


Remote Between Visit Monitoring in Inflammatory Bowel Disease Care: A Qualitative Study of CAPTURE-IBD Participants and Care Team Members

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Introduction: We recently showed that CAPTURE-inflammatory bowel disease (IBD)—a care coordination intervention comprised of routine remote monitoring of patient-reported outcomes (PRO) and a care coordinator-triggered care pathway—was more effective at reducing symptom burden for patients with IBD compared to usual care. We aimed to understand how patients and care team providers experienced the intervention and evaluate purported mechanisms of action to plan for future implementation.

Methods: In this study, 205 patients were randomized to CAPTURE-IBD (n = 100) or usual care (n = 105). We conducted semi-structured interviews with 16 of the 100 participants in the CAPTURE-IBD arm and 5 care team providers to achieve thematic saturation. We used qualitative rapid analysis to generate a broad understanding of experiences, perceived impact, the coordinator role, and suggested improvements.

Results: Findings highlight that the intervention was acceptable and user-friendly, despite concerns regarding increased nursing workload. Both participants and care team providers perceived the intervention as valuable in supporting symptom monitoring, psychosocial care, and between-visit action plans to improve IBD care and health outcomes. However, few participants leveraged the care coordinator as intended. Finally, participants reported that the intervention could be better tailored to capture day-to-day symptom changes and to meet the needs of patients with specific comorbid conditions (eg, ostomies).

Conclusions: Remote PRO monitoring is acceptable and may be valuable in improving care management, promoting tight control, and supporting whole health in IBD. Future efforts should focus on testing and implementing refined versions of CAPTURE-IBD tailored to different clinical settings.

Lay Summary

In a randomized study, patient-reported outcomes (PRO) monitored remotely and routinely, were acceptable to inflammatory bowel disease (IBD) patients. Study findings indicate routine remote PRO monitoring may be valuable for improving care management, promoting inflammation control, and supporting whole health in IBD.

Key Words: remote monitoring, digital health, self-management, proactive care

Introduction

An estimated 3 million Americans live with inflammatory bowel disease (IBD), a chronic gastrointestinal disorder that frequently leads to disability, high symptom burden, and poor quality of life.^{1–3} Despite the availability of effective therapeutics, up to 30% of patients with IBD experience a flare each year and 10% are hospitalized in their lifetime.^{4,5} Patients with IBD require proactive care to detect early inflammatory changes, optimize IBD-directed treatment, and

prevent IBD-related complications.⁴ However, most IBD management occurs between office visits, requiring patients' active participation in their care.^{4,6}

Patient-reported outcomes (PRO) have become an effective means for engaging patients in their care and facilitating patient-clinician communication.^{7,8} We, therefore, created CAPTURE-IBD (Clinical coordination And intense Proactive symptom monitoring To improve Utilization of Resources and reduce Expenditures in high-risk IBD patients), a care

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coordination intervention comprised of remote risk-targeted monitoring of IBD-specific PROs and a care coordinator-triggered care pathway algorithm.^{9,10} We showed that CAPTURE-IBD was more effective at reducing symptom burden for patients with IBD at the highest predicted risk for healthcare utilization, as compared to usual care in a randomized design.¹¹ While remote PRO monitoring has the potential to reduce symptom burden, it is critical to assess patient and provider perspectives on the utility and acceptability of this approach. Therefore, using these qualitative interview data, we aimed to evaluate patient and clinician perspectives on CAPTURE-IBD and its components of remote PRO monitoring and a care coordinator-triggered algorithm. We also aimed to better understand the intervention's purported mechanisms of action.

Methods

Study Population

Adult patients 18–90 years old who carried a diagnosis of IBD, who was seen in the gastroenterology clinic at a tertiary referral center within 1 year prior to enrollment, and who were considered high-risk (ie, in the top quintile) for future healthcare utilization and costs were identified and enrolled in CAPTURE-IBD between April 2019 and January 2020. Patients were excluded if they had a non-IBD driver for high utilization; diagnosis of severe renal, hepatic, hematological, non-IBD gastrointestinal, metabolic, endocrine, pulmonary, cardiac, neurological disease, or cancer; an anticipated or recent solid organ or bone marrow transplant within 1 year; or if they were residing in a long-term care facility.

