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Peppermint Oil Formulations for Irritable Bowel Syndrome: A Scoping Review of Symptom-Specific Outcomes

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Summary

Background

Irritable bowel syndrome (IBS) is a common disorder affecting 7-11% of the global population. Antispasmodics are usually first line of drugs because of their action on gut motility. However, herbal remedies are often preferred, and peppermint oil (PO) is one such commonly available over-the- counter remedy in many countries.

Purpose

This study aims to map and characterize existing evidence on peppermint oil for IBS, with particular focus on symptom-specific outcomes.

Method

This study is designed as a scoping review according to Arksey & O'Malley, with a literature search conducted in PubMed and Embase.

Result

A total of seven studies were included: four RCTs and three meta-analyses. The RCTs were conducted in different countries (Iran, the United States, and the Netherlands) and used diagnostic criteria from Rome II to Rome IV. The meta-analyses included 9–12 RCTs each (726–1 030 patients). Reduction in abdominal pain was the most consistently reported outcome, while findings for global symptoms varied. Adverse events were mild and transient, with no serious events documented.

Conclusion

Overall, the findings suggest that PO may reduce abdominal pain in IBS while its effects on other symptoms remain less certain. Short-term efficacy appears to be acceptable. Results and conclusions of this scoping review should be interpreted with caution as analysis was based on short-term studies with heterogenous methodologies. Future studies with longer duration of treatment, common diagnostic criteria and direct comparison of different PO formulations are needed.

Keywords

Peppermint oil (PO), Irritable bowel syndrome (IBS), Rome criteria, Formulation.

Introduction

Irritable bowel syndrome (IBS)

Irritable bowel syndrome (IBS) is a common functional gastrointestinal disorder defined according to Rome IV criteria (1). The disorder is divided into four main subgroups according to Bristol scale: IBS-C (constipation), IBS-D (diarrhea), IBS-M (mixed) and IBS-U (unclassified) (1). It is estimated that 7-10 % of world´s population suffers from IBS (2). The disease is most common among women and people of all ages are affected (3). Despite being a benign disorder, IBS symptoms are, for many patients, associated with difficulties in daily life (3). A considerable overlap with other functional gastrointestinal symptoms is also present in many patients as well as non- colonic symptoms such as gynecological and urinary symptoms (4). Moreover, IBS contributes to a substantial economic burden to society, both regarding direct and indirect costs (5).

Pathophysiology

IBS is classified as a disorder of gut-brain interaction (DGBI), but its pathophysiology is not completely understood (6). The term “gut-brain interaction” underlines the existing anatomical and bi-directional communication between the central nervous system and the gut, mediated by the autonomic nervous system. This framework helps explain several recognized mechanisms involved in the pathophysiology of IBS including abnormal motility and altered visceral sensitivity which can be triggered by emotional or environmental stress (7,8). Several factors contribute to this complex pathophysiology, including genetic predisposition, environmental factors (stress) and infectious gastroenteritis (8).

Treatment

The complexity of IBS pathophysiology is one of the reasons why currently available treatments remain focused on managing symptoms rather than on drugs that target pathophysiological mechanisms (4). Current treatments include dietary modification (e.g., low-FODMAP diet), psychological intervention and pharmacologic therapies such as antidiarrheal agents, antispasmodics, laxatives and antidepressants (4,7). However, many of these treatments focus on specific symptoms and may provide limited overall symptom relief. Consequently, there has been increasing interest in complementary and alternative therapies that may provide broader symptom relief with favorable safety profiles (9).

Peppermint Oil

One such therapy is peppermint oil (PO) (Mentha piperita Linnaeus) which has been used to treat stomach upset for centuries (9). PO contains menthol which relaxes intestinal smooth muscle cells by antagonizing calcium channels receptors thus producing antispasmodic effects in the gastrointestinal tract (7,10). Additionally, modulation of visceral sensitivity (via transient receptor potential cation channels), anti-microbial effects and anti-inflammatory activity have also been reported in studies (10). PO is available as an over-the-counter drug in various commercial formulations across different countries. In Sweden, the most common formulation is Colpermin, which contains PO in an enteric-coated capsule designed to release the active ingredient in the proximal small intestine (11).

