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A Pilot Study Evaluating the Impact of an Adherence-promoting Intervention Among Nonadherent Youth With Inflammatory Bowel Disease

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ABSTRACT

Purpose: This study examined the feasibility and impact of a multicomponent adherence intervention among youth with Inflammatory Bowel Disease (IBD) who presented to clinic with poor adherence.
Design and Methods: Medical providers referred twelve adolescents for the intervention, who participated in 4 weekly visits with a caregiver aimed at improving adherence.
Results: Intervention session attendance was 100% and the intervention was rated as feasible and acceptable. Mean adherence increased 12% from baseline to post-intervention ($p < 0.01$), and 6% from baseline to 1-month follow-up ($p < 0.025$). A generalized linear model revealed significantly greater adherence from baseline to post-intervention ($p < 0.001$), and from baseline to 1-month follow-up ($p < 0.01$). Logistic Regression revealed a nearly 2:1 odds ratio during post-intervention when compared to the Baseline period ($p < 0.001$).
Conclusions: Findings suggest that the delivery of a multicompoment adherence intervention to poorly adherent youth with IBD can result in significant improvements in their adherence to oral medication.
Practice Implications: An intervention individually tailored to each family's unique adherence barriers is a feasible and promising treatment approach for improving medication adherence among nonadherent youth seen in clinical care.

Introduction

Poor adherence to treatment regimens, which is often defined as taking <80% of all prescribed medication, is a significant problem across pediatric conditions that carries considerable implications for morbidity and mortality, cost-effectiveness of medical care, and disease management decisions by health care providers (Rapoff, 2010). Compared to other pediatric populations, pediatric Inflammatory Bowel Disease (IBD) remains largely understudied in adherence research. A review of pediatric IBD studies documents nonadherence rates to oral medication as high as 64–88% (Hommel, Davis, & Baldassano, 2009), yet rates vary largely based on the type of medication, the complexity of the treatment regimen, as well as the adherence measures used. For example, adolescents with IBD report greater barriers to their adherence when their treatment regimen consists of more than once-daily oral medication administration (Greenley, Stephens, Doughty, Raboin, & Kugathasan, 2010). There is also evidence in pediatric IBD that objective measures of adherence reveal lower actual adherence estimates compared to subjective measures. Compared to some self-report adherence estimates of 94–97% (Hommel et al., 2009), studies reveal adherence estimates obtained via electronic monitors (e.g., pill boxes) between 51 and 70% (Greenley et al., 2010; Hommel et al., 2009; LeLeiko et al., 2013).

Pediatric Inflammatory Bowel Disease (IBD), namely Crohn's disease and ulcerative colitis, is a chronic inflammation of the intestines that is diagnosed in approximately 71 of every 100,000 children in the United States (43 per 100,000 for Crohn's disease and 28 per 100,000 for ulcerative colitis), with peak prevalence during adolescence (Kappelman et al., 2007). IBD is characterized by abdominal pain, diarrhea or bloody stools, frequent and uncontrollable bowel movements, fatigue/lethargy, weight loss, and joint pain, which have long-term effects including notable growth retardation and delayed puberty. Consequently, symptoms alone render IBD an embarrassing and socially-limiting disease and causes youths to experience long absences from school, frequent doctor visits, hospitalizations and surgeries, and emotional/behavioral difficulties. Moreover, IBD disease management can be overwhelming for youth and their caregivers due to an unpredictable disease course, frequent periods of increased disease activity (flares) and a treatment regimen that is burdensome, time-consuming, and complex

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(Kappelman et al., 2007). Youth with IBD are treated with numerous medications (e.g., 5-ASA, 6MP), each with a unique dosing schedule and dosage, and unpleasant side effects (e.g., weight gain, facial swelling, nausea), as well as dietary and lifestyle modifications (e.g., restricted physical activity) (Hommel et al., 2009).

The most commonly identified barriers to adherence in pediatric IBD include forgetting, interference with other activities, difficulty swallowing pills, and not being at home (Ingerski, Baldassano, Denson, & Hommel, 2010). Some families also intentionally do not follow the IBD treatment regimen particularly in the absence of disease symptoms in order to simplify the treatment regimen and/or to alleviate side effects (Schurman, Cushing, Carpenter, & Christenson, 2011). Research has shown that nonadherent patients with IBD experience a fivefold increased risk of relapse of their disease (Kane, Huo, Aikens, & Hanauer, 2003). This is evidenced by a higher likelihood of symptom flares, disease complications, limitations in their daily functioning, as well as significant impairments in their overall quality of life. Taken together, the current literature demonstrates that nonadherence to prescribed medications in youth with IBD yields significantly increased adverse effects on disease course and quality of life.

