Received: 24 October 2023 | Accepted: 26 March 2024

DOI: 10.1002/jpn3.12229

JPGN

ORIGINAL ARTICLE

Gastroenterology: Inflammatory Bowel Disease

Pilot and feasibility of the SMART IBD mobile app to improve self-management in pediatric inflammatory bowel disease

Kevin A. Hommel[1,2] | **Amy E. Noser**[3] | **Jill Plevinsky**[4] | **Kate Gamwell**[5] | **Lee A. Denson**[2,6]

[1]Division of Behavioral Medicine and Clinical Psychology, Cincinnati Children's Hospital Medical Center, Center for Adherence and Self-Management, Cincinnati, Ohio, USA

[2]Department of Pediatrics, University of Cincinnati College of Medicine, Birmington, Alabama, USA

[3]Department of Family Medicine and Community Health, University of Minnesota Medical School, Minneapolis, Minnesota, USA

[4]Children's Hospital of Philadelphia, Greenville, South Carolina, USA

[5]Children's Hospital in the Upstate, University of South Carolina School of Medicine Greenville, Cincinnati, Ohio, USA

[6]Division of Gastroenterology, Hepatology, and Nutrition, Cincinnati Children's Hospital Medical Center, Birmington, Alabama, USA

Correspondence

Kevin A. Hommel, 3333 Burnet Ave, MLC 7039, Cincinnati, OH 45229, USA.
Email: kevin.hommel@cchmc.org

Funding information

David R. Clare and Margaret C. Clare Foundation

Abstract

Objectives: Access to evidence-based self-management support in pediatric inflammatory bowel disease (IBD) is a significant challenge. Digital therapeutic solutions can increase access and provide data to patients and providers that would otherwise not be available. We have iteratively developed a mobile application, Self-Management Assistance with Recommended Treatment (SMART) IBD, that allows patients to access self-management support and record symptoms and medication adherence.

Methods: We conducted a pilot and feasibility study for this digital therapeutic tool in which patients used SMART IBD for 30 days.

Results: Results indicated that patients rated the app quality as good and accessed the app adequately overall, with some pages being used often. Medication adherence increased over the course of the study and was associated with sleep duration, mood, and stool consistency and blood content.

Conclusions: Overall, this study demonstrated adequate feasibility for the SMART IBD app and initial findings suggest that additional research is needed to explore the potential impact of this tool in clinical care.

KEYWORDS

adherence, digital health, IBD, pediatrics, self-management

1 | INTRODUCTION

Poor self-management in pediatric chronic conditions is a significant behavioral health issue that results in poor health outcomes and treatment nonadherence,[1,2] relapse of symptoms,[3] and excessive health care costs.[4,5] Adolescents demonstrate significant difficulty with adherence to treatment regimens,[2,6] and our prior research in adolescents with inflammatory bowel disease (IBD) has documented that as much as 88% of adolescents are nonadherent to medications, with 40-50% of doses missed.[7] Additionally, the prospective cost of health care in this population is 3.7 times greater for nonadherent patients.[8]

Specific challenges with the delivery of self-management interventions include the lack of qualified behavioral health care providers as well as the distance and time associated with weekly in-person treatment protocols. Accordingly, our efforts to improve self-management in this population have recently focused on digital therapeutic development and testing. Digital health care approaches are not uncommon, and there

Clinicaltrials.gov #: NCT06023667; URL: https://clinicaltrials.gov/study/NCT06023667.

are several that have been developed for patients with IBD.[9–14] However, many of the applications that have been developed for IBD lack inclusion of evidence-based intervention content, rigorous evaluation and validation, and input from multiple stakeholders including providers,[15] and several of these applications are no longer available. Importantly, most of the prior or current applications have little, if any, pediatric focus in their development or delivery of intervention. Therefore, they rely on a downward extension of adult-focused intervention, which is not effective given the complex nature of pediatric care and the developmental needs of youth with IBD. Additionally, the target of intervention has typically been broad, focusing on improving factors such as quality of life, while self-management is either a minor focus or not included.

We previously reported data from the Self-Management Assistance with Recommended Treatment (SMART) portal in IBD, which revealed promising results for improving medication adherence and reducing self-management barriers.[16] Nevertheless, patients recommended making the intervention content even more accessible, including streamlining the intervention delivery and providing care via a mobile app for easier use with smartphones and tablets. To be responsive to the unique needs of patient users and address the current limitations in research and clinical care, we developed the SMART IBD mobile app to provide evidence-based behavior change techniques, similar to what is provided in the SMART portal, to promote self-management in adolescents with IBD. We then evaluated the feasibility, usability, and preliminary impact of the SMART IBD app on medication adherence. Additional general and IBD-specific health factors were also examined as part of this pilot study.

