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Randomised controlled trials of non-pharmacological interventions to improve patient-reported outcomes of colonoscopy: a scoping review

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ABSTRACT

Background and aims Non-pharmacological interventions to improve patient-reported outcomes of colonoscopy may be effective at mitigating negative experiences and perceptions of the procedure, but research to characterise the extent and features of studies of these interventions is limited.

Methods We conducted a scoping review searching multiple databases for peer-reviewed publications of randomised controlled trials conducted in adults investigating a non-pharmacological intervention to improve patient-reported outcomes of colonoscopy. Study characteristics were tabulated and summarised narratively and graphically.

Results We screened 5939 citations and 962 full texts, and included 245 publications from 39 countries published between 1992 and 2022. Of these, 80.8% were full publications and 19.2% were abstracts. Of the 41.9% of studies reporting funding sources, 11.4% were unfunded. The most common interventions were carbon dioxide and/or water insufflation methods (33.9%), complementary and alternative medicines (eg, acupuncture) (20.0%), and colonoscope technology (eg, magnetic scope guide) (21.6%). Pain was as an outcome across 82.0% of studies. Studies most often used a patient-reported outcome examining patient experience during the procedure (60.0%), but 42.9% of studies included an outcome without specifying the time that the patient experienced the outcome. Most intraprocedural patient-reported outcomes were measured retrospectively rather than contemporaneously, although studies varied in terms of when outcomes were assessed.

Conclusion Research on non-pharmacological interventions to improve patient-reported outcomes of colonoscopy is unevenly distributed across types of intervention and features high variation in study design and reporting, in particular around outcomes. Future research efforts into non-pharmacological interventions to improve patient-reported outcomes of colonoscopy should be directed at underinvestigated interventions and developing consensus-based guidelines for study design, with particular attention to how and when outcomes are experienced and measured.

PROSPERO registration number 42020173906.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Non-pharmacological interventions to improve patient-reported outcomes of colonoscopy may be safe, affordable, and effective adjuncts and/or substitutes for pharmacological interventions. However, there is limited research into the range of available interventions and the evidence available to support them.

WHAT THIS STUDY ADDS

⇒ While some non-pharmacological interventions such as CO_2 and water insufflation methods have been extensively studied, others such as patient education have received relatively little attention. A standardised approach to defining, measuring and prioritising patient-reported outcomes was lacking, which poses a barrier to evidence synthesis.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Underinvestigated interventions should be seen as potentially high-value targets for future primary research and evidence synthesis. Consensus-based best practices for outcome selection, measurement and reporting should be established to facilitate efficient, high-quality evidence syntheses.

INTRODUCTION

With over half of US adults having undergone colonoscopy, access to the procedure rising globally, and screening attendance being only 42% in a recent trial of colonoscopy screening, it is of broad societal importance to mitigate the pain, discomfort, fear, anxiety and embarrassment associated with colonoscopy.[1–10] Supported by best practice guidelines, sedative and analgesic drug regimens are often used to improve these patient-reported outcomes (as a component of the overall patient experience of the procedure), with significant international variation in use

patterns.[11 12] However, pharmacological interventions are themselves a source of fear for some patients, and endoscopists require sufficient training, team coordination and monitoring equipment to administer medications safely.[11 13] Conversely, non-pharmacological interventions may be used as adjuncts or—where cultural context or resource constraints dictate—alternatives to improve patient-reported outcomes. These interventions, defined as those interventions excluding sedation and analgesic medications, may be affordable, widely accessible and pose few risks adverse effects than pharmacological interventions.[14] Examples include acupuncture, less bulky colonoscopes and audiovisual distraction methods.

Research systematically examining the extent and characteristics of studies of non-pharmacological interventions to improve patient-reported outcomes of colonoscopy is limited. The only prior review in this area is no longer contemporary, having been published in 2008, and many additional studies have been published since.[15] As a result, it is unclear for clinicians and researchers what non-pharmacological interventions are available, how research efforts have been distributed across different interventions and how existing studies have operationalised patient-reported outcomes. Addressing these areas of uncertainty is important to aid rational planning of future research efforts and ultimately build a more complete suite of interventions to improve the quality of colonoscopy. To achieve this aim, an updated review of the existing literature is required.