Overall, 205 patients met inclusion criteria and agreed to participate in the CAPTURE-IBD study.¹¹ Among these, 100 participants were randomized to the CAPTURE-IBD intervention in addition to usual care, and 105 participants were randomized to usual care only. We conducted post-intervention semi-structured interviews with a sample of study participants who were randomized to the active portion of the intervention. These participants were purposefully sampled to include participants with low and high adherence to the study protocol and PRO questionnaire completion. Adherent participants completed a baseline and all 9 monthly PRO questionnaires, while non-adherent participants completed 1–2 monthly questionnaires in total. We also conducted interviews with care team members including gastroenterologists, nurses, and the care coordinator who cared for participants enrolled in the study.

The CAPTURE-IBD Intervention

The CAPTURE-IBD intervention has been described in detail previously.¹¹ In brief, participants were asked to electronically complete monthly PRO questionnaires. These validated and reliable IBD-specific PRO measures were developed for patients with IBD to assess bowel symptoms, functional symptoms, systemic symptoms, daily coping, weekly life impact, and weekly emotional impact.^{9,10} These measures were reviewed monthly by a care coordinator with a certified health educator background. Scores that exceeded a certain range for each domain triggered a PRO-specific care pathway leading to stricter evaluation and monitoring of inflammatory disease activity, medical treatment adjustments, behavioral counseling, and referrals to specialists or other resources.

Data Collection

Interviews were conducted using interview guides, which focused on 4 main domains related to participants' and care teams' experience with the intervention, perceived impact of the intervention, the care coordinator's role, and suggested improvements for further intervention refinement. Each interview was completed over an estimated 20 minutes and recorded and transcribed.

Qualitative Analysis

We used a rapid analysis approach to generate a broad understanding of participants' experiences, perceived impact, coordinator role, and suggested improvements to aid further tailoring and refinement of a routine remote PRO monitoring system and care coordinator-triggered algorithms.¹² Transcripts were independently analyzed by 2 team members (SCM, DA). We first created a summary of each interview transcript using a structured template and then transferred interview summaries into a matrix by each of the key domains mentioned above. Next, we wrote detailed descriptions of our experiences with the intervention. Four members of the research team (SCM, DA, JB, and MD) met to review and discuss the interview summaries to establish rigor and validity. Themes were developed within groups (patients, clinical team) and then compared between groups. In the sections that follow, the perspectives of the care team are presented in aggregate to protect participant anonymity (ie, rather than by provider role).

Results

Study Sample

Twenty participants who were randomized to the CAPTURE-IBD intervention arm were invited to participate in a semi-structured interview, and 16 agreed to be interviewed (Table 1). Out of the 16 study participants interviewed, 9 (56%) had high adherence and 7 (44%) had low adherence to the study protocol and PRO questionnaire completion. We also conducted interviews with 2 gastroenterologists, 2 nurses, and the CAPTURE-IBD care coordinator. In the results that follow, perspectives of the clinical care team are

Table 1. Demographics

	Participants (N = 16)
Age, mean(SD)	41.12(12.61)
Sex, n(%)	
Female	12(75.0%)
Male	4(25.0%)
IBD type, n(%)	
Crohn's disease	12(75.0%)
Ulcerative colitis	4(25.0%)
Primary payer, n(%)	
Commercial	13(81.2%)
Medicare	2(12.5%)
Self-pay	1(6.2%)
Biologic, n(%)	6(37.5%)
Immunomodulator, n(%)	8(50.0%)
Psychiatric Disorder, n(%)	5(31.2%)

presented as a group rather than by individual roles. The final sample size was selected as sufficient to achieve data saturation (ie, information redundancy), based on the concept of information power since our interviews elicited data on a focused topic that is limited in scope and that we have high sample specificity given that interviewees have experienced the phenomenon under study.¹³ Findings highlight that both participants and care teams found the intervention acceptable and user-friendly, despite concerns regarding increased nursing workload. They also perceived the intervention as valuable in supporting symptom monitoring, psychosocial care, and between-visit action plans to improve IBD care and health outcomes. However, few participants accepted support or resources from the care coordinator as intended. Finally, participants reported that the intervention could be better tailored to capture day-to-day symptom changes and to meet the needs of patients with specific comorbid conditions. Interviewees identified several opportunities for intervention refinement.

The Intervention was Acceptable and User-Friendly, Despite Concerns Regarding Increased Nursing Workload

Respondents described an overall positive experience with participation in the CAPTURE-IBD intervention. Routine collection of PRO questionnaires outside of the office visit setting was reported to be feasible and acceptable.

