

# BMJ Open Perspectives on the sustained engagement with digital health tools: protocol for a qualitative interview study among people living with Inflammatory Bowel Disease or irritable bowel syndrome

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## ABSTRACT

**Introduction** Digital health tools can be beneficial in the care of patients with chronic conditions and have the potential for widespread impact as readily scalable and cost-effective health interventions. However, benefits are often contingent on users sustaining their engagement with these tools over time. Sustained engagement with digital health tools can be challenging, and high rates of attrition from digital interventions are common. Inflammatory Bowel Disease (IBD) and irritable bowel syndrome (IBS) are prominent gastrointestinal conditions resulting in significant burdens for individuals and society. Emerging evidence suggests digital health tools can be beneficial for IBD and IBS management; however, it is not clear what barriers and enablers are experienced by people living with these conditions to sustaining their engagement with these tools, when necessary. Such knowledge could inform the tailoring of new and existing digital health tools to the needs of people living with IBD and/or IBS. This study will seek to identify the barriers and enablers of sustained engagement with digital health tools among adults living with IBD and/or IBS.

**Methods and analysis** We will conduct semistructured interviews with a purposive sample of approximately 30 adults (>18 years) who (a) reside in Canada, (b) self-report that they have been diagnosed with IBD and/or IBS, (c) have ever used a digital health tool (ie, any application/platform) to manage their condition and (d) are capable of providing informed consent. Interviews will be audio and video recorded and transcribed verbatim. Data will be coded deductively and barriers and enablers to sustained engagement will be categorised in accordance with the Theoretical Domains Framework. Data analysis will be verified by a patient research partner.

**Ethics and dissemination** The study has been approved by the Ottawa Health Science Network Research Ethics Board. The findings will inform the codevelopment of strategies to overcome modifiable barriers and leverage identified enablers of sustained engagement with digital

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ People with lived experience of Inflammatory Bowel Disease (IBD) and/or irritable bowel syndrome (IBS) have been engaged as patient research partners and will provide feedback on all aspects of the study, from conceptualisation to interpretation and dissemination.
- ⇒ Qualitative research methods (ie, semistructured interviews) will be used to elicit a detailed account of the perspectives of Canadian adults living with IBD and/or IBS on what impacts their sustained engagement with digital health tools.
- ⇒ The study draws on an established theoretical framework from implementation science, specifically the Theoretical Domains Framework, to conceptualise barriers and enablers of sustained engagement with digital health tools.
- ⇒ The study is supported through the Inflammation, Microbiome and Alimentation: Gastro-Intestinal and Neuropsychiatric Effects (IMAGINE) network as part of the Strategy for Patient Oriented Research, an initiative of the Canadian Institutes of Health Research. Network members will promote study recruitment and be instrumental in the dissemination of study findings, and subsequent codesign of strategies to support sustained engagement with new and existing digital health tools for IBD and/or IBS care.
- ⇒ A pragmatic decision to include participants who self-report that they have received a diagnosis of IBD and/or IBS, without requiring evidence of the diagnosis from a treating physician is a potential limitation of the study, and the findings should be interpreted accordingly.

health tools for IBD and IBS care. These strategies can inform the design of new, or modifications to existing, digital health tools for IBD and IBS care where sustained

engagement is desirable. Strategies will be compiled into a guidebook and disseminated via the Inflammation, Microbiome and Alimentation: Gastro-Intestinal and Neuropsychiatric Effects (IMAGINE) Strategy for Patient Oriented Research chronic disease network in Canada.

## INTRODUCTION

Digital health tools have been associated with improved outcomes in people living with a variety of chronic conditions<sup>1–3</sup>, including Inflammatory Bowel Disease (IBD) and irritable bowel syndrome (IBS).<sup>4</sup> These tools can facilitate timely access to healthcare information, diagnoses and treatments and include ‘stand-alone software applications as well as integrated hardware and software systems which can utilise platforms, such as computers, smartphones, tablets and wearables’.<sup>5</sup> Furthermore, as emerging technologies, including artificial intelligence, are increasingly applied in digital health,<sup>6</sup> we may anticipate ongoing growth in the digital health tools available to people living with chronic conditions. Digital health tools hold considerable potential for widespread impact as cost-effective and readily scalable health interventions.<sup>7</sup> For individuals to obtain the full benefit of these resources, it is necessary for them to engage effectively with these tools. Depending on the nature of the tool and desired outcomes, sustained engagement over time is sometimes required.<sup>8</sup> However, sustained engagement can be challenging, as high rates of attrition from digital health interventions are common, particularly when delivered in real-world settings.<sup>9</sup> It is not clear what factors might impede or support people living with IBD and/or IBS to continue to engage with digital health tools when sustained engagement is indicated. The perspectives of individuals living with these conditions can help us to identify barriers and enablers to sustained engagement. This information could be used to inform the development and tailoring of strategies to combat high rates of attrition, support sustained engagement when indicated and optimise the benefits of these tools.

