# Abdominal Wall-targeted Myofascial Release Therapy in Pediatric Patients with Irritable Bowel Syndrome: A Feasibility and Acceptability Study

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Background: Myofascial release (MFR) is a form of massage therapy that involves identifying and releasing restrictions in the fascia and muscles. MFR-like techniques have shown improvement in abdominal pain, distention, constipation, and quality of life (QoL) in adults. Therefore, MFR may be helpful in patients with irritable bowel syndrome (IBS), a disorder of gut-brain interaction or functional gastrointestinal disorder, mainly presenting with prolonged abdominal pain, bloating, and altered defecation patterns, leading to impairment in QoL. Treatments for IBS are limited and do not always completely relieve pain. To date, no studies have evaluated the feasibility and acceptability of MFR for children with IBS as a potential therapy.

*Purpose:* The aim of the study is to assess the feasibility and acceptability of administering abdominal wall-targeted MFR in children with IBS.

*Setting:* This study was approved and conducted at Children's Hospital of Philadelphia.

Participants: Males and females aged 13–18 years meeting Rome IV criteria for IBS were included in the study.

Research design: Participants underwent six 1-h weekly sessions of abdominal wall-targeted MFR with a licensed massage therapist (LMT) and performed self-MFR at home between sessions. Feasibility and acceptability data were collected via REDCap (Research Electronic Data Capture) by the study team and LMTs. Symptoms and QoL were assessed before and after the intervention period using child and parent versions of validated pediatric questionnaires.

*Results:* Of 10 participants aged 14–18 years, 60% females underwent the MFR intervention and completed the 6-week protocol. The median visit compliance with questionnaire completion was 90%. All participants received self-MFR education and performed self-MFR between sessions. Fascia restrictions were identified and released in all participants, as reported by the LMTs. Most participants voluntarily provided positive feedback on MFR. All participants reported no or minimal soreness during or after MFR, and no adverse events were reported.

*Conclusions:* Abdominal wall-targeted MFR is feasible to administer and well accepted in pediatric IBS patients.

KEYWORDS: Myofascial release therapy; irritable bowel syndrome; massage therapy; pediatrics; feasibility study

## INTRODUCTION

Myofascial release (MFR) is a specialized hands-on manual therapy technique that aims to treat pain and improve mobility via applied adapted pressure and manipulation of tight fascia and release of fascia when and where possible.<sup>(1)</sup> Although the origins of MFR can be traced back to the early 1900s with the rise of osteopathic medicine,<sup>(2)</sup> the current approach of sustained fascial manipulation was popularized by John F. Barnes around 1960.<sup>(1)</sup> The currently used technique involves applying gentle continuous pressure and stretching to areas of fascial tension to release pressure-exerting fascial restrictions without use of lubricants.<sup>(3)</sup> By facilitating the mobilization of the fascia (a web-like structure of connective tissue that supports other tissues, such as muscle) and the release of fascial restrictions (which exert pressure on surrounding tissues creating pain and dysfunction), this approach aims to reduce pain and restore motion to reduce dysfunction in the body.<sup>(3)</sup> MFR has demonstrated benefits in numerous musculoskeletal and pain syndromes, including chronic plantar fasciitis, fibromyalgia, epicondylitis, and others.<sup>(4-7)</sup> Despite the broad range of issues that may effectively be addressed by MFR, there has been a lack of studies that evaluate the effects of MFR on gastrointestinal (GI) disorders, especially those exhibiting a great degree of pain.

Irritable bowel syndrome (IBS) is a disorder of gut-brain interaction (previously known as a functional GI disorder) characterized by frequent episodes of abdominal pain, bloating, and alterations in bowel patterns affecting children and adults, with great impact on quality of life (QoL).<sup>(8,9)</sup> IBS treatment is targeted mainly at symptom management, which frequently results in a lack of complete alleviation of symptoms.<sup>(9,10)</sup> Safe and effective medical treatments specifically for children with IBS are still needed.<sup>(10)</sup> Non-invasive abdominal MFR could serve as a potential treatment for IBS in children and adults. For instance, a case report series of five pediatric patients showed that abdominal massage led to an increase in bowel movements without any adverse events.<sup>(11)</sup> Abdominal massage therapy is also known to increase gastric motility in preterm infants.<sup>(12)</sup> A study in adults showed that abdominal massage resulted in an increase in bowel movements and relief of constipation.<sup>(13)</sup> Similar to MFR, body-based osteopathic manipulative treatments (OMTs), including abdominal osteopathy and vertebral osteopathy, have shown promise in relieving IBS symptoms.(14)

We aim to uncover a novel and promising approach in the management of IBS symptoms in children. This initial study aims to determine whether the MFR intervention is feasible and acceptable in pediatric IBS patients.