METHODS

We designed and reported this scoping review in accordance with the Arksey and O'Malley framework and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews (online supplemental file 1).[16 17] The protocol was published[18] and pre-registered as a systematic review (PROSPERO CRD42020173906). Substantial heterogeneity in the interventions and study outcomes reported among a large number of studies precluded a quantitative meta-analysis and would make qualitative synthesis following systematic review methodology suboptimal for comparing features across the included studies that are unique to the study question (eg, detailed assessments of outcome types). Consequently, prior to extracting and synthesising the study results, we revised our approach to a scoping review.[19]

Eligibility criteria

Peer-reviewed abstracts and full publications of randomised controlled trials (RCTs) written in English were eligible for inclusion. We included studies randomising adults >18 years of age (or where >80% of patients were judged to be ≥18 years of age) to a non-pharmacological intervention for improving patient-reported outcomes of colonoscopy delivered within 1 week of colonoscopy, compared with placebo or usual care. We included studies reporting at least one patient-reported outcome (eg, pain, anxiety and comfort). Although there exist comprehensive patient experience measurement tools for endoscopy (eg, ENDOPREM and Comprehensive Endoscopy Satisfaction Tool), these are relatively recent developments and they also assess items as diverse as the ease of appointment booking and the availability of on-site parking.[20 21] We thus included studies that reported any patient-reported outcome and did not require studies to have reported on the whole of the patient experience.

Exclusion criteria

We excluded studies of non-elective, non-outpatient colonoscopies. We excluded studies of interventions that aimed solely to improve patient-reported outcomes of bowel preparation rather than colonoscopy.

Two independent reviewers (CS-C-L and MC or AB) conducted a title screen, followed by an abstract screen, and finally a full-text screen in duplicate using piloted forms on the DistillerSR platform (Evidence Partners, Ottawa, Ontario, Canada). Disagreements were resolved through discussion and consensus, involving a third reviewer if necessary.

Information sources and search strategy

We designed the search strategy in collaboration with an expert information specialist (TK) using the Peer Review of Electronic Search Strategies checklist.[22] The search terms included variations on 'colonoscopy', 'comfort', 'discomfort', 'pain', 'anxiety', 'satisfaction' and 'perception' (online supplemental file 2). Terms for patient-reported outcomes were derived from a preliminary review of the literature in this domain, including recently published studies in high-impact gastroenterology journals. MEDLINE, Embase, CINAHL, PsycINFO, Scopus and the Cochrane Central Register of Controlled Trials were searched for publications from inception to April 12 2022. In addition to these databases, reference lists of included articles, reference lists of relevant systematic reviews, clinicaltrials.gov, a PubMed-related article search and OpenGrey were searched (online supplemental file 2).

Data charting

Two reviewers independently charted data into a piloted data charting form developed in Microsoft Excel. Any disagreements were resolved through discussion, involving a third reviewer if necessary.

Study-level charting elements included year of publication, publication type (abstract or full publication), study country of origin, number of patients randomised, number of endoscopists, sedation type (routine sedation with propofol, routine sedation with non-propofol agent, unsedated/on-demand sedation or other), non-pharmacological intervention type, funding source (foundation/government, hospital/university, any industry, mixed without industry, not funded or not identified[23])

and whether patient characteristics were reported by treatment arm (age, sex and colonoscopy indication). Where multiple countries contributed to the study or the location of the study was not specified, we used the first author's primary affiliation.

We charted the following outcome characteristics: outcome type, outcome scale, time when the patient experienced the outcome relative to the procedure (eg, during procedure and immediately after procedure), time when the outcome was measured (retroscopective, contemporaneous or not stated), and outcome assessor. All data were charted as reported by the included studies (eg, if a study reported an outcome as discomfort, this was charted as discomfort and not aggregated with other study outcomes reported as comfort) with the aim of capturing subtle but important differences between similarly named constructs (eg, comfort vs discomfort, Visual Analogue Scale (VAS) vs Numerical Rating Scale).[24 25]

Data handling

To summarise publication year, we plotted the raw count of publications published per year against calendar year. We also plotted the time when the outcome was measured (contemporaneously, retrospectively, not stated) against the when the outcome was experienced (eg, immediately after the procedure, at discharge). The remaining data elements were categorical data summarised both qualitatively and quantitatively as counts and proportions and presented in tables. For our analysis of outcome characteristics (eg, type, scale, assessor and timing), counts represent the number of studies having at least one outcome with that characteristic.

RESULTS

We screened 5939 citations and 962 full-text publications for potential inclusion, ultimately including 245 RCTs published between 1992 and 2022 (figure 1). Of these 245 RCTs, 198 (80.8%) were full publications and 47 (19.2%) were abstracts.

