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Optimizing Management of Crohn's Disease within a Project Management Framework: Results of a pilot study

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Abstract

Background—Psychotherapy for CD has focused on patients w/psychological distress. Another approach to optimize management of CD is to target patients who do not exhibit psychological distress but engage in behaviors that undermine treatment efficacy/increase risk for flare. We sought to determine the feasibility/acceptability and estimate the effects of a program framed around Project Management (PM) principles on CD outcomes.

Methods—Twenty-eight adults w/quiescent CD w/o history of psychiatric disorder were randomized to Project Management (N = 16) or treatment as usual (TAU; N=12). Baseline and follow-up measures were IBDQ, Medication Adherence Scale (MAS), Perceived Stress Questionnaire (PSQ) and IBD Self-Efficacy Scale (IBD-SES).

Results—There were significant group X time effects favoring PM on IBDQ-Total Score [F(1) = 15.2, p = .001], IBDQ-Bowel [F(1) = 6.5, p = .02] and IBDQ-Systemic [F(1) = 9.3, p = .007] but not IBDQ-Emotional [F(1) = 1.9, p = ns] or IBDQ-Social [F(1) = 2.4, p = ns]. There was a significant interaction effect favoring PM w/ respect to PSQ [F(1) = 8.4, p = .01] and IBD SES [F(1) = 12.2, p = .003]. There was no immediate change in MAS [F(1) = 4.3, p = ns]. Moderate effect sizes (d > .30) were observed for IBDQ total score (d = .45), IBDQ bowel health (d = .45) and systemic health (d = .37). Effect sizes for PSQ (d = .13) and IBDSSES (d = .17) were smaller.

Conclusions—Behavioral programs that appeal to patients who may not seek psychotherapy for negative health behaviors may improve quality of life and potentially disease course and outcomes.

Keywords

Crohn's Disease; Inflammatory Bowel Disease; Self-management; Project Management

Introduction

Crohn's Disease (CD), one of the most disabling and costly forms of Inflammatory Bowel Disease (IBD)^{1, 2}, is systemic with inflammation affecting the entire gut mucosa from mouth to anus³⁻⁷. During periods of flare, CD is associated with severe abdominal pain, urgent diarrhea, weight loss, malnutrition and disabling fatigue¹⁵. Extraintestinal symptoms include mouth sores, eye inflammation, joint pain and skin lesions⁸. Even in remission, patients struggle with consequences of intestinal damage including abdominal pain, discomfort and bloating⁹.

The average patient with IBD spends in total about 3 hours per year with their gastroenterologist¹⁰. In the time spent outside the immediate care of their

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gastroenterologist, patients are left to manage the burden of uncomfortable and embarrassing symptoms, disability and functional impairment, complicated medication regimens, demanding lifestyle changes and coordination of medical care and health insurance. CD is typically diagnosed in early adulthood and as a result influences one's decision-making around careers, romantic relationships and finances^{1, 11-13}. In anticipation of disease flares, patients with CD may restrict personal travel, limit their activities, avoid stress or challenges and bank sick days at work¹⁴. Underemployment is common as patients attempt to preserve employer-based health benefits^{7, 15, 16}. Furthermore, the challenges of CD are lifelong and will change over time, requiring ongoing adaptation and acquisition of new skills.

Despite recent medical advances that can inhibit disease flares for up to 2 years¹⁷⁻¹⁹ treatment for CD remains suboptimal because flares are an inevitable part of the disease²⁰⁻²⁴. Therefore, it is important that health care providers look for alternative ways to enhance the efficacy of treatment. One approach to optimizing the management of CD is to target the health behaviors that undermine treatment efficacy or increase individual risk for flare. For example, the efficacy and dosing of medications needed to induce and sustain remission is directly influenced by behavioral factors including medication adherence^{9, 25-37}, stress and psychological well-being^{38-45 46, 47}, coping^{6, 46-48}, the patient-physician relationship^{27, 49-54}, smoking^{55, 56} and disease knowledge^{13, 57, 58}. We have also previously demonstrated that IBD patients who have difficulty adapting to disease-related demands report more bowel and systemic symptoms, more pain, less engagement in activities, higher perceived stress, an emotional representation of illness and higher rates of health care use⁵⁹.

