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A systematic review of mindfulness-based therapies for functional abdominal pain.

Masterproef huisartsgeneeskunde

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Abstract (EN)

Purpose: Functional abdominal pain poses a significant challenge in clinical practice. As symptoms are often exacerbated by stress, mindfulness-based therapies (MBTs) have gained attention as potential therapeutic strategies. This systematic review aims to evaluate the efficacy of MBTs in managing functional abdominal pain disorders.
Methods: A systematic literature search was conducted across MEDLine (PubMed), Embase, and CINAHL databases from 2003 to 2023. Clinical trials focusing on mindfulness-based interventions for adults with functional abdominal pain, such as irritable bowel syndrome or functional dyspepsia, were included. Outcome measures included symptom severity and quality of life (QOL). Data synthesis was performed through a narrative description. Study quality was assessed using the ROBINS-I tool.
Results: Among 528 articles identified, eight studies met inclusion criteria, predominantly focusing on irritable bowel syndrome (IBS). While all studies showed
a trend toward improvement in symptom severity or quality of life post-treatment or during follow-up, not all results were statistically significant. All studies had a high risk of bias.
Conclusion: Mindfulness-based therapies present a promising approach for managing functional abdominal pain, offering potential benefits in symptom improvement and enhanced quality of life. However, limitations in methodological quality necessitate further investigation with well-designed trials.

Keywords: Functional abdominal pain, mindfulness, meditation, mind-body interventions, irritable bowel syndrome, functional dyspepsia, patient-centered care, stress reduction, systematic review.

Abstract (NL)

Doel: De aanpak van functionele buikpijnklachten kan uitdagend zijn voor zorgverleners. Aangezien stress vaak aan de basis ligt van deze klachten, lijken mindfulness interventies veelbelovende strategieën. Deze systematische review heeft als doel de doeltreffendheid van mindfulness interventies voor de behandeling van functionele buikpijnklachten te beoordelen.
Methoden: Er werd een systematisch literatuuronderzoek uitgevoerd in de databases MEDLine (Pubmed), Embase en CINAHL. Klinische studies gepubliceerd tussen 2003 en 2023, die gericht zijn op mindfulness interventies bij volwassenen met functionele buikpijnklachten (zoals het prikkelbare darmsyndroom of functionele dyspepsie) werden geïncludeerd. Ernst van symptomen en levenskwaliteit werden gekozen als uitkomstmaten. De studies werden samengevat in een beschrijvende synthese. Studiekwaliteit werd beoordeeld op basis van de ROBINS-I tool.
Resultaten: Van de 528 gescreende studies, voldeden er acht aan de inclusiecriteria. De meerderheid hiervan (7 studies) onderzocht het prikkelbare darmsyndroom. Alle studies vertoonden een positieve trend in symptoomcontrole en levenskwaliteit na behandeling of follow-up periode. Echter, niet alle resultaten waren statistisch significant. Alle studies vertoonden bovendien een hoog risico op bias.
Conclusie: Mindfulness interventies kunnen een potentieel positief effect hebben op de symptomen en levenskwaliteit bij patiënten met functionele buikpijnklachten. Echter, beperkingen in methodologische kwaliteit benadrukken de noodzaak tot verder onderzoek via goed ontworpen klinische studies.

Introduction

Functional abdominal pain or discomfort is a common reason for patients to consult their primary care physician. Examples are irritable bowel syndrome (IBS), functional dyspepsia (FD) and centrally mediated abdominal pain (CAPS) – formerly known as functional abdominal pain syndrome (FAP). These disorders are all characterized by recurrent abdominal pain without any clear organic cause.
Despite their prevalence (IBS has a prevalence of 11.2%, FD of 10-30%, CAPS of 0.5-2.1%), effective treatment remains challenging, significantly impacting patient's quality of life and posing a substantial burden on healthcare systems.[1–3] Standard treatment options, such as diet, medication, supplements and psychotherapy, are often inadequate, time-consuming, or inaccessible, leading to frustration for both patients and primary care professionals.[4,5] Hence, alternative treatment options, such as mindfulness-based therapies (MBTs), are emerging. This article aims to systematically review the current evidence on the efficacy of MBTs for managing functional abdominal pain disorders. By synthesizing the available evidence, we hope to gain a deeper understanding of the potential role MBTs could have as a primary-care treatment option. For a deeper knowledge of the research topic, background information is provided below, serving as a framework for GPs or other primary care practitioners.

Definition, epidemiology, and diagnosis

Functional gastrointestinal disorders (FGIDs) are classified using the Rome criteria, of which Rome IV are the most recent. IBS is defined as the presence of recurrent abdominal pain, associated with defecation or a change in stool frequency and/or stool form.[3] FD can be diagnosed in the presence of one or more of the following symptoms: postprandial fullness, early satiation, epigastric pain, or epigastric burden. These symptoms should be bothersome and could not be explained by any evidence of a structural disease (upper endoscopy included).[1] CAPS is characterized by (nearly) continuous abdominal pain, that has no or only an occasional relationship with physiological events, that limits some aspect of daily functioning, that is not feigned and that cannot be explained by another structural or functional gastrointestinal disorder or other medical condition.[2] For all three of them, criteria should be fulfilled for the last 3 months (with symptom onset at least 6 months before diagnosis). These Rome criteria are useful for research purposes, however for clinical use and daily care of patients, these criteria might fall short.[6] A more applicable definition for IBS would be 'abdominal pain or discomfort, in association with altered bowel habits, for at least 6 months, in the absence of alarm symptoms or signs.[4] In this regard, the less strict Rome III criteria, might be more suitable epidemiologically.[7]