PRO questionnaires were quick and easy to complete. Most interview participants reported that electronically completing monthly PRO questionnaires was quick, easy, comfortable, and not time-consuming. This was true for both participants who were compliant with monthly PRO questionnaire completion and those who were not compliant (Figure 1, Participants 2 and 15) While user-friendly, one participant who was non-adherent to PRO questionnaire completion reported apprehension with the process, indicating that self-monitoring may have felt uncomfortable (Figure 1, Participant 12). One participant said it was easier to complete the PRO questionnaire on the computer rather than by mobile application (Figure 1, Participant 3)

The care team had positive experiences with the intervention. Several care team providers expressed support for the concept of early intervention and remote monitoring. They thought it was good to be notified when patients had symptoms and would conduct follow-up assessments leading to further evaluation and physician notification (Figure 1, Providers 1, 3).

The CAPTURE-IBD intervention led to increased nursing workload. Despite an overall positive experience, care team providers also reported that symptom notifications led to follow-up assessments requiring extra time and effort. For example, care team providers expressed frustration with notifications for patients with chronic but stable symptoms (Figure 1, Provider 1).

PRO questionnaires were quick and easy to complete

- *“[The questionnaires were] very easy to answer. As you went on, they became easier to answer because you become more familiar with them. [They were] not too time-consuming.” (Participant 2, adherent with monthly PRO questionnaires)*
- *“It was easy, and I could do it at my convenience. (Participant 15, adherent with monthly PRO questionnaires)*
- *“Super easy to answer [questions] but seemed like a looming thing for some reason.” (Participant 12, non-adherent with monthly PRO questionnaires)*
- *“Hard to do [questionnaire] on cellphone, had to do them on a bigger screen so had to do them on the computer.” (Participant 3, adherent with monthly PRO questionnaire)*

The care team had positive experiences with the CAPTURE IBD intervention

- *“When patients were symptomatic, I thought that it was good to be notified so we can contact them.” (Care team member 1)*
- *“I think it’s a great idea to capture high utilizers and try to encourage a different relationship with healthcare system than the ER or more frequent calling...A lot of communication [was] sent to the nurses, more so than they would receive through the patients.” (Provider 3)*

The CAPTURE IBD intervention led to increased nursing workload

- *“[The intervention] was kind of annoying because it would add to the workload. There were a few times that it wasn’t even necessary to contact that patient [when symptoms were not substantially changed].” (Provider 1)*

Figure 1. Acceptability and user-friendliness of the intervention.

The Intervention was Valuable in Supporting High-Quality IBD Care and Health Outcomes

Both participants and care team providers described the positive impact of the CAPTURE-IBD intervention on symptom monitoring, psychosocial care, and between-visit action plans. Even participants who did not perceive a personal benefit from the intervention due to well-controlled disease or confidence in navigating the health system, described the potential benefit of the intervention for other patients with IBD.

CAPTURE-IBD promoted symptom monitoring. Participants found that completing monthly PRO questionnaires helped them to keep track of their symptoms and disease, and month-to-month changes as they were working towards remission. The intervention encouraged enhanced awareness, both of symptom improvement as well as worsening symptoms (Figure 2, Participants 2, 6, 8). One participant who was not very engaged with the intervention said, “it would have been more effective if [I] did the surveys and if [I were] talking to the care coordinator.” (Participant 5)

CAPTURE-IBD supported patients in understanding their mental health. One of the major impacts of the intervention was enhanced understanding of IBD’s effect on mental health. Participants reported that the intervention made them think more about their emotions and the way IBD influenced their mental health, and that it supported them in self-monitoring (Figure 2, Participant 1). One participant discussed how speaking about their IBD in the context of PRO questionnaires was helpful in destigmatizing their symptoms (Figure 2, Participant 5). Care team providers also reported

that the intervention “*was especially helpful in... connecting [participants] with mental health resources.* (Provider 5)

The intervention supported between visits care, but gaps in PRO-guided action plans were identified. Many but not all interview participants reported that they would recommend the intervention to others. One participant believed it was an important resource, since it could be difficult to get support from physicians’ offices (Figure 2, Participant 15). Another participant who was non-adherent to PRO questionnaire completion stated that while staff addressed their mental health, they did not address their labs or medications (Figure 2, Participant 13). Both participants and care team providers also felt that the intervention could be refined with more transparent PRO-guided action plans (Figure 2, Provider 5, Participant 9).