Overall, there is currently a lack of both knowledge and guidelines regarding whether different PO formulations affect IBS symptoms and regarding safety profiles to different extents. Studies in this area could contribute to the development of more evidence-based recommendations for clinical practice.

Purpose

This scoping review aims to map and summarize the existing evidence on peppermint oil formulations for IBS, with a particular focus on symptom-specific outcomes.

Method

Study Design

This study was designed as a scoping review according to the framework proposed by Arksey & O'Malley (12). A review of the existing literature was conducted to gain an overview of the current state of knowledge within the research field, to identify gaps or deficiencies in the current state of knowledge and to pinpoint areas of investigation that may be relevant for future research. Quality assessment of included studies is not a requirement in a scoping review.

Identification of research question

A PEO model (P=Population, E= Exposure, O=Outcome) was used to structure the research question.

P: Adults diagnosed with irritable bowel syndrome according to any recognized diagnostic criteria.
E: Any peppermint oil formulation administered orally (including enteric-coated preparations, small-intestinal-release, ileocolonic release).
O: Symptom-specific outcomes and reported adverse effects.

Research Question

"What evidence exists regarding the symptom-specific outcomes of PO formulations in adults with IBS?"

Selection (eligibility criteria)

Inclusion criteria:

- Articles written and published in English.
- Adults ≥ 18 years of age.
- Studies published from 2005 and onwards. This cut-off was chosen to prioritize the most recent evidence.
- Randomized controlled trials (RCTs), Systematic reviews, meta-analysis and clinical trials are included.

Exclusion criteria:

- Articles not available in full text.
- Animal trials.
- Other study designs (e.g., case studies, cohort studies, conference abstracts, editorials, commentaries, narrative reviews) and grey literature (e.g., dissertations, unpublished reports).

Data Collection and analysis

To identify relevant articles, a search was conducted in two databases, Pubmed and Embase. The search string was developed through multiple pilot searches, by combing MeSH Terms and synonyms, with the assistance of a professional librarian. The search strings used in each database are presented in Table 1.

Table 1: Search strings used in databases.

Database	Search String
PubMed	("Irritable Bowel Syndrome" OR IBS OR "irritable bowel") AND ("Mentha piperita" OR "Peppermint Oil" OR peppermint) AND ("Treatment Outcome" OR efficacy OR effectiveness OR "drug therapy" OR "therapeutic use")
Embase	('irritable bowel syndrome'/ OR 'irritable bowel syndrome' OR ibs) AND ('peppermint oil'/ OR 'peppermint oil' OR peppermint OR Mentha piperita OR menthol) AND (efficacy OR effective OR benefit OR outcome OR improvement OR treatment OR therapy OR response) AND (abdominal OR pain OR bloating OR discomfort OR stool OR bowel OR diarrhea OR diarrhea OR constipation)

The search results were systematically analyzed based on predefined inclusion and exclusion criteria as described above.

Ethics in included studies

Ethical review has not been conducted. This is not only because study design is a literature review, but because this scoping review is based on data from already published articles. However, it was intended to assess whether the included studies had obtained ethical approval and reported informed consent from participants.

Results

A PRISMA flow chart (see figure 1 below) was used to describe the screening process. The search in PubMed and Embase yielded 654 articles. Duplicates were removed (n = 71). Database filters for English language, adults (≥ 18 years), and publication year (2005–current) were then applied, removing an additional 262 records. This left 321 records for title screening. After title screening, 298 records were excluded because they were not relevant to peppermint oil or IBS, leaving 23 records for abstract review. During abstract screening, 13 records were excluded: eight due to ineligible study design, and five due to other reasons (wrong population, non-English language).