#### METHODS

#### **Study Design and Overview**

This single-center, open-label study was conducted at and approved by the Institutional Review Board at Children's Hospital of Philadelphia (CHOP). Our aim was to develop the MFR intervention and evaluate the feasibility and acceptability of administering the abdominal MFR intervention to children with IBS. During screening, ICD-10 codes for IBS (K58.0, K58.1, K58.2, K58.8, and K58.9)<sup>(15)</sup> were used to identify potential participants, and diagnosis was confirmed based on Rome IV criteria. Rome IV criteria for IBS include the following: recurrent abdominal pain on average at least 1 day/ week in the last 3 months, associated with two or more of the following criteria related to defecation, associated with a change in the frequency of stool, and associated with a change in form (appearance) of stool for the last 3 months, with the onset of symptoms at least 6 months prior.<sup>(16,17)</sup> Participants were offered two outpatient locations and all-day availability to receive the MFR intervention. At the first visit, informed consent was obtained, a pregnancy test was administered if pregnancy was possible based on age and sex, and the first MFR intervention was administered. Participants received six weekly, 1-h MFR sessions by a licensed massage therapist (LMT) specialized in the administration of MFR. Participants were educated and encouraged to self-administer abdominal MFR daily between sessions. Symptoms and QoL were tracked weekly during the intervention period (6 weeks) and for 1 month immediately following the conclusion of the intervention period. Subsequent follow-up evaluations were conducted 3 and 6 months after the end of the intervention. For this preliminary feasibility study, participants served as their own controls as symptoms were compared pre- and postintervention using a within-subject design. Participants continued to receive standard clinical care as indicated by their primary physician. Participants were also compensated for their time and effort in accordance with institutional guidelines<sup>(18)</sup> (Table 1).

#### **Patient and Public Involvement**

This study was originally proposed by a CHOP LMT (TSC) and study team member

Study Phase	Screening 1 (10-Day Screening Period at Home)	Trea Expe	tment ected t	/Interve o Last 1	ention (A h)	II Visits /	Are	Follow-up Phase (Online)
Visit number	0	1	2	3	4	5	6	7–12
Study days	-14 to 0	1–7	8–15	15–21	22–28	29–35	36	37–126
Informed consent/assent	Х	Х						
Review inclusion/exclusion criteria	Х							
Demographics/medical history	Х							
Pediatric Quality of Life Inventory (parent report and child report)	Х	Х					Х	Х
Pediatric Quality of Life Inventory Gastrointestinal Symptoms Module (parent report and child report)	X	Х					Х	Х
Pregnancy test		Х						
Myofascial release therapy (in-person)		Х	Х	Х	Х	Х	Х	
Myofascial release therapy (self-administered at home)		Х	Х	Х	Х	Х	Х	
Symptom diary (including Bristol Stool Form Scale and Visual Analog Scale)	Х	Х	Х	Х	Х	Х	Х	Х

#### TABLE 1. Overview of the Study Procedures

who works with patients with IBS in a clinical setting. A collaboration between the LMT, pediatric gastroenterologists, and GI researchers was established to develop the MFR intervention protocol. In the study, LMTs led the development of an MFR fidelity checklist to ensure adherence to the intervention protocol. LMTs actively participated in all aspects of the project, attended weekly study meetings, obtained informed consent, collected data, ensured participants' completed pre-intervention questionnaires, and assisted in composing abstracts, posters, and presentations related to the study. Opportunities to engage the community and populations affected with IBS will be implemented to disseminate additional study information, its results, potential clinical impact, and service delivery options of MFR. This study highlights the leadership and participation of LMTs in research. This publication is intended to share acceptability and feasibility findings and the evolving role of LMTs in advancing research within the field.

## **Enrollment of Study Participants**

A multi-step process was implemented to identify eligible participants and con-

firm eligibility for those who met the inclusion and exclusion criteria.

#### Recruitment

Identification of potential study participants included querying CHOP's Electronic Health Record, utilizing CHOP's Recruitment Enhancement Core (REC), and internal referrals. A query in CHOP's Electronic Health Record generated a list of active CHOP patients with an ICD-10 diagnosis of IBS. The REC also generated a list of potentially eligible participants and emailed study details to 50 individuals per week. Potential participants were then contacted by a team member via phone to provide study information and obtain consent/assent if interested in participating.