Pathophysiology and the effect of psychological distress

Functional abdominal pain disorders are characterized by their complex pathophysiology, where different mechanisms interact. There is a role for central and autonomic nervous system modulation, dysregulation of motility, visceral hypersensitivity, an impaired microbial balance, altered immune activation, increased permeability of the gut, and genetic and epigenetic factors.[4,8]

The biopsychosocial model offers an important framework to understand how biological, environmental, and psychological factors contribute to the development of FGIDs.[9] In this model, there's a key role for the interaction between brain and gut.[10] Partly through involvement of the vagal nerve, stress plays a major part. Taking IBS as a key example, psychological distress is known to be a significant trigger for symptoms, affecting the mind-body connection through several pathways. First, stress causes an imbalance in the autonomic nervous system (ANS) through sympathetic activation, resulting in altered gut motility, visceral hypersensitivity, and an increased pain perception.[4–6,9,11] Next, stress-induced immune responses could trigger low-grade inflammation in the gut, disrupting the intestinal barrier, also contributing to gut hypersensitivity.[4,11,12] Furthermore, disruption of the stress hormone system also affects gut motility and sensitivity.[9] Finally, stress might also impact the microbiome, contributing to IBS symptoms through several complex mechanisms.[11,13]

A need for better therapeutic options

Treating FGIDs requires a supportive doctor-patient relationship and a shared understanding of these diseases.[2,4,14] Educating the patient, by explaining the link between stressors and symptoms, not focusing too much on the biomedical aspect, is key.[9] Lifestyle changes, including dietary changes, should be discussed, and pharmacotherapy could be considered.[6] Due to heterogeneity of the population, symptoms and disease mechanisms, traditional approaches often fall short. In the context of the biopsychosocial model and the association between symptoms and stress, it is not surprising that alternative treatment options are arising, offering a patient-centered approach addressing both the physical and psychological aspects of these disorders.[5] In most guidelines, psychological therapies are rather seen as a 'last resort' treatment. However, accessibility might be improved through the creation of low-threshold interventions embedded in primary care.

Mindfulness-based therapies

In this study, we are specifically focusing on mindfulness-based therapies. Mindfulness could be defined as the intentional practice of paying attention to the present moment, in an open, nonjudgmental manner.[15,16] This awareness of the 'here' and 'now' contrasts to the current times where our minds are often in a state of distraction, thinking about the past or future, on automatic pilot, or suppressing unwanted thoughts or feelings. Practicing mindfulness cultivates an awareness towards present sensations.
Mindfulness skills could be developed through specific, science-based programs such as mindfulness-based stress reduction (MBSR) or mindfulness based cognitive therapy (MBCT), but other types of interventions or internet-based training forms exist too and might be more accessible.[16]

MBSR is an 8-week program developed by Jon Kabat-Zinn in 1979 where mindfulness skills are taught using body scans, sitting meditation, gentle yoga, as well as practicing mindfulness during daily activities. The program consists of weekly group sessions, along with daily home practice.[16,17] MBCT, frequently used in the treatment of depression, extends the principles of MBSR with influences of cognitive-behavioral therapy, learning to be aware of and observe negative thoughts and feelings, to eventually prevent them from influencing mood.[16] MBT have

potential benefits for FGID management. First, their stress reduction qualities counteract the negative effects of stress stated before. Second, fostering acceptance and non-judgmental awareness of pain, MBTs could contribute to better pain management. At last, acquired emotion regulation skills help manage emotions, such as anxiety, that could exacerbate pain.[16]

Rationale, value, and objective

Considering the pathophysiology of functional abdominal pain disorders, the shortcoming of current treatment options and the benefits of mindfulness, it seems crucial to explore MBTs as a treatment option for functional abdominal pain disorders. If MBTs would seem to be effective, patients could be guided towards more self-management and empowerment, improving their overall well-being. Given the challenges in symptom management, leading to frustrations for both patients and caregivers, these effects could benefit primary care practitioners as well. In this systematic review, we are hoping to provide some valuable insights from the existing research, by evaluating whether MBT could improve symptoms or quality of life in patients suffering from any type of functional abdominal pain.

Methods

Search strategy:

This literature search was conducted through the electronic databases MEDLine via PubMed, Embase, and CINAHL. The exact search strategy and search terms used per database can be found in the supplementary materials (table S1). English-language studies published between January 1, 2003, and November 11, 2023, were included. The selection of articles from the past 20 years allows to capture the emergence of these 'newer' therapies, while also accommodating the potentially limited number of studies in this field. Prior to the literature search, the protocol of the study was registered on PROSPERO with reference n° CRD42023478562.

Eligibility

We selected clinical trials, single-arm intervention studies, and pilot studies according to the following criteria:

Population:

Adults with abdominal pain or discomfort, without any organic or structural cause, were included. We could use the term' functional abdominal pain disorders' for this population. This is not necessarily the same as 'functional gastrointestinal disorders' but has an overlap with conditions such as irritable bowel syndrome, functional dyspepsia, and functional abdominal pain syndrome. Hence, the studied population is a group of functional gastrointestinal disorders manifesting with chronic abdominal pain or discomfort as a primary symptom. Diseases with a distinct cause, such as Inflammatory Bowel Disease (IBD), surgical pain, Anterior Cutaneous Nerve Entrapment Syndrome (ACNES), oncological disorders, and similar pathologies, are excluded. Functional gastrointestinal diseases, which do not necessarily include pain as a main characteristic, were also excluded. Pelvic pain, too, falls outside the scope of this study since it is usually caused by gynecological or urological (instead of gastrointestinal) causes.

