

Peer Health Coaching Intervention to Improve Patient Care and Shared Decision-Making Between Young Adult Patients with Inflammatory Bowel Disease and Their Health Care Team

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Abstract

Almost 25% of all new diagnoses of Inflammatory Bowel Disease (IBD) are made in childhood or adolescence, and the incidence rate continues to increase, which, accompanied by greater complexity and severity of the disease, have contributed to more young adults with IBD requiring care in adult gastroenterology settings (1, 2). Successfully addressing adaptive challenges, such as adhering to complex medication regimens and learning to navigate the adult health system is fundamental during this transitional phase into young adulthood. However, young adults often lack the skills of self-management and independent healthcare navigation to adequately communicate with their providers about their symptoms and their related life and health concerns. Interventions are needed for young adults with IBD to develop skills and knowledge to increase their adaptive capacity for navigating the process of shared decision-making with their healthcare team. A peer-based coaching intervention for young adults with IBD is a novel approach that utilizes an established telephone/text based secure interface to allow young adults with IBD to access the knowledge, experience, and instrumental and emotional guidance from a trained peer coach with the shared experience of living with IBD. The purpose of this study is to examine the feasibility, acceptability, and effectiveness of a peer health coaching intervention for young adults with IBD. This study will lead to further refinement and multisite testing of this intervention, which has the potential to be deployed across a range of settings to promote the development of shared decision-making and self-management skills among young adults with IBD.

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Background

The incidence of child and adolescent inflammatory bowel disease (IBD) diagnoses has risen, with one-fourth of diagnoses occurring prior to the age of 20 (3). Given the increased pediatric-onset of IBD, which is often more severe and complex compared to adult-onset counterparts (2), there has been greater emphasis placed on ensuring the health and well-being of young adult patients, 18-26 years of age (3-8). As children and adolescents transition into young adulthood, they are required to take on increasing responsibility to navigate multicomponent treatments that can include medications, laboratory testing, lifestyle modifications, and attendance at clinic appointments. In particular, this time presents high stakes for young adults in a period of particular health vulnerability, in which adherence lessens and disease complication risk heightens (9).

Young adults with IBD are at risk for a range of challenging physical, psychological, and social outcomes, such as growth failure or pubertal delay, that are associated with earlier-onset of their IBD diagnosis (2, 10, 11). Studies also describe challenges associated with living with IBD in adolescence and young adulthood, including depressive and internalizing disorders (10), fatigue (12), difficulty obtaining health insurance (13), self-image, and sexual health (14). Although this group demonstrates heightened disease severity compared to older adults, young adults generally miss more appointments (15) and utilize emergency services more frequently than other age cohorts (16). Less than half of adolescents and young adults with chronic conditions meet minimum standards of having a plan for their adult healthcare needs (17). Young adults with IBD, specifically, are at increased risk for poor medication adherence (8, 18). This is especially critical for young adults with IBD, in which literature suggests that non-adherence can be severely harmful. Adult patients with ulcerative colitis, for instance, who were non-adherent, demonstrated a five times greater risk for clinical relapse and 12.5 times greater annual healthcare cost compared to adherent patients (19). Becoming a successful young adult IBD patient requires skills in navigating the complex health system, mastering important self-management behaviors, navigating complex relationships with family, peers, and others, and advocating for oneself with healthcare professionals and auxiliary support. Gastroenterologists report that young adults are often unprepared to transition to adult care, citing lack of disease knowledge, medication regimen, self-advocacy skills, and care coordination (4, 6). Generally, patients who are more involved in their care are more satisfied and have better health outcomes (20-25). Young adult patients, however, struggle with developing the self-advocacy skills necessary to adequately understand, question, and collaborate with providers to ensure appropriate and value-based care. Shared decision making has been shown to promote patient adherence, satisfaction, well-being, and lower healthcare costs amongst IBD patients (26). While shared decision making requires an engaged provider and dedicated healthcare system, it also requires an active and engaged patient. One common barrier for young adults becoming more independent in the management of their care is overinvolved parenting (5). During this transitional period, young adults are becoming more independent and a parental shift from active decision-making agent to supporting ally is necessary to enable the young adult to thrive.

Theoretically guided interventions that target such barriers are needed to build the capacity of young adults to develop and implement self-management of their condition and self-advocacy skills that facilitate the shared decision making process. Peer health coaching is a potentially powerful intervention strategy to promote the active engagement of young adult patients with both their support team and provider.