There is mounting evidence to support the role of psychological interventions for patients coping with Inflammatory Bowel Diseases⁶⁰⁻⁶². However, most of these programs limit their scope to IBD patients with psychological distress. In doing so, we fail to reach the patients who engage in and exhibit the very disease-modifying behaviors we are concerned about (smoking, obesity, poor adherence, excessive stress). Comprehensive, structured disease self-management programs that are driven by the values of patient empowerment, self-efficacy and the acquisition of disease-specific skills could potentially become an integral component of IBD management. To our knowledge, there is only one published trade book aimed at this unique patient population⁶³ and the book is too new to determine its impact on patient outcomes.

We have re-packaged our traditional cognitive-behavioral therapy training program to appeal to a group of CD patients who may not otherwise seek psychological support. “*Project Management*” for *Crohn's Disease* is a program modeled after substantiated problem-solving processes typically found in corporate America (e.g., Six Sigma, Lean, Agile, Scrum, PMBOK, Waterfall). There are several parallels between traditional elements of project management and disease self-management demonstrated in our program.

1. Projects are *time-limited and discrete*. This adaptation is helpful for patients who feel overwhelmed by disease management. Encouraging patients to focus on 1 or 2 key behavior changes will improve their sense of self-efficacy and increase their likelihood of success.
2. Successful project managers *allocate limited resources* carefully. In our program, CD patients are encouraged to view their resources as limited and consider how to distribute the personal, financial and emotional resources that they do have; this may vary according to whether they are in flare or remission.
3. Projects are rarely executed independently; *they utilize a team of people* with varying skill sets to effectively communicate, share in decision-making and manage each other's concerns and expectations. This is also true when managing disease;

patients must use decision-making skills and communicate with their physician and other health care providers in order to improve the quality of their care.

4. Projects usually require consultation with *subject matter experts* who can shed light on certain aspects of the project because of their unique content knowledge. We encourage patients to take advantage of outside physicians, dieticians, nurse educators, psychologists and even peers that can provide important information to incorporate into their self-management plan.
5. Projects acknowledge risks and potential barriers to success. Projects usually have a *risk management plan* that can be implemented promptly when necessary. An important part of chronic disease management is self-monitoring and awareness of triggers, early signs and symptoms and behaviors that directly contribute to disease activity. Patients can take control and reduce stress with advanced planning for what to do or who to contact in the event of an emergency or case of flare.
6. Projects are *flexible in their approach* but not their scope. Patients are expected to continue working towards their specified goal while managing frustrations and unexpected barriers (flare, surgeries, opportunistic infections) that occur along the way. This approach also addressed the tendency to wax and wane with respect to health promoting behaviors (eating healthy, exercise, relaxing, good sleep), often driven by symptoms.
7. All projects have a *leader and key stakeholders* in the outcome. In our program, the patient must take charge as well as identify the role, contribution and interest of those around them (e.g., physician, psychologist and family).

For an example project outline, see Table 1.

The scope of our study was to roll out a program focused on project management principles to CD patients *without apparent psychological distress*. We involved psychologists, physicians and a dietician in our team of subject matter experts to develop the skills training materials. Our outcome metrics were chosen carefully to determine whether this approach to CD management would be feasible, acceptable and useful for a population of non-psychologically distressed patients. We predicted that this type of program would draw a slightly different CD patient population and that our approach would be superior to treatment as usual. We also expected PM patients to demonstrate immediate improvement in quality of life, self-efficacy and perceived stress.

Materials and Methods

Participants

Adult men and women (aged 18-70) with Crohn's Disease confirmed by a gastroenterologist via clinical and endoscopic standards⁶⁴ were recruited by a study coordinator following a routine well-visit with their gastroenterologist at our outpatient faculty practice group at Northwestern University Feinberg School of Medicine. Inclusion criteria included clinical remission at the time of baseline as determined by Crohn's Disease Activity Index [CDAI; REF] < 150 and a stable medication regimen > 30 days. Exclusion criteria were active disease [CDAI ≥ 150], a psychiatric diagnosis (e.g., depression, anxiety disorder, substance abuse), a history of psychiatric hospitalization or suicidal ideation, a permanent ileostomy, ulcerative or indeterminate colitis, renal or hepatic disease, short bowel syndrome, refusal to be randomized and contraindications for disease self-management training (e.g., serious cognitive impairment, serious mental illness).

