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Abstract

Introduction: Irritable Bowel Syndrome is the most common cause of recurrent abdominal pain in children. IBS is a functional gastrointestinal disorder that is linked to motor and sensory physiology, as well as the central nervous system, that presents as abdominal pain with abnormal defecation patterns {Drossman et al., 2002}. This discomfort leads to emotional stress, decreased quality of life, and anxiety. We are proposing that yoga and mindfulness will decrease anxiety and increase quality of life for patients with IBS. The aim of this study is to measure the impact of a brief, at-home, 6-week twice per week Standardized Yoga & Meditation Program for Stress Reduction program on anxiety, IBS symptoms, and quality of life in children ages 12-21 diagnosed with IBS.

Methods and Analysis: This is a pilot, IRB approved, prospective study. Each subject will fill out the Screen for Child Anxiety Related Disorders to measure anxiety, and Children Somatic Symptoms Inventory and Pediatric Quality of Life Inventory questionnaires to measure quality of life, before and after an online yoga course. Results of the questionnaires total scores and sub-scales will be analyzed as continuous variables using paired t-tests or the Wilcoxon signed rank tests for the pre-post results and ANCOVA for repeated measures incorporating age, sex, baseline scores, etc. as covariates. Comparisons within the group will be done using Student paired t-test for continuous data. A minimum sample size of 45 subjects will be required. This estimate is based on a standard deviation of the SCARED total score of 10, a two-tailed p-value of 0.05 and 80% power.

Ethics and Dissemination: All subject information will be kept strictly confidential, except as may be required by law. Data will be published and disseminated through future publications. IRB 19-126

Strengths and Limitations of the Study

Strengths:

- Alternative medical treatment
- Accessible to many families
- Does not alter original treatment plan
- Very low risk

Limitations:

- Takes 6 weeks to complete

Standardized Yoga & Meditation Program for Stress Reduction for Adolescents with Irritable Bowel Syndrome

Sydney Topfer, Alla Kushnir MD, Marisa Wozniak, Basant Pradhan MD

A. Objective/Purpose

The aim of this study is to measure the impact of a brief, at-home, 6-week twice per week Standardized Yoga & Meditation Program for Stress Reduction (SYMPro-SR) program on anxiety, IBS symptoms, and quality of life in children ages 12-21 years old diagnosed with Irritable Bowel Syndrome.

B. Hypothesis

A brief, at-home, yoga and mindfulness program will decrease anxiety and irritable bowel symptoms while increasing quality of life in children ages 12 to 21 years old diagnosed with Irritable Bowel Syndrome.

C. Background

IBS, or Irritable Bowel Syndrome, is the most common cause of general recurrent abdominal pain (RAP) in children. IBS is a functional gastrointestinal disorder that is linked to motor and sensory physiology, as well as the central nervous system, that presents as abdominal pain with abnormal defecation patterns [1]. This discomfort often significantly impacts the patient's life, leading to emotional stress, decreased quality of life due to necessary changes in daily living to accommodate bathroom patterns, as well as anxiety and depression. When children present with RAP, the Rome IV is used to clinically diagnose patients with a specific type of IBS. These criteria include recurrent abdominal pain at least one day per week in the last three months on average, associated with greater than or equal to two of the following: related to defecation (either increasing or improving pain), associated with a change in stool frequency, and associated with a change in stool form [2]. There are four distinct types of IBS, which are IBS with predominant constipation (IBS-C), IBS with predominant diarrhea (IBS-D), with mixed bowel habits (IBS-M) or IBS, unsubtyped [3]. IBS-C is accompanied by stomach discomfort, bloating, and infrequent or difficult evacuation of feces (a bowel movement every three to four days). IBS-D is also accompanied by stomach pain, but the patient has an urgent need to move the bowels and the feces is usually loose and watery. IBS-M is accompanied by an alternation between the patient not being able to make a bowel movement and the patient making frequent, urgent, loose and watery bowel movements [4]. The last type, IBS, unsubtyped, is accompanied by hard or loose stools less than 25% of the time [3]. In children, it is especially important to make the correct diagnosis of IBS as early as possible in order to implement the most appropriate treatment at the earliest time possible.

Since IBS is often accompanied by anxiety, along with other psychological and quality of life issues, we are proposing that practicing yoga and mindfulness will decrease anxiety and increase quality of life for patients with IBS. Yoga includes postures, exercises, various

breathing techniques, relaxation practices, and meditation to improve the mental and physical health of the person [5]. Mindfulness as a practice is based on focusing all of the person's attention on the sensations around them and their own breathing in order to fully take in the current moment [6]. Both yoga and mindfulness have been used in various settings as a way to decrease anxiety and manage stress. For example, Huguet et al found that using mindfulness-based group therapy significantly lowered levels of anxiety, depression, and aggression of children with ADHD [7]. They force the person to be aware of their own bodies and how they feel in the present moment, and help to balance all of the internal and external stimulation they are receiving. Yoga and meditation are beginning to be used as part of a holistic therapy approach to various medical treatment plans. For example, Evans et al found that relative to controls, young adults (18–26 years) assigned to yoga as part of their IBS treatment plan reported significantly improved IBS symptoms, global improvement, disability, psychological distress, sleep quality, and fatigue [8]. The idea behind these studies is to decrease the anxiety and stress that accompany difficult diagnoses, painful treatments, and the overall stress that patients undergo in their disease state.

The goal of this study is to use a brief yoga and mindfulness program to decrease anxiety and irritable bowel symptoms while increasing quality of life in children ages 12 to 21 who suffer from IBS. Yoga and mindfulness help people become more aware of their bodies and physical functions, so by making children with IBS more aware of how they feel and correlating that with their IBS symptoms, we are hoping that the symptoms themselves become more controllable and eventually decrease. IBS has a strong psychological component, which is why using techniques such as yoga and mindfulness as therapy options are promising for patients.

Description of the Standardized Yoga & Meditation Program for Stress Reduction (SYMPro-SR): SYMPro-SR is the wellness program developed by Pradhan in 1993 during his monastic training. Initially he piloted it in a normal and healthy population in India as a means for stress reduction, improvement of productivity, and improvement of quality of life. This model purports to use Yoga in its entirety (i.e., all eight limbs including meditation, its 7th limb) rather than in a piecemeal fashion. SYMpro-SR has been adapted from the three original traditions of Yoga and mindfulness, i.e., Buddha's vipassana meditation (satipat- thana), Patanjali's Eight-Limbed Yoga (ashtanga), and the standardized and technique-rich traditions of Tantra (Pradhan, 2014). This model uses neurobiologically informed bottom-up model of meditation (Pradhan, 2014, chapter three) and are compatible with other Western models of therapy including cognitive behavioral therapy (CBT). The efficacy of this model for wellness has been established by Pradhan and colleagues in healthy and clinical population including in a population of Resident physicians and medical students in Thomas Jefferson University (2011-2012) and Cooper University Hospitals (2014-2017).

D. Significance of this Research

Finding ways to improve symptoms of chronic illness in children is pivotal to their quality of life. Devanarayana states that Irritable Bowel Syndrome has significant effects on the quality of life of patients, so it is important to continuously research ways to improve symptoms [9]. By implementing a mind-body approach to care, we are giving patients tools to take with them

beyond their pediatric years so that they are able to control their symptoms long-term. This study will determine if yoga and mindfulness can be integrated into their care.

E. Proposed Research Plan

1. ***Subjects:***
   a. ***Number of subjects***

      Based on the primary outcome, SCARED scores, in order to detect a difference of 20% in the pre and post yoga SCARED scores (i.e, 30 vs 24), a minimum sample size of 45 subjects will be required. This estimate is based on a standard deviation of the SCARED total score of 10, a two-tailed p-value of 0.05 and 80% power. Subjects will be chosen from January 1st 2021 to January 1st 2022.

   b. ***Inclusion Criteria***
      i. Patients of Cooper Pediatric Gastroenterology practice in Camden, NJ or Voorhees, NJ
      ii. Subjects must be able to access the internet to be able to watch the yoga videos on Youtube
      iii. Must be ages 12-21
      iv. Patients must complete 4/6 modules to stay in the study

   c. ***Exclusion Criteria***
      i. Under the age of 12 or over the age of 21

   d. ***Recruitment Methods***: Patients at Cooper's pediatric gastroenterology offices in either Camden, NJ or Voorhees, NJ will be screened for our study and approached by researchers over the phone for agreement to be in the study. If they agree, they will provide their email address, we will send over the consent forms to be read over, and an additional meeting will be set up for verbal consent.

   e. ***Informed Consent Process***: Parents will be approached by researchers over the phone, based off of Cooper Pediatric Gastroenterology IBS patient list, to see if they want their child to participate in our study. If so, parents and/or children will be emailed a consent form to read over, and we will set up an additional phone call to gather consent verbally. This second phone call may be approximately 30 minutes to 120 minutes. Parents and their children will be requested to verbally consent and/or the assent.Parents and/or children will be emailed to read for their information and allowed until the end of the phone call to decide whether they want to participate in the study. If so, a consent form will be emailed to parents to read over, and we will set up an additional phone call to gather consent. This may be approximately 30 minutes to 120 minutes. If they agree, they and their children will be requested to verbally consent and/or the assent. Subjects ages 18-21 will verbally consent an adult consent/HIPPA authorization to participate, children ages 14-17 will verbally consent an assent form and we will obtain verbal assent from children ages 12-13 with an age appropriate assent script. Parental permission will be obtained from the parent of every child participant. Questions can be answered by the researchers.