A long-established pattern of findings in behavior therapy is the value of a peer support model for addressing fears, reservations, or attitudinal barriers to desired behaviors and has been found to increase engagement in health care, improve self-agency, effective coping strategies, and quality of life, and reduce psychological distress (27). Peer support programs, including peer health coaching models, have been used across many chronic conditions in adults and have been shown to provide both instrumental (helping people with concrete tasks) and emotional benefits (27). Health coaching has been shown to improve patient engagement for adults with type II diabetes (28), and a recent systematic review (29) revealed the efficacy of health coaching with IBD patients to promote treatment adherence, advice seeking from the healthcare team, quality of life, and satisfaction with one's healthcare provider. While shared decision-making aids and models exist, most focus on the provider side of the process; however, in the clinic setting, adult gastroenterologists often have minimal time to meet with patients and do not fully understand the unique needs and challenges of young adult patients (5, 8). Consequently, young adult patients need to be able to advocate for themselves to obtain value-based care, understand treatment protocol, and uphold a shared decision making model that is consistent with their level of understanding and maturity.

To address the challenges of engaging in the shared decision-making process, we propose to implement a peer-based health coaching intervention for young adult IBD patients. The coaching intervention is based on Deci and Ryan's Self-Determination Theory, which posits that the actualization of intrinsic motivation and innate human potential can be fostered through the development of competence (experiencing mastery of behaviors or skills), autonomy (having a sense of internal locus of control), and relatedness (being connected to others) (30), which in turn can result in positive health behavior change, increased engagement, and overall well-being. To move from a place of lack of motivation or inertia, young adults must identify their own goals and feel a sense of success in making change towards goals within a supportive environment. Health coaching is a patient-centric process that is based on health behavior change theory and involves goal-setting, the development of self-discovery and patient education, and provides accountability for changes in health behavior (31). Peer coaching elicits the young adult's vision of his/her optimal health, in addition to identifying values that underlie change behaviors. As patients identify a vision of their health and wellness and develop goals and actions steps to progress towards that vision, the peer health coach will elicit the patient's intrinsic motivation and activate skill development in self-advocacy and communication, which will in turn facilitate engagement in the shared decision-making process with their healthcare team. Our peer coaches undergo training in motivational interviewing techniques paired with a patient-centric approach to facilitate the realization of the young adult autonomy over their

own choices and lives. This framework models a shared decision making model, in which the patient learns how to take charge of their care while collaborating with their peer coach, which can then be translated to the patient-provider relationship. Through the peer health coaching process, the patient acquires self-efficacy and self-advocacy skills that facilitate an open dialogue with their healthcare providers, including having sufficient knowledge about their own condition, asking questions about symptoms and treatments, and collaborating with the healthcare team to make the best choices for their individual situation. The health coaching process utilizes a gradual and intentional shift in perspective and skill-building where the patient gains both the self-confidence and capacity to take a more active role in their care. The peer coach assists the patient to make this transition in care by guiding the identification and connection of long-term visions or health and wellness goals and short-term objectives. The coach then collaborates with the patient to move towards accomplishing those goals.

Overall Goal & Objectives

The purpose of this proposal is to enhance the shared decision-making process between young adult patients with IBD and their healthcare team by improving patient activation, self-management and healthcare navigation skills, self-efficacy, and emotional health and coping strategies through a mobile-based, peer health coaching intervention. Through semi-monthly, phone-based coaching sessions occurring over three to four months, the health coach will serve as a member of the healthcare team and will partner with the young adult patient to identify and reach short-term goals related to the course of their treatment, connecting treatment choices with the patient's long-term vision of their health and well-being. As a part of the healthcare team, the coach will serve as a clinical link to the patient's healthcare team by communicating with providers about the patient's concerns and challenges that should be addressed with making decisions about the patient's care. This goal will be addressed through two specific aims.

The first aim of this study is to evaluate the feasibility and acceptability of the peer coach intervention for young adults with IBD engaging in the shared decision-making process with their providers. This peer health coaching intervention has been pilot tested with 20 adolescent and young adult patients with various chronic conditions, including IBD. Patients and coaches reported that the pilot health coaching intervention was acceptable and noted that the mobile-based platform facilitated engagement in the intervention. This proposal will determine the feasibility of the health coaching intervention as a part of adult and pediatric, hospital-based gastroenterology clinics. Patient, coaches, and providers will assess the acceptability of the intervention within the clinic's practice as a part of the shared decision-making process.

The second aim of this study is to assess the impact of the coaching intervention on the shared decision making process, patient activation, self-management and healthcare navigation skills, self-efficacy, and emotional health and coping strategies. Findings from the pilot study show clinically significant patterns of improvement in healthcare engagement and self-efficacy. The proposed project will focus solely on young adult patients with IBD and examine the

effectiveness of this intervention on the shared decision-making process within busy hospital-based gastroenterology clinic setting.

Current Assessment of need in target area

For the past four years, our study team has been working across Duke Health to better understand the challenges facing young adult patients and their families. We have started a multi-disciplinary Transition Taskforce, worked with dozens of high school and college students and parents through a peer group mentoring program, and over the past two years have built a multidisciplinary transition clinic which has involved youth peer coaches as a part of the healthcare team. We have identified that many of our young adult patients with chronic conditions disengage from the healthcare system, resulting in poor health outcomes, and many families struggle to figure out how best to support the young adult during the tumultuous transitional period. This prior work informs our proposed innovation to deploy an intervention to support young adults with IBD to engage further in their healthcare and decision-making processes.