Few Participants Accepted Support or Resources From the Care Coordinator

While a few participants described their positive experiences with receiving support and resources from the care coordinator, a majority of participants did not interact with or deferred to the coordinator’s offer of support or resources.

Few participants leveraged care coordinator support. Speaking with the coordinator was helpful to participants when closing the loop on their PRO questionnaire results (Figure 3, Participant 15). However, the coordinator was less helpful when participants did not feel that they were needed. Most interview participants reported that the coordinator communicated PRO results effectively and offered assistance,

CAPTURE IBD promoted symptom monitoring

- “The surveys helped me to keep track of what was going on with me. It was easy to do, the questions weren’t invasive or anything” ...” Being able to track my own symptoms [helped me]” (Participant 2, adherent with monthly PRO questionnaire)
- “It kind of just updated where my symptoms were, kind of helped to reflect [on] what [I] was going through... [questionnaires] were helpful because [they] helped me to see if anything has changed since the last time I filled [them] out.” (Participant 8, adherent with monthly PRO questionnaire)
- “It was interesting because I don’t think about changes month to month, and then I started going into remission and I thought about the questions I answered in the prior month, and it was helpful.” (Participant 6, adherent with monthly PRO questionnaire)

CAPTURE IBD supported patients in understanding their mental health

- “Mental aspects make you think about how you’re thinking and help to put it in a different perspective.” (Participant 1, non-adherent with monthly PRO questionnaire)
- “It was a good way to start talking about [my IBD] more and de-stigmatizing it.” (Participant 5, non-adherent with monthly PRO questionnaire)

The intervention supported between visits care, but gaps in PRO-guided action plans were identified

- “When you’re dealing with this kind of health issue, it’s nice to have an advocate. You can’t always get something you need from the doctor’s office quite as quick.” (Participant 15, adherent with monthly PRO questionnaire)
- “There were a couple times I answered, and I was having a flare, and people were calling me about the [questionnaires] but nobody was calling me about my labs and medications. This was frustrating.” (Participant 13, non-adherent with monthly PRO questionnaire)
- “Make sure clear delineation of responsibilities, and coordination plans [are] in place.” (Provider 5)
- “These surveys are just questions, so there’s nothing really there to help get us through anything.” (Participant 9, non-adherent with monthly PRO questionnaire)

Figure 2. Value of the intervention in supporting high-quality inflammatory bowel disease care and health outcomes.

Few participants leveraged care coordinator support

- “[CAPTURE IBD] was good because I could let them know where things were going. [The care coordinator] would call and follow up on it to make sure everything was going well, which I liked.” (Participant 15, adherent with monthly PRO questionnaire)
- “[The care coordinator] basically called me. I never felt the need to call [them] because I didn’t need any of the resources.” (Participant 8, adherent with monthly PRO questionnaire)
- “[The care coordinator] did provide me with resources, I didn’t use them but I still have them.” (Participant 9, non-adherent with monthly PRO questionnaire)
- “[The care coordinator] always asked if I needed assistance but I never did.” (Participant 10, non-adherent with monthly PRO questionnaire)
- “I don’t know if [the care coordinator] added much to the care. There was all this data coming in and since [the care coordinator was] not a clinician, it was put on the nurse or [physician]. [Instead], there could be an algorithm put in place based on labs or communication for what to do next.” (Provider 3)
- “I’m a nurse so I know who to contact when I have issues, but I’m sure in other cases [a care coordinator] would be helpful.” (Participant 13, non-adherent with monthly PRO questionnaire)

The coordinator role could be transformed into a nursing role

- “The biggest [barrier] is that [the care coordinator] should be a nurse. [They] should know about our Crohn’s and Colitis protocols, [our] system that monitors the patient’s labs...That would reduce some back and forth.” (Provider 1)
- “[The intervention could be improved] if an actual nurse was in [the care coordinator role]. [They] could actually make decisions...and communicate with the provider directly instead of using the staff nurse as the middle person” (Provider 2)

The coordinator could be more focused on providing mental health and social work resources

- “Transportation to the hospital, mental health resources would be helpful.” (Provider 1)
- “I think it would be helpful if [the care coordinator] could help navigate...medication co-pay issues, or social work resources because those are huge barriers to patients continuing their medication...would be helpful.” (Provider 2)

Figure 3. Accepting support or resources from the care coordinator as intended.

but most participants also reported not needing or deferring on coordinator support (Figure 3, Participants 8, 9, 10). One care team provider questioned whether the coordinator role was a necessary component of the intervention (Figure 3, Provider 3). Some participants did not leverage support from the coordinator because they were not members of the care team. One participant reported that they preferred to speak with their medical team to address their flare rather than a coordinator (Figure 3, Participant 13).