What is Known

- Poor self-management is prevalent in pediatric inflammatory bowel disease (IBD), with nonadherence impacting costs and escalation in treatment.
- Access to evidence-based self-management intervention resources is limited across clinical settings.

What is New

- The Self-Management Assistance with Recommended Treatment (SMART) IBD app offers a digital therapeutic solution providing better access to evidence-based self-management support in a highly accessible mobile app. Providers can also access data from the app to inform care provision.
- SMART IBD app feasibility was acceptable, and patients rated the quality as good. Improvement in medication adherence was observed, and this was associated with clinical outcomes.

2 | METHODS

2.1 | SMART IBD app description

The SMART IBD app is a mobile app for use with smartphones or tablets (iOS or Android). It contains a Diary page for reporting of symptoms and behaviors, Treatments page for setting up users' treatment regimen and reminder messages and recording treatment completion, Charts page for graphical feedback to participants on symptoms and health behaviors (e.g., medication adherence) so that relationships could be observed (e.g., progress toward goals and activity limitations), IBD 101 page for IBD education, Calendar page for visualizing diary and treatment completion. Additionally, a subset of participants were able to access a Video page for videos focused on IBD-related issues and cognitive-behavioral treatment content, and a Challenges page in which users were able to engage in competitive health challenges with other users anonymously.

2.2 | Study design and participants

Given the novelty of this mHealth intervention, this study was a single arm pilot and feasibility trial designed to examine change in key variables within patients using the SMART IBD app. Approval for study procedures was obtained from the Cincinnati Children's Hospital Medical Center Institutional Review Board. Participant demographics were obtained via chart review and parent report. Participants were 31 adolescents (female = 58.1%) with IBD (ulcerative colitis [UC] = 48.4%; Crohn's disease [CD] = 51.6%) between the ages of 13–17 years ($M_{age} = 14.31 \pm 1.3$ years). Eighty-four percent of adolescents identified as White, 6.4% as Black, 6.4% bi- or multi-racial, and 3.2% as American Indian or Alaska Native. All adolescents reported living with their parents.

2.3 | Measures

2.3.1 | Daily diary

Participants were asked to complete a diary comprised of 10 items each day during the 30-day intervention period. Items in the diary assessed adherence, stool frequency, consistency, and blood content; nocturnal stools; abdominal pain; activity limitations; overall well-being; and progress toward goals.

2.3.2 | Medication adherence

Adherence to prescribed medications and supplements (e.g., Vitamin D) was assessed via the daily diary using a 5-point scale (0 = None to 4 = All, or users could indicate that they did not have any scheduled medications that day) and recording of treatment completions on the Treatments page of the app.

2.3.3 | App usage

Google Analytics was used to generate app usage data. These data were used to describe app access timing and frequency overall as well as individual page access within the app over the course of the study period.

2.3.4 | User version of the mobile app rating scale (uMARS)

The uMARS is a 26-item measure designed and validated for usability testing with mobile health apps.[17] Participants rate items pertaining to each subscale (engagement, functionality, aesthetics, and quality of information) on a 5-point scale, from 1—inadequate to 5—excellent. A score for each of these subscales is calculated as the average of the individual items and a total score is calculated as the mean of these four subscale scores. Participants also answer questions pertaining to each app's overall subjective quality (e.g., "Would you recommend this app to others who might benefit from it?") and perceived impact of app use on attitudes, knowledge, and intentions.

2.4 | Data analysis

Descriptive statistics were conducted to characterize the study sample and SMART IBD app use. The rate of SMART IBD app use was calculated by taking the ratio between the number of days with app use and the period of study enrollment (i.e., 30 days). Frequency of daily app use was examined by calculating the mean frequency of unique app logins per day. Medication adherence assessed by the SMART IBD app was calculated via reported medication adherence on the Daily Diary page using the 5-point scale, with incomplete daily diaries marked as missing. Multilevel models were used to assess change over time in medication adherence and symptoms monitored via the daily dairy (e.g., pain and sleep). One-way repeated measures analysis of the variances (ANOVAs) were used to test differences in group means at baseline, Day 15 and 30 of the study. SPSS was used for examining descriptives and one-way repeated measures ANOVAs. SAS was used to conduct multilevel models.

