Published in final edited form as:

Neurogastroenterol Motil. 2015 January ; 27(1): 128–134. doi:10.1111/nmo.12487.

Development and Pilot Testing of an Integrated, Web-Based Self-management Program for Irritable Bowel Syndrome (IBS)

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Abstract

Background—Although essential, many medical practices are unable to adequately support irritable bowel syndrome (IBS) patient self-management. Web-based programs can help overcome these barriers.

Methods—We developed, assessed, and refined an integrated IBS self-management program (IBS Self-care). We then conducted a 12-week pilot test to assess program utilization, evaluate its association with patients' self-efficacy and quality of life, and collect qualitative feedback to improve the program.

Results—40 subjects with generally mild IBS were recruited via the internet to participate in a 12-week pilot study. Subjects found the website easy to use (93%) and personally relevant (95%), and 90% would recommend it to a friend. Self-rated IBS knowledge increased from an average of 47.1 on a 100-point VAS scale (SD 22.1) at baseline to 77.4 (SD: 12.4) at week 12 ($p < 0.0001$). There were no significant changes in patient self-efficacy (Patient Activation Measure) or quality of life (IBS -Quality of Life Scale).

Conclusions—The IBS Self-Care program was well received by users who after 12 weeks reported improved knowledge about IBS, but no significant changes in self-efficacy or quality of life. If applied to the right population, this low cost solution can overcome some of the deficiencies of medical care and empower individuals to better manage their own IBS.

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Potential Conflicts: none.

BACKGROUND

Irritable bowel syndrome (IBS) affects up to 10% of the population and significantly impairs health related quality of life. It is also a leading reason for health care visits and accounts for direct medical costs exceeding \$1 billion annually.¹ Because there is no cure, patients with IBS must be supported to develop the knowledge and skills needed to effectively manage their own condition.² In a systematic review, we found that various IBS self-management support interventions improved symptoms and enhanced quality of life, with gains often exceeding those reported in IBS drug studies.³ Yet most physicians working in the “real world” lack the training, time, office infrastructure (including nurses skilled in managing IBS), and incentives needed to support patient self-management.⁴ Consequently, self-management support is rarely integrated into care.

Web-based self-management support programs have the potential to address these barriers. Such programs use multimedia formats to deliver health information, as well as tools to support decision making and/or behavior change. By moving beyond the clinic walls, these programs allow patients to access the support they need on-demand, at any time, and for minimal cost. Additionally, because these programs incorporate multiple, self-paced components (e.g., education, support networks, self-care activities), support can be tailored to continually meet patients’ needs as they change over time. Across a range of conditions, these programs positively affect knowledge, social support, health behaviors, self-efficacy, and clinical outcomes.⁵

To date, there have been no published reports of web-based self-management support programs for patients with IBS. The purpose of this study was to develop, refine, and pilot test an integrated, web-based IBS-self management program for patients with IBS.

METHODS

We modeled our program on the Comprehensive Health Enhancement Support System (CHESS).⁶ We first developed a conceptually-based prototype that would be feasible for patients with IBS. Next we assessed its usability among a small group of patients with IBS and used their feedback to refine the program. Finally, we pilot tested the refined prototype to: (1) determine how patients utilized the program, (2) evaluate its association with patients’ health status and self-efficacy; (3) collect qualitative feedback about how to improve the program.

Prototype Development

Conceptual Model—*Self-determination theory* suggests that e-health interventions benefit emotional health and wellbeing by meeting three key needs. The first need is autonomy, the need to feel a sense of control over one’s condition. The second need is competence, the perceived ability able to do something about one’s condition. Educating subjects about IBS and providing them tools to help track their symptoms can help them better understand IBS in general, and their own bodies in particular, as well as recognize different choices and response options that they can pursue. In sum, these components should increase participants’ sense of autonomy and competence. The third need is

relatedness or feeling a common experience with others.⁷ Considering the stigma surrounding IBS, connecting with others online can help individuals feel less isolated and alone in their suffering. Combined, increasing autonomy, competence and relatedness can improve self-management behaviors and emotional well-being, thereby improving health status. These relationships are outlined in figure 1.