Over the past year with the support of a grant from the Department of Pediatrics we have pilot tested the Transition Peer Coach program for adolescents and young adults with chronic conditions, including IBD. Our work for the past year included developing a curriculum for the transition peer coaches and developing a training program for peer coaches that utilizes motivational interviewing and health behavior change theory. We have also made significant progress in developing the mobile health infrastructure of the coaching intervention. We have worked with a peer-mentoring technology company to tailor their Mentor1to1™ platform software to securely facilitate the smartphone-based peer coaching process, integrating our curriculum into the interface in a way that ensures institutional compliance and security. This pilot program has been well-received by participants, and participating clinics has expressed a need to further extend the capacity of this program.

Duke Health cares for over 200 young adult patients with inflammatory bowel disease each year. Similar to other young adults with chronic conditions, young adults with IBD seen at Duke face challenges during this transition phase that are largely adaptive, such as adhering to complex medication regimens, learning to navigate the adult health system, and communicating with their providers. Adding to this complexity is the need for young adults to progressively take over greater self-management responsibilities from parents as they transition from pediatric- to adult-based care systems. Promoting self-management and taking on an active role in the decision-making process with their providers is critically important given that this shift in health care management from parents and health care providers to the young adult is identified as key to successful outcomes throughout adulthood (32, 33). Recently, Duke's gastroenterology clinics joined the Improve Care Now collaborative network, and through participation determined that young adult patients would benefit from psychosocial assessments and follow-up services through the clinics. In addition, there is no existing mechanism for tracking the shared decision-making process and communication efforts from

providers or patients. Currently, in Duke's gastroenterology clinics, providers lack sufficient time during their appointments to address the psychosocial needs of their young adult patients and thus focus on addressing and educating patients about the medications and their related side effects. Providers have noted that patients and their families would benefit from an intervention that can facilitate broader discussions about the impact of IBD on the patient's overall life, which can then inform the shared decision-making process. Young adult patients who learn self-management and communication skills through the health coaching intervention will then self-advocate and ask questions of their providers that will assist in making the choices that fit the needs and concerns of that particular patient.

Target Audience

Potential participants will be primarily recruited through Duke's pediatric and adult gastroenterology clinics, led by the collaborative investigator on this project, Dr. Nancy McGreal. At Duke Health Systems, adolescents and young adults transfer from pediatric to adult care at different ages, depending on their individual needs and circumstances, thus it is important to collaborate with both clinics to recruit young adults with IBD. As a collaborative investigator on this project, Dr. McGreal is committed to assisting with identifying potential participants and coaches and supporting and communicating with coaches throughout the study. Potential participants will also be recruited through Duke's peer support program, Adolescents Transitioning to Leadership and Success (ATLAS), led by the PI for this proposal, Dr. Gary Maslow. The ATLAS program is a peer mentoring program based at Duke University that brings together high school students with childhood onset chronic illness and college student mentors, also with chronic illness. The program has been ongoing at Duke for the past seven years. The group meets monthly for dinner and participants follow a curriculum that goes through self-management and health-care navigation skill development. The ATLAS program leadership is fully supportive of identifying potential participants and coaches for this study.

We will enroll 160 young adults from the Duke pediatric gastroenterology clinic, the adult gastroenterology clinic, and the ATLAS program. Each program reviewed their lists of young adult patients with IBD and reported a total of approximately 250 young adults who would be eligible to participate in this project. Our study staff will coordinate with the providers in the gastroenterology clinics by reviewing electronic health records for patients attending the clinics and determining eligibility to participate. Those patients and families who are eligible will be invited to participate in the study.

Because young adults face particular challenges that inhibit the shared decision-making process with providers, this population is ideal for targeting an intervention that supports and facilitates the development of healthcare navigation and self-management skills. Young adults with shared experiences serve as a resource for identifying areas of need or concern for the participant and then determining action steps to move towards understanding their condition and its impact on their lives as well as how to communicate with their providers to foster a partnership when determining options and making decisions. For this study, the target sample

size of 160 young adults (80/arm) will be sufficient to provide reliable estimates for effect sizes for each quantitative outcome of interest. Additionally, the projected sample size will provide at least 80% statistical power if a medium to large effect size is observed.

Young adult patients (18-26 years of age) with IBD will be the direct beneficiaries of the peer health coaching intervention. Through this intervention, they will receive a supportive framework through which they can develop skills related to self-management, self-efficacy, coping, and communicating with their healthcare team. While this will provide direct and immediate benefit to the shared decision-making process with their current providers, these skills can also be applied throughout their adult experiences navigating the healthcare system. Providers and Duke clinics will also benefit from a more informed patient population, including young adult patients who are more engaged in the health care decision process. Because the shared decision-making process consists of the patient as well as the provider, interactions with patients who are engaged in their healthcare decisions may indirectly influence how providers communicate with their patients. Thus, this intervention and its impact on providers will help change the culture of the clinics, and other patients who are not study participants may benefit from a clinic culture that is more receptive to patient involvement in treatment decisions and discussions.