Study-level characteristics

The volume of studies published increased and subsequently decreased over the past 20 years (online supplemental file 3). The greatest number of studies originated in the USA (13.8%, 34 of 245), China (11.8%, 29 of 245), Japan (10.2%, 25 of 245) and Taiwan (9.8%, 24 of 245) (online supplemental file 4).

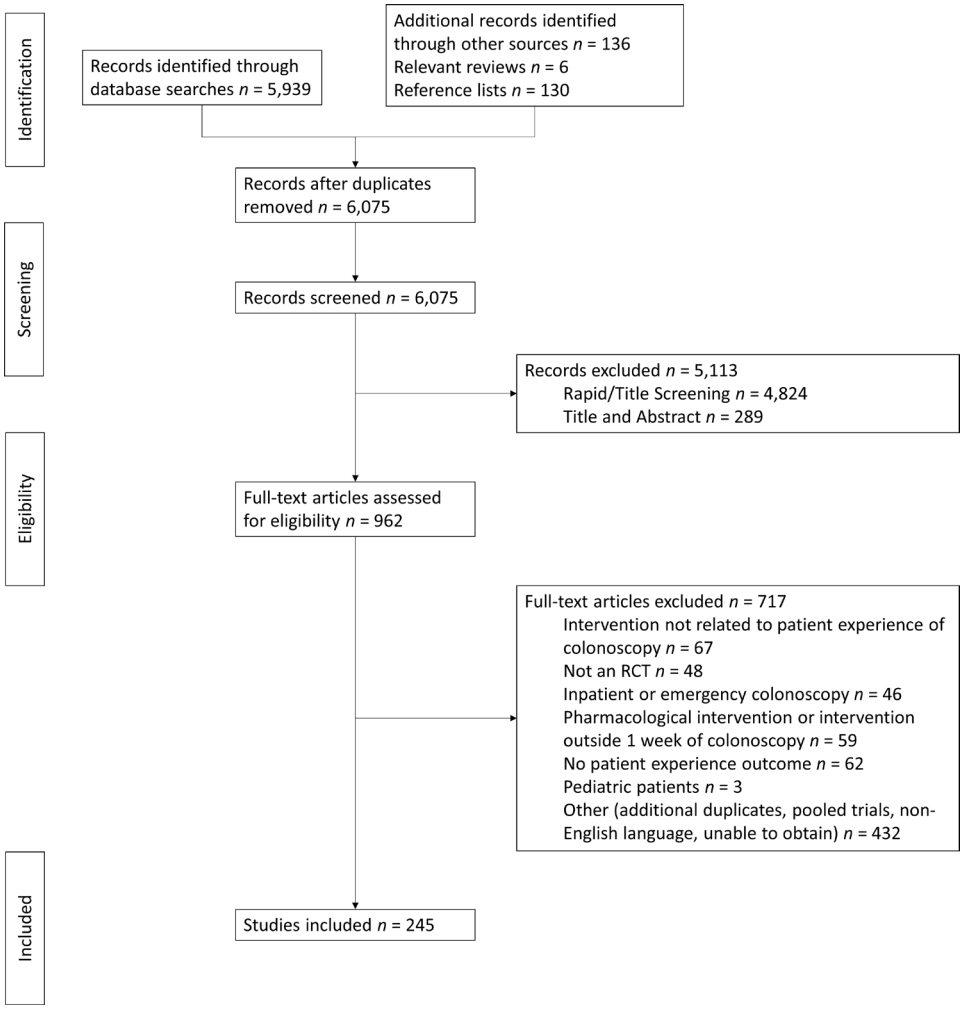

Figure 1 Study flow diagram. RCT, randomised controlled trial.

Most studies were conducted in the hospital setting (52.7%, 129 of 245) (table 1). The median number of randomised patients per study was 181 (IQR 105–280). The median number of endoscopists was 3 (IQR 2–5). In a plurality of studies, colonoscopy was carried out under sedation for all patients (44.9%, 108 of 245), either with propofol (12.2%, 30 of 245) or a non-propofol agent (eg, midazolam) (32.7%, 80 of 245). Studies conducting colonoscopy without sedation (21.2%, 52 of 245) or only with on-demand sedation (18.0%, 44 of 245) comprised 39.2% (96 of 245) of the sample. While most studies reported the age (84.1%, 206 and 245) and sex (82.4%, 202 and 245) composition of their study arms, a majority did not report indications for colonoscopy (55.1%, 135 and 245).