3 | RESULTS

3.1 | App usage

On average, participants interacted with the SMART IBD app on 13.8 days (range 2–30 days) over the 30-day study period with 64.5% of participants accessing the app at least once on ≥20 days and 19.5% on all 30 days. Participants accessed the app 1.5 times per day (range 0–13 times per day). See Table 1 for additional app features and usage data.

3.2 | Medication adherence

Participants were tracking the following prescription medications in the app: Mesalamine (26%), Adalimumab (22%), Infliximab (17%), 6-MP (9%), Methotrexate (9%), Prednisone (9%), Budesonide (4%), Lansoprazole (4%), Sulfasalazine (4%), and Azathioprine (4%). Mean medication adherence reported on the Daily Diary was 3.7 out of 4 (see Figure 1). Specifically, participants reported taking all of their daily medications on 80.5% of days, more than half of their medications on 2.1% of days, half their medications on 4.2% of days, less than half their medications on 3.3% of days, none of their medications on 2.7% of days, and did not have any scheduled medication on 7.8% of days. Medication adherence increased significantly over the course of the study ($B = 0.03$, SE = 0.01, $p = 0.03$).

3.3 | Daily dairy

Participant completion of self-monitoring on the Daily Diary was 35.8% across the study period. Mean time of diary completion was 5:28 p.m. with the majority of diaries being completed between 5 p.m. and 11:59 p.m. Descriptive statistics for self-monitoring variables are reported in Table 2. Bivariate correlations indicated that higher medication adherence was associated with longer sleep duration (0.16, $p < 0.01$), better mood (0.12, $p < 0.05$), having more formed stools (−0.24, $p < 0.01$) and less blood in stools (−0.15, $p < 0.05$). Activity limitations and overall well-being did not change over the course of the study; though, this was anticipated given the short duration of the trial.

3.4 | uMARS

Twenty-four participants (77.4%) provided a quality assessment of the SMART IBD app via the uMARS. The mean overall quality rating for the SMART IBD app was 3.7 ± 0.4 out of 5, which corresponds to adequate to good overall quality. The 4 uMARS subscales scores

TABLE 1 Additional app features and usage data.

Page	Description	Usage
Calendar	Monthly calendar that provides feedback about days the user completed their daily diary and tracked medication adherence	Accessed 1–12 times by 29.0% of participants
Charts	Provides graphical feedback on the user's self-monitoring of IBD symptoms and associated factors (e.g., pain, sleep, and stress) from the Daily Diary	Accessed 1–16 times by 77.4% of participants
IBD 101	Includes psychoeducation on IBD and its management	Accessed 1–14 times by 64% of participants, with over half (55%) accessing it on the first day of the study
Treatments	Prompts the user to add their IBD medications, which they then track on the Treatment page, and schedule reminder messages	Accessed 1–4 times by 71% of participants
Video	Hosts six videos including an introduction to the SMART IBD app, regimen adherence, healthy habits, problem-solving, relaxation training, and communication about IBD	Accessed 1–19 times by 90.5% of participants
Challenges	Includes weekly competitive health challenges (e.g., medication adherence, sleep), where users can compete with other app users to improve health behaviors	Accessed 1–20 times by 95.2% of participants
Leaderboard	Compares users' progress on weekly challenges	Accessed 1–16 times by 57.1% of participants

Note: A subset of participants ($n = 21$) used an updated version of the SMART IBD app that included access to the Video, Challenges, and Leaderboard pages.

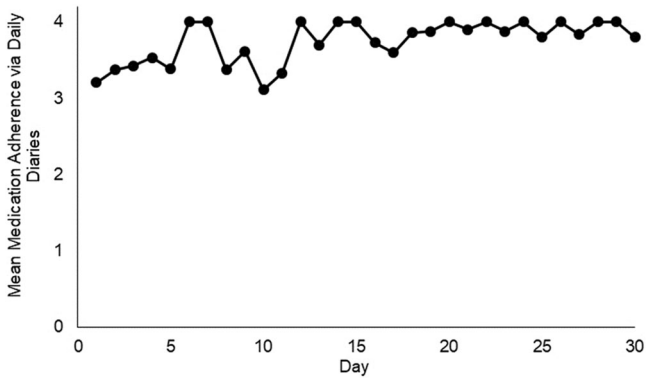

FIGURE 1 Mean medication adherence via daily dairies per day. Medication adherence reported on a 5-point scale: 0 (None), 1 (<Half), 2 (Half), 3 (>Half), 4 (All); Users could also indicate if no medication was scheduled that day.

that comprise the uMARS total score (Engagement, Functionality, Aesthetics, and Information Quality) along with the Subjective Quality subscale score were in the adequate to good range (3.3 ± 0.8–4.0 ± 0.7).