Given the mobile-based nature of the peer health coaching intervention, other young adult patients with IBD could also receive this intervention and its benefits, regardless of where they receive their healthcare. This intervention is not restricted by geography or clinic capacity, therefore all young adults with IBD could benefit from this intervention. In the future it could be deployed broadly in settings where young adult IBD patients receive care.

Project Design and Methods

This randomized controlled clinical trial (RCT) will evaluate the feasibility of a three-month peer coaching intervention using mobile based communication and determine the acceptability for young adults with IBD using a pilot RCT to compare the intervention group to an education-only comparison group. Acceptability of the intervention for coaches and Pediatric and Adult Gastroenterology providers will also be assessed. The second aim of this proposal is to determine the impact of the coaching intervention on the shared decision-making process. We will also determine the impact of the coaching intervention on the shared decision-making process for young adults with IBD through: patient activation; self-management and healthcare navigation skills; self-efficacy; and emotional health and coping strategies.

Evaluation of recruitment rates and individual interviews will assess the feasibility and acceptability or level of engagement of this intervention. Changes to shared decision-making competencies and all secondary outcomes among young adults will be measured through electronic surveys completed by participants at baseline, end of intervention (3 months), and three-months after completion of intervention (6 months). The intervention involves semi-monthly calls over three months using a novel multimedia interface to facilitate communication between participants and peer health coaches who have the shared experience of living with

IBD and who have been trained in coaching techniques. Coaches support participants through assessment of individual needs and goals, exploration of vision and values, and motivational and behavior change strategies. We will enroll 160 young adults between 18-26 years of age who will be randomized to receive the health coaching intervention (N=80) or comparison condition (N=80).

Research Team and Preliminary Studies. This project is feasible because of the expertise of our multidisciplinary team of nurses, physicians, psychologists, a supportive environment, and our experience developing a peer coaching intervention for youth with chronic conditions, including IBD, who are transitioning into a leadership role in their own health care and developing negotiation and communication skills. We have experience recruiting AYA with chronic conditions (including IBD) and their parents, to participate in several prior studies. Dr. Maslow has successfully recruited AYA with chronic conditions, including IBD, across two studies: (1) Positive Development for Youth with Chronic Illness (John Templeton Foundation, Maslow-PI) studied development among 400 AYA and their parents, (2) Evaluation of a Positive Youth Development Program for Adolescents with Chronic Illness (Rhode Island Foundation, Maslow-PI) which examined the experience of adolescents with chronic conditions participating in a peer support program and demonstrated short-term improvements in health care self-advocacy. Dr. Docherty successfully recruited parents of children with chronic conditions in a study of parent and provider decision making (1R01NR010548, Docherty-PI), as well as a study of parent adaptation to caregiving for children undergoing stem cell transplantation (R15 NR009041, Docherty-PI). Dr. Docherty recruited AYA in a multicenter RCT (R01 NR008583, Haase-PI) testing the efficacy of a music intervention for increasing resilience, quality of life, coping and decreasing distress in AYA with cancer.

Drs. Docherty and Maslow have been collaborating on studies of children and AYA with chronic conditions and their families for over a decade (34-36). Bringing her expertise in health coaching, Dr. Pollock has joined our investigative team over the past two years on a pilot RCT study of transition coaching for AYA with chronic conditions (Duke Center for Nursing Research Pilot Award, Docherty/Maslow-Co-PIs). Preliminary analysis of this mixed-methods, wait-list control group design to provide a 3-month peer coaching intervention to enroll 18 AYA (25 enrolled) with cancer, lupus, sickle cell disease, and inflammatory bowel disease, indicate increases from baseline in transition readiness, patient activation, self-regulation, and hopeful future expectations. The qualitative data indicate that AYA felt supported and were more confident as they continued along the trajectory of transition. Participants noted that the coaching intervention provided emotional support while also enhancing confidence in their ability to move forward with their lives as young adults with a chronic condition. The five young adult coaches who were also studied in this pilot, completed an adapted Integrative Health Coach training program (Duke Integrative Medicine) prior to serving as coaches for this study.

Sample and Recruitment. We will enroll and randomize 160 young adults from the Duke Pediatric Gastroenterology Clinic, the adult Gastroenterology Clinic, and the Adolescents Transitioning to Leadership and Success (ATLAS) program. Each program reviewed their lists of young adult patients with IBD and reported a total of approximately 250 young adults who

would be eligible to participate in this project. Our study staff will coordinate with the eight providers in the Gastroenterology clinics by reviewing electronic health records for patients attending the clinics and determining eligibility to participate. Those patients and families who are eligible will be invited to participate in the study.