Information Architecture—A team of IBS experts, experienced web designer, a usability specialist, health behavior specialist, and applications programmers worked collaborative to design an interactive website that appealed to and benefitted individuals with IBS.⁸ First, we developed a paper prototype with a basic site map that organized content in a nonlinear, hierarchical structure that would be easy to navigate and connect areas to form an integrated program. Second, we developed individual pages with a consistent, easy-to-use layout that combined content with appealing graphic design elements and multimedia. Third, we used the site map to organize pages into an integrated web-based program.

Content Development—We created a closed, guided universe of information integrated within a single, secure, and easy-to-use website. Topic areas were identified from (1) prior patient needs assessment,⁹ (2) interviews with IBS experts and patients to determine what is needed and what works, and (3) results of our systematic review of self-management interventions.³ Content was then developed accordingly and then all topics were reviewed and revised to ensure logical and consistent organization.¹⁰ Multiple content formats (including text, video, audio, and interactive response) were used to allow users to choose the tools that best match their needs and learning style.⁶ These were grouped into three categories: information services, tracking and planning tools, and communication support services (Figure 2).

Education included topic summaries about three broad, previously identified needs: IBS overview, IBS symptoms, and IBS treatments.⁹ The content for each topic was developed by a gastroenterologist expert in IBS (SDD) using direct and clear language that would be understandable to lay persons with IBS. Once developed, the content was reviewed by another gastroenterologist expert in IBS (DAD), and then edited for style and clarity by an experienced health behavior and education specialist. When available, these topics were linked to patient-centered, multimedia presentations by faculty members from the UNC Center for Functional GI Disorders.

Tracking and planning tools (“Tools”) included: (a) a *symptom diary* through which patients recorded gastrointestinal symptoms, stress level, physical exercise,¹¹ and health status over time; (b) an *expressive writing journal* in which individuals anonymously recorded their thoughts and feelings in a private and controlled environment, with the option to save entries for later review;¹² (c) a 10-minute *progressive muscle relaxation*¹³ digital audio recording created by an expert in psychotherapy and hypnosis for IBS (OSS); and (d) a *doctor visit planner* that clearly displayed subjects’ responses to the BEST Questionnaire¹ (an IBS assessment tool), as well as a their most bothersome gastrointestinal symptom(s), list of current medications, main concern(s), and main expectation(s) from the visit. Patients were instructed to print the planner and bring to their physician office visits. All four tools were available to patients to use however and whenever they desired.

Communication support services (“Community”) included: (a) a series of de-identified text-based personal stories developed based upon interviews with IBS patients to illustrate how other patients manage their IBS and (b) *peer-to-peer discussion groups* (i.e., virtual community) through which patients were able to learn from and support one another. All entries were reviewed by a moderator (medical professional) before being posted to the general community. The moderator also responded to some posts with general information or directions to the section of the web site where the topic was covered.

Usability Testing

We used a database of research subjects, the UNC Gastroenterology Clinic, and a University-wide e-mail advertisement to recruit adults aged 18-80 with physician-diagnosed, Rome III criteria-positive IBS who saw a physician at least once over the prior 12-months. Subjects who were not proficient English, lacked at least basic computer skills, had cognitive impairment and/or major active psychiatric diseases were excluded.

After informed consent was obtained, a usability specialist observed individual participants as they moved through the online program. The usability specialist encouraged users to verbalize their actions and, at any points of hesitation, to explain why they decided to do what they did and how the program/ instructions might have been clearer. The interaction was videotaped, and qualitative analyses of these videotapes, observer notes, and user feedback were used to identify any usability problems and modify the program as needed.

Pilot Testing

For the 12-week pilot test, we sent a university-wide e-mail to recruit subjects who met the same criteria as the usability testing (above). Interested subjects contacted a trained study coordinator who explained the study, assessed eligibility, and obtained informed consent. After informed consent was obtained, each subject was given the website address along with a study ID and password.