The remaining 10 full-text articles were assessed. Of these, two were excluded because full text was not available, and one was excluded as grey literature (conference abstract without peer review). The final seven articles met all inclusion criteria and were included in the review.

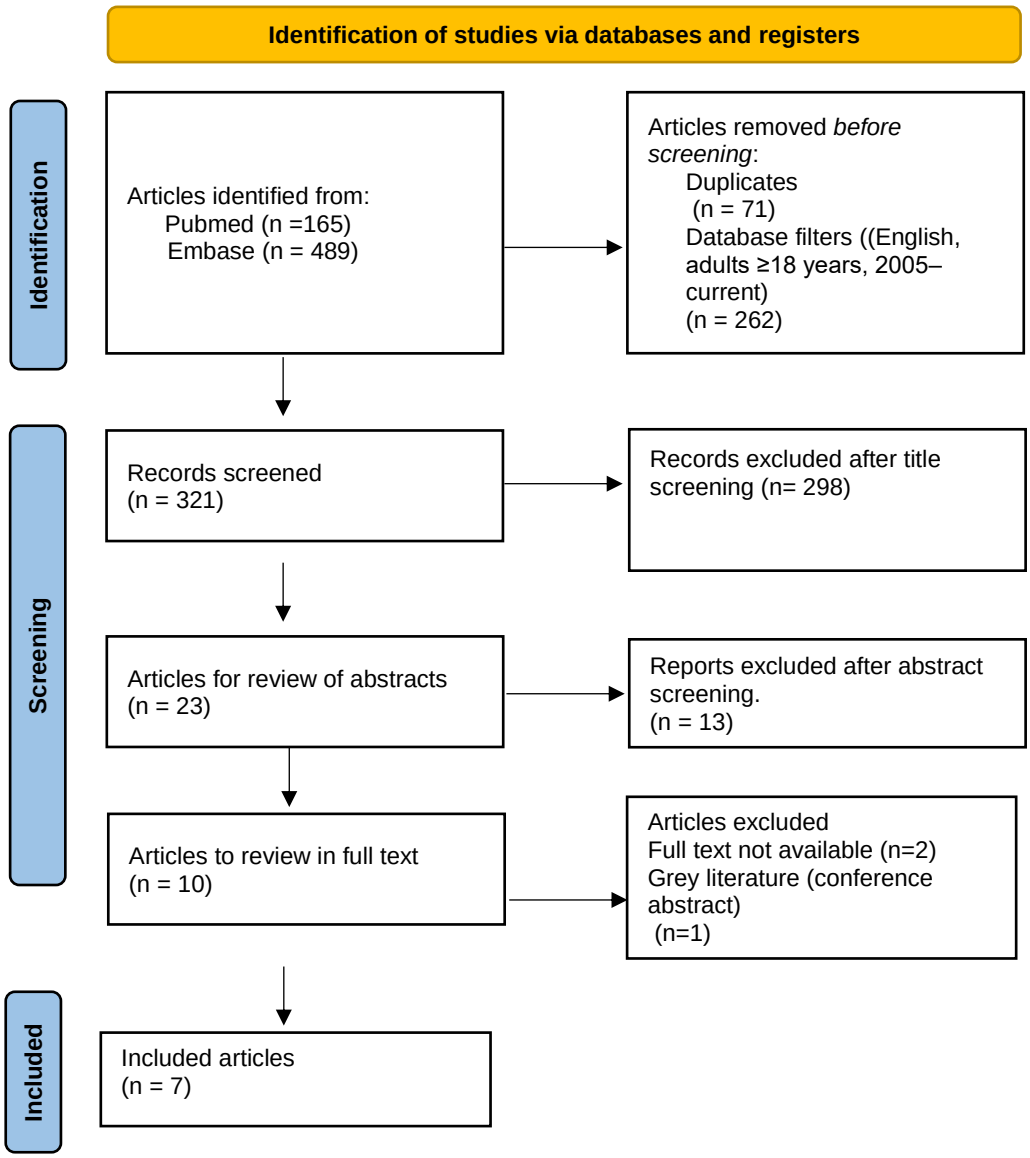

FIGURE 1. Flowchart of the selection process according to PRISMA (13).