A permuted block randomization (block size of 4) will be used to randomly assign the 160 young adults to one of two treatment arms: health coaching intervention or comparison arm with educational resources only (n=80/group). Inclusion criteria for young adults: ages 18-26 years; history of a diagnosis of Crohn's disease or ulcerative colitis; have access to a computer and internet, and cell phone or land-line; read and understand English; live in the US; absence of a cognitive disability that would limit ability to give informed consent.

Recruitment plan. Directors of the gastroenterology clinics and ATLAS program will perform proactive outreach to eligible patients to ensure that all eligible persons are aware of the study. Clinical research coordinators (CRCs) will conduct daily EHR screening of AYA being seen at the programs/clinics described above. Health care providers will introduce the study to patients. Enrolled participants will then be randomized to one of the two experimental groups (coaching for young adult and young adult's parent or coaching for young adult only) or the education resource only comparison group by the study statistician. CRCs will inform participants of randomization arm and then move forward with scheduling the intervention or educational resources.

Individuals who are 26 years or older and have been a patient with Crohn's disease or ulcerative colitis for at least five years will be eligible to apply to be young adult health coaches. We anticipate coaches will be recruited through referral by gastroenterologists at Duke or by the ATLAS Program Director. Coaches will undergo informed consent for participation as described in the human subjects section and will be selected for maturity, conscientiousness, overall interest in the program, and willingness to devote time.

Intervention:

Coaches: Six young adult peer health coaches will be hired as part-time Duke employees and receive training using the health and wellness coaching training designed and previously tested by the study team. Each young adult peer health coach will be paired with 12-14 participants in the experimental group over the two-year grant period. Pairings will be made by the study team and will be based upon scheduling availability.

Training/supervision: Training is composed of a two-day orientation and ongoing semi-monthly to monthly supervisory sessions. Training content includes a review of the coaching framework including the Self-Determination Theory, motivational interviewing techniques and information about health behavior change. Training sessions focus on the coach-participant relationship and use of motivational interviewing techniques to incorporate an interactive approach. Various role playing sequences are used throughout the training program to provide coaches with the opportunity to test skills they have learned. Semi-monthly supervisory sessions will be conducted with coaches and leadership staff at a Duke Hospital facility for continued education

and support. Supporting patients with a similar condition as oneself can be emotionally distressing at times, and both Gary Maslow, MD who is a licensed pediatrician and pediatric psychiatrist, and McLean Pollock, LCSW who is a licensed clinical social worker, can consult and refer coaches experiencing problems.

InquisitHealth Mentor 1:1™ Web Based Portal: Coach and participant interactions will occur using telephone and a peer-support interface, designed by InquisitHealth and deployed commercially across multiple settings for peer support. This informatics technology interface has been used successfully in a preliminary study for youth with chronic condition, as well as for adults with chronic conditions (37). Through the software interface, the participant and coach arrange a time to speak semi-monthly for three to four months, allowing for six to eight coaching sessions. They can exchange in secure communication via phone and text messages, and coaches can send them monthly educational newsletters. The coaches will track participants' progress over time using the InquisitHealth web-based software. This database includes progress on key health behaviors discussed and notes the coaches submit after each session.

Intervention approach/content: The coaching intervention is flexible and tailored to the individual needs of the young or parent. The focus of the intervention is on four specific domains relevant to the shared decision-making process: patient activation; self-management and healthcare navigation; self-efficacy; and emotional health and coping strategies. Each of these domains has specific sub-behaviors that focus on behavior goals. For example, healthcare navigation includes the sub-behavior of interaction with medical providers, planning for appointments, and becoming the "CEO" of one's healthcare team. Prior to starting coaching, each participant completes an intake interview with a project coordinator who reviews the domains and sub-behaviors. Participants identify specific sub-behaviors to focus on with their coach. After the intake interview, the project coordinator uploads the participant's chosen domain and sub-behavior to the Mentor 1:1 interface and assigns a coach to the participant. The coach is then sent an automated email from the software indicating he/she has been assigned a participant. The summary of the participant's intake interview with the domain and sub-behavior of choice is also included.

Using the software, the coach and participant schedule the first call. This call is an opportunity for the coach to establish rapport with the participant and review the goals selected. In general, calls last 20-30 minutes. During the first call, the coach and participant would have the opportunity to learn about one another's experiences with IBD. During subsequent calls, the coach focuses primarily on the specific sub-behavior elected by the participant. The coaching process model described above helps the coach guide behavior change, beginning with assessing the participant's vision for the future, establishing focus, readiness to change, and then pursuit and maintenance of identified goals. As goal progress is made, the coach and participant work to identify a new goal, or if there is not progress, they discuss barriers to progress and strategies, with an option to move on to another goal. Between sessions the coach and participant can exchange text messages including an update on progress towards a

goal. At the end of the intervention the final call involves an opportunity for closure and for the coach and participant to review progress on goals and future steps.