4 | DISCUSSION

Digital therapeutics offers new opportunities to provide evidence-based care to patients in a more accessible manner, thus reaching patients who might not otherwise receive specialty care such as self-management support. Indeed, a primary goal of digital interventions is to increase spread of specialized care to those who have fewer resources and more barriers to care, are minoritized, have lower socioeconomic status, and/or receive care at institutions with fewer resources. However, this is an underdeveloped area in pediatric IBD. In this pilot and feasibility study, we demonstrated that the SMART IBD app has potential to be impactful in care. Medication adherence increased over the study period, and higher adherence was associated with better sleep, mood, and stool consistency and blood content.

The usage data indicated that the majority of patients accessed the various components of the app and felt the app had good overall quality. The high use of the Challenges, Charts, Video, and IBD 101 pages in particular underscores the importance of integrating evidence-based behavior change techniques (i.e., goal setting, graphical feedback on performance, and education) that patients want to and will use.

Nevertheless, there is certainly room for improvement in regular engagement with the app, specifically with some components. One improvement we have made with continued development of the app is to improve report of medication adherence in the treatment page by integrating it with the diary page; thus, we will have more granular adherence data, which will be more informative to patients and providers going forward. In this study, biologics were counted in the medication adherence section along with oral medications. That is, patients did not discriminate between types of therapies in their adherence reporting. Of the patients prescribed biologics, 88% of them were also prescribed oral medications (e.g., methotrexate, 6-MP, vitamin D) that they tracked in the app. Since the adherence assessment considered the extent to which patients took *all* medications, patient reports represented adherence to all therapies including biologics.

TABLE 2 Descriptive statistics for self-monitoring variables.

	M(SD)	%	Range
Medication adherence	3.7 (0.9)		0–4
Feel: Overall, how do you feel today?	7.8 (2.1)		2–10
Pain: How would you rate your pain today?	1.4 (2.1)		0–9
Stress: What was your level of stress today?	2.8 (2.4)		0–10
Sleep: How many hours did you sleep last night?	7.8 (1.5)		3–12
Limit: Did IBD symptoms limit your other activities today?	0.2 (0.5)		0–2
Miss: Did IBD symptoms cause you to miss school/work today? (%yes)		2.4	
Stool: How many stools did you have?	1.9 (1.3)		0–7
Texture: What was the consistency of most stools?	1.4 (0.6)		1–3
Blood: How much blood was in most of your stools today?	0.1 (0.4)		0–2
Wake: Did you wake up to pass a stool? (%yes)		8.7	

Abbreviations: *M*, mean; SD, standard deviation; %, percentage.

However, discriminating between types of therapies is an important issue and should be a subject of future investigation. Additionally, comparison of adherence by disease is an important consideration for an appropriately powered future study as adherence can vary based on type of medication, and primary treatment with oral medication is more common in patients with UC. Finally, any form of self-report of behavior is subject to social desirability bias and assessment of adherence via a mobile app is certainly not immune to this. While electronic adherence monitoring devices (EAMDs) provide a more objective assessment of accessing medications and are worth implementing in a future trial of the SMART IBD app, they are also prone to reliability and validity issues as well due to mechanical failure, phantom openings, unscheduled openings due to acute treatments, white coat compliance, and so forth. The data obtained from them also requires significant cleaning, which is not clinically feasible, and the cost for these devices can be prohibitive for clinical care. We have also shown that adherence data obtained via an electronic diary yields rates similar to that which has been reported with EAMDs,[18] though this requires a more thorough evaluation that is outside the scope of this manuscript. Our goal with the SMART IBD app is to provide a clinically feasible tool that assesses multiple symptoms and self-management behaviors, including adherence, and provides evidence-based self-management support intervention, ultimately yielding data that can be used to guide conversations with care providers to optimize care and self-management.

The iterative development process for the SMART IBD app is critical to its long-term success. We continue cycles of development, testing, and feedback to improve the functionality, engagement, and quality of data produced. We anticipate that with continued use, this technology can be a valuable option for self-management support in pediatric IBD.