Thirty participants were consented and enrolled, 2 of whom discontinued after randomization but prior to intervention (one from each condition), resulting in a total of 28. Randomization occurred on a 1:1 ratio using Random Allocation Software⁶⁵. Upon randomization, participants were assigned either the experimental condition of 6 weekly, 60 minute sessions of “Project Management” with a health psychologist (LK) (N = 16) or the control condition, receiving treatment as usual (N = 12). Power analysis indicated that based on a 25 point change in our primary outcome variable, IBD specific quality of life, we had 85% power to detect differences between two groups using baseline as a covariate.

Treatment Conditions

Project Management (PM)—The “Project Management” Program for Crohn’s Disease is a 6-session weekly, 60 minute individualized outpatient protocol. The first author derived the program based on several years of clinical experience with the IBD population and prior work with self-management program development for other chronic gastrointestinal conditions. The program is based upon cognitive-behavioral principles of health behavior change and social learning theory⁶⁶⁻⁶⁸. This foundation allows for a flexible program in that the patient creates a “project scope statement” at Session 1, identifying therapy goals to address during the course of treatment. Future sessions are structured around implementing these individualized goals and may include skills training in areas such as smoking cessation, weight loss, stress management, medication adherence, physician-patient communication, medical decision-making, work difficulties, financial concerns, parenting and interpersonal relationships. All participants received formal instruction in relaxation training and a nutritional consult from an advanced practice dietician (BD).

Treatment as Usual (TAU)—Patients randomized to TAU completed questionnaires on the same interval as the PM group. These subjects received care from their primary gastroenterologist as they usually would during the 6 weeks. While not disallowed, no participants in either condition reported a change in medication or the occurrence of a flare during the 8 week intervention period.

Measures

Sociodemographics and Clinical Information—Participants were asked to report demographic and illness-related variables on our standard IBD Center-wide questionnaire. They also provided a general medical history upon enrollment.

Inflammatory Bowel Disease Self-Efficacy Scale (IBD-SES)—The IBD-SES is a 29-item validated disease-specific self-efficacy measure. Responses are rated on a 10-point Likert scale ranging from “not sure at all” to “totally sure.” Questions are grouped into 4 theoretical subscales: managing stress and emotions, managing medical care, managing symptoms and disease and maintaining remission. The overall score of the IBD-SES ranges from 29 to 290 with a higher score suggesting greater disease-specific self-efficacy.

Perceived Stress Questionnaire-Recent (PSQ-R)^{69, 70}—The PSQ-Recent is a 30-item validated measure of stress in the past month across 7 factors: harassment, overload, irritability, lack of joy, fatigue, worries and tension. Items are rated on a 4-point Likert scale from “almost never” to “usually.” Higher scores suggest greater perceived stress. Norms have been previously reported in IBD^{69, 71}.

Medication Adherence Scale (MAS)⁷²—is a 4-item questionnaire that quantifies adherence to an IBD medication regimen. The four domains of adherence assessed are 1) forgetting to take medications; 2) being careless around timing of medications; 3) stopping medication when feeling better; and 4) stopping medication when feeling worse. A sum

score of 0 reflects 100% adherence in the past month and a sum score of 4 reflects complete lack of adherence.

Inflammatory Bowel Disease Questionnaire (IBDQ)⁷³—The IBDQ is a 32-item validated questionnaire to assess disease severity and quality of life in IBD, yielding four subscale scores: bowel health, systemic health, emotional functioning, and social functioning. Responses are given on a 7-point Likert scale, from “worst function” to “best function”. Lower scores indicate greater disease severity and lower quality of life.

Statistical Analyses

Statistical analyses were completed using SPSS 18.0 for Windows (SPSS Inc., Chicago IL). Central tendency and variability were calculated including frequencies, means, standard deviations, and ranges. Data were normally distributed across total scale scores. Chi-square and Fisher’s exact tests were used to evaluate differences in proportions of categorical variables across groups. Repeated measures ANOVA was performed to determine the effect of treatment group on outcomes over time. Effect sizes were calculated by dividing the difference in change means at post-treatment by the average pooled baseline variance.

Ethical Considerations

The study was approved by the Institutional Review Board (IRB) at Northwestern University. All participants provided informed consent.

Results

Twenty-eight (18F, 10M) adults with stable and quiescent Crohn’s Disease were randomized to Project Management (N=16) or Treatment as Usual (N=12). Mean age of PM subjects was 34.5 years (range 29-39) and the mean age of the TAU group was 40.8 (range 31-49). Ninety-two percent of the sample was white, 70% was female, 50% were married, 60% had a prior history of FMLA/disability for their CD, 73% had a prior hospitalization for CD and 61% reported that they flare at least once per year. There were no differences between conditions on any clinical or demographic variables.