Table 2. Characteristics and overall results of included studies

Reference (year); country	Study design	Population	Diagnostic Criteria	Peppermint Oil Formulation	Duration of intervention	Primary Outcomes	Main findings
Merat et al. (2010) Iran (14)	RCT	60 (33 PO, 27 placebo); Female gender 75%	Rome II; adults; no organic disease	Enteric-coated delayed release, PO capsules (Colpermin); 187 mg; three times daily	8 weeks	Absence of abdominal pain /discomfort at week 8	Pain and discomfort free: 42.5% (PO) vs 22.2% (placebo), p<0.001 AEs: 19 (PO) vs 14 (placebo); not significant
Cash et al. (2015); USA (15)	RCT	72 (35 PO, 37 placebo); Female gender 75%	Rome III (IBS-D or IBS-M)	Novel multibead, triple-coated SST formulation of PO; 180 mg; three times daily	4 weeks	Change in TISS from baseline to day 28	TISS reduction: 40% (PO) vs 24.3% (placebo), p=0.0246; Abdominal pain reduction: 41.8% vs 22.1%, p=0.0495 AEs: 1 (PO) vs 2 (placebo); mild; not statistically significant
Weerts et al. (2020) Netherlands (16)	RCT	189 (62 small-intestinal, 63 ileocolonic, 64 placebo); Female gender 78%	Rome IV	Small-intestinal release (SIR); 182mg vs Ileocolonic release (ICR) 182 mg; three times daily	8 weeks	FDA pain responder; EMA global relief responder	Primary outcomes not statistically significant: SIR 46.8% vs placebo 34.4%, p=0.170; ICR 41.3% vs placebo 34.4%, p=0.385. Secondary: pain reduction SIR vs placebo, p=0.016; IBS-SSS reduction SIR vs placebo, p=0.020 Total AEs: SIR 4.26 (p=0.012), ICR 4.54 (p=0.001) vs placebo 2.78; heartburn, belching; all mild
Nee et al. (2021) USA (17)	RCT	133 (46 PO, 87 placebo); Female gender 74%	Rome IV. IBS-SSS ≥175	Enteric coated PO (Peppest); 180 mg; three times daily	6 weeks	Mean improvement in IBS-SSS (baseline to week 6)	IBS-SSS improvement: 90.8 (PO) vs 100.3 (placebo), p=0.97; 50-point reduction: 70.0% vs 70.4%, p=0.99; Global* improvement: 23.3% vs 21.1%, p=0.80 AEs: 47.8% (PO) vs 31.0% (placebo), p=0.062; Reflux/heartburn: 26.1% vs 11.5%, p=0.031; Belching: 10.9% vs 2.3%, p=0.048
Khanna et al. (2014) Canada and USA (18)	Meta-analysis	9 RCTs; 726 patients (exact PO/placebo split not reported); Female % not reported	Variable. Rome I, II, or clinical assessment	Enteric coated PO; variable doses; three times daily	2-12 weeks	Global symptom improvement; abdominal pain improvement.	Global symptoms and pain improvement: Global: RR 2.23 (95% CI 1.78–2.81), NNT=3; Pain: RR 2.14 (95% CI 1.64–2.79), NNT=4 AE: 22% (PO) vs 13% (placebo), RR 1.73 (95% CI 1.27–2.36); heartburn common
Alammar et al. (2018/2019) USA (19)	Meta-analysis	12 RCTs; 835 patients (exact PO/placebo split not reported); Female % not reported	Variable, Rome I-IV	Enteric-coated PO; variable doses; three times daily	2-12 weeks	Global symptoms and abdominal pain improvement	Global symptoms and pain improvement. Global: RR 2.39 (95% CI, p<0.00001); Pain: RR 1.78 (95% CI, p<0.00001) AE: 9.3% (PO) vs 6.1% (placebo), RR 1.40 (95% CI)