Over three months the education-only comparison group participants will receive a monthly electronic newsletter with educational content about IBD and a monthly phone call from study staff to ensure receipt of the newsletter and to answer questions regarding content, and an opportunity to link them to other resources. These resources will be based on materials used in the Duke Gastroenterology Clinics regarding living with IBD, including types of medications and treatments available, information about one's condition and related anatomy and symptoms, prompts to use when requesting additional information from healthcare providers, and a list of strategies for keeping one's healthcare team informed (38). If participants report health concerns they will be directed to contact their health care team.

Data collection: Participants will enter data via a secure, HIPAA-compliant, REDCap database housed on a Duke server (39) [please see Table 1. Measurements Timeline below]. Data entry will be completed through a tablet computer, computer or smartphone at baseline, three months and six months follow-up. Study interviews will be completed by participants of both the intervention and comparison groups at baseline and three months or end of the coaching intervention. Coaches and providers who choose to participate will also be asked to participate in interviews at baseline and 18 months after the coaching interventions begin. Data will also be captured from Mentor 1:1 interface including call times, call recordings, and text-message exchanges.

Outcome assessment

Aim 1: The first aim of this study is to evaluate the feasibility and acceptability of the peer coach intervention for young adults with IBD engaging the shared decision-making process with their providers.

Process assessments of the feasibility, acceptability, and fidelity will include both qualitative and quantitative data. Assessments of feasibility and fidelity will be facilitated through the InquisitHealth Mentor 1:1 platform, which allows for the systematic tracking of phone- and text-based interactions. Since all calls are facilitated through the platform, the system automatically tracks call length and frequency, and records these interactions.

Feasibility will be assessed by examining recruitment success, participant attrition, and engagement. Participant engagement will be quantified by the number of contacts and average length of contacts per week. These two measures will be aggregated and plotted for the participants in the intervention group. Feasibility will also be assessed through semi-structured focus groups with the coaches and providers, which will examine areas of strength and improvement of the intervention from their perspectives. Together with the qualitative analyses of the calls and text messages, these data will allow us to isolate particular periods of time, age, or condition-related factors, such as diagnosis or type of treatment, which promote or obstruct participant engagement. By collecting and examining these data bi-monthly, we will

be in a position to investigate the cause of sudden changes in engagement and discover solutions for future implementations of the intervention.

Acceptability will be assessed using post-intervention semi-structured interviews conducted with participants and coaches to explore their experience with the intervention. Fidelity will be assessed by examining participant engagement and content of the call recordings (40). Participant engagement will be evaluated through the post-intervention interview and by aggregated number of contacts and length of contact time for the coaches. These data will be broken down by periods of time, age, and condition-related factors. This will allow us to assess the extent to which participants are engaged in the coaching process and to explore the reasons for increases or decreases in engagement prior to the end of the pilot phase. This will be performed bi-monthly by the study team so that adjustments to the content/direction of the calls and text messages may be made by the coach at the subsequent call. A log will be kept of these assessments and any subsequent adjustments. At the end of the study, call recordings will be examined using content analysis to refine the study.

Aim 2: The second aim of this study is to assess the impact of the coaching intervention on the shared-decision making process, self-management and healthcare navigation skills, self-efficacy; and emotional health and coping strategies.

Outcome assessments. We will use the following concepts as outcome assessments at baseline, 3 months, and 6 months to examine the effect of the coaching intervention on: (a) the shared decision-making process; (b) patient activation; (c) self-management and healthcare navigation; (d) self-efficacy; and (e) emotional health and coping strategies. (a) The shared decision-making process will be assessed using the Shared Decision-Making Questionnaire (SDM-9). The SDM-9 is a 9-item instrument that measures the shared decision-making process from the patient's perspective (41). (b) Patient activation will be examined through the Patient Activation Measure (PAM). The PAM measures patient activation through self-reports of knowledge, skills, and confidence related to self-management of one's own health care (42). (c) Self-management and healthcare navigation will be assessed by the Transition Readiness Assessment Questionnaire (TRAQ). The TRAQ measures the young adult's self-management and health care navigation capability by examining medication management, appointment management, tracking health issues, communication with one's healthcare team, and managing daily activities (43). (d) Self-efficacy, or a person's belief in their ability to handle challenges or difficulties, will be assessed by the General Self-Efficacy Scale, a 10-item scale that assesses overall self-efficacy (44). (e) Emotional health and coping will be assessed using the abbreviated Brief Symptom Inventory (BSI) and the Response to Stress Questionnaire (RSQ). The BSI is an 18-item measure of overall psychological distress and three subdomains: somatization, depression, and anxiety (45). The RSQ contains a checklist of stressors that pertain to a specific condition and coping responses and has been validated with children and adults regarding their own personal coping and involuntary stress responses (46).