At their initial logon, subjects read a study orientation page and then agreed to the terms of the study. The following questionnaires were then completed (Figure 3):

1. Basic Demographic information
2. *Functional Bowel Disorder Severity Index (FBDSI)*: a five-item questionnaire that assesses IBS severity based on patient pain behaviors.¹⁴
3. *Adequate relief question*: “In the past 7 days have you had adequate relief of your gastrointestinal symptoms”. This binary outcome measure has demonstrated a high degree of reliability and longitudinal construct validity in IBS trials.²⁹⁻³¹
4. *Patient Activation Measure (PAM) Short Form*: A reliable and responsive 13-item scale that measures self-management attitudes and behaviors.¹⁵
5. *Perceived IBS Knowledge*: patients will be asked to rate their perceived knowledge of IBS on a 100mm visual analog scale (0 = no knowledge at all; 100 = extremely knowledgeable).^{16, 17}

6. *Irritable Bowel Syndrome Quality of Life Scale (IBS-QOL)*: a standard, condition-specific measure of quality of life for patients with IBS.¹⁸ An improvement of 10 points in score is considered clinically meaningful.¹⁹

Upon completing these surveys, subjects were given full access to the site for a 12-week study period. Safeguards were in place to protect confidentiality (e.g., subjects used a pseudonym when posting on the community message board). To encourage participation, users received weekly e-newsletters that discussed one aspect of the online program and encouraged users to explore various site features. We did not offer any incentive to use the site; rather we left it up to the subject. At the end of the 12-week testing period, users completed three of the baseline measures (perceived IBS knowledge, PAM short form and IBS-QOL), as well as the following questionnaires:

1. *Satisfactory relief scale*: A single-item, ordinal outcome measure that assesses global treatment effectiveness was asked as follows: "How would you rate your relief of IBS symptoms (abdominal discomfort/pain, bowel habits, and other IBS symptoms) over the past week compared to how you felt before entering the study?" This measure has been shown to reliably assess changes in overall wellbeing, abdominal pain, and bowel function.²⁰
2. Pilot Testing Completion Survey that ascertained (using a 5-point response) the website's appearance, ease of use, content (interest, relevance, understandability, and usefulness), relevance, features most/least liked, and weaknesses. Open-ended questions were also used to elicit feedback, including recommended changes.

For this pilot test we conducted both process and outcome evaluations. For the former, we used Google Analytics software to track the date and time of use, as well as the specific areas visited. Process evaluation was supplemented with data from the pilot testing completion survey. Descriptive statistics (means and standard deviations for continuous measurements, and frequencies for categorical measurements) were used to assess how the program was used and overall usability. General feedback was evaluated qualitatively.

Our choice of outcome measures was guided by our conceptual model (Figure 1). Change in perceived IBS knowledge is a surrogate for perceived autonomy and competence; better informed subjects should feel more in control and better able to manage their condition. Change in Patient Activation Measure scores reflects change in overall self-management behaviors. Change in symptoms (Satisfactory Relief Scale) and IBS-QOL taps into how the intervention may have affected health status from the patient's perspective.

We used descriptive statistics to report the distribution of satisfactory relief ratings after the intervention. Using normative data and clinically meaningful change scores when available, we used paired t-tests to estimate change from pre- to post-intervention in IBS-QOL, PAM, and Perceived IBS Knowledge. Post-hoc Person correlation analysis was performed to assess whether age and duration of illness affected these variables. All analyses were performed using SPSS.