Ingrosso et al. (2022) Italy and USA (20)	Meta-analysis	10 RCTs; 1030 patients (525 PO, 505 placebo); Female % not reported	Rome or clinical assessment	Primarily enteric coated, small-intestinal-release PO; 180-182mg; three times daily	4-8 weeks	Persistent symptoms (global or pain; global alone; pain alone)	Pain improved; global uncertain (not significant in low-bias trials): RR 0.65 (95% CI 0.47–0.88), NNT=4; Pain alone: RR 0.76 (95% CI 0.62–0.93), NNT=7; In low-bias trials: pain superior (RR 0.78, 95% CI 0.61–0.99), global not significant (RR 0.77, 95% CI 0.28–2.08) AEs more frequent with PO; AE: RR 1.57 (95% CI 1.04–2.37), NNH=14.5; GERD: RR 1.67 (95% CI 1.18–2.38), NNH=19.5

Abbreviations: PO, Peppermint Oil; IBS, Irritable Bowel Syndrome; TISS, Total IBS Symptom Score; IBS-SSS, Irritable Bowel Syndrome Severity Scoring System; AEs, adverse events; EMA, European Medicines Agency; FDA, Food and Drug Administration; RR, relative risk; CI, confidence interval; NNT, number needed to treat; NNH, number needed to harm; GERD, gastroesophageal reflux disease; RCT, randomized controlled trial; SIR, small-intestinal release; ICR, ileocolonic release.

* "Global symptoms" refers to an overall assessment of IBS symptom severity or improvement (e.g., global improvement scale, adequate relief, or composite scores), rather than a single symptom such as abdominal pain.

Characteristics of included studies and findings

Seven studies were included in this scoping review, including four RCTs and three meta-analyses (14-20). The RCTs were conducted in Iran, the United States, and the Netherlands and enrolled adults aged 18–75 years with irritable bowel syndrome (IBS). These trials were small to medium in size, ranging from the smallest study by Merat et al. (14) with 60 participants to the largest study by Weerts et al. (16) with 189 participants. The proportion of female participants ranged from 63% to 85%. The diagnostic criteria used across the RCTs ranged from Rome II to Rome IV, as shown individually in Table 2 above. The primary outcomes also varied, as did the peppermint oil formulations. Merat et al. (14) and Nee et al. (17) used standard enteric-coated capsules, Cash et al. (15) used a novel sustained-release formulation, and Weerts et al. (16) compared small-intestinal-release (SIR) with ileocolonic-release (ICR) capsules.

The three meta-analyses (18-20) were published between 2014 and 2022 and originated from Canada, the United States, and Italy. Khanna et al. (18) included nine RCTs (total n = 726), Alammar et al. (19) comprised twelve RCTs (total n = 835), and Ingrosso et al. (20) included ten RCTs (total n = 1 030). The individual RCTs included in the meta-analyses originated from diverse geographic regions, including Europe (Italy, Germany, the Netherlands, Denmark), North America (USA), and Asia (Iran, Bangladesh, Taiwan) (18–20). Inclusion of the four RCTs from the present review varied across the meta-analyses: Merat et al. (14) was included in all three, Cash et al. (15) was included in two meta-analyses (19,20), while Weerts et al. (16) and Nee et al. (17) were included only in the most recent meta-analysis (20). Thus, there is an overlap between the included RCTs and the meta-analyses. Across the three meta-analyses (18-20), the constituent RCTs varied in diagnostic criteria (Rome I to Rome IV) and study designs. Peppermint oil formulations were primarily enteric-coated or small-intestinal-release capsules. Primary outcomes were global IBS symptom improvement and abdominal pain reduction, with Ingrosso et al. (20) also assessing persistent symptoms.