Integrally tied to the concept of adherence among youth with IBD is that of transition, a highly pertinent topic in this patient population given the peak prevalence of the disease during adolescence. The treatment regimen is often lifelong and thus requires ongoing medical care and adherence across the pediatric and adult care continuum. Yet, many adolescents struggle to manage their treatment regimen, make appropriate health decisions, and maintain health-promoting behaviors. Data suggests that most patients ages 16–18 with IBD defer responsibility almost entirely to parents for various health maintenance tasks, including medication management (Fishman, Barendse, Hait, Burdick, & Arnold, 2010). These gaps in knowledge and skills likely explain why the time of transition from child-centered to adult-oriented health care systems is associated with poorer adherence across various patient populations (Annunziato et al., 2007; Pai & Ostendorf, 2011).

As a result of high nonadherence rates, research has begun to test multicomponent adherence interventions among youth with IBD that combine empirically supported treatment components such as behavior management (e.g., behavioral contracting), guided problem solving, self-management training, and disease education. These multicomponent intervention packages (MIP) have been shown to be effective in promoting greater adherence among chronically ill youth and reflect current recommended methods for adherence promotion (Rapoff, 2010). Support for MIPs to improve adherence in pediatric IBD is available from a small number of randomized clinical trials (RCTs) (Hommel, Hente, Herzer, Ingerski and Denson, 2013; Hommel, Hente, Odell, Herzer, Ingerski, Guilfoyle and Denson, 2012; Hommel, Herzer, Ingerski, Hente and Denson, 2012), showing improvements in adherence ranging from 25% to 29% among adolescents with IBD after receiving an MIP.

Yet, to date, application of this MIP in clinical settings is lacking and it remains unknown whether youth with IBD who present to clinical care with poor adherence actually benefit from this intervention. Participants recruited for previous feasibility trials (Hommel, Hente, et al., 2013; Hommel, Hente, et al., 2012; Hommel, Herzer, et al., 2012) were not randomized based on non-adherence data, and thus included both non-adherent and adherent patients. Consequently, the findings cannot be extrapolated to a clinical population that includes only non-adherent patients. Given the prevalence of nonadherence in pediatric IBD and the negative ramifications of poor adherence, this study replicated this MIP and examined the feasibility and impact of this intervention on medication adherence among nonadherent youth with IBD. It was hypothesized that the intervention would be considered feasible and that participant adherence would increase from baseline levels during the intervention phase.

Materials and Methods

Participants

The study was approved by the Institutional Review Board at the study hospital. Eligible participants included youth with IBD and one primary caregiver, recruited from the IBD Clinic at a pediatric hospital in the Midwest. Inclusion criteria were confirmed diagnosis of IBD (i.e., Crohn's disease, ulcerative colitis, or indeterminate colitis), nonadherence to prescribed oral medication based on provider estimates, aged 11–17, current prescription of an immunomodulator (e.g., 6-MP) and/or a 5-aminosalicylic acid (5-ASA), living with a primary caregiver, and English fluency. For electronic monitoring purposes, participants were required to have phone service (cell or land line) and wireless coverage in the area of residence.

Procedures

Potential participants were identified by their primary IBD medical provider; that is, providers referred participants for the study on the basis of either patient/family self-report or the provider's own estimate of the patient not taking medications as prescribed. Informed consent was obtained from all individual participants included in the study. Completion of assent/consent took place in the IBD Clinic, after which families were given a Maya™ pillbox with education and instructions for use at home. At that visit, four weekly intervention sessions and three assessment time points (baseline, post-intervention, one-month follow-up) were scheduled at times that were convenient for families; See Table 1 for a content overview of the MIP.

Table 1
Summary of intervention session content.

Session number	Session duration (minutes)	Session content
1	60–90	Educational and organizational: - education regarding IBD disease course and treatment(s) - education regarding scope of the problem of non-adherence in IBD - discussion/identification of perceived barriers and facilitators of adherence - discussion of organizational cues to prompt adherence.
2	60–90	Behavior modification: - discussion/problem solving of organizational changes made in home - education regarding positive reinforcement and extinction - training in behavioral contracts and goal setting
3	60–90	Problem solving skills and adherence monitoring: - discussion of behavioral contracts and goal setting - training in guided problem-solving skills - training in caregiver monitoring and self-monitoring of adherence.
4	60–90	Family functioning: - discussion of behavioral contracts and goal setting - discussion of adherence monitoring - training in positive family communication strategies, active listening, and conflict resolution