#### Inclusion/Exclusion criteria

Males and females aged 13–18 years who met Rome IV criteria for IBS were included.<sup>(16,17)</sup> Exclusion criteria encompass individuals with significant interfering comorbidities, diabetes, pregnancy, migraines, inflammatory bowel disease, any overlapping GI motility disorder (i.e., gastroparesis), and those unable to cooperate with study procedures.

#### Informed consent

Legal guardians or parents of potential participants were contacted for a verbal explanation of the study (i.e., study procedures, risks, benefits, etc.). Information about the patient/family's availability and incentives for study involvement (i.e., parking reimbursement, debit card for related expenses) were also discussed. Verbal consent to screening was obtained over the phone by authorized study staff. Written or electronic informed consent was obtained from the participant's parent or legal guardian, and verbal assent was obtained from the participants if they were under 18 years of age. If the participant was already 18 years old, written informed consent was obtained from the participant. Informed consent was obtained by either the principal investigator, co-investigator, LMTs, or research assistants.

#### Screening

Screening questionnaires were emailed to the child and/or parent (depending on their preference) using REDCap (Research Electronic Data Capture), a secure web application for building and managing online surveys and databases. The questionnaires were sent with automated reminders in case of non-completion within 1 day. Screening responses were then reviewed by the study team to confirm eligibility.

#### Eligibility

Eligibility was verified through a review of medical records, ensuring that potential participants had a current IBS diagnosis and no significant interfering comorbidities. The potential participant's primary care physician or CHOP physician was contacted to obtain approval of participation. Additionally, approval was obtained from the participant's mental health provider if psychological comorbidities were present.

#### **Development of the MFR Intervention**

The study team that included an LMT with experience providing massage in clinical settings, a pediatric gastroenterologist with integrative health background, and a pediatric GI researcher met to discuss potentially effective massage techniques that could address IBS symptoms. Clinicians identified IBS as a condition that could potentially benefit from complementary therapies given the incomplete symptom relief provided by current therapies. Researchers were able to conduct literature reviews that supported the use of MFR (and MFR-like treatments such as OMM and abdominal massage therapy) as a treatment for motility issues such as IBS while also ensuring the protocol was replicable and adapted to the pediatric population. LMTs identified MFR specifically as the form of massage therapy with the greatest potential therapeutic benefit in this population based on their knowledge of the technique and existing research on similar therapies. LMTs and clinicians discussed how to adapt MFR to IBS by specifically targeting the abdomen and performing the technique over clothes for pediatric populations. The team concluded that MFR would be the most appropriate technique after a review of the existing literature and considering the evidence behind the effectiveness of MFR-like therapies in treating abdominal pain disorders and potential mechanisms involved.

Various mechanisms have been proposed to explain the benefits of MFR. The fascial adhesions model suggests that restoring adhered fascial tissue to normal mobility through a full range of motion and tension application can enhance blood flow and reduce inflammation.<sup>(19)</sup> Mechanical displacement of the fascia may trigger the Golgi reflex arc, leading to a reduction in motor activity.<sup>(19)</sup> The mechanoreceptor model posits that pressure on corpuscle receptors can activate the nervous system, reducing muscle tension.<sup>(19)</sup> There is evidence that massage and similar osteopathic manipulative treatments may relieve chronic abdominal and pelvic pain.<sup>(13,14,20,21)</sup> Other studies support growing evidence of the effectiveness of MFR in relieving pain and function in chronic plantar fasciitis, fibromyalgia, low back pain, and epicondylitis.<sup>(4–7)</sup> OMM techniques (direct and indirect), involving pressure application using the hand, knee, or chest, have shown promise in alleviating constipation, reducing abdominal distension, and mitigating pain in patients with IBS.<sup>(14)</sup>

This protocol was adapted from Wasserman et al. and informed by John F. Barnes' Myofascial Release techniques.<sup>(1,21)</sup> The MFR model, typically applied broadly to the entire fascial system, focuses specifically on the abdominal area in this study. However, we acknowledge its potential impact on the entire fascial system. In line with traumainformed care principles (the consideration of experiences with, responses to, and recovery from trauma),<sup>(22)</sup> we adapted the MFR approach for this study by performing it over the patients' clothes—an approach taught in advanced MFR classes and the pediatric MFR course. The decision to narrow the study's age range was driven by the goal of optimizing patient and parent feedback while assessing the feasibility of the approach. The session length was determined based on common durations for pediatric populations, allowing sufficient time for sustained holds needed to achieve fascial release. Self-MFR with an inflatable ball supported the treatment and encouraged patients to form a habit of daily self-MFR, aligning with our study's objectives.