Study funding was commonly not identified (57.1%, 140 of 245). Of those reporting funding sources, 26.7% (28 of 105) reported being unfunded. Among studies reporting a funding source, funders were evenly distributed across categories of industry, government, foundation, hospital, university and mixed sources (table 1).

We identified several categories of interventions under study. These included carbon dioxide (CO_2) (13.9%, 34 and 245) and water insufflation methods (16.7%, 41 and 245), colonoscope technology (21.6%, 53 of 245; eg, responsive insertion technology[26]), complementary and alternative medicines (20.0%, 49 of 245; eg, acupuncture[27]), patient and endoscopist positioning (5.3%, 13 of 245; eg, right-sided patient position[28]), patient education (2.4%, 6 of 245), postprocedure care (2.9%, 7 of 245; eg, rectal decompression[29]) and others (13.9%, 34 of 245). Complementary and alternative medicines included acupuncture (6 studies), aromatherapy (5 studies), audiovisual distraction (27 studies), relaxation techniques (7 studies) and transcutaneous electrical nerve stimulation (4 studies).

Outcome types, scales and assessors are described in table 2. Some variation of a pain measure was used as an outcome across 82.0% (201 of 245) of studies. While 174 of these studies used a pain outcome (eg, 'subject pain score'[30]), 20 used maximum pain over a period (eg, 'maximum insertion pain score'[31]) and 7 took the difference between patient pain at a given point and patient pain at a baseline (eg, 'pain difference'[32]). Other outcomes reported using difference from baseline included anxiety (one study), distension (three studies) and nausea (one study), while the maximum approach was also used for discomfort (three studies). Other outcome types included satisfaction (28.2%, 69 of 245), willingness to repeat the procedure (24.5%, 60 of 245), comfort or discomfort (23.7%, 58 of 245), and distension (14.7%, 36 of 245). Patient-reported outcomes were most often operationalised using VAS (46.9%, 115 of 245) and binary scale (34.3%, 84 of 245); however, some studies reported an outcome without stating how the outcome was measured (18.8%, 46 of 245). In 84.5% (207 of 245) of the studies, patient-reported outcomes were used. Fifty-six studies (22.9%) used an outcome where the assessor was not disclosed.

Table 1 Study-level characteristics

Characteristic	n	%
Total number of included studies	245	100.0
N randomised, median (IQR)		
N endoscopists, median (IQR)		
Publication type		
Abstract	47	19.2
Full publication	198	80.8
Sedation type		
Routine sedation, non-propofol agent	80	32.7
Routine sedation, propofol	30	12.2
On-demand sedation	44	18.0
Unsedated	52	21.2
Other	39	15.9
Intervention		
CO_2 and/or water methods*	83	33.9
CO_2 methods	34	13.9
Water methods	41	16.7
CO_2 and water methods	8	3.3
Complementary and complementary medicine	49	20.0
Acupuncture	6	2.4
Aromatherapy	5	2.0
Audiovisual distraction	27	11.0
Relaxation	7	2.9
Transcutaneous electrical nerve stimulation	4	1.6
Colonoscope technology	53	21.6
Colonoscopy dimensions	17	6.9
Cap	12	4.9
Magnetic endoscopy	13	5.3
Responsive insertion technology	2	0.8
Variable stiffness	9	3.7
Patient and endoscopist positioning	13	5.3
Endoscopist positioning	1	0.4
Patient positioning	12	4.9
Patient education	6	2.4
Postprocedure care	7	2.9
Other	34	13.9
Procedure setting		
Clinic	7	2.9
Hospital	129	52.7
Unclear	109	44.5
Funding source		
Foundation/government	25	10.2
Hospital/university	16	6.5
Mixed without industry	12	4.9

Continued

Table 1 Continued

Characteristic	n	%
Any industry	24	9.8
Not funded	28	11.4
Not identified	140	57.1
Measured patient characteristics		
Age	206	84.1
Sex	202	82.4
Indications	135	55.1

*Water methods include exchange, immersion and undifferentiated methods using water.

Times when patients experienced outcomes and when they were measured are described in figure 2 and table 3. In most studies, intraprocedural patient experience was the outcome of interest (60.0%, 147 of 245), followed by overall patient experience (39.6%, 97 of 245) and patient experience from 0 min to 30 min after the procedure (10.2%, 25 of 245). However, 42.9% (105 of 245) of studies included an outcome without specifying the time that the patient experienced the outcome.