The coordinator role could be transformed into a nursing role. Most care team providers felt that the coordinator role should be transitioned to a nurse with more knowledge and familiarity with clinical IBD and institutional IBD protocols, to minimize redundancy in between visit patient assessments for abnormal PRO results (Figure 3, Providers 1 and 2).

The coordinator could focus more on mental health and social work resources. Care team providers felt that it would be helpful to expand psychosocial resources as part of the intervention (Figure 3, Providers 1,2).

The Intervention Could be Better Tailored to Patients With Specific Conditions

Participants reported that the intervention could be better tailored to capture day-to-day symptom changes and to meet the needs of patients with specific comorbid conditions.

PRO questionnaires were not representative of day-to-day changes. A few participants found that monthly PRO

collection was not representative of daily changes in their lived experiences (Figure 4, Participants 4 and 10).

PRO questionnaires were difficult to answer for participants with active non-IBD issues. A few participants including one who was non-adherent to PRO questionnaire completion also felt that IBD-specific PRO questions did not always allow them to differentiate their IBD-related symptoms from non-IBD issues such as ostomy-related symptoms and other autoimmune disorders (Figure 4, Participants 7,12).

Monthly monitoring is less helpful for participants in remission. Some participants, who were in clinical remission, felt that the intervention was not directly helpful to them but would be helpful to someone with active symptoms. One participant who was asymptomatic throughout the intervention found the questionnaires repetitive (Figure 4, Participants 3,11).

Some patients are more likely to benefit from CAPTURE-IBD. Care team providers felt that the intervention was most impactful when patients had true changes in symptoms and escalation of treatment or further evaluation was appropriate (Figure 4, Providers 1,2). One provider found the intervention to be especially useful for helping patients with new IBD diagnoses navigate their healthcare (Figure 4, Provider 5).

Discussion

In order to achieve proactive IBD management, it is important to understand both patients and the care teams’ experiences

PRO questionnaires were not representative of day-to-day changes

- "...when you have IBD, symptoms change from day to day, so [monthly questionnaires] may not be reflective of how I was doing in the particular month of when I filled out the [questionnaire]." (Participant 4, adherent with monthly PRO questionnaire)
- "When you are in a flare, things change daily, so two weeks prior or two days earlier it could've been different. So maybe changing the format of the question or the timeframe of the question." (Participant 10, non-adherent with monthly PRO questionnaire)

PRO questionnaires were difficult to answer for participants with active non-IBD issues

- "A lot of the questions were just not good questions for me...I have other issues than Crohn's disease [an ostomy]. They should have a branch off part that asks do you think this is from your Crohn's disease or something else?" (Participant 7, non-adherent with monthly PRO questionnaire)
- "I have other autoimmune diseases, so it was sometimes difficult to answer the questions." (Participant 12, adherent with monthly PRO questionnaire)

Monthly monitoring is less helpful for participants in remission

- "[They] didn't help catch a flare because I didn't have any... my symptoms haven't changed over this period, so I was just giving the same answers. Not sure if this would be more helpful to someone who had different treatment or symptoms than me." (Participant 3, adherent with monthly PRO questionnaire)
- "It didn't help me personally so much because I've been feeling pretty well lately, maybe it would've been different if I was having a flare or something... I'm sure one day I will have symptoms that I wouldn't call the doctor for, and it would be helpful for when I'm not doing so well." (Participant 11, adherent with monthly PRO questionnaire)
- "My symptoms haven't changed over this period, so I was just giving the same answers...It got kind of repetitive." (Participant 3, adherent with monthly PRO questionnaire)

Some patients are more likely to benefit from CAPTURE IBD

- "[The intervention was particularly impactful] when the patient was truly symptomatic, because then we could contact the patient." (Provider 1)
- "I think that having someone contact them and touch base with them, that's definitely helpful especially for the high acuity patients. We find patients who fall off the beaten path medication-wise...Having someone reach out and make sure they're still taking their medications and finding out why they stopped if they did [is helpful]. (Provider 2)
- "[The intervention was] especially helpful in new diagnoses to help with navigation and connecting with mental health resources." (Provider 5)

Figure 4. Tailored the intervention to patients with specific conditions.

and perceptions of remote monitoring programs such as CAPTURE-IBD. These study findings will help us to improve on the remote PRO collection and care coordinator-triggered care pathway components of the intervention. The routine use of PROs in the clinical care of patients with IBD has been studied, with results demonstrating PROs correlate with IBD disease activity.^{9,10,14,15} Our study highlights how patients and care teams can provide novel insights into experiences with remote PRO monitoring, its perceived impact, the coordinator role, and opportunities for intervention refinement.