Intervention:

All types of mindfulness-based therapies, including but not limited to mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), and mindfulness meditation, are included. Unguided mindfulness-based interventions (such as self-help interventions), as well as online interventions, are also included. Interventions with virtual reality are excluded due to the need for specific devices. Mindfulness should be the core component of the intervention, but patient education or elements of yoga added to the therapy are not exclusion criteria. However, if mindfulness is not the main component, such as with ACT or plain yoga therapy, studies are excluded.

Control:

Regarding the control group, standard care, no-treatment, and wait-list control are all included. Other types of relaxation therapy or psychotherapy as a control group are excluded.

Outcome:

As a primary outcome, we used treatment response, including symptom severity and quality of life (QOL).

Data collection and analysis

One reviewer independently conducted title and abstract screening using Rayyan, followed by full-text screening. The full-text screening was verified by a second member of the research team. Data was extracted by one reviewer in a prespecified extensive Excel sheet. The data included information about the article (author, year, country, title), the population, the study design (study type, inclusion/exclusion criteria), the intervention and control group (type, description, definition of mindfulness), the outcomes (timing of assessment, effect on symptom severity/pain, effect on QOL, effect on psychological status, adverse events) and the main conclusion. A second member of the research team checked this data.
Findings are presented through a narrative synthesis, assessing the effectiveness of mindfulness-based interventions. A summary of each included article will be provided, qualitatively describing study characteristics, effect sizes, variations in effectiveness, outcomes, adverse effects, and demographics.

Quality analysis and risk of bias

The Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool was used to assess the risk of bias. This assessment was executed by one reviewer.

Results

Study selection:

Our literature search identified a total of 528 articles, of which 165 duplicates were removed. Figure 1 shows the PRISMA flow diagram for the study selection process. Twelve articles remained after title and abstract screening. In two of those articles, the interventions were tested in the normal population, one article used another psychological intervention as a control group, and another article included the same population as another study, but its outcome measures were not specifically related to ours. In the end, eight studies were reviewed.

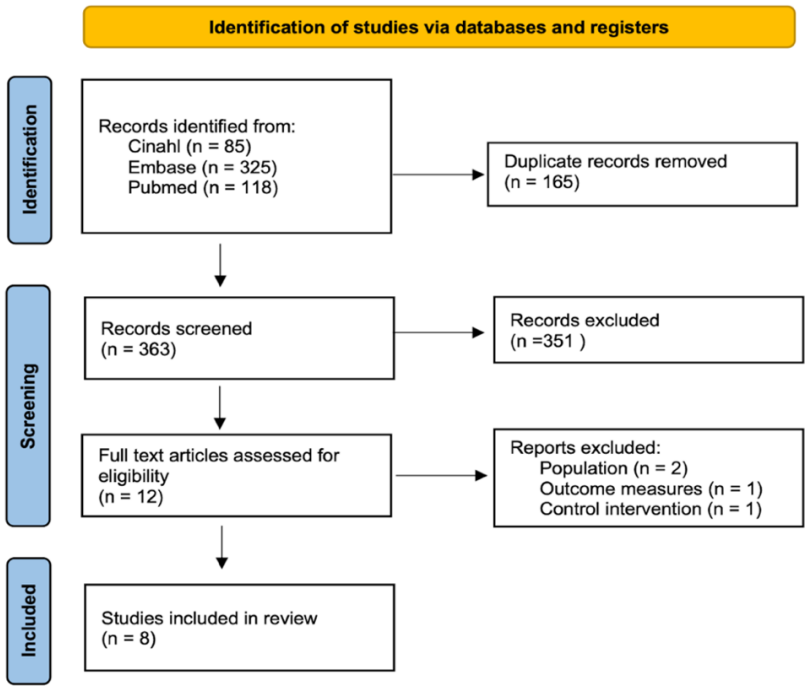


Figure 1: Prisma flow diagram for new systematic reviews which included searches of databases and registers only.

Study characteristics.

Six studies are randomized clinical trials (two of them are smaller experimental or pilot studies), and two are single-arm intervention studies. The year of publication ranges from 2011 to 2023. In seven studies, the population consists mainly of IBS patients. The other one includes patients with functional dyspepsia. There is also one study where all participants have concomitant PTSD. Regarding FGID classification, one study uses Rome II, six studies use Rome III and the most recent one uses Rome IV. For illustration purposes, Table 1 shows the difference between these different Rome criteria for IBS. The total population of all studies together consists of 454 patients. Two studies only included female patients. All studies except one, exclude certain (medical, psychiatric, ...) comorbidities. In the remaining one study, no exclusion criteria are mentioned. An overview of study characteristics and their in- and exclusion criteria, are visualized in Table 2. [3,18,19]

Table 1: Comparison of the different versions of the Rome criteria. [3,18,19]

	Rome II	**Rome III**	**Rome IV**
Abdominal Pain/Discomfort	Abdominal discomfort or pain for at least 12 weeks (not necessarily consecutive)	Recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months	Recurrent abdominal pain on average at least 1 day per week in the last 3 months
Duration of Symptoms	in the preceding 12 months	onset at least 6 months prior to diagnosis	onset at least 6 months prior to diagnosis
Associated Symptoms: at least 2 of the 3 required	(1) relief with defecation, (2) onset associated with a change in stool frequency (3) onset associated with a change in form (appearance) of stool	(1) improvement with defecation (2) onset associated with a change in frequency of stool (3) onset associated with a change in form (appearance) of stool.	(1) related to defecation (2) associated with a change in frequency of stool (3) associated with a change in form (appearance) of stool