#### **MFR Intervention Procedures**

#### Preparation for the MFR intervention

Participants were instructed to wear comfortable attire that allowed the therapist to manipulate abdominal fascia over clothing. No lubricants were used during administration of the MFR intervention. The room conditions were standard across all MFR interventions: individuals laid on the exam table with the lights on, in the absence of music or other noises, and offered a pillow. Participants remained awake during the session and provided feedback to the LMTs. Participants initially assumed a supine position. If participants were uncomfortable or demonstrated tactile defensiveness in the abdominal area. therapists accommodated alternative postures to facilitate MFR application, while noting such variations. Caregivers were encouraged but not required to be present during the MFR treatment sessions.

#### Application of the MFR intervention

The LMT-administered MFR intervention ranged between 45 and 60 min. The LMT identified tight bands of tissue in the abdominal area using the techniques outlined in Table 2. The LMT used these techniques with ongoing discussion with the participant. Active verbal and nonverbal feedback from participants were used to help ensure they were comfortable, engaged, and awake, so they could notice and report how they felt to the LMT. Trauma-informed consent-based practices were employed throughout the session to ensure participants were comfortable with the techniques being performed.<sup>(22)</sup> LMTs also had comprehensive training in responding to safety incidents and were equipped to report any adverse events had they occurred.

#### Education on self-MFR

The self-MFR practice was explained to participants by the LMTs for 10–30 min during the first visit. An inflatable therapy ball was provided at visit 1. Participants were instructed to apply pressure over the abdominal wall by lying down on a bed, mat, or couch or leaning against a doorway and rolling on the ball slowly until encountering a tight or tender (but not painful) restriction area or working on areas identified as restricted in the weekly MFR sessions. Upon identifying a restriction, participants added meaningful pressure and held until an MFR tension release was felt or the time was up. Therapists demonstrated the technique, explained it, and reinforced techniques to ensure participants correctly followed it, also encouraging a daily or weekly habit of its use to be formed. The self-MFR protocol was adapted from Xu et al.<sup>(20,23)</sup>

Participants were instructed to practice self-MFR for 5–20 min a day on the days they did not receive an LMT-administered MFR session. Once the 6-week MFR period was completed, participants were encouraged to continue the at-home MFR practice daily at least for the month following the intervention period, but ideally maintaining a daily or weekly habit of self-MFR. Participants documented weekly records of the general timing, frequency, and duration of at-home self-MFR sessions in the weekly symptom diary and reported weekly updates on self-MFR to the MFR therapist, and this was captured in notes and REDCap.

# Documentation and fidelity to the massage protocol

LMTs collected information during the MFR intervention including participants' symptoms, reactions to MFR, the presence or absence of restrictions, MFR techniques used, duration of the session, and type of (if any) MFR education provided. Fidelity to the intervention protocol and the intervention's acceptability in this patient population were reflected in the therapists' notes. Session notes for the 10 participants who received the MFR intervention were reviewed for themes on feedback on MFR and acceptability of treatment.