Participant experiences with the CAPTURE-IBD intervention were overall positive. Most interview participants found electronic monthly PRO questionnaires to be easy and low burden to complete from home. Care team providers also noted their value in remote monitoring and early intervention. However, participants provided insight that IBD-specific PROs were not necessarily representative of patients' whole health, particularly in the context of active comorbidities (eg, ostomy status). They also suggested that shorter interval monitoring (eg, weekly) may be more representative of IBD patients' lived experiences. While shorter interval monitoring needs to be balanced against the added burden of frequent

questionnaires, prior studies support the feasibility of weekly PRO collection.^{7,16,17} Furthermore, PRO questionnaires should be expanded to include both IBD-specific measures and more general PRO measures such as Patient-Reported Outcomes Measurement Information System (PROMIS®)-29 profile measures.¹⁸

Participants who found the CAPTURE-IBD intervention impactful benefitted from self-monitoring, reflection on stigmatization, and understanding the way IBD affected their mental health. Half of patients with IBD experience comorbid mental health symptoms and stigma in their daily lives, including but not limited to depression and anxiety.¹⁹ Therefore, mental health is an important aspect of IBD treatment, but mental health education and treatment are not often well integrated into IBD care. These findings suggest that it may be important to incorporate mental health assessments, education, and referral pathways as part of remote PRO monitoring in IBD. These insights are supported by behavioral theory. Symptom monitoring is an active component of many effective self-management interventions, where symptom monitoring drives self-efficacy or confidence in managing disease and symptoms. Bandura's theory of self-efficacy states

that one's confidence regarding one's own capabilities can be achieved through mastery experiences such as symptom monitoring.²⁰ These findings suggest that one mechanism by which CAPTURE-IBD may achieve its intervention effect is through improvement in self-efficacy and self-care. Other studies have started to examine the link between self-care and symptom monitoring in IBD.^{14,21} These concepts need to be further examined in a larger-scale randomized controlled trial of CAPTURE-IBD through mediation analysis.

While asymptomatic participants believed that the CAPTURE-IBD intervention would be beneficial to other patients, they personally found monthly PRO monitoring to be redundant and less helpful. This suggests that the intervention could be tailored to patients' individual needs or deployed for patients at higher risk of negative outcomes. A tailored approach with more frequent monitoring for patients with active IBD and less frequent monitoring for patients with inactive IBD could also potentially address perceived redundancy with scheduled questionnaires. Future iterations of CAPTURE-IBD could be adapted to include artificial intelligence-driven algorithms to identify patients who would benefit from more or less frequent remote monitoring.^{22,23}

It is interesting that insights from both participants and care teams suggested that the coordinator role may increase inefficiencies. Few participants interacted with and leveraged support from the coordinator, suggesting that the intervention effect may have been driven more by remote monitoring rather than coordinator interactions. Furthermore, nursing staff and physicians found the coordinator to be redundant and suggested that sharing PRO data directly with nursing staff may be more efficient and less burdensome on patients. These findings suggest that nursing staff can take on the role of the coordinator after considering adjustments in workload and education on referral to psychosocial resources. Alternatively, clinics could empower coordinators to concentrate more effectively on navigational challenges around mental health and non-medical aspects of care, thus allowing clinical teams to focus on medical decision-making.

The strengths of this study include the purposeful sample of participants with high and low adherence to PRO collection to gather diverse perspectives and experiences, and a sample size sufficient to achieve thematic saturation. However, this sample may not be fully representative of the experiences of all patients with IBD. Therefore, ongoing process evaluation will play an important role in larger-scale studies and implementation efforts of routine remote PRO monitoring.