Table 2: study characteristics

Author, Year, Country, Title	**STUDY TYPE**	**POPU-LATION**	**INCLUSION CRITERIA**	**EXCLUSION CRITERIA**
Gaylord, 2011, USA, *Mindfulness Training Reduces The Severity Of Irritable Bowel Syndrome In Women: Results Of A Randomized Controlled Trial.*[20]	randomized controlled parallel-group trial	female IBS patients (n = 75)	IBS diagnosis (Rome II and physician diagnosis); female; age 18-75; understanding English; willing to document symptoms/medication use and complete assessments; willing to attend 8 weekly sessions + one half day session.	history of psychosis; inpatient admission for psychiatric disorder in the past 2 years; IBD or GI malignancy; active liver/pancreatic disease; uncontrolled lactose intolerance; celiac disease; history of abdominal trauma/surgery involving GI resection; pregnancy
Zernicke, 2013, Canada, *Mindfulness-Based Stress Reduction For The Treatment Of Irritable Bowel Syndrome Symptoms: A Randomized Wait-List Controlled Trial.*[21]	randomized treatment as usual wait-list controlled trial	IBS patients (n = 90)	IBS confirmed by gastroenterologist (Rome III); age 18+; English-speaking	a concurrent self-reported diagnosis of a DSM-IV axis I mood/anxiety/psychotic disorder; current use of antipsychotics; past participation in an MBSR group.
Zomorrodi, 2015, Iran, *Long Term Effects Of Mindfulness On Quality Of Life In Irritable Bowel Syndrome.*[22]	randomized experimental study	IBS patients (n = 24)	IBS (Rome III); age 18-40; associate degree as minimum requirement; informed consent; active participation in the study	/
Harding, 2018, USA, *Reduced Symptoms Of Post-Traumatic Stress Disorder And Irritable Bowel Syndrome Following Mindfulness-Based Stress Reduction Among Veterans.*[23]	single arm-intervention study (open trial)	veterans with PTSD and IBS (n = 55) (85.5% male)	Veterans who met a symptom cutoff score for PTSD and met criteria for IBS (based on Rome III) at baseline	a history of a psychotic disorder; mania or poorly controlled bipolar disorder; known borderline or antisocial personality disorder; current suicidal or homicidal ideation with intent; active substance use disorder.

Naliboff, 2020, USA, *Mindfulness-Based Stress Reduction Improves Irritable Bowel Syndrome (Ibs) Symptoms Via Specific Aspects Of Mindfulness.*[24]	single arm longitudinal trial	IBS patients (n = 68)	Adults with IBS (Rome III)	serious medical condition or medications that would limit full participation or could compromise interpretation of fMRI; psychiatric diagnosis with psychotic or suicidal features; active substance use disorder
Henrich, 2020, UK, *A Randomized Clinical Trial Of Mindfulness-Based Cognitive Therapy For Women With Irritable Bowel Syndrome-Effects And Mechanisms***.**[25]	randomized non-blinded waitlist-controlled trial	female IBS patients (n = 67)	Diagnosed with IBS by a gastroenterologist or GP (Rome III); female; age 18-65; informed consent; English fluency; (corrected-to-) normal vision.	insufficient manual dexterity for the computerized tasks; severe DSM-5 Axis I or II psychiatric disorder; recent bereavement (within 1 year); GI diagnosis other than IBS; pregnancy; no internet access; prior participation in any structured mindfulness training; regular meditation practice (more than once per month); not able/unwilling to commit to the prescribed amount of sessions and home practice; concurrent enrollment in another study assessing a pharmacological or psychological treatment for IBS.
Teh, 2021, Singapore, *Mindfulness-Based Cognitive Therapy In Functional Dyspepsia: A Pilot Randomized Trial.*[26]	pilot randomized trial	FD patients (n = 28)	FD (Rome III) with normal upper GI evaluation; adult; English-speaking	psychiatric illness; H. Pylori infection; IBD; GI malignancy; acute liver/pancreatic disease; previous abdominal trauma or surgery involving GI resection; pregnancy; change in psychotropic medications in the preceding 3 months; any condition that would prevent from participation in group therapy
Ashraf, 2023, India, *A Study To Evaluate The Effectiveness Of "Mindfulness-Based Stress Reduction Therapy (Mbsrt)" In Reducing Symptom Severity And Improving Quality Of Life In Patients Suffering From Irritable Bowel Syndrome***.**[27]	randomized controlled trial	IBS patients (n = 47)	IBS (Rome IV); age 18-65; attained primary education; ability to understand the local language; willing to document symptoms and take medications regularly; willing to complete assessments, willing to comply with the protocol of the study; written informed consent	diagnosis of mental illness with psychosis; history/diagnosis of IBD or GI malignancy or any other organic GI disorder; active liver or pancreatic disease; uncontrolled lactose intolerance; celiac disease; endocrine disorders; history of abdominal trauma or surgery involving GI resection; pregnancy

Of the six studies that involved a control group, one study had a social support group as control intervention. Two studies had a wait-list design. In one study, the control group received only treatment as usual (TAU). In two other studies, the control group received pharmacotherapy, which was administered to the mindfulness-group as well. Regarding type of mindfulness intervention, six studies used an intervention based on MBSR. The two other studies had an MBCT program. In seven studies, the program consisted of 8 weekly sessions (length between 30 minutes and 2.5 hours) and five of them included an extra (half-)day retreat. One study had only six weekly sessions. Six studies included home practice; in the two other studies this was not mentioned.

Details of these interventions and the definition used for 'mindfulness', are presented in Table 3.

Table 3: Overview of the interventions and definition of mindfulness.