All included RCTs reported informed consent, and three specifically mentioned ethical approval. Three of the RCTs (14-16) explicitly stated approval from an ethics committee or institutional review board. One RCT (17) did not report ethical approval in the published article.

Regarding symptom-specific outcomes, abdominal pain was the outcome most consistently reported as improved. Merat et al. (14) and Cash et al. (15) reported positive effects, whereas Nee et al. (17) found no significant improvement, and Weerts et al. (16) did not meet their primary endpoint but showed secondary improvements for the small-intestinal-release formulation. All three meta-analyses (18-20) reported positive pooled effects for abdominal pain. In the largest and most recent meta-analysis Ingrosso et al. (20), this positive effect remained even when the analysis was restricted to studies with low risk of bias.

For global IBS symptoms, Merat et al. (14) and Cash et al. (15) reported positive results, while Weerts et al. (16) and Nee et al. (17) both applying Rome IV criteria - did not demonstrate significant improvements based on their defined primary endpoints. All three meta-analyses (18-20) showed positive pooled estimates for global symptoms. However,

Ingrosso et al. (20) reported that this effect was no longer present when the analysis was restricted to low risk-of-bias trials.

Adverse events (heartburn, belching, reflux) were reported in all studies (14–20). They were more frequent with peppermint oil in three RCTs (14,15,17) and two meta-analyses (18,20), but all were mild and transient, with no serious events.

Discussion

This scoping review aimed to map the evidence on PO formulations for IBS based on seven included studies (four RCTs and three meta-analyses). The findings across the studies are conflicting. Abdominal pain was the outcome most consistently reported as improved across most studies, with the exception of one trial (17). In contrast, findings for global IBS symptoms remain less certain, particularly among studies using stricter diagnostic criteria (Rome IV) and more thorough methodological designs.

The included studies differ in several key aspects. Diagnostic criteria evolved from Rome II to Rome IV over time. Among the included RCTs, the two most recent RCTs (16,17) both using the stricter Rome IV criteria did not demonstrate significant improvements for their primary endpoints, whereas older RCTs (14,15) and the two older meta-analyses (18,19), using earlier diagnostic criteria (Rome I-III), generally reported positive effects. This pattern is also observed in external literature. The older RCT by Cappello et al. (21) and the meta-analysis by Ford et al. (7), both based on earlier diagnostic criteria, reported positive effects consistent with the older studies in this review.

PO formulations differed across the included studies, ranging from standard enteric-coated capsules in some studies (14,17) to more targeted release profiles such as small-intestinal release (SIR) and ileocolonic release (ICR) in one study (16), as well as a novel sustained-release formulation in another (15). The three meta-analyses primarily included studies using enteric-coated or small-intestinal-release formulations (18-20). Despite this variation, no consistent pattern emerged linking a specific formulation to better efficacy. Notably, the two trials that used targeted-release formulations (15,16) produced divergent results: one reported significant benefit, while the other did not for its primary outcomes. This suggests that site-specific formulation alone does not necessarily guarantee improved outcomes. Furthermore, the most recent meta-analysis (20), which included all four formulation types, still reported a positive pooled effect for abdominal pain, indicating that formulation differences may not be the primary explanation for the heterogeneous findings across studies.

The included studies used a range of different endpoints, including simple measures (such as absence of abdominal pain), composite scores (such as TISS and IBS-SSS), and stricter FDA/EMA responder definitions (14-17). The three meta-analyses (18-20) primarily assessed global symptom improvement and abdominal pain improvement, with one also evaluating persistent symptoms (20). This variation makes direct comparison of effect sizes across studies difficult. Nevertheless, the findings indicate that studies applying stricter outcome measures (such as FDA/EMA responder definitions) generally reported less positive findings than those using simpler endpoints (16,17,20).