Outcome	Measures	Study Entry/ Baseline	Three months follow-up/end of intervention	Six months follow-up	18 months	Instrument Description
Shared Decision-Making	SDM-9	Young Adult	Young Adult	Young Adult		Shared Decision-Making Questionnaire-9: 9-item
Patient Activation	PAM	Young Adult	Young Adult	Young Adult		Patient Activation Measure: 22- item
Self-management/ healthcare navigation	TRAQ	Young Adult	Young Adult	Young Adult		Transition Readiness Assessment Questionnaire: 20-item
Self-efficacy	GS-ES	Young Adult	Young Adult	Young Adult		General Self-Efficacy Scale: 10-item
Emotional health	BSI	Young Adult	Young Adult	Young Adult		Brief Symptom Inventory (adults): 18-item
Coping Strategies	RSQ	Young Adult	Young Adult	Young Adult		Response to Stress Questionnaire: 57-item
Feasibility	Recruitment rates and call frequencies, duration, & content	Mentor 1:1 platform	Mentor 1:1 platform	Mentor 1:1 platform		Enrollment log will track recruitment and enrollment rates; Mentor 1:1 will track data on coaching calls
Acceptability and patient engagement	Qualitative Interviews/ Focus Groups	Young Adult, Coach, Provider	Young Adult		Coach, Provider	Semi-structured individual interview focused on acceptability and user experience with intervention.

Protection of Human Subjects

Recruitment: This proposed project will include 160 young adults with IBD. We anticipate that the young adults will be aged between 18 and 26 years at the time of recruitment. We will also collect data from the six peer coaches and eight providers from the pediatric and adult gastroenterology clinics. Young adult participants will be recruited from our partner clinics/programs as described above. After the provider has introduced the study to the eligible participant, the clinical research coordinator (CRC) will arrange an information meeting and go through process of informed consent as detailed below. Recruitment will involve direct outreach via letter from our partners as well as the CRC monitoring clinic lists to identify eligible patients. This activity will be approved under the IRB. Coaches and providers will be approached by study staff and asked to participate in this pilot study. They will have an opportunity to ask and have questions answered. If they are interested they will be asked to give verbal and written consent.

Human subject involvement - The study will be reviewed and monitored by the Duke University Institutional Review Board. Procedures will be followed to ensure that young adults adequately participate in informed consent, this will include meeting in a private room and opportunity for all eligible participants to ask questions. Study participants will be asked to give written and verbal consent. This study has not yet been approved by the IRB, however a similar study

following the same protocol was approved. The study timeline includes time for the IRB review as part of the two year grant period.

Potential risks to subjects. Participation in the proposed research study involves minimal risks. Participants may feel uncomfortable answering some questionnaires and may skip those questions. However, no serious adverse effects are expected from completing the study documents.

Procedures to minimize risk: Every reasonable effort will be made to ensure confidentiality by properly following best practices for data security and implementing standardized operating procedures. To minimize risks to confidentiality, data will only be monitored by the Principal Investigator, Dr. Gary Maslow, and trained research staff who have proper authorization denoted on the study's Signature and Delegation of Responsibility Log to view study records. At a minimum, research staff will have completed the 1) Collaborative Institutional Training Initiative (CITI) Biomedical Research Basic Human Subject Research Curriculum, 2) CITI Vulnerable Subjects- Research Involving Children modules, and 3) Duke Human Research Training. Coaches, who serve as an extension to the clinic team, will disclose all information to the program medical director, Dr. Gary Maslow, MD, who is a licensed pediatrician and child psychiatrist. Dr. Maslow will manage any clinical issues encountered during the study.

Evaluation Design

The data for this evaluation will include primary data collected from participants directly using electronic surveys and qualitative interviews or focus groups. Patient engagement will also be assessed through primary data collection through the coaching platform.

Participants will complete the study surveys via a secure, HIPAA-compliant, REDCap database housed on a Duke server (39). Data entry will be completed through a tablet computer, computer or smartphone at baseline, three months and six-months follow-up. Study interviews with participants at baseline and three-months follow-up and study interviews with coaches and providers at baseline and 18-months follow-up will be recorded using Audacity software, which is stored on a secure server and analyzed using Thematic Framework Analysis. Data on acceptability and patient engagement in the coaching intervention will also be captured from Mentor 1:1 interface including call times, call recordings, and text-message exchanges.

The quantitative data will be evaluated using SAS statistical software. Non-directional statistical tests will be performed with the level of significance set 0.05 for all tests. The significance level will not be adjusted for the multiple outcomes and tests as we explore the set of young adult outcomes. The specific methods to test for treatment arm differences in these outcomes are described below. Additionally, effect sizes and their 95% confidence intervals will be estimated.