ACKNOWLEDGMENTS

This study was supported by the David R. Clare and Margaret C. Clare Foundation.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

REFERENCES

1. World-Health-Organization. Adherence to long-term therapies: evidence for action. 2003.
2. Rapoff MA. *Adherence to Pediatric Medical Regimens*. 2nd ed. Springer; 2010.
3. Kane S, Huo D, Aikens J, Hanauer S. Medication nonadherence and the outcomes of patients with quiescent ulcerative colitis. *Am J Med*. 2003;114(1):39-43. doi:10.1016/s0002-9343(02)01383-9
4. DiMatteo MR. The role of effective communication with children and their families in fostering adherence to pediatric regimens. *Patient Educ Couns*. 2004;55(3):339-344. doi:10.1016/j.pec.2003.04.003
5. Berg JS, Dischler J, Wagner DJ, Raia JJ, Palmer-Shevlin N. Medication compliance: a healthcare problem. *Ann Pharmacother*. 1993;27(9 suppl):1-24.
6. Logan D. The illness management survey: identifying adolescents' perceptions of barriers to adherence. *J Pediatr Psychol*. 2003;28(6):383-392.
7. Hommel KA, Davis CM, Baldassano RN. Objective versus subjective assessment of oral medication adherence in pediatric inflammatory bowel disease. *Inflamm Bowel Dis*. 2009;15(4):589-593. doi:10.1002/ibd.20798
8. Hommel KA, McGrady ME, Peugh J, et al. Longitudinal patterns of medication nonadherence and associated health care costs. *Inflamm Bowel Dis*. 2017;23(9):1577-1583. doi:10.1097/MIB.0000000000001165

9. Kelso M, Feagins LA. Can smartphones help deliver smarter care for patients with inflammatory bowel disease. *Inflamm Bowel Dis*. 2018;24(7):1453-1459. doi:10.1093/ibd/izy162
10. Ehrlich O, Atreja A, Markus-Kennell S, Frederick K. CCFA GI buddy provides patient reported outcomes and IBD symptoms evaluation: P-50. *Inflamm Bowel Dis*. 2012;18:S35-S36.
11. Atreja A, Otobo E, Ramireddy K, Deorocki A. Remote patient monitoring in IBD: current state and future directions. *Curr Gastroenterol Rep*. 2018;20(2):6. doi:10.1007/s11894-018-0611-3
12. Van Deen WK, van der Meulen-de Jong AE, Parekh NK, et al. Development and validation of an inflammatory bowel diseases monitoring index for use with mobile health technologies. *Clin Gastroenterol Hepatol*. 2016;14(12):1742-1750.e7. doi:10.1016/j.cgh.2015.10.035
13. de Jong MJ, van der Meulen-de Jong AE, Romberg-Camps MJ, et al. Telemedicine for management of inflammatory bowel disease (myIBDcoach): a pragmatic, multicentre, randomised controlled trial. *Lancet*. 2017;390(10098):959-968. doi:10.1016/s0140-6736(17)31327-2
14. Atreja A, Khan S, Rogers JD, et al. Impact of the mobile HealthPROMISE platform on the quality of care and quality of life in patients with inflammatory bowel disease: study protocol of a pragmatic randomized controlled trial. *JMIR Res Protoc*. 2015;4(1):e23. doi:10.2196/resprot.4042
15. Chang S, Hamilton M, Lees C, Atreja A. Mobile health in IBD: enhancing care, one phone at a time. *Inflamm Bowel Dis*. 2020;26(2):163-166. doi:10.1093/ibd/izz262
16. Hommel KA, Ramsey RR, Gray WN, Denson LA. Digital therapeutic self-management intervention in adolescents with inflammatory bowel disease. *J Pediatr Gastroenterol Nutr*. 2023;76(1):38-42. doi:10.1097/mpg.0000000000003623
17. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and validation of the user version of the mobile application rating scale (uMARS). *JMIR Mhealth Uhealth*. 2016;4(2):e72.
18. Plevinsky JM, Denson LA, Hellmann J, Minar P, Rosen MJ, Hommel KA. A micro-longitudinal approach to measuring medication adherence in pediatric inflammatory bowel diseases. *J Pediatr Gastroenterol Nutr*. 2020;71(3):366-370. doi:10.1097/mpg.0000000000002778

How to cite this article: Hommel KA, Noser AE, Plevinsky J, Gamwell K, Denson LA. Pilot and feasibility of the SMART IBD mobile app to improve self-management in pediatric inflammatory bowel disease. *J Pediatr Gastroenterol Nutr*. 2024;1-6. doi:10.1002/jpn3.12229