A repeated measures (Group X Time) ANOVA demonstrated differences between groups over time on self-report measures of quality of life, perceived stress, self-efficacy and medication adherence effect [$F(7, 12) = 4.1, p = .02$]. When compared to the Treatment as Usual (TAU) Project Management reported more improvement on the IBDQ-Total Score [$F(1) = 15.2, p = .001$], IBDQ-Bowel Score [$F(1) = 6.5, p = .02$] and IBDQ-Systemic Score [$F(1) = 9.3, p = .007$] but not the IBDQ-Emotional Score [$F(1) = 1.9, p = ns$] or IBDQ-Social Score [$F(1) = 2.4, p = ns$]. When compared to TAU, PM also experienced significant improvement on the Perceived Stress Questionnaire [$F(1) = 8.4, p = .01$] and the IBD Self-Efficacy Scale [$F(1) = 12.2, p = .003$]. There was no immediate change in either group on medication adherence [$F(1) = 4.3, p = ns$]. Effect sizes were calculated by dividing the difference in mean change between groups (baseline to post-treatment) by the pooled baseline standard deviation for each variable. Moderate effect sizes were observed for the primary outcome measures: IBDQ total score ($d = .45$), IBDQ bowel health ($d = .45$) and systemic health ($d = .37$). Effect sizes for PSQ ($d = .13$) and IBDSSES ($d = .17$) were small. See Table 2.

Discussion

Framed around project management principles in order to appeal to a non-traditional group of IBD patients, the goal of our program was to optimize management of CD by addressing

health behaviors that undermine medical therapies, increase risk of disease flare and hinder quality of life. In this study, 28 psychologically healthy patients with quiescent Crohn's Disease were randomized to a 6-week skills-based program or to receive treatment as usual. Project Management outperformed Treatment as Usual in each of our short-term target areas—quality of life, self-efficacy and perceived stress. Medication adherence did not change, likely a result the short window between assessments.

Interestingly, changes in the IBDQ score were limited to bowel and systemic symptoms and did not extend to emotional/social concerns. This underscores the ability of such a program to have a direct impact on actual disease outcomes and supports our claim that neither our patient population nor our therapy focused on negative emotions or psychological distress commonly associated with CD. These results are inconsistent with a previous survey suggesting that the IBD patients who self-report a benefit from counseling are those with high anxiety, many disease concerns and short disease duration⁶². Our sample could not be characterized in this way and it is possible we have found a unique approach to providing behavioral services for a wider variety of patients with IBD.

The efficacy of the “Project Management” Program for CD is not surprising when one considers health behavior change across other medical populations. For example, there is considerable support for the role of behavioral training in disease management and health promotion⁷⁴⁻⁷⁷. Our program is similar to other successful disease self-management programs in that it draws heavily from social learning theory^{67, 78}. Social learning theory posits that individuals are most likely to make a behavior change when certain environmental contingencies are present. Consider this example: a 33-year old married, white female patient is told by her long-term gastroenterologist that she will have to upgrade to the use a biologic agent to reduce her need for surgery in the next 6 months. Social Learning Theory would predict that the patient would be most likely to use and stay on the biologic if she: 1) *had positive expectations* (e.g., the patient trusts Dr X's recommendation for treatment with the biologic and is confident she will be able to reduce her need for surgery with proper use); 2) *learned about the experiences of others* (e.g., Dr. X's nurse puts the patient in contact with another young woman who started on the same biologic for similar reasons); 3) *acquired the skills necessary* (e.g., the patient signs up for an online medication support program to better understand how to order the drug through her insurance company, store the medication when it comes, inject the medication herself and identify potential side effects); 4) *Immediately experienced positive effects* (e.g., within two weeks the patients reports noticing less diarrhea); 5) *received positive reinforcement* (e.g., after 6 months on the medication the patient applied for and receives a promotion at work, reporting that she was able to do this because of the confidence she has gained since beginning her new medication regimen); and 6) *developed high self-efficacy* (e.g., the patient is confident she can successfully perform the skills necessary to use and stay on this medication).