AUTHOR, YEAR	INTERVENTION VS CONTROL	DESCRIPTION OF MINDFULNESS INTERVENTION, INCLUDING LENGTH & DURATION	MINDFULNESS DEFINITION
GAYLORD, 2011	Mindfulness group (MG) (n=36) vs. social support group intervention (SG) (n=39)	Mindfulness-based stress and pain management program, based on MBSR with 8 weekly 2-hour sessions + one half day retreat; taught by trained mindfulness instructors. Homework included daily mindfulness practices and psychoeducational readings.	The basic technique involves self-regulation of attention to present-moment experience, using the breath or other object as the focal point, combined with release of cognitive fixation on thoughts of past and future.
ZERNICKE, 2013	MBSR (n=43) vs. treatment-as usual (TAU) waitlist (n=47)	MBSR with 8 weekly 90-minute group sessions + one 3-hour retreat, taught by a certified yoga instructor-nurse. Daily 45-minute home meditation and yoga through a booklet and CD was encouraged.	The cultivation of conscious awareness in the present moment in an open and nonjudgmental manner.
ZOMORRODI, 2015	Mindfulness based therapy (MBT) + drug treatment (n=12) vs. drug treatment only (n=12)	Mindfulness-based on pain and stress management, based on MBSR. 8 weekly 2-hour sessions. *Home practice was not mentioned.*	The instantaneous non-judgmental awareness and acceptance demonstrated by a person.
HARDING, 2018	only MBSR (n=55), no control	MBSR with 8 weekly 2.5-hour group sessions + one 7-hour retreat. *Home practice was not mentioned.*	*not mentioned*
NALIBOFF, 2020	only MBSR (n=67), no control	MBSR (based on standard protocol combined with the one used by Gaylord et al) with 8 weekly 2-hour classes + a 4-hour retreat, taught by MSBR-trained and experienced clinicians. Daily 30-minute meditation home practice was required.	Intentional, non-judgmental, present-focused awareness
HENRICH, 2020	MBCT-IBS (n=36) vs. waitlist (WL) (n=31)	MBCT adapted for IBS, with 6 weekly 2-hour sessions (with a one week break after week 5), delivered by clinical psychologists experienced in MBCT. Encouragement of daily home practice (up to 1 hour).	No definition mentioned; however, two core aspects of mindfulness are described: the cultivation of a decentered perspective and nonjudgmental interoceptive awareness.
TEH, 2021	MBCT (n=15) vs TAU (n=13)	MBCT program with 8 weekly 2-hour sessions and one half-day retreat (after week 6), delivered by qualified mindfulness instructors. Home practice with handouts and audio tracks had to be documented.	*not mentioned*
ASHRAF, 2023	MBSR in addition to pharmacological therapy (n=30) vs. pharmacotherapy only (n=17)	MBSR therapy with 8 weekly sessions of 30-45 minutes, performed by a clinical psychologist. Home practice included.	No definition mentioned; however, MBSR is described as using meditation and relaxation to foster awareness and acceptance of the present moment. Individuals practice noticing and observing details about their surroundings without passing judgement or reacting to triggers in the environment.

Effectiveness of interventions

Outcome measures were assessed at different time points, visualized in Table 4. Only 2 studies did not have a follow-up period. In other studies, the follow-up period varied between 6 weeks and 6 months. Tables 5 and 6 gives an overview of the results of our primary and secondary outcome measures for each study.

Table 4: Timing of assessment points for each study.

AUTHOR, YEAR	TIMING OF ASSESSMENT POINTS
GAYLORD, 2011	Baseline, post-intervention, 3-month follow-up (after completion)
ZERNICKE, 2013	Baseline, post-intervention, 6-month follow-up
ZOMORRODI, 2015	Baseline, post-intervention, 2-month follow-up
HARDING, 2018	Baseline, post-intervention, 4-month follow-up
NALIBOFF, 2020	Baseline, post-intervention, 3-month follow-up Primary outcomes were additionally assessed at week 4 (mid-treatment)
HENRICH, 2020	Baseline, after 2 treatment sessions, at post-intervention and at 6-week follow-up
TEH, 2021	Baseline, post-intervention
ASHRAF, 2023	Baseline, post-intervention

Symptom severity

Seven studies measured the effect on symptom severity. Five used the IBS Symptom Severity Scale (IBS-SSS) as a measure, one used the Gastrointestinal Symptom Rating Scale for IBS (GSRS-IBS) and one the subjective-clinical-assessment of FD symptoms (SCA-FD).

Regarding improvement posttreatment compared with baseline, two studies showed significantly greater improvements for MBT compared to a control group. One study saw a trend towards feeling better but showed no statistically significant improvement. A significant within-group improvement at posttreatment was seen in the two single-arm intervention studies, as well as one RCT, that did not mention the results of the comparison with the control group. One study did not see any greater improvements at posttreatment but did see a difference at 6-week follow-up compared to the control group. At three-month follow-up, one study observed a significantly greater improvement than the control group and one single-arm intervention study maintained significant withing group changes. The two studies with the longest follow-up periods (4 and 6 months), did not show any significant results in their follow-up periods. Table 5 gives a visual overview of at which timepoint the studies showed statistically significant results.

Quality of Life (QOL)

Of the seven studies that measured QOL (of which 6 are controlled trials), 5 used the IBS-quality of life scale (IBS-QOL) which measures changes in physical and psychosocial functioning because of IBS (high internal consistency and reproducibility).[20] One study used the Short-from Nepean Dyspepsia index (SF-NDI) for FD-specific QOL combined with the EuroQoL-Visual Analog Scale (EuroQoL-VAS) for general-health related quality of life. One study used the World Health Organization Quality of Life-BREF (WHO-QOL-BREF), containing physical, psychological, social, and environmental domains.