MFR Technique	Description
Nurturing touch	Introduce touch by lightly placing palms of the hands on the person's abdomen and back (over clothes). If tactile defensiveness is observed in the abdominal area, begin nurturing touch on other areas of the body as preferred by the patient. Then return to the abdomen and back to assess for fascial restrictions. (Use at the start and end of work on any new areas: This introduction of touch to the area is engaging the muscles and connective tissue system but also engaging the parasympathetic nervous system's rest and digest response.)
Palpation check for fascial restrictions	To check for fascial restrictions, apply gentle and sustained pressure with the whole hand to the abdomen and back, then sink the hand to a depth of comfort for 90 s and then slowly moving the hand on the abdomen in multiple directions (toward the person's left, right, head, and feet). Assessment is done for 3–5 min. (Use at the start and end after nurturing touch: This assessment technique is applied to detect fascial restrictions. Address areas of most restriction first, unless too sensitive/painful, then start at least working toward greatest restriction.)
Skin rolling	Use fingers to gather, stretch, and roll the skin bundle while gliding with thumbs along the middle of the fascial line. If areas are stuck and skin not able to roll, try from a different direction or area first then going back over this area. (Use between other techniques: This facilitates the release of smaller adhesions.)
Cross-handed MFR	Plant the base of the palm at one side and opposing palm on the other side of a restriction, one arm crossed over the other. Gently sink while applying pressure in opposite directions within the patient's comfort level. Pressure should be applied for at least 90 s, up to 5 min, or when fascia releases. (Use anytime: This is to release surface fascial restrictions or deeper ones depending on the depth used.)
Sacral release	Apply gentle sustained pressure on the sacrum with the flat of the hand or palm. Sink into the sacral area to the person's depth of comfort. Sustain pressure or subtly apply pressure toward the feet. (Use anytime, in any position: This pressure into the transverse plane engages and connects into the sacral area both at the surface and deeper levels and then mobilizes connective tissue release.)
Pin and stretch	Apply pressure near an area of restriction with one hand/arm while the other sinks into proximal tissue and stretches away from the initial point of contact. (Use anytime, in any position: This pressure across the transverse plane with counter stretch mobilizes the superficial and deeper connective tissue to shift and helps repattern.)
Gentle static pressure	Start with nurturing touch and slowly sink into the area of restriction for at least 90 s to 5 min. Continue to sink to the patient's comfort level or until a restriction is felt and wait, do not try to push past it or force it, wait to feel for it to melt or slowly loosen the myofascial barrier and get fascial release. (Use anytime, in any position: This pressure across the transverse plane mobilizes the superficial connective tissue never forcing, instead waiting for it to release.)
Deep static pressure	Start with gentle pressure and increase to deeper static pressure for 90 s to 5 min. To disengage, slowly release from the point of pressure. (Use anytime, in any position: This pressure across the transverse plane mobilizes the deeper layers of connective tissue. The pace of easing out of a release is just as important as pace going into it.)
Cross-fiber friction or strumming	Sink finger pads into the area of fibrous restriction and move fingers across parallel fibers. Always in a manner that is not causing pain, tightening by the patient, or guarding. Play around with slow pace and doing lighter first then easing into more pressure and faster pace if tolerated well and comfortable. (Use anytime, in any position: This technique can release fibers with a tight ropey feel. It is often employed first to prepare the area for traditional MFR techniques.)

TABLE 2	(Part 2 of 2)	MFR	Techniau	ies
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MFR Technique	Description
Psoas release	Sink finger pads gently into the psoas muscle. This point on the psoas is located midway between the belly button and hip. To confirm, the therapist can have the patient lift the straight leg into air to engage the psoas and then have them set the leg down and engage in release, with both legs relaxed on the table. Align arms stacked fingers out and apply gentle, sustained, meaningful pressure from the core. Apply pressure at a 45° angle and sustain for 90 s to 5 min until psoas tissue releases. Take care to check in on the pressure and pace as you get into this area. If too intense at any point, ease the back out slowly and try the other side or another technique. (Use anytime, in supine position: This pressure across the transverse plane mobilizes the deeper layers of connective tissue. The pace of easing out of a release is just as important as the pace going into it.)

MFR = myofascial release.

## **Feasibility and Acceptability**

The feasibility and acceptability of the MFR intervention was assessed based on the information obtained by LMTs during the study visits. Feasibility was defined as the ability to effectively recruit eligible participants, retain participants, perform the intervention, and adhere to the protocols and procedures. Acceptability was defined as the ability to perform the intervention and all study procedures as defined in the study protocol without any adverse events or other negative effects on patients' health and well-being.

#### **Data Collection**

All questionnaires were sent via email to participants using REDCap I day before their scheduled visits with the instructions for them to complete the surveys prior to the visit. Reminders were also sent if they were not completed within 24 h. If participants had not completed the forms before the visit, the LMT reminded them to do so at the start. For post-intervention follow-up visits, surveys were sent with instructions to complete within 48 h of receipt. Participants were reminded via email if forms were not completed within 24 h.

## RESULTS

#### Feasibility of the MFR Intervention Protocol

Initial screening was conducted by performing an electronic health record query TABLE 3. Summary of the Recruitment Methods

Recruitment Method	Epic Query	REC Emails
Eligible	60	20
Successfully contacted	23	20
Consented to screening	6	11
Consented to study	3	8

REC = Recruitment Enhancement Core.

for patients with an ICD-10 diagnosis of IBS seen at CHOP within the last 2 years. We identified 60 potential participants, of which 23 were contacted successfully, 6 consented to screening, 3 asked to be contacted later, and 3 consented to the MFR intervention (Table 3). We then employed the services of the REC, which identified 2,021 potential participants who met IBS diagnosis and enrollment criteria. Automatic emails containing study details and study team contact information were then sent to 50 of these potential participants each week for ~1 year (June 28, 2022 to June 1, 2023). Thirty families contacted the study team, and of these, 20 met the inclusion criteria, and 11 provided verbal consent for screening procedures. From this group, 8 participants consented to the MFR intervention (Table 3). In total, these 2 recruitment methods resulted in 11 participants who consented to the study. One participant withdrew from the study before the study intervention was administered due to an unforeseen scheduling conflict.