Of the 147 studies reporting on intraprocedural patient experience, most (68.0%, 100 of 147) assessed this outcome retrospectively or without reporting when they were measured. Thirty-six studies (32.0%) indicated a contemporaneous time of measurement. Outcomes experienced preprocedure or post procedure were more often measured contemporaneously than retrospectively (figure 2).

DISCUSSION

In this scoping review of RCTs of non-pharmacological interventions to improve patient-reported outcomes of colonoscopy, we identified 245 publications investigating diverse interventions. We identified that CO_2 and water insufflation methods have been extensively investigated, with 33.9% (83 of 245) of all studies investigating one or both of these interventions. Interventions using colonoscope technologies were also heavily represented. Though interventions such as positioning, patient education, and complementary and alternative medicines have the potential advantages of being low-cost, relatively simple interventions, these have received comparatively less attention and are potentially worthwhile targets for further investigation.

We found that studies used a wide range of patient-reported outcome constructs and outcome measures. These included pain, anxiety, comfort, discomfort, distension, satisfaction, nausea and willingness to repeat the procedure. There were many variations on these, including the use of difference from baseline and maximum values. While it has previously been recommended to use per cent change from baseline VAS where applicable,[33] more recent analyses indicate that this

Table 2 Outcome types, scales and assessors

Outcome characteristic	n	%
Outcome type		
Acceptability	2	0.8
Anxiety	49	20.0
Anxiety	20	8.2
Anxiety difference	1	0.4
STAI	19	7.8
STAI difference	9	3.7
Comfort/discomfort	58	23.7
Comfort	20	8.2
Gloucester Comfort Score	4	1.6
Discomfort	31	12.7
Maximum discomfort	3	1.2
Distension	36	14.7
Distension	33	13.5
Distension difference	3	1.2
Experience	4	1.6
Satisfaction	69	28.2
Satisfaction	66	26.9
GHAA9 satisfaction	3	1.2
NAPCOMS	5	2.0
Nausea	7	2.9
Nausea	6	2.4
Nausea difference	1	0.4
Pain	201	82.0
Pain	174	71.0
Pain difference	7	2.9
Maximum pain	20	8.2
Tolerance	6	2.4
Willingness to repeat	60	24.5
Other	35	14.3
Outcome scale		
Binary	84	34.3
Faces	3	1.2
Likert	16	6.5
Numerical Rating Scale	21	8.6
Visual Analogue Scale	115	46.9
Verbal scale	4	1.6
Not stated	46	18.8
Other	85	34.7
Assessor description		
Patient	207	84.5
Nurse	14	5.7
Endoscopist	6	2.4
Research staff	1	0.4
Not stated	56	22.9

Percentages for outcome-related characteristics may sum to greater than 100 because some studies report multiple outcomes.
STAI, State-Trait Anxiety Inventory (state component); GHAA9, Group Health Association of America-9; NAPCOMS, Nurse-Assessed Patient Comfort Score.