Four studies observed a significantly greater improvement posttreatment compared with a control group. The single-arm intervention study observed a significant within-group difference at posttreatment and at 3-month follow-up. One study that had no effect posttreatment, did show a significantly greater improvement at 3-month follow-up. Two other studies maintained a significant effect at (2 month- and 6 week-)follow-up. Only one study showed no significant difference posttreatment or at follow-up.

Table 5: Overview of whether effect measures were significant at a given timepoint. Green = significant results. Red = no significant results.

		SYMPTOM IMPROVEMENT		QOL IMPROVEMENT	
		Post treatment	Follow-up	Post treatment	Follow-up
GAYLORD	3 months				
ZERNICKE	6 months				
ZOMORRODI	2 months				
HARDING	4 months				
NALIBOFF	3 months				
HENRICH	6 weeks				
TEH	No follow-up				
ASHRAF	No follow-up				

Psychological status

Six studies (of which 4 controlled trials) measured the effect on psychological status. Different measurements are used in each study: the brief symptom inventory-18 (BSI-18) with subscales for anxiety, depression somatization and general severity, the Calgary Symptoms of Stress Inventory (C-SOSI) measuring the physical, psychological and behavioral response to stressful situations, the Profile of Mood States (POMS) measuring six dimensions of mood, the GI symptom-specific anxiety (GSA) describing anxiety resulting from GI symptoms including context, the Patient Health Questionnaire 9-item Depression Scale (PHQ-9) measuring depression symptoms, the Hospital Anxiety and Depression (HAD) scale, and the pain-catastrophic thinking scale (PCS). Only two studies used the same measure, namely the Depression, Anxiety and Stress Scale-21 (DASS-21). The results are variable, but in general improvement is seen in the MG. In Table 5, the individual results per scale are shown.

Adverse events

Only one study mentions that there were no reported adverse effects from participation in the mindfulness program.[26] All other studies did not measure adverse events. Even though one study mentions the analysis of diaries for adverse events, it does not display any data hereabout in the results section.[20]

Table 6: Results of different effect measures.

AUTHOR, YEAR	EFFECT ON SYMPTOM SEVERITY	EFFECT ON QUALITY OF LIFE	EFFECT ON PSYCHOLOGICAL STATUS
GAYLORD, 2011	**IBS-SSS**: MG had greater improvements compared with baseline than SG: 26.4% vs 6.2% reduction posttreatment (p=0.006) and 38.2% vs 11.8% at 3-month follow-up (p=0.001).	**IBS-QOL**: only a trend towards significance posttreatment, but at 3-month follow-up a significantly greater improvement for MG compared with SG (p=0.027).	**BSI-18**: anxiety and depression scales showed a significantly greater improvement compared to SG at 3-month follow-up. Within-group improvement for MG was seen in all subscales at 3-month follow-up and for anxiety and depression also at posttreatment. For the SG, this was not seen in any subscale at any time point.
ZERNICKE, 2013	**IBS-SSS**: MBSR had significantly greater improvements than TAU posttreatment: 30.7% vs 5.2% (completers analysis) and 16.9% vs 3.5% ITT analysis). There were no significant differences after 6 months.	**IBS-QOL**: no significant difference at posttreatment or 6-month follow-up (improvement in both groups)	**C-SOSI:** greater improvement posttreatment compared to TAU (p=0.02), no difference at 6-month FU. **POMS:** improvements in both groups, with no significant differences.
ZOMORRODI, 2015	/	**IBS-QOL**: compared to the control group, MFT significantly improved QOL posttreatment (p<0.001) and had a lasting effect at 2-month follow-up (p = 0.01).	/
HARDING, 2018*	**IBS-SSS**: significantly lower symptom scores post-intervention (p<0.01) but not at 4-month follow-up.	/	**GSA:** significantly lower scores posttreatment, not after 4 months. **PHQ-9:** significantly lower scores posttreatment and after 4 months.
NALIBOFF, 2020*	**IBS-SSS:** significant changes from pre- to posttreatment and pretreatment to 3-month follow-up (p<0.001)	**IBS-QOL**: significant changes from pre- to posttreatment and pretreatment to 3-month follow-up (p<0.001)	**HAD-Anxiety and PCS:** significant declines from pre- to posttreatment and pretreatment to 3-month follow-up. **HAD-Depression:** no significant differences.
HENRICH, 2020	**GSRS-IBS:** no significantly greater reduction posttreatment, but significant greater reductions compared with baseline at 6-week follow-up (28% for MG vs <1% for TAU, p<0.01).	**IBS-QOL**: significantly greater improvements at posttreatment and 6-week follow-up compared with baseline (39% for MG vs -1% for TAU, p<0.001, at 6-week follow-up)	**DASS-21**: Overall, MG showed significantly greater reductions compared to WL.
TEH, 2021	**SCA-FD:** there is non-significant trend towards feeling somewhat or much better for the MBCT group compared to TAU (posttreatment).	**SF-NDI:** There was a significant improvement compared with TAU (p=0.018) posttreatment **EuroQoL-VAS**: no significant improvement.	**DASS-21:** a non-significant reduction in mean scores was observed.
ASHRAF, 2023	**IBS-SSS:** There was a significant improvement within the MBSR group posttreatment, however no comparison with the control group is mentioned.	**WHO-QOL:** There was a significant improvement posttreatment compared with the control group.	/

**=single-arm trial*

Quality assessment

The ROBINS-I tool revealed that all studies were at a serious risk of bias, except one study that showed a critical risk of bias. This overall high risk was primarily due to the reliance on self-reported questionnaires for outcome measurement, inherently predisposing the studies to a serious risk of bias. Further details can be found in Table 7.