RESULTS

Subject Characteristics

We recruited 40 patients for the pilot, 35 (88%) of whom were female and 34 (85%) were Caucasian. On average, subjects were 34.2 years old (SD: 13.5; Range: 18-78 years) and were diagnosed 7.1 years ago (SD: 6.3 years, range 3 months – 23 years). Thirty-seven (92.5%) graduated high school and 28 (70%) graduated college. Eighty-percent reported feeling very comfortable using the internet and 95% had broadband (DSL or cable) internet access. Twenty-three (58%) had visited a physician at least once over the prior 6 months for gastrointestinal symptoms (13 with 1 visit, 5 with 2 visits, 2 with 3 visits, 2 with 4 visits, and 1 with 15 visits). Mean abdominal pain rating on a 0-100 scale over the 24 hours prior to study entry was 25.9 (SD: 27.42; range 0-80). Mean FBDSI was 56.9 (range 0-299).

Utilization

The frequency with which subjects used various parts of the program is listed in table 1.

Feedback

Responses to pilot testing completion survey are summarized in table 2.

Self-Efficacy Measures

1. *IBS Self-reported Knowledge:* Self-rated IBS knowledge increased markedly from baseline (mean: 47.1; SD 22.1; Range: 7-85) to Week 12 (mean: 77.4, SD: 12.4, Range: 49-94) ($p < 0.0001$) on a 100-point VAS scale where 0 = “no knowledge at all” and 100 = “extremely knowledgeable.”
2. *Patient Activation Measure:* There was no statistically or clinically significant change in mean PAM score from Week 0 to Week 12: Mean (SD): Week 0: 59.6 (10.5) vs. Week 12: 62.0 (9.6), ($p = 0.1$).

Health Status Measures

1. *Satisfactory Relief:* roughly three-fourths of all subjects reported at least some relief at week 12 relative to baseline. Overall, two (5%) reported significant relief, 9 (23%) moderate relief, 20 (50%) a little relief, 6 (15%) no change, 2 (5%) a little bit worse, 0 moderately worse, and 1 (3%) significantly worse.
2. *IBS-QOL:* there was a statistically significant increase in mean IBS-QOL scores from week 0 (mean 63.3; SD: 19.3) to week 12 (mean: 68.2; SD: 19.4) ($p = 0.02$). However, this change fell short of being clinically meaningful. The post-hoc analysis revealed that, compared to those who did not achieve clinically significant improvement in IBS-QOL, those who did were younger (mean: 27.3 (SD: 7.7) vs. 36.9 (14.2) years; $p = 0.04$) and had a shorter duration since diagnosis (mean: 3.6 (4.7) vs. 8.5 (6.5) years; $p = 0.03$). There was no difference in level of education (15.6 (2.3) vs. 16.6 (2.5) years; $p = 0.82$). Finally, there was no statistically significant correlation between change in PAM and change in IBS-QOL ($r = 0.05$; $p = 0.76$).

3. Correlation between change in knowledge and satisfactory relief scale and IBS-QOL. Post-hoc analysis revealed no statistically significant correlations between change in knowledge and IBS-QOL change ($r=0.22$; $p=0.18$) nor satisfactory relief scale scores ($r=0.17$; $p=0.29$).
4. *Adequate Relief*: At baseline, 25 (63%) reported adequate relief of their symptoms compared to 30 (75%) at week 12 ($p=0.33$). Post-hoc sub-group analysis of the 15 patients without baseline adequate relief revealed no significant change in IBS-QOL from baseline (mean: 55.8; sd: 16.5) to week 12 (mean: 61.4; sd: 18.7) ($p=0.11$).

DISCUSSION

IBS is an extremely common and costly condition. Because there is no cure, affected individuals must manage the physical and emotional consequences, as well as lifestyle changes inherent to living with a chronic illness. Research studies have demonstrated that patients with IBS who are supported to manage their own condition have improved outcomes. Yet where – in the real world – are individuals suffering from IBS to turn for such support? The structure of most medical practices and underlying incentives of a still largely fee-for-service driven US health care system²² leave most physicians unable able to adequately support their patients, not to mention that many providers dislike working with IBS patients.²³ Furthermore, at least half of those with IBS do not seek medical care for their condition, meaning they need help from outside the health care system.²⁴ A new model is therefore needed.