Study visits were offered at two different locations: CHOP's main hospital outpatient campus located in the city of Philadelphia and the CHOP Specialty Care Clinic in the suburbs of Voorhees, New Jersey. Six of the 11 participants preferred the city location, while 5 preferred the suburban location. Fifty percent of the participants preferred evening study visits (after 5 pm), 30% preferred afternoon visits (12 pm-4:30 pm), and 20% preferred morning visits (before 12 pm). During recruitment, the availability of visits in the afternoon and evening after school was important to families and essential to their participation in these studies, as was the proximity of the centers to their homes.

#### Adherence to Study Protocol Procedures

Overall, the median adherence to study questionnaires (completion of questionnaires within the window outlined in the protocol) for each visit was 90%, with 7 of 10 subjects completing all study surveys. There was 90.7% compliance during visits 1–6, 81% during the weekly follow-up phase for 1 month after study visits were completed, 89% at the 3-month follow-up, and 100% at the 6-month follow-up (Table 4). Ten participants completed all six study visits; however, six were rescheduled for a time outside of the 6-week intervention window outlined in the protocol due to family schedule conflicts.

#### Feasibility and Acceptability of the MFR Therapy Intervention

LMTs successfully administered the complete MFR intervention to all 10 participants for the 6-week period. All participants were fully receptive to receiving the MFR intervention and self-MFR education and expressed confidence in their ability to complete self-MFR at home. One participant reported, "MFR at home still going well and helpful, even did on trip to Florida and helped with discomfort." Participants also offered feedback on MFR during sessions without a formalized process, which was then recorded by LMTs in their session notes. This feedback included statements such as "(MFR) helped release discomfort and gas," "I feel like my stomach muscles opened up," and "feeling much better than before the session." Furthermore, through this unprompted feedback, 60% of the participants reported that they experienced no pain or tenderness with MFR, 40% stated that their muscles felt more relaxed following MFR, and 40% reported feeling more relaxed overall following MFR.

## Safety

The LMTs administered the massage within their scope of practice and adhered to the intervention protocol ensuring safety and trauma-informed care.<sup>(22)</sup> Effective communication between the LMTs and the participant was maintained throughout the sessions. No adverse events were reported by any of the participants during the MFR intervention period or follow-ups. Mild muscle soreness following a session was reported in one participant after the first session; in this case, massage pressure and pace were adapted for the following sessions to mitigate future soreness.

## DISCUSSION

We effectively conducted preliminary studies to assess feasibility and acceptability of an abdominal wall-targeted MFR intervention in patients with IBS. We identified and enrolled eligible patients with IBS, provided six weekly MFR interventions to each participant and successfully collected symptoms and QoL data during the intervention and follow-up periods. The MFR intervention was highly acceptable to adolescents with IBS. There was excellent participant adherence to the study procedures and questionnaires. Participants provided positive feedback during the MFR intervention, and no adverse events were

TABLE 4. Adherence to the Protocol Procedures

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Date	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	1-Month Follow-up	3-Month Follow-up	6-Month Follow-up
Percentage of questionnaires completed (%)	88	90	90	100	100	90	81	89	100

reported. This approach ensured an intervention that was feasible to implement, well accepted in this population, and with great potential to be administered in clinical settings.

The successful design, development, and implementation of the MFR intervention was a result of a thoughtful collaboration between expert LMTs, pediatric gastroenterologists, and researchers. This multidisciplinary collaboration ensured that there was a strong scientific rationale for the study, that the intervention and study would be feasible and potentially well accepted by patients with IBS, that there was a potential therapeutic benefit of the intervention, and that the study would produce replicable results. Moreover, continued communication between researchers, clinicians, and LMTs throughout the study ensured that any challenges that arose in terms of scheduling, implementation, standardization, and protocol compliance could be timely addressed and navigated based on the collective knowledge of the study team. Therefore, integrating different areas of expertise in the development of complementary therapies for patients with IBS is essential to ensure well-accepted and successful interventions.

Although sparse, other integrative and complementary health strategies are currently used to address symptoms of IBS. The clinical guidelines from the American College of Gastroenterology only suggest gut-directed hypnotherapy and peppermint oil as viable treatment options for global IBS symptoms.<sup>(24)</sup> Evidence supporting the effectiveness of acupuncture, yoga, and meditational and mindfulness practices in managing IBS remains inconclusive.<sup>(25–27)</sup> These integrative approaches reflect the ongoing exploration of complementary therapies in the comprehensive care of individuals with IBS, emphasizing the need for additional studies to assess their effectiveness. Using a team-based integrative approach may potentially aid in the successful establishment of these therapies as feasible treatment options for IBS. There is also limited research on the effect of massage therapy in children with IBS. Therefore, establishing the feasibility and acceptability of our MFR intervention protocol contributes to the growth and expansion of research in this field with potential for clinical implementation once efficacy studies are conducted.