IBD and IBS are prominent gastrointestinal conditions and result in considerable burden on individuals and society.<sup>10 11</sup> IBD is a collective term for chronic inflammatory disorders of the gastrointestinal tract, the most common subtypes being Crohn’s disease and ulcerative colitis.<sup>12</sup> Symptoms include but are not limited to abdominal pain, diarrhoea, bloody stools, rectal bleeding and diminished absorption of nutrients, which can result in malnutrition.<sup>13</sup> IBS is a common form of functional gastrointestinal disorder, now referred to as ‘gut–brain interaction’ disorders.<sup>14</sup> Subtypes include IBS with predominant constipation, IBS with predominant diarrhoea, IBS with mixed bowel habits and IBS unclassified.<sup>15</sup> Symptoms vary widely between individuals, and in addition to disordered bowel movements, may include bloating, pain and psychological stress.<sup>15</sup> Almost 40% of patients living with IBD also experience symptoms of IBS.<sup>16</sup> Both conditions are associated with significantly diminished quality of life.<sup>17 18</sup> The economic burden of these gastrointestinal

conditions is also considerable.<sup>18–20</sup> Digital health tools have been associated with improved quality of life, illness-related knowledge, and medication adherence, and lower levels of psychological distress and decreased healthcare utilisation in people living with IBD and/or IBS.<sup>4</sup>

Sustained engagement is often necessary when using digital health tools for IBD and/or IBS care. For instance, digital health tools hold utility in ‘treat-to-target’ approaches recommended for IBD care, including approaches aiming to improve quality of life and reduce flares, hospitalisations and surgeries and can be applied for remote monitoring of data, conducting repeated assessments and the delivery of interventions.<sup>21</sup> Monitoring, assessment and intervention delivery may take place over multiple weeks, months or years. Similarly, tele-nutrition interventions for the management of IBD may involve long-term monitoring.<sup>22</sup> Digital symptom trackers are commonly used for the management of IBS,<sup>23</sup> and symptom tracking typically necessitating sustained engagement over time. Strategies are needed to support people living with IBD and/or IBS to sustain their engagement with digital health tools where sustained engagement is needed to facilitate therapeutic benefit. The development of such strategies necessitates an understanding of what factors impede or support people living with these conditions to effectively engage with digital health tools over time. Such factors may be different from those which influence the initial adoption of digital health tools.

## Aim

The aim of this study is to identify barriers and enablers of sustained engagement with digital health tools from the perspectives of people living with IBD and/or IBS. Digital health tools encompass any mobile application or web-based technology used to manage IBD and/or IBS, including tools supporting the adoption and maintenance of healthy lifestyle behaviours such as diet or physical activity. Tools may include those that are commercially available and those that have been specifically designed and tested for intervention studies. The findings will inform the selection and tailoring of evidence-informed strategies that can be used to address modifiable barriers and leverage identified enablers of sustained engagement with digital tools for IBD and IBS care. Strategies will be compiled into a guide that can support the design of new, or modifications to existing, digital health tools for IBD and IBS care where sustained engagement over time is required.

## METHODS AND ANALYSIS

### Study design

Qualitative methods are useful for identifying barriers and enablers of health behaviour change.<sup>24</sup> We will apply qualitative methods, in the form of one-on-one semi-structured interviews with individuals living with IBD and/or IBS, to build an understanding of their perspectives on what impedes and/or supports them to sustain

engagement with digital health tools. Two individuals with lived experience of IBD and/or IBS have been engaged as patient research partners. The patient research partners will be actively involved in all stages of the research, from planning to dissemination.

### Setting and context

This study will be led by researchers at the Ottawa Hospital Research Institute's Centre for Implementation Research and will involve community-dwelling individuals living in Canada.

### Sample and recruitment

We will use purposive sampling to recruit approximately 30 adults ( $\geq 18$  years) living in Canada who self-report that they have been diagnosed with IBD and/or IBS and have previously used any kind of digital health tool for care of their condition. These tools may range from those specifically tailored for IBD or IBS to other tools tailored to generic chronic conditions or those aiming to support engagement in healthy lifestyle behaviours, such as physical activity. This will include tools available commercially and those developed for research purposes. In collaboration with partner organisations, patient partners and people with lived experience, we will conduct a national-level recruitment programme, aiming to recruit diverse members of these communities, with representation across genders, age, cultural backgrounds, geographic locations (across provinces; rural/urban), and time since diagnosis, age at diagnosis, condition type and level of engagement with digital health tools in the past. To be eligible to participate, individuals must be (a) able to understand, speak, and read English or French; (b) have access to a computer, phone or tablet with the internet; (c) be willing to take part in an interview and share their personal experiences of using any type of digital health tools (ie, any application or platform) and (d) be able to provide informed consent.