We developed and refined a new web-based self-management support program that included educational, tracking, planning, and communication tools previously shown to be effective when delivered on their own in non-web formats. In a 12-week pilot test we found that subjects used the program frequently and rated it favorably (90% would recommend to others with IBS). The topic summaries and message boards were especially popular. Most criticism was related to the site's design and appearance, likely related to the small development budget we worked with.

After using the site for 12-weeks subjects reported significantly improved knowledge about IBS. In addition, three-fourths reported at least some relief relative to baseline. Yet there were no clinically meaningful changes in self-efficacy (as measured by the Patient Activation Measure) nor health-related quality of life (IBS-QOL). The characteristics of the study population likely affected the results. Overall, this was primarily an internet-seeking population rather than a clinical population; more than forty-percent had not seen a physician in the prior six-months and subjects generally had very mild IBS at baseline (e.g., nearly two-thirds reported adequate relief of IBS at baseline). Thus subjects may have had little room to improve (i.e., a “ceiling effect”).

Additional factors may have limited the program's perceived effectiveness. First, only forty subjects participated and not all at the same time. Metcalf's Law of Networks states that a service becomes increasingly more valuable to a user as the number of additional users grows.²⁵ We suspect that the message board/communication activity would be more useful

in a larger online community. Also, we reviewed all comments before they were posted. Notably, all but one comment was posted. Still, it is unclear whether “experts” truly understand the patient experience and are qualified to moderate a message board. In theory, censorship could diminish self-efficacy. Second, although we sent out a weekly e-newsletter, the site's content (other than message board) remained static, possibly limiting the frequency with which subjects returned. Finally, whereas participants were able to discuss various aspects of their experience, specific discrete data on medications, symptoms, and physiological markers were not tracked or shared. Newer patient communities are incorporating this information to help patients “hack” their health care and care experience.²⁶ Study limitations include that the pilot study was uncontrolled, and that we were not able to assess change in clinical outcomes relative to the frequency with which individuals used the site, nor could we assess for possible synergist effects between the different components of the intervention. Finally, we recruited subjects using e-mails to a university community. This strategy resulted in a relatively specific sub-set of the IBS population, namely well-educated, Caucasian women with mild IBS. Subjects recruited directly from primary care and gastroenterology practices would be more likely to have moderate and severe IBS.

In sum, we developed and refined an integrated, web-based program to help individuals manage their IBS. We then pilot tested the program among a generally mild, internet-seeking population. The program was well received by users and improved knowledge. If applied to the right population, this low cost solution can overcome some of the deficiencies of medical care and empower individuals to better manage their own IBS.

Acknowledgements

This work was supported by NIH Grant K12HS019468. The website was development by the UNC Communication for Health Application and Interventions (CHAI) Core, which is supported, in part, by P30 DK56350 and P30-CA16086.

Abbreviations

FBDSI	Functional Bowel Disorder Severity Index
IBS	irritable bowel syndrome
PAM	Patient Activation Measure
PI	principal investigator

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Figure 1.

Figure 2.
Information Architecture

Figure 3.

Table 1

IBS Self-Care Usage

	Total Views	Views/Subject
Community	3476	86.9
Message Board	2840	71.0
Patient Stories	510	12.8
Tools	927	23.2
Symptom Tracker	231	5.8
Journal	153	3.8
Relaxation Exercise	117	2.9
Doctor Visit Planner	62	1.6
Education	1161	29.0
Overview	579	14.5
Symptoms	225	5.6
Treatment	299	7.5
FAQs	58	1.5
Total	5564	139.1

Table 2

Qualitative Feedback (n=40)

Website was easy to use	93%
Website was easy to navigate	85%
Website was visually attractive	83%
Content was interesting	85%
Content was personally relevant	95%
Would recommend program to others with IBS	90%
Features liked most	
• Topic summaries	70%
• Patient stories	53%
• Message board	50%
Features liked least	
• Expressive writing diary	38%
Recommended improvements (open-ended)	
• User friendliness/ease of navigation	33%
• General appearance	25%
• Mobile/tablet compatability	18%