We successfully recruited and retained 10 participants in about 1.5 years. Considering we identified over 2,000 potential participants using two different methods, we were only able to enroll a small number of these. We believe the COVID-19 pandemic has a significant impact on our recruitment and participant engagement. The concerns over viral exposure during the in-person visits to the MFR intervention sites and close contact with the LMTs and study team may have influenced individuals' willingness to participate in our research study during the specified 1.5-year period. However, we implemented several items that would make attendance to study visits more accessible, including the availability of evening appointments and both an urban and suburban location. These options may have made the study more convenient and, therefore, more appealing for families, as 50% of the participants chose to have evening appointments, and participants were approximately evenly split between the two sites. We realize that the significant time commitment required for participation (six inperson visits for 6 consecutive weeks) and required travel time to CHOP contributed to the relatively low recruitment numbers for this study. However, the need for more effective IBS treatments with minimal side effects and the rise in research investigating integrative approaches for IBS may have influenced the participants' decision to enroll and remain engaged in the study, outweighing the time and travel inconveniences.(10,24-27)

Overall, the abdominal wall-targeted MFR intervention was well accepted and received by all participants. LMTs identified and successfully released fascial restrictions using MFR in all 10 participants. Additionally, participants were all receptive to the self-MFR education and reported feeling more confident in their ability to perform self-MFR by the end of the 6-week MFR intervention period. Similar to other studies utilizing MFR for musculoskeletal issues and pain, which have demonstrated no adverse effects.<sup>(19)</sup> participants in this study reported minimal discomfort throughout the intervention period, affirming the low-risk nature of the intervention. Most participants provided positive feedback on MFR, such as "feeling good," "helpful," or "relaxing." This positive feedback implies a potential favorable outcome of our study, possibly attributed to the benefits associated with MFR including pain reduction and enhanced functional improvement.<sup>(19)</sup> While this feedback collection was not standardized, these voluntary responses to the MFR intervention provided by participants indicate that MFR was well accepted in IBS patients. The MFR intervention was administered by highly trained and experienced LMTs with specialized MFR training and may have ensured that participants felt comfortable and confident about the study environment and intervention. Additionally, the constant communication between the participant and the LMTs ensured the intervention never reached a physically or emotionally painful or uncomfortable level. As we expand beyond the pilot, we will implement a protocol fidelity measure to reduce variability in therapy and education delivery and standardized documentation (Appendix A). We must note that we excluded participants with physical or psychosocial comorbidities that may have interfered with the initial assessment of the MFR intervention. Future studies will determine whether the MFR intervention would be feasible and acceptable in a more general IBS population.

## CONCLUSIONS

We are confident this study will contribute to the advancement of the massage profession, the expansion of massage therapy in clinical settings, and the Massage Therapy Foundation's Research Agenda.<sup>(28)</sup> This study highlights the importance of the involvement of experienced LMTs in study design and administration of the massage intervention to ensure successful outcomes. Additionally, our findings provide best practices on the use of massage therapy in research, and future iterations of this study will inform how massage and specifically MFR can be used in "real-world" multidisciplinary clinical settings and integrated into traditional health-care systems. Understanding the feasibility and acceptability of this intervention is foundational to advancing the understanding of the basic mechanisms of massage in the management of chronic GI conditions and guiding future research to assess mechanisms associated with the benefits of MFR and how the practice could be broadly applied to

other conditions where massage therapy is thought to be beneficial.

# **AUTHOR CONTRIBUTIONS**

MM, AB, JE, and TSC designed the study. JD and AR conducted screening and enrollment for the study and conducted literature reviews. JD extracted compliance data. XW completed the data analysis. AR and JD wrote the first draft. MM, TSC, AB, RM, JE, and ZRV corrected the manuscript. RM, JE, and TSC performed the MFR intervention. RM and TSC wrote up the MFR techniques table, with editing help from the whole team. AB and MM supervised the conduct of the study. All authors have read and approved the final submitted version.

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## CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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#### **APPENDIX**

# Massage Therapist Fidelity Checklist

Please complete the survey below.

Thank you!