The study will be promoted to people living with IBD and/or IBS through the Inflammation, Microbiome and Alimentation: Gastro-Intestinal and Neuropsychiatric Effects (IMAGINE) chronic disease network, including the network's patient research partner team. The IMAGINE network is funded through the Canadian Institutes of Health Research Strategy for Patient Oriented Research initiative. Members include representatives of partner organisations (ie, Crohn's and Colitis Canada, Canadian Association of Gastroenterology, Canadian Digestive Health Foundation, GI Society), healthcare practitioners, people with lived experience of IBD and/or IBS, patient partner researchers, and academic and clinical researchers.<sup>25</sup> The study will be promoted in English and French and may include posts on social media platforms and websites (including the IMAGINE website), advertisements in newsletters and flyers in clinical settings where people living with IBD and/or IBS seek treatment. Partner organisations may also forward details of the study to individuals listed on their databases. Individuals

interested in taking part will be invited to express interest by emailing or phoning the study team. Participants will receive a CAD\$20 electronic gift card for a retailer of their choice (eg, Walmart; Home Depot; Tim Hortons) to compensate them for participating in the interview.

### Theoretical framework

Theoretical frameworks can be used to systematically identify barriers and enablers of behaviours, which can then inform the development of theoretically and empirically informed solutions.<sup>24</sup> The Theoretical Domains Framework (TDF) is one such framework and is suitable for building an understanding of the factors that influence patient behaviour.<sup>24 26 27</sup> The TDF includes 84 theoretical constructs from 33 theories of behaviour and behaviour change, clustered into 14 domains: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention, and decision processes; environmental context and resources; social influences; emotion; and behavioural regulation. These domains represent mechanisms of action, theorised to be determinants of behaviour change and will be applied in this study to classify barriers and enablers of sustained engagement with digital health tools, from the perspectives of individuals living with IBD and/or IBS.

### Interviews

Eligible, consenting participants will take part in a single interview of approximately 60 min duration, conducted virtually via MS Teams (Microsoft). Interviews will be conducted by a member of the research team who is trained in qualitative research methods and has no prior relationship with study participants (CD and AP).

Semistructured interview guides have been developed in French and English, to elicit participants' perspectives on their previous use of digital health tools for IBD or IBS care, and any barriers or enablers they may have encountered to sustaining their engagement with those tools over time (see online supplemental file 1). Development of the guides was informed by the TDF.<sup>27 28</sup> The guides are semistructured and intended to be flexible, to allow the interviewer to adapt based on the perspectives and experiences of individual participants. In addition to collecting information about participants' views on sustained engagement with digital health tools, we will also collect information about participants' demographic (ie, age, gender, ethnicity, province or territory of residence, rurality, education and marital status) and health-related characteristics (ie, diagnosis type, time since diagnosis, perceived overall health and perceptions of how condition is being managed) during the interviews. The English and French versions of the interview guide were pilot tested with the patient research partners, who provided feedback to ensure the line of questioning was clear and suitable to the needs of the participants and the study. The interview guides were adapted based on the feedback provided by the patient research partners and

the experience of the researchers facilitating the pilot interviews.

Interviews will be audio and video recorded and transcribed verbatim, using the record and transcribe functions in MS Teams (Microsoft) or an external transcription service. A member of the research team will compare the transcription against the recording to verify the accuracy of the transcription. Recordings will be deleted after transcripts have been verified for accuracy. Transcripts of interviews conducted in French will be translated into English prior to analysis.

### Sample size determination

In line with guidance on sample size for interview studies, the sample size has been pragmatically estimated based on the nature of the research question, study design, the directed nature of the theoretically informed analysis and the available resources.<sup>29</sup> The exact number of participants will be decided by the research team during data collection and concurrent analysis, based on the quality of the data collected (ie, breadth, depth and richness) to ensure the research question can be adequately addressed.<sup>30</sup> To achieve the approximate sample size of around 30 individuals, we expect to screen up to 50 people. Low rates of attrition are anticipated because the eligibility criteria will be advertised in the recruitment materials and because of the single time point interview design, with interviews to be conducted shortly after obtaining informed consent.

### Data analysis

Interviewing and analysis will be undertaken concurrently to allow the researchers to monitor the progress of data collection, permit follow-up of issues that may emerge from the data and facilitate determination of adequate sampling.

