion

In conclusion, the proposed study is needed to explore the lived experience of adults with chronic gastrointestinal disorder. There are millions of adults living with chronic gastrointestinal disorders throughout the United States. To date there is no study exploring their lived experience. Data collected will provide implications for future research. Data will benefit health care providers, who will use their greater understanding of this lived experience to provide more empathetic care to their patients with chronic gastrointestinal disorders.

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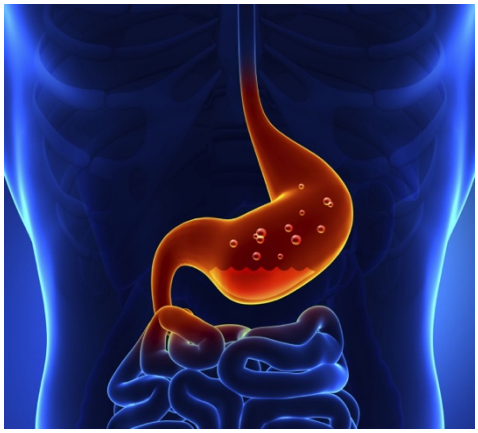
Appendix A

Recruitment Flyer

Do you suffer from stomach pain, nausea or vomiting, gas or bloating, and/or constipation or diarrhea?

Have you been diagnosed with a chronic gastrointestinal disorder?



I'd like to talk to you about your experience living with a chronic GI disorder.

I am a student associated with the University of Texas Medical Branch

A gift card of $10 value will be provided to those who complete the study.

Contact Kelsey at kgkent@utmb.edu or 423-506-9193 to participate!

Appendix B

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: The Lived Experience of Patients with Chronic Gastrointestinal Disorders

IRB Number:

Principal Investigator: Kelsey Kent, 115 Carriage Court, Brentwood, TN, 37027; 423-506-9193

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have identified yourself as living with a chronic gastrointestinal disorder that has been diagnosed by your healthcare provider.

What is the purpose of this research study?
The purpose of this study is to explore what it is like to live with a chronic gastrointestinal disorder and reveal methods that participants use to manage their condition.

How many people will take part in this study?
About 25 people will take part in this study.

What procedures are involved as part of this research study?
If you agree to take part, you will be asked to sign this consent form and complete the following procedures. You will be asked to complete a short demographic form and to participate in up to two interviews with the principal investigator, either by phone or in person, each of which will last no longer than 90 minutes. These interviews will be audiotaped and transcribed, and you will be given the opportunity to review the transcripts for accuracy. Direct quotes may be taken from the transcript to use in reports of the study, but your name and personal information will be kept confidential. All materials, including audiotapes, transcripts, and forms will be assigned an individual identification number so that your name and personal information cannot be directly linked to the materials. All materials will be kept in a locked safe.

What are the possible risks for choosing to participate in this research study?
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. There is also a risk of emotional distress during interviews.

What are the potential benefits for participating in this research study?
You will not directly benefit from your participation in this research project. By explaining the lived experience of having a chronic gastrointestinal disorder, this study will benefit society in that it will identify the patient's perspective and provide information to enhance future research and treatment.

Will I be reimbursed for participating in this research study?
There will be no reimbursement for participation in this study. A gift card valued at $10 will be provided as a token of appreciation for your participation in the study.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?

Yes. The researchers may decide to take you off this study if

- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.
- The researchers believe that participation in the research is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group. Although your direct statements may be quoted in the report, your name or other personal identifiable information will not be included in the report.

How will my privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Kelsey Kent, MSN, PMHNP at 423-506-9193 or, if after normal office hours, at kgkent@utmb.edu

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, at (409) 266-9475 or irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained

Printed Name of Person Obtaining Consent

Appendix C

Demographic Form

Participant ID: _____ Date: _____

Gender: ____ Male ___ Female

Age: _____

Ethnicity:

___ White or Caucasian ___ Black or African American

___ Asian ___ Hispanic

___ American Indian or Alaska Native ___ Native Hawaiian or Pacific Islander

City & State of residence: _____

Highest completed level of education: _____

What is your diagnosed gastrointestinal disorder? _____
Date of diagnosis? _____

Please list any other current medical or mental health conditions:
_____
_____
_____

Appendix D

Interview Guide

Participant ID: _____ Date: _____

Main Questions:

1. What is it like to have a chronic gastrointestinal disorder (insert participant's specific disorder here)?
2. What kinds of changes in your life have you experienced as a result of your (insert participant's specific gastrointestinal disorder)?
3. What has been your experience with treatment of your (insert participant's gastrointestinal disorder)?

Probing Questions:

Can you give me an example?

Could you tell me more about that?

Then what?

Appendix E

Expected Study Time Frame

Proposal editing and approval: 1 month

Recruitment and collection of data (up to 25 participants): 6 months

Transcription of Data: 1 month

Analysis of Data: 1 month

Dissertation writing time: 2 months

Dissertation defense, editing, re-defend if needed: 1 month

Total proposed time frame: 1 year

Appendix F

Proposed Budget

Travel Expenses: 2 Trips from Nashville to Galveston, TX for Defense	
Flights (2 for $250 each)	$700
Car rental (2 for $100 each)	$200
Hotel – 1 night per trip (2 for $100 each)	$200
Data Collection Expenses	
Tape recorders (2 for $30 each)	$60
Transcription fee ($1.40 per minute, 25 90-minute interviews)	$3,150
Participant gift cards (#25 for $10 each)	$250
Data Storage Expenses	
External hard drive	$70
Locked file cabinet	$70
Dissertation Editing fee ($1 per page, estimated 200 pages)	$200
Total:	$4,900