Intention-to-treat analyses will be conducted, and completers analyses will be performed as a supplemental analysis. Imputation methods for missing data will be applied as needed. Age of the participant, age of the coach paired with the participant, condition-related factors, and other baseline characteristics will be evaluated as potential covariates in the analysis. However,

it is expected that the randomization method will balance the two arms with regard on baseline participant and coach characteristics and covariates will not be required. Secondly, a trajectory analysis approach comparing the two treatment arms will be conducted on outcomes collected at baseline, month 3, and month 6 (see Table 1). It is hypothesized that the intervention group will have a greater improvement in the outcomes over time (baseline, 3 months, and 6 months). The trajectory analysis will be conducted using random coefficients regression models for repeated measurements (a type of hierarchical mixed effects model for longitudinal data), and will be used to estimate and compare the direction and rate of change each outcome over the six-month period in the two arms. Fixed effects will be treatment, time, and treatment-by-time interaction, randomized effects will be participant and participant-by-time. The data will be evaluated for non-linear temporal effects, and the assumption of missing at random (MAR) will be checked. A priori contrasts will be performed to compare the treatment arms at each of three assessment points.

Statistical Power. The target sample size of 160 young adults (80/arm) will provide reliable estimates for effect sizes (direction and magnitude of effect) for each quantitative outcome. A sample size of 80/arm will provide at least 80% statistical power if a medium to large effect size is observed (Cohen d equivalent of 0.43 or larger). Based on our preliminary findings, we expect an attrition rate of less than 5%. For continuous outcomes (shared decision-making, patient activation, self-management/healthcare navigation, self-efficacy, and emotional health and coping strategies), a 15%-20% improvement in scores is expected in the intervention arm relative to no change in the comparison arm. The expected changes in outcomes suggest that small to medium clinically meaningful effects will be observed, and the study may not be adequately powered to detect treatment differences. Thus, although we will perform statistical significance testing, we focus on reporting and interpreting effect sizes and their 95% confidence intervals.

The health coaching intervention to enhance shared decision-making can be disseminated broadly across geographic areas given the mobile-based technology that facilitates the program. Because this intervention does not rely on face-to-face interactions with coaches, clinics across the state and nation can access coaches to support any of their patients who have access to a phone. Since almost all young adults have a mobile phone and almost 90% have a smartphone (47), this will not be difficult to deploy.

Detailed Workplan and Deliverables Schedule

The overall objective of this proposal is to deploy the peer health coaching program for young adults with IBD in order to enhance the shared decision-making process. This project will take place over two years in order to customize the intervention, evaluate the feasibility, acceptability and effectiveness of the intervention, and examine areas for refinement in order to disseminate this intervention to other hospitals and clinics [Please see table 2 below].

Year 1

During the first year, the team will also submit our application to approve human subjects research under this study from Duke's IRB. The preliminary pilot test of this intervention was approved by the IRB. During this time, our team will also focus on the initial customization and

deployment of the intervention. This will consist of customizing the InquisitHealth Mentor 1:1 platform to incorporate the needs and goals of young adults with IBD. Goals to enhance the shared decision-making process for young adults will be divided into four categories: (1) Patient activation; (2) Self-management and healthcare navigation; (3) self-efficacy; and (4) emotional health and coping strategies. Next, potential coaches will be identified by the ATLAS program and gastroenterologists at Duke. Both programs have helped with recruiting coaches for the pilot study and are familiar with characteristics of a successful peer health coach. After hiring the six peer coaches as part-time (0.25 FTE) Duke employees, coaches will receive an initial training on health behavior change and motivational interviewing and active listening skills development. Coaches will be provided opportunities to practice their new skills during this training and during the ongoing training and supervision provided throughout the span of this project. Halfway through the first year, we will invite gastroenterologists at Duke to participate in a semi-structured interview to assess the existing practices and perspectives about shared decision-making with young adults with IBD. Coaches will also be asked to participate in pre-intervention interviews to examine their perceptions about the existing role of young adults in the shared decision-making process and their own experiences with and perspectives about this process. During the same time, we will begin recruitment of study participants. As young adults are recruited, they will be enrolled in the study and randomized to the intervention or comparison group and then begin study assessments. Participants who are randomized to the health coaching intervention will be assigned to a peer coach and then begin their three/four-month coaching intervention. This process will continue through the second year until the project is complete.

Year 2

During the second year of the project, coaching training and supervision will continue, along with study recruitment and data collection and the study intervention. Near the end of the second year, providers will be asked to participate in a follow-up interview, re-assessing their perspectives and experiences with the shared decision-making process. Coaches will also be asked to participate in a follow-up interview to examine their perspectives about the health coaching intervention and perceived impact. After all study data are collected, the team will begin analysis of the dataset and report these findings in a final report. Results from this study will also be reported and published in peer reviewed journals and presentations for grand rounds and other conferences where clinics and providers can learn about this novel intervention.