Data will be analysed qualitatively via directed content analysis<sup>31</sup> using Dedoose software for qualitative analysis (V.9.2.007, Sociocultural Research Consultants). Data will be coded using predetermined codes, consistent with the definitions of each domain of the TDF.<sup>26,27</sup> To allow for the identification of novel factors of influence, any data that cannot be coded in accordance with the TDF domains will be identified and assessed to determine if they represent a new domain of constructs, not currently characterised by the TDF. We will contrast perspectives of participants who report being diagnosed with IBS, IBD (and condition subtypes), and both IBD and IBS, to understand the impact of these health conditions on the sustained use of digital health tools. To verify the emerging analyses, a second analyst will review a preliminary set of codes to assess how well the data are represented. Where differences in interpretation arise, the two analysts will discuss to ensure all interpretations are considered until arriving at one that best accounts for participant views and experiences. Additionally, emerging analyses will be reviewed by a patient research partner to ensure interpretations reflect the sentiment expressed by participants from the perspective of someone with lived expertise.

The demographic and health-related characteristics of participants will be described using frequencies and percentages (categorical variables) or means and SDs (continuous variables). Codes identified through the qualitative analysis will be re-examined, to determine any differences or similarities in perspectives on sustained engagement with digital health tools based on these characteristics.

Once factors that impact behaviour have been identified in accordance with the domain of the TDF and reviewed by a patient research partner, modifiable barriers and enablers will be mapped to relevant behaviour change techniques (BCTs) using the theory and techniques tool.<sup>32</sup> BCTs are strategies designed to support an individual to change a targeted behaviour<sup>33</sup> and can be applied to support behaviour change among patients. The theory and techniques tool was created through a 'triangulation' of evidence from a systematic review of implementation intervention trials<sup>34</sup> and expert consensus,<sup>35</sup> and links domains from the TDF to relevant BCTs. Thus, this tool will facilitate the identification of evidence-informed strategies that could be applied to support sustained engagement with digital health tools among people living with IBD and/or IBS.

After a preliminary endeavour by the research team to select relevant BCTs using the theory and techniques tool and to strategise feasible ways to operationalise the BCTs, a patient research partner will be engaged to obtain feedback on the appropriateness of the suggested strategies, ensuring they are acceptable and sensitive to the needs of people living with IBD and/or IBS. The final selected strategies will be compiled into a guidebook of relevant implementation strategies that can be used by researchers and developers of digital health tools when developing or modifying digital health tools for use in IBD and IBS care.

### Patient and public involvement

This study was conceived under the guidance of an IMAGINE Network working group focused on supporting the uptake and sustained use of digital solutions/apps in IBD/IBS care. Members of the working group include people with lived experience of IBD and/or IBS, a representative of a partner organisation, healthcare practitioners and researchers. A subset of members of the working group with lived experience of IBD and/or IBS are graduates of the University of Calgary Patient and Community Engagement Research Programme.<sup>36</sup> Patient research partners with lived experience of IBD and/or IBS are also more directly involved as active members of the research team. A patient research partner reviewed the study protocol, and two patient research partners were involved with pilot testing of the interview guides (English and French versions). Patient research partners will also assist with promoting the study to people living with IBD and/or IBS, reviewing the analysis, selecting and tailoring BCTs, and compiling and designing a guidebook of strategies to be disseminated throughout the IMAGINE network.

## ETHICS AND DISSEMINATION

### Ethical/safety considerations

Participants will provide verbal informed consent prior to taking part in the study. Details of the informed consent process will be logged by a member of the research team. Human research ethics approval was sought from the Ottawa Health Science Network Research Ethics Board (protocol number 20240198-01H) prior to the commencement of data collection.

## IMPACT AND DISSEMINATION

Findings of this study will be presented in a peer-reviewed publication and scientific presentations targeting clinical and research audiences. The scientific manuscript will adhere to the authorship criteria established by the International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts submitted to Biomedical Journals,<sup>37</sup> with findings presented in accordance with Consolidated criteria for Reporting Qualitative research guidelines.<sup>38</sup> A description of the barriers and enablers perceived by people living with IBD and/or IBS to inhibit or support sustained engagement with digital health tools will also be disseminated in lay language format to members and partners of the IMAGINE network. Deidentified data and meta-data will be deposited on the Open Science Framework.

Strategies to support sustained engagement with digital health tools for IBD and IBS care will be compiled into a guide that can be used by researchers and digital tool developers to inform modifications to existing digital health tools and the development of new tools for IBD and IBS care where sustained engagement is indicated. This guide will be reviewed by a patient research partner. The guide will be electronically disseminated to members and partners of the IMAGINE Network, and national IBD and IBS organisations throughout Canada.

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