Conclusion

In conclusion, remote PRO monitoring is tolerable and acceptable to patients with IBD. Additional work is needed to better tailor remote symptom monitoring to IBD patients with the option for shorter interval monitoring and collection of both IBD-specific and more general PRO measures. Increased clinical workload issues also need to be considered and proactively addressed for routine remote PRO collection and PRO-guided care pathways to be sustainable. Finally, in the context of IBD care, nursing staff may be better suited to acting on PRO data than care coordinators. Shifting the care coordinator role to nursing staff could reduce redundancy in the care coordination process. Alternatively, standardized

IBD training of coordinators could improve the efficiency of clinical workflow. Ultimately, study findings indicate that routine remote PRO monitoring may be valuable in improving care management, promoting tight control, and supporting whole health in IBD. Future efforts should focus on testing and implementing refined versions of CAPTURE-IBD tailored to patients with IBD in different clinical settings.

Authors' Contributions

D.A., S.C.M., J.B., D.W., and P.D.H. contributed to the conceptualization of the study, methodology, drafting of the manuscript, and critical revisions. S.C.M., D.A., and J.B. also contributed to supervision. G.G. contributed to data curation. M.D. contributed to methodology. All authors contributed to investigation, methodology, writing the original draft, and critical revisions. All authors approved the final version of the manuscript. This manuscript has not been previously published and is not under consideration in the same or substantially similar form in any other peer-reviewed media. All authors listed have contributed sufficiently to the project to be included as authors, all contributors agreed to submit this paper for publication and have reviewed this final version, and all those who are qualified to be authors are listed in the author byline.

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Conflict of Interest

None.

Data Availability

The dataset supporting the conclusions of this article is available on reasonable request by emailing the corresponding author.

Ethics Approval and Consent to Participate

Approval for the study was obtained from the University of Michigan Institutional Review Board (HUM00147500). Informed consent was obtained from all study participants. The trial was registered on Clinicaltrials.gov (ID#NCT04796571).

References

1. Dahlhamer JM, Zammitti EP, Ward BW, Wheaton AG, Croft JB. Prevalence of Inflammatory Bowel Disease among adults Aged ≥ 18 Years - United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2016;65:1166-1169. doi: [10.15585/mmwr.mm6542a3](https://doi.org/10.15585/mmwr.mm6542a3)

