INFLAMMATORY BOWEL DISEASE PATIENTS' PERSPECTIVES OF CLINICAL TRIALS
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Background: Despite recent progress in treatment for inflammatory bowel diseases (IBD), there is a need for therapies with long-term efficacy and improved safety. Clinical trials in IBD face challenges with patient recruitment because of study designs, inclusion/exclusion criteria, or overlapping trials, and a limited number of eligible patients. We sought to better understand patients' motivations, awareness of, and experience with IBD clinical trials.
Methods: We conducted an international survey of adult patients with IBD consisting of 2 components. The quantitative component, a 15-minute online survey, was completed by all patients. A qualitative component, a 30-minute telephone interview, was completed by a subset of patients from the United States (US). All percentages indicate results from the online survey.
Results: 226 patients (mean age, 41.9 ± 10.0) completed the online survey. Survey respondents included patients with ulcerative colitis (52%) and Crohn's disease (48%) from the US (n=100, 21 of whom underwent a phone interview), Brazil (n=26), Canada (n=25), France (n=25), Germany (n=25), and Spain (n=25). Ninety-six percent of respondents reported at least a basic understanding of clinical trials, and 34 (15%) were current or past clinical trial participants.
Patients reported learning about trials through 1 or more sources (could select as many as applicable); health care providers (42%), pharmaceutical manufacturer websites (31%), social media (30%), online support groups (28%), and foundations (18%-23%). In the survey, patients rated conversations with health care providers most helpful, but patients who were interviewed revealed that most physicians often do not initiate conversations about clinical trials, and patients typically do not ask.
Primary motivators for trial participation (rated from “does not encourage me at all” to “encourages me very much”) included altruistic goals of advancing medicine (67%), potentially mitigating risks of uncontrolled IBD such as colon cancer (59%), and access to treatment options that could improve quality of life (59%) or would otherwise be unaffordable (52%). Major barriers to participation (rated from “does not discourage me at all” to “discourages me very much”) included invasive screening and monitoring (35%), concern over receiving placebo (35%), or suboptimal treatment (33%), and concerns about posttrial access to study medication (27%).
Conclusion: Opportunities to improve patients' clinical trial experience in IBD include better communication with health care providers and improved patient education about clinical trial design and ethics. Ultimately, a better understanding of the patient perspective will be important for more informed patients and potentially higher recruitment and enrollment.
INFLAMMATORY BOWEL DISEASE: YOUTH BELIEFS AND BARRIERS TO TRANSITION
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Introduction: Transitioning from pediatric to adult care remains a vulnerable time for all youth, especially those with inflammatory bowel disease (IBD). While the medical community recognizes this, it is still an understudied phenomenon and youth are left to be the experts in their own transition. Our mixed methods study is unique in that it comprehensively assesses youth/caregiver understanding and priorities through interviews and surveys surrounding the transition process for youth with IBD.
Methods: This is a prospective chart review. English speaking youth with IBD ages 12–25 and their caregivers at a tertiary care center were given the Transition Barriers and Beliefs scale (TBAB). Data were analyzed by descriptive statistics and frequencies. A subgroup of youth/caregiver dyads from the above sample were asked a semi-structured set of questions. The answers were audio recorded and transcribed. Results: 70% of caregivers reported they are not discussing transition with their youth.
74% of caregivers and 70% of youth reported that no provider initiated a transition discussion.
40% of youth older than 16 reported providers initiated a transition discussion.
25% of youth and 33% of caregivers expressed concern over transition.
90% of caregivers reported there was no transition plan regardless of age.
53% of youth and 73% of caregivers believed that similar support services are offered in adult care.
Caregivers and youth shared similar priorities to discuss prior to transition, the most important being insurance.
Caregivers and youth overwhelmingly prefer information be relayed face-to-face. Youth and caregivers agreed providers should begin talking about transition at age 16–17, seeing the provider alone at 17–18, and transitioning at 18.
Conclusion: Discussion around transition in IBD care is not happening at home or with providers. Accordingly, most youth and their families have no plan for this process. Our data agree with other research indicating that youth and their caregivers view transition more as an event and less as a process (e.g., transition discussions and transfer to adult care around the same age 17 to 18). This is highlighted by the finding that youth/caregiver dyads reported that seeing the physician alone should happen just before transition. As a whole, our data indicate that youth and their families are underprepared to transition care, with a majority expressing the expectation that similar support services will be offered in adult care. This leaves them vulnerable to a lapse in medical care, unmanaged flares, and negative consequences of drug holidays. Interestingly, youth and their families are worried about the transition from pediatric to adult IBD care and are interested in receiving this information in person, reinforcing that this information should be incorporated into routine care and is best received from their IBD providers.
INTERNET DIETS: ONLINE INFORMATION REGARDING NUTRITIONAL TREATMENTS FOR IBD
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Background: Nutrition is a vital component in the management of IBD and can be an effective primary therapy for many patients. Certain types of diets, including the Western diet, have been speculated to be associated with increased IBD risk or exacerbations. There are currently no specific dietary recommendations for IBD risk reduction. However, online resources may offer nutritional guidance to patients seeking information. This study evaluated specific nutritional and dietary treatment information for IBD on the Internet.
Methods: The Google search engine was used to query “nutrition and inflammatory bowel disease” to obtain the first 100 websites. Websites that were non-accessible, duplicates, videos without transcripts, or evaluated animal models were excluded. Websites were categorized as informational or academic/professional. Websites were reviewed for discussion of specific nutritional treatments, acknowledgement of areas of uncertainty and references. Statistical analysis was performed using a two-tailed Fisher’s Exact Test with a significance value set at p <0.05.
Results: 89 (50 informational, 39 academic) met the inclusion criteria. No websites were commercial or personal. 49 (55%) websites discussed nutrition as a treatment modality. Enteral nutrition was discussed in 38 (77.6%), probiotics in 22 (44.9%), parenteral nutrition in 21 (42.9%), elimination diet in 19 (38.8%), and low FODMAP diet in 15 (30.6%). Academic resources discussed specific nutritional therapy more often than informational resources (82.1% and 45.0%, respectively; p=0.003) (Figure 1). Academic resources acknowledged areas of uncertainty more frequently than informational resources (64.1% and 30.0%, respectively; p=0.024). Academic resources cited references significantly more often than informational resources (80.9% and 10.6%, respectively; p=0.001).
Discussion: This study shows that the most commonly discussed nutritional therapy was enteral feedings (77.6%), followed by probiotics (44.9%), parenteral feeding (42.9%), elimination diet (38.8%), and the low FODMAP diet (30.6%). Academic websites discussed dietary options significantly more than informational websites. These results suggest that there is a paucity in consumer-oriented literature regarding nutrition in IBD. Academic websites are the primary online resources for information about nutrition in IBD, discuss areas of uncertainty, and offer references. As patients with IBD are increasingly utilizing the Internet for recommendations regarding disease management, it is important that both academic and informational online IBD resources provide comprehensive nutritional information to enhance patient education.