Finally, this study supports earlier research in IBD self-management from our group and others^{79,80,81,82, 83}. We have recently shown the potential benefits of gut-directed hypnotherapy for reducing perceived stress, enhancing quality of life and improving disease self-efficacy in patients with quiescent Ulcerative Colitis⁸³. We are optimistic that if patients were able to gain more control over certain health behaviors known to affect CD, they may require less medication, have fewer hospitalizations and surgeries and experience better quality of life. Further, if these behavior changes can be maintained over the long term, patients could potentially reduce other risks associated with the progression of CD. Finally, if patients are feeling well and more confident in their ability to manage their disease, they may be more likely to recognize their full potential in the areas of work, relationships and finances.

Limitations

This is a pilot study and as such has a few important limitations. First, our Project Management program was not evaluated against a comparable time/attention control condition. As a result, we are unable to determine whether specifically our program was effective or more generally, the participation in disease self-management. That said, consistent with the primary goals of the program, we did see positive changes in measures of IBD symptoms and disease specific self-efficacy, suggesting that the treatment was internally valid. The second limitation of this study was the small sample size. While we had enough power to detect differences in our primary outcome measure of IBDQ score, it is possible that the nonsignificant effect sizes seen for self-efficacy and perceived stress were a function of inadequate power and/or were more subtle changes.

Conclusion/Future Directions

IBD self-management programs that target non-traditional psychotherapy patients have the potential to influence the course of IBD by minimizing the health behaviors that undermine the efficacy of medical treatment and/or increase risk for disease flare. Future research in this area should focus on identifying the specific components of comprehensive programs that are most effective, make an effort to disseminate tools for personal disease management directly to the patient and compare the effectiveness of these approaches to traditional psychotherapy and counseling for IBD.

At present, we recommend that such skills-based interventions such as Project Management for Crohn's Disease be administered by a psychologist with training in IBD and experience with coordinated patient care. Depth of knowledge around the physical and emotional demands of Crohn's Disease is likely critical for adequate implementation of a skills-driven, disease-specific intervention. Of note, most insurance companies cover behavioral interventions for IBD through *medical benefits* [health and behavior code, 96152] when a patient does not present with a comorbid psychiatric diagnosis. This approach allows for improved reimbursement and decreased stigma associated with a psychologist referral. Ultimately, these types of programs may be made available online, a growing trend in chronic disease management^{66, 84}. Finally, it is important that other markers of disease course (e.g., medication needs, natural observation of disease progression, mucosal healing, etc) are included in future studies in order to support the direct impact of skills training on the natural history of IBD.

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Table 1

Sample Program

Wk	Session Theme	Session Activity
1	Rationale for viewing CD as a Project that can be managed; Identify strengths and limitations of current management, allocate personal resources	Project Scope Statement Make list of potential barriers
2	Self-monitoring of key metrics, Identify key stakeholders, using medications effectively	Symptom Monitoring Project Communication Plan Medical Decision Making Tree
3/4	Strive for optimal balance between individual goals and competing demands; remove barriers when possible	Time management, sleep hygiene, relaxation training, smoking cessation, problem solving
5	Consultation with dietician; identify potential nutritional deficiencies, review supplement use, review dietary habits	Establish/outline a plan towards achieving a dietary or exercise goal
6	Risk Management and Relapse Prevention	Create a customized emergency protocol, revise project scope as needed, reward self for completion

Table 2

Change in outcomes over time by condition

Variable	Project Management		Treatment as Usual		F-ratio(1)
	Pre-Tx	Post-Tx	Pre-Tx	Post-Tx	
IBDQ Total	153.8(22.5)	171(18.1)	154.3(30.2)	146.1(27.5)	15.2, p = .001
IBDQ Bowel	4.8(.48)	5.4(.52)	4.8(1.5)	4.7(1.1)	6.5, p = .02
IBDQ Emotional	4.6(.92)	5.2(.76)	4.3(1.5)	4.4(.96)	1.9, p = ns
IBDQ Systemic	4.4(1.1)	4.8(.79)	3.9(1.2)	3.5(1.2)	9.3, p = .007
IBDQ Social	5.71.0	6.1(.83)	5.9(1.3)	5.8(.31)	2.4, p = ns
PSQ	.5(.21)	.37(.18)	.43(.23)	.28(.16)	8.4, p = .01
IBD-SES	162.8(64.1)	215.5(36.2)	162.8(66.7)	86.4(103.5)	12.2, p = .003
MAS	89.2(20.2)	76(35.6)	92.7(11.5)	66.5(40.8)	4.3, p = .ns