Table 7: Quality assessment according to ROBINS-I.

	bias due to confounding	bias in selection of participants into the study	bias in classification of interventions	bias due to deviations from intended interventions	bias due to missing data	bias in measure-ment of outcomes	bias in selection of the reported result	**overall bias**
Gaylord, 2011	low	low	low	low	low	serious	serious	**serious**
Zernicke, 2013	low	low	low	low	low	serious	moderate	**serious**
Zomorrodi, 2015	low	low	low	low	low	serious	moderate	**serious**
Harding, 2018	low	low	low	moderate	serious	serious	moderate	**serious**
Naliboff, 2020	low	serious	low	low	low	serious	serious	**serious**
Henrich, 2020	low	low	low	low	low	serious	low	**serious**
Teh, 2021	low	low	low	low	moderate	serious	moderate	**serious**
Ashraf, 2023	low	low	low	low	no information	serious	critical	**critical**

Discussion

Key Findings

The review included eight studies investigating mindfulness-based therapies for patients with IBS or FD. Both MBSR and MBCT based programs were used, varying in duration and format, with all but one compromising 8 weekly sessions. Due to the limited representation of MBCT studies (only two), direct comparisons between the effectiveness of MBSR and MBCT remain inconclusive.
Overall, MBTs demonstrated improvements in both symptom severity and QOL, although statistical significance was not consistently achieved in all trials. Despite the heterogeneity in outcome measures for psychological status, a general trend towards improvement was observed. Notably, divergent results were observed across various timepoints within individual studies and no uniform pattern emerged regarding early or sustained therapeutic gains. According to *Zomorrodi et al*, other psychological interventions may not yield comparable long-term effects.[22]

Quality of studies

All studies were assessed to have a serious risk of bias, primarily due to self-reported questionnaires and methodological limitations, such as unclear reporting and potential procedural oversights. Despite some studies demonstrating strengths, such as successful randomization and comprehensive follow-up, limitations such as small sample sizes, methodological ambiguities, and reporting inconsistencies were noted, potentially compromising the reliability and generalizability of the findings.
Conducting high-quality studies for MBT presents inherent challenges. Firstly, blinding patients is not feasible. Secondly, effectiveness is predominantly measured through subjective questionnaires. Thirdly, the act of filling out questionnaires prompts patients to reflect on or engage in self-monitoring – a component of IBS therapy – potentially leading to improvement in control groups as well, thus resulting in reduced effect sizes.[21] Additionally, the quality of group therapy sessions may vary depending on the skills and expertise of the facilitator.

Prior research:

Previous studies have indicated the efficacy of psychological interventions in functional bowel disorders, with most evidence for cognitive-behavioral therapy (CBT) and hypnotherapy.[4,28,29] Hypnotherapy aims to induce a state of deep relaxation, empowering patients to self-manage their symptoms and regulate bowel functioning. However, these approaches may not always be accessible and might be less cost-effective compared to mindfulness-based therapies (MBT).
Systematic reviews addressing mindfulness meditation for chronic pain, mindfulness-based therapies in functional gastrointestinal disorders (FGIDs), and meditation in IBS have reported similar findings to our study. While these results are promising, the need for more robust studies remains evident.[30–32]

Mechanisms of action

In theory, MBT present a promising intervention for managing symptoms and QOL in patients with functional abdominal pain.[5] Chronic stress is a significant predictor for symptom intensity in IBS, underscoring the importance of stress reduction as a treatment strategy.[9] Psychological interventions such as MBTs are emerging as promising therapies, due to their ability to address stress-related symptoms effectively.

Individuals with FGIDs also exhibit catastrophizing tendencies, hypervigilance, and gastrointestinal-specific anxiety.[5] MBTs operate through various mechanisms, such as promoting non-reactivity to catastrophic thoughts and anxiety, increasing awareness of symptoms as harmless signals, and reducing stress responses.[33]

Moreover, mindfulness training enhances emotional regulation skills, enabling individuals to manage unpleasant moods. Most studies in this research indicate significant reductions in distress and or mood disturbances among participants undergoing MBTs. Unlike conventional medical treatments that aim to alter or alleviate unpleasant sensations, mindfulness encourages the acceptance of these sensations, potentially leading to more effective symptom management and improved overall well-being.[5]

By cultivating a nonjudgmental, decentered awareness of sensations, MBTs enhance emotion regulation and stress reduction capacities, thereby reducing physiological disturbances.[25] Studies showing continued symptom improvement during follow-up periods highlight the sustained effectiveness and long-term benefits of MBTs.[20,22,24,25] Additionally, MBTs empower patients by enabling them to play an active role in their own health and well-being, creating a sense of control, which contributes to improved outcomes.

Future directions

Future research should prioritize better designed clinical trials to further establish the efficacy of MBTs for functional abdominal pain. These trials should incorporate larger sample sizes, longer follow-up periods and standardized outcome measures to provide more robust evidence.

Moreover, it could be useful to explore the potential benefits of MBTs among various patient groups. It is plausible that certain subgroups may have greater benefits from these interventions than others. Future research could aim to identify these patient characteristics to tailor treatment approaches and optimize treatment outcomes accordingly.

To improve access to these interventions, a consideration could involve integrating MBTs in primary care. Clinical trials assessing the impact of online courses could yield valuable insights into the feasibility and effectiveness of delivering MBTs in primary care settings, thereby expanding accessibility for patients.