Treatment duration ranged from 4 to 8 weeks across the RCTs (14–17), meaning that the evidence only covers short-term use. No conclusions about long-term efficacy can be drawn from the current literature. Sample sizes also varied. Some RCTs had fewer than 80 participants each (14,15), while other two RCTs included in this scoping review were larger and had higher methodological quality (16,17). The three meta-analyses included substantially larger sample sizes, ranging from 726 to 1 030 participants (18–20). Notably, the smaller studies reported positive effects (14,15), while the larger studies did not show significant improvements for their primary endpoints (16,17,20).

The overall certainty of the evidence for peppermint oil in IBS is low. A recent umbrella review of 58 meta-analyses concluded that while peppermint oil may improve IBS symptoms, the evidence certainty was low to very low and effect sizes were small (2). This aligns with the findings of the most recent and largest meta-analysis included in this review Ingrosso et al. (20), which reported that while peppermint oil had a positive effect on abdominal pain, the effect on global IBS symptoms disappeared when the analysis was restricted to low risk-of-bias trials (20).

Strengths and Weaknesses

A strength of this scoping review is the inclusion of both RCTs and meta-analyses, which provides a broad overview of the evidence. Detailed description of study characteristics helps readers understand methodological heterogeneity in the field. The geographic diversity of the included studies (USA, Canada, the Netherlands, Iran) supports generalisability across different healthcare settings.

Several limitations must be acknowledged. The search was limited to two databases (PubMed and Embase), and a single person performed screening and data extraction, which introduces potential bias. The search string was limited in scope; however, a broader search string would not necessarily have led to stronger conclusions – it could equally have introduced more heterogeneous studies and made the synthesis more complex. Another limitation is that three of the four RCTs are also included in one or more of the

meta-analyses. This overlap means that the same primary data are represented multiple times, but the purpose of including both was to describe different levels of evidence synthesis, not to count participants twice. The overlap does not directly affect the conclusions, as the review is descriptive without statistical pooling.

The included studies themselves have important limitations. Treatment durations were short (4–8 weeks), meaning that long-term efficacy and safety cannot be assessed. Moreover, safety aspects were outside the scope of this scoping literature review. The predominance of female participants (63–85 %) limits the generalisability of the findings to men with IBS. Different primary outcomes were used across trials (absence of pain, TISS, IBS-SSS, FDA/EMA responder definitions), which makes direct comparison of effect sizes difficult.

Suggestions for future research

Future research regarding PO usage in IBS should focus on certain areas. IBS subtype-specific trials with patients including equal number of participants of IBS-C, IBS-D and IBS-M would facilitate understanding of symptom-specific effects.
RCTs with longer duration of treatment (3 to 6 months) are crucial to investigate long-term safety and efficacy of treatment. Comparative studies that directly compare different peppermint oil formulation including colpermin, ileocolonic release PO and placebo will help to evaluate relative effectiveness and tolerability of each formulation in management of IBS. Considering these suggestions for future research can enhance our knowledge and understanding of the effects and safety profile of peppermint oil in the management of IBS. This may consequently help physicians to improve patient care in IBS management.

Conclusion

The seven studies included in this scoping review show great variation in reported effects of PO on IBS symptoms. Overall, the findings suggest that PO may reduce abdominal pain in IBS, while its effects on other symptoms remain less certain. Across the included studies, PO was generally reported as well tolerated with mild adverse effects, and no serious events were documented. The results and conclusions of this scoping review should be interpreted with caution, as the analysis is based on short-term studies (4–8 weeks) with heterogeneous methodologies. Future studies in this area are crucial and should not only focus on IBS subtypes but also on quality of PO, including its formulation, dosage and duration of treatment. This would further help to improve clinical guidelines and, in the long term, help to improve the quality of life of individuals with irritable bowel syndrome.

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