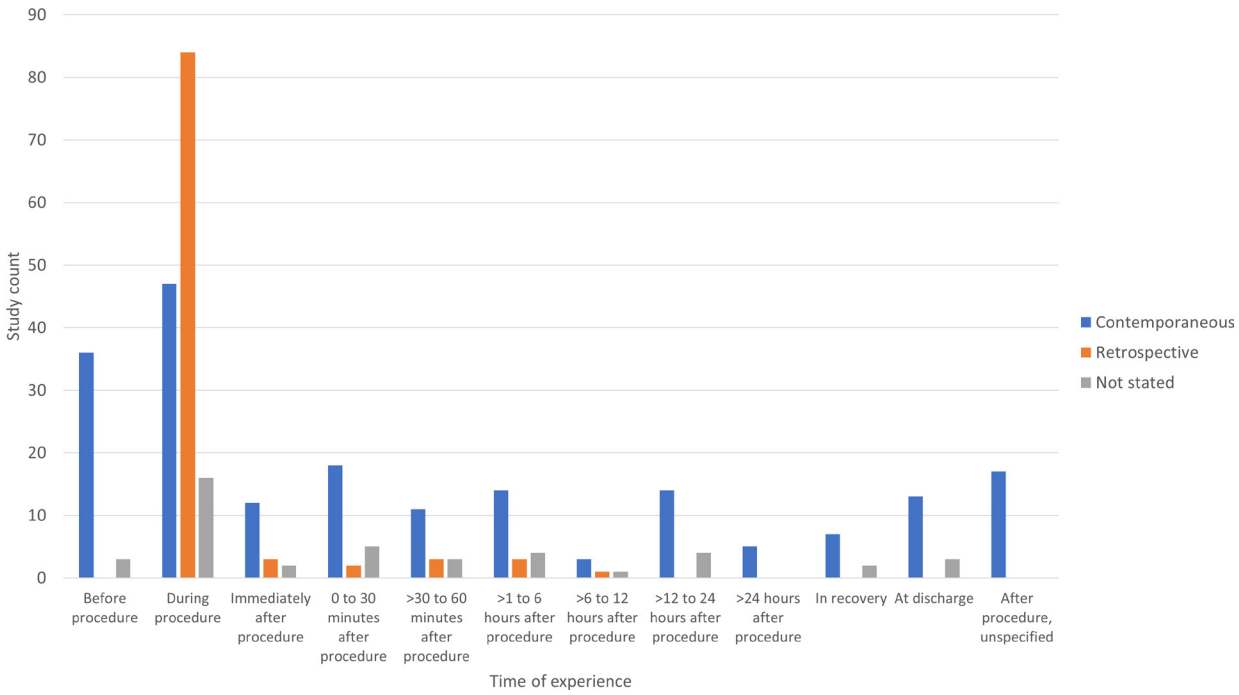

Figure 2 Outcome time of measurement by time of experience.

approach is inefficient and potentially biased.[34 35] The diversity in outcome constructs and measures is important because outcome measures must measure similar constructs and be similarly valid, responsive and reliable to yield meaningful pooled results from quantitative syntheses, or to be easily compared qualitatively.[36] Yet, pain, pain difference and maximum pain, which were all reported among the included studies, are not interchangeable.[33] Moreover, superficially similar outcome measures (eg, VAS and Numeric Rating Scale) may have divergent validity, responsiveness and reliability across different settings.[25 37] In the absence of a consistent approach to patient-reported outcomes and measures, researchers undertaking evidence synthesis are forced to compromise by either pooling dissimilar measures or discarding valuable information.

Adding further complexity is the variation we found in the times when patients experienced outcomes and when they were measured. Although almost two-thirds of studies reported on patient experiences during the procedure, in 47% of studies, the authors did not specify when at least one of the outcomes was measured. Furthermore, we saw inconsistencies in when outcomes were measured (ie, contemporaneously or retrospectively, or not reported at all). Variation and ambiguity in when patients experience an outcome is of consequence because the patient experience is not expected to hold constant from the start of the procedure to several days later. Variation in and reporting of when outcomes are measured matters because patient-reported outcomes measured contemporaneously capture a distinct construct from those same outcomes measured retrospectively. The former can be thought of as reflecting the 'experiencing self' and the latter as reflecting the 'remembering self'.[38 39] While the remembering self may be more important for planning whether to return for colonoscopy, the degree of discomfort faced by the experiencing self is important to minimise in its own right. An additional complication is that studies took varying approaches to sedation, which may interact with recall and patient-reported outcomes more generally; patients undergoing deep sedation with propofol would be less likely to benefit from interventions administered during the procedure. Given these complexities, it would be prudent for future studies to report and justify their choice of timing for outcome experience and measurement.

Additionally, we found that the included studies failed to identify funding sources at a rate exceeding that of a random sample of trials from the 119 Core Clinical Journals (59.4% vs 14%).[40] Whereas 4% of a general population of studies reported being unfunded, 10.7% of studies included here reported being unfunded. This relative underfunding of studies of non-pharmacological interventions is potentially reflective of broader trends in research funding favouring resource-intensive interventions.[41]

Our results update and extend the 2008 review of methods to reduce discomfort during unsedated colonoscopy.[15] Methods found in the present review but not in the prior review included water methods, acupuncture, aromatherapy, relaxation techniques, transcutaneous electrical nerve stimulation, colonoscope caps, responsive insertion technology, variable stiffness colonoscopes, patient education, postprocedure care and patient/endoscopist positioning. Likely explanations for the differences in our findings are that we included procedures conducted under a range of sedation regimes rather than solely unsedated procedures, searched

Table 3 Times when outcomes were measured according to the times when patients experienced the outcomes

Time patient experienced outcome	Time outcome was measured	n	%
Overall		97	39.6
	