2. Farrell D, McCarthy G, Savage E. Self-reported symptom burden in individuals with inflammatory bowel disease. *J Crohns Colitis*. 2016;10(3):315-322. doi: [10.1093/ecco-jcc/jjv218](https://doi.org/10.1093/ecco-jcc/jjv218)
3. Mitropoulou MA, Fradelos EC, Lee KY, et al. Quality of life in patients with inflammatory bowel disease: importance of psychological symptoms. *Cureus*. 2022;14(8):e28502. doi: [10.7759/cureus.28502](https://doi.org/10.7759/cureus.28502)
4. Limsrivilai J, Stidham RW, Govani SM, Waljee AK, Huang W, Higgins PDR. Factors that predict high health care utilization and costs for patients with inflammatory bowel diseases. *Clin Gastroenterol Hepatol*. 2017;15(3):385-392.e2. doi: [10.1016/j.cgh.2016.09.012](https://doi.org/10.1016/j.cgh.2016.09.012)
5. Buie MJ, Coward S, Shaheen AA, et al. Hospitalization rates for inflammatory bowel disease are decreasing over time: a population-based cohort study. *Inflamm Bowel Dis*. 2023;29(10):1536-1545. doi: [10.1093/ibd/izad020](https://doi.org/10.1093/ibd/izad020)
6. Al Khoury A, Balram B, Bessissow T, et al. Patient perspectives and expectations in inflammatory bowel disease: a systematic review. *Dig Dis Sci*. 2022;67(6):1956-1974. doi: [10.1007/s10620-021-07025-y](https://doi.org/10.1007/s10620-021-07025-y)
7. Basch E, Deal AM, Kris MG, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. *J Clin Oncol*. 2016;34(6):557-565. doi: [10.1200/JCO.2015.63.0830](https://doi.org/10.1200/JCO.2015.63.0830)
8. Ishaque S, Karnon J, Chen G, Nair R, Salter AB. A systematic review of randomised controlled trials evaluating the use of patient-reported outcome measures (PROMs). *Qual Life Res*. 2019;28:567-592. doi: [10.1007/s11136-018-2016-z](https://doi.org/10.1007/s11136-018-2016-z)
9. Higgins PDR, Harding G, Revicki DA, et al. Development and validation of the Ulcerative Colitis patient-reported outcomes signs and symptoms (UC-pro/SS) diary. *J Patient Rep Outcomes*. 2017;2:26. doi: [10.1186/s41687-018-0049-2](https://doi.org/10.1186/s41687-018-0049-2)
10. Higgins PDR, Harding G, Leidy NK, et al. Development and validation of the Crohn's disease patient-reported outcomes signs and symptoms (CD-PRO/SS) diary. *J Patient Rep Outcomes*. 2017;2:24. doi: [10.1186/s41687-018-0044-7](https://doi.org/10.1186/s41687-018-0044-7)
11. Berinstein JA, Cohen-Mekelburg SA, Greenberg GM, et al. A care coordination intervention improves symptoms but not charges in high-risk patients With Inflammatory Bowel Disease. *Clin Gastroenterol Hepatol*. 2022;20(5):1029-1038.e9. doi: [10.1016/j.cgh.2021.08.034](https://doi.org/10.1016/j.cgh.2021.08.034)
12. Lewinski AA, Crowley MJ, Miller C, et al. Applied rapid qualitative analysis to develop a contextually appropriate intervention and increase the likelihood of uptake. *Med Care*. 2021;59:S242-S251. doi: [10.1097/MLR.0000000000001553](https://doi.org/10.1097/MLR.0000000000001553)
13. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. *Qual Health Res*. 2016;26(13):1753-1760. doi: [10.1177/1049732315617444](https://doi.org/10.1177/1049732315617444)
14. IsHak WW, Pan D, Steiner AJ, et al. Patient-reported outcomes of quality of life, functioning, and GI/Psychiatric Symptom Severity in Patients with Inflammatory Bowel Disease (IBD). *Inflamm Bowel Dis*. 2017;23(5):798-803. doi: [10.1097/MIB.0000000000001060](https://doi.org/10.1097/MIB.0000000000001060)
15. Kappelman MD, Long MD, Martin C, et al. Evaluation of the patient-reported outcomes measurement information system in a large cohort of patients with inflammatory bowel diseases. *Clin Gastroenterol Hepatol*. 2014;12(8):1315-1323.e2. doi: [10.1016/j.cgh.2013.10.019](https://doi.org/10.1016/j.cgh.2013.10.019)
16. Yount SE, Rothrock N, Bass M, et al. A randomized trial of weekly symptom telemonitoring in advanced lung cancer. *J Pain Symptom Manage*. 2014;47(6):973-989. doi: [10.1016/j.jpainsymman.2013.07.013](https://doi.org/10.1016/j.jpainsymman.2013.07.013)
17. Cross RK, Langenberg P, Regueiro M, et al. A randomized controlled trial of TELEmedicine for Patients with Inflammatory Bowel Disease (TELE-IBD). *Am J Gastroenterol*. 2019;114(3):472-482. doi: [10.1038/s41395-018-0272-8](https://doi.org/10.1038/s41395-018-0272-8)
18. Hays RD, Spritzer KL, Schalet BD, Cella D. PROMIS((R))-29 v2.0 profile physical and mental health summary scores. *Qual Life Res*. 2018;27:1885-1891. doi: [10.1007/s11136-018-1842-3](https://doi.org/10.1007/s11136-018-1842-3)
19. Bernstein CN. Psychological stress and depression: risk factors for IBD? *Dig Dis*. 2016;34(1-2):58-63. doi: [10.1159/000442929](https://doi.org/10.1159/000442929)
20. Bandura A. Health promotion by social cognitive means. *Health Educ Behav*. 2004;31(2):143-164. doi: [10.1177/1090198104263660](https://doi.org/10.1177/1090198104263660)
21. Lee CK, Melmed GY, Mann A, et al. A multidisciplinary approach to biopsychosocial care for adults with Inflammatory Bowel Disease: a pilot study. *Inflamm Bowel Dis*. 2018;24(12):2550-2554. doi: [10.1093/ibd/izy215](https://doi.org/10.1093/ibd/izy215)
22. Stidham RW, Takenaka K. Artificial intelligence for disease assessment in inflammatory bowel disease: how will it change our practice? *Gastroenterology*. 2022;162(5):1493-1506. doi: [10.1053/j.gastro.2021.12.238](https://doi.org/10.1053/j.gastro.2021.12.238)
23. Piette JD, Newman S, Krein SL, et al. Patient-centered pain care using artificial intelligence and mobile health tools: a randomized comparative effectiveness trial. *JAMA Intern Med*. 2022;182(9):975-983. doi: [10.1001/jamainternmed.2022.3178](https://doi.org/10.1001/jamainternmed.2022.3178)