Furthermore, the bulk of research has been predominantly focused on IBS, resulting in a limited understanding of the efficacy of MBTs for other functional abdominal pain problems. To bridge this gap, conducting a study that enrolls patients with a variety of functional abdominal pain syndromes could be useful. By employing this strategy and including patients through GP offices, a more diverse spectrum of patients would be represented, distinct from those typically encountered in secondary or tertiary care centers, thus covering a wider range of symptom severity and comorbidities. This approach could offer valuable insights in de generalizability of findings and the potential impact of MBTs on the broader population with functional abdominal pain symptoms.

Clinical implications for health care professionals

MBTs present a safe and patient-centered approach that holds promise for the integration into conventional care for a broad range of patients. Despite their potential, accessibility remains a challenge, particularly with logistical and cost barriers associated with real-time group sessions. For widespread implementation, future efforts should prioritize enhancing accessibility through the development of self-management-based mindfulness programs, including online or app-based formats. General practitioners (GPs) could play an important role in facilitating access to MBTs, by referring patients to existing MBT group sessions. 'Mindfulness-based therapist' is not a protected title, so GPs should try to refer patients to trained mindfulness instructors, preferably clinical psychologists. Regarding online resources, more research is needed to assess the effectiveness.

Education is paramount in the management of functional abdominal diseases, with GPs serving as key educators informing patients about the link between stressors and symptoms. A supportive patient-practitioner relationship significantly improves outcomes, underscoring the importance of addressing psychological factors, instead of mainly focusing on biomedical issues.[6]

Stress management strategies taught through mindfulness practices can empower patients to take control of their symptoms, potentially reducing the frequency of consultations and the need for other therapies over time.[5] While MBTs may not be suitable for all patients, they can offer benefits for many, especially when stress plays a significant role in symptomatology.

In clinical practice, MBTs can be viewed as both complementary and alternative treatments, offering a holistic approach that might be more cost-effective than standard therapies. While guidelines often prioritize pharmacotherapy, there is a growing recognition for psychological interventions, such as MBTs. Many guidelines reserve psychological therapies more as a last-resort option, however, future research should also explore the efficacy of MBTs as first-line treatment, given their potential benefits for symptom management and overall well-being.[4]

Integrating MBTs to primary care settings, including through online courses or GP-facilitated interventions, could possibly enhance patient-centered care and improve treatment outcomes. By providing educational resources and fostering strong patient-practitioner relationships, GPs can guide patients towards potentially effective management strategies for FGIDs.[4] This approach enhances patient empowerment and contributes to improved overall well-being.

Conclusion

Overall, mindfulness-based therapy appears to be a promising therapeutic approach for managing symptoms and enhancing QOL in patients with functional abdominal pain conditions, such as IBS or FD. However, the variability in study methodologies and limitations in study quality highlight the need for further investigations with more rigorous designs and larger sample sizes to validate these findings. Future research could also focus on the identification of patient characteristics that may influence treatment outcomes or explore more accessible formats suitable for integration in primary care. By deepening our understanding of mindfulness and stress reduction, healthcare professionals can enhance patient-centered care and potentially alleviate the burden of functional abdominal pain conditions.

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Supplementary Material

Supplementary Table S1: search terms

	Search terms for ‘functional abdominal pain’	**Search terms for ‘mindfulness-based interventions’**
Pubmed	"Irritable Bowel Syndrome"[Mesh] OR "irritable bowel syndrome"[tiab] OR "IBS"[tiab] OR "Functional Dyspepsia"[tiab] OR "abdominal pain syndrome"[tiab] OR "functional abdominal pain"[tiab] OR "chronic abdominal pain"[tiab] OR "functional bowel"[tiab] OR "functional gastrointestinal"[tiab] OR "recurrent abdominal pain"[tiab]	"Mindfulness"[Mesh] OR "mindful*"[tiab] OR "Meditation"[Mesh] OR "Meditation"[tiab] OR "MBT"[tiab] OR "MBCT"[tiab] OR "MBSR"[tiab]
Embase	'irritable colon'/exp OR 'irritable bowel syndrome':ti,ab,kw OR 'IBS':ti,ab,kw OR 'dyspepsia'/exp OR 'functional dyspepsia':ti,ab,kw OR 'abdominal pain syndrome':ti,ab,kw OR 'functional abdominal pain':ti,ab,kw OR 'chronic abdominal pain':ti,ab,kw OR 'functional bowel':ti,ab,kw OR 'functional gastrointestinal':ti,ab,kw OR 'recurrent abdominal pain':ti,ab,kw	'mindfulness'/exp OR 'mindful*':ti,ab,kw OR 'meditation'/exp OR 'meditation':ti,ab,kw OR 'MBT':ti,ab OR 'MBCT':ti,ab OR 'mindfulness-based cognitive therapy'/exp OR 'MBSR':ti,ab OR 'mindfulness-based stress reduction'/exp
CINAHL	(MH "Dyspepsia") OR (MH "irritable bowel syndrome") OR TI ("IBS" OR "irritable bowel syndrome" OR "functional dyspepsia" OR "abdominal pain syndrome" OR "functional abdominal pain" OR "chronic abdominal pain" OR "functional bowel" OR "functional gastrointestinal" OR "recurrent abdominal pain") OR AB ("IBS" OR "irritable bowel syndrome" OR "functional dyspepsia" OR "abdominal pain syndrome" OR "functional abdominal pain" OR "chronic abdominal pain" OR "functional bowel" OR "functional gastrointestinal" OR "recurrent abdominal pain")	(MH "Mindfulness") OR (MH "Meditation") OR TI ("Mindfulness" OR "mindful*" OR "Meditation" OR "MBT" OR "MBCT" OR "MBSR") OR AB ("Mindfulness" OR "mindful*" OR "Meditation" OR "MBT" OR "MBCT" OR "MBSR")