Massage Therapist Name		<ul><li>○ Massag</li><li>○ Massag</li><li>○ Massag</li><li>○ Massag</li></ul>	e Therapist 1 e Therapist 2 e Therapist 3	
Date of service:				
Pre Therapy Assessmen	t			
Are all REDCap surveys for the	e visit completed?	○ Yes ○ No (If no, hav	e subject/parent com	pleted)
Patient Comments about Sym Right Before Session	ptoms in the Last Week &			
Any changes in medications ir	n the last week?			
Patient Reported Pain Pre The	гару	1	5 (Place a mark on the sc	10 
Self MFR				
How many days in the last we practice self-MFR?	ek did the patient			
On average, how long did the for? (minutes)	patient perform self-MFR			
In general, what time of day d self-MFR?	lid the patient practice	○ Morning ○ Afterno ○ Evening ○ Don't ki	) on J now	
Location of Fascial Rest	rictions			
	Towards head	Towards feet	Towards patient's right	Towards patient's left
Right upper quadrant				
Right lower quadrant				
Left upper quadrant				

Additional Information about Fascial Restrictions

Left lower quadrant

Page 1

			Page 2
Tightness of Fascia Pre Therapy	1	5	10
		(Place a mark on the scale abov	/e)
Session Details			
Techniques Used	<ul> <li>Palpation</li> <li>Nurturin</li> <li>Rocking</li> <li>Sacral re</li> <li>Cross ha</li> <li>Pin and s</li> <li>Skin rolli</li> <li>Gentle s</li> <li>Deep sta</li> <li>Cross fib</li> <li>Psoas re</li> <li>Static pr</li> <li>restriction</li> </ul>	n check for fascial restrict g touch elease inded pressure stretch ng tatic pressure atic pressure er friction/strumming lease essure in one hand while ons in other hand	ions checking
Did you apply any techniques not listed above?	○ Yes ○ No		
If so, which additional techniques did you apply?			
Generally, where were techniques applied?	☐ Abdome ☐ Most late ☐ Most late ☐ Back ☐ Other	n eral right side eral left side	
Where else were techniques applied?			
Pressure Used (Walton Pressure Scale)	1	(Place a mark on the scale abov	5 
What was the general length of time myofascial stretching, holds/pressure was applied?	◯ Under 3 ◯ 3-5 minu ◯ 6 or mor	minutes ites e minutes	
Did you encourage the patient to breathe and relax?	⊖ Yes ⊂	) No	
Did you ask for patient feedback during session?	⊖ Yes ⊂	) No	
Patient Position During Session	□ Supine □ Sitting u	🗌 Prone 🔲 Side lying Jp	
Duration of Session (minutes)			
Tightness of fascia post therapy (compared to pre therapy) as assessed by the massage therapist	<ul> <li>Less res restriction</li> </ul>	striction O Same level o	f

#### RANA: ABDOMINAL MFR THERAPY IN PEDIATRIC PATIENTS WITH IBS

			Page 3
Patient feedback after session:			
Other session notes			
Did you deviate from the protocol? Y/N	⊖ Yes	○ No	
Protocol: 45-60 minute session, patient fully clothed, limited changes to room (i.e. keep lights on, one pillow, no blanket/sheet, no music or video on computer), techniques as listed above in no particular order, techniques generally applied in and around the abdomen (could also include back), patient is awake during the massage.			
Why did you deviate from protocol and how did you deviate from protocol?			
Blanket?	⊖ Yes	⊖ No	
Lights on?	⊖ Yes	⊖ No	
Music?	⊖ Yes	⊖ No	
Other Aspects of the Room Conditions			
Post Therany Assessment			
Tightness of Fascia Post Therapy	1	5	10
		(Place a mark on the scale above)	
Patient Reported Pain After Session	1	5	10
		(Place a mark on the scale above)	
Adverse Events?	⊖ Yes	⊖ No	
Fundation that a shareness success			

Explain the adverse event

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#### RANA: ABDOMINAL MFR THERAPY IN PEDIATRIC PATIENTS WITH IBS

MFR Education	
Did you provide education about self-administering MFR?	○ Yes ○ No
Did patient receive MFR ball?	○ Yes ○ No
Did you explain to patient that pressure should be applied against a surface such as wall or bed?	○ Yes ○ No
Did you explain they should apply the ball to the abdominal region and slowly roll it until they find a tight area?	○ Yes ○ No
Did you explain they should hold the pressure for 3-5 minutes?	○ Yes ○ No
Did you explain the pressure should not cause pain?	⊖ Yes ⊖ No
Did you tell them to administer for 10-30 minutes per day on the days they do not receive a massage?	⊖ Yes ⊃ No
Did you ask the participant to model the technique?	⊖ Yes ⊖ No
How long did education take?	○ < 5 min ○ 5-10 min ○ 10< min

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