2. ***Research Methods and Procedures***

   a. ***General Description of Methods and Procedures***

   Patients of Cooper's pediatric gastroenterology offices in either Camden, NJ or Voorhees, NJ will be screened for our study. Children ages 12-21 who suffer from any of the four types of Irritable Bowel Syndromes will be identified. Parents will be called to see if patient wants to be involved in the study. If yes, parents will provide an email address where a consent or assent form can be sent. An additional phone call will be scheduled to provide verbal consent over the phone, in addition to the questionnaires. Patients ages 12-17 will verbally agree to an assent form and their parent or guardian will verbally agree to a consent form. Patients ages 18-21 will verbally agree to their own consent form. Each subject will be asked over the phone to fill out the Screen for Child Anxiety Related Disorders (SCARED) [10] and Pediatric Quality of Life Inventory (PedsOL) [8] questionnaires. Researchers will perform the study assessments with the children. The primary outcome of the study will be the measurement of child anxiety using the 41-item SCARED questionnaire (with 5 subscales) before and after the six-week Yoga-meditation intervention. Secondary outcomes include the Pediatric Quality of Life Inventory (PedsQL) and Children Somatic Symptoms Inventory measured before and after the yoga program. Subjects will be emailed a private youtube.com link with access to 6 yoga videos for their 6- week course. Each video will be played two times per week. Both survey instruments have been validated and used in pediatric studies. A standardized meditation home practice log will be used to objectively measure the daily practice pattern and duration of meditation.

   Subjects will fill out a calendar for the days and times they completed the modules. After three weeks, researchers will call subjects with the phone number provided to assess adherence. After 6 weeks, researchers will call the subjects again with the phone number provided and fill out the Screen for Child Anxiety Related Disorders and Pediatric Quality of Life Inventory questionnaires again, this time over the phone.

   b. ***Summary of Visits and Procedures***

   Patients of Cooper's pediatric gastroenterology offices in either Camden, NJ or Voorhees, NJ will be screened for our study. Parents will be called to see if they want to participate in our study. If so, parents and/or children will be emailed a consent form to read over, and we will set up an additional phone call to gather consent verbally. This second phone call may be approximately 30 minutes to 120 minutes. Parents and their children will be requested to verbally consent and/or the assent.

   c. ***Procedures Just for Research Purposes***

   Screen for Child Anxiety Related Disorders, Pediatric Quality of Life Inventory and Children's Somatic Symptoms Inventory

   d. ***How Participation Differs from Standard-of-Care***

Patients will fill out the Screen for Child Anxiety Related Disorders, Children Somatic Symptoms Inventory and Pediatric Quality of Life Inventory questionnaires and participate in a brief, at-home, 6-week twice per week yoga module. All of the above screening tools and modules are not the standard of care for IBS patients and would not be done if patient were not to be participating in the study. They will continue to receive the standard of care medical management for IBS as provided by their gastroenterologist

e. Patient and Public Involvement

The development of the research question and outcome measures informed by patients priorities were determined based on the need for alternative treatment methods for children who suffered with IBS. Patients were not involved in the design of the study. Patients were not involved in the recruitment to and conduct of the study. Results will be published publicly after the data collection is complete. This was not a randomized control trial. We thank all of our patients for their contribution to our study.

3. Data Analysis

Children who qualify for this study will be given a pre-test and post-test to measure anxiety and quality of life, as described above. Anxiety will be measured using the Screen for Child Anxiety Related Disorders and quality of life will be measured using Pediatric Quality of Life Inventory test. Results of the SCARED and PedsQL total scores and sub-scales will be analyzed as continuous variables using paired t-tests or the Wilcoxon signed rank tests for the pre-post results and ANCOVA for repeated measures incorporating age, sex, baseline scores, etc. as covariates. Comparisons within the group will be done using Student paired t-test for continuous data. The difference will be considered significant at $p \leq 0.05$.

F. Risk and benefits

1. Potential Risks to Subjects

One potential risk is loss of subject's privacy and confidentiality. All information about patients and the study will be kept strictly confidential, except as may be required by law. Another potential risk is minor a minor injury due to yoga. The modules require minimal strenuous activity, but there is always a risk and patient will need to reach out to a physician with a concerns immediately.

2. Potential benefits

The subjects may benefit from this study if their anxiety levels decrease and/or their quality of life increases. The knowledge gained from this study may benefit future IBS patients and help in integrative care of a pediatric chronic illness.

3. Risk: benefit ratio

The potential risk to the subject is of loss of privacy and confidentiality, which can be minimized by keeping information strictly confidential, and minor yoga-related injury,

which can be minimized by careful description of specific postures. There is a potential benefit for current and future patients. The benefit outweighs the risk for the integrative care of IBS.

G. Monitoring Subject Safety

The subjects will be called after 3 weeks to ensure they are doing well with the yoga modules. An email address will be provided if the subjects have questions about the study.

H. Procedures Necessary to Maintain Privacy and Confidentiality

All information obtained in this study will be strictly confidential, except, as may be required by law. Each subject will be assigned a number and patient's name and identifying information with that number will be kept in a separate locked cabinet. We will use only the assigned number to the subjects on the questionnaires and calendar tracker. All the files and records created for this study will be stored in Dr. Kushnir's office at 755 Dorrance and Cooper Hospital in a locked cabinet or in a computer with a password. Any publication resulting from this study will refer to the patient by a pre-assigned number. No published data will disclose the identity of any patient.

I. Strengths and Limitations of the Study

Strengths:

- Alternative medical treatment
- Accessible to many families
- Does not alter original treatment plan
- Very low risk

Limitations:

- Takes 6 weeks to complete

J. Funding

- contributorship statements – not applicable
- competing interests – not applicable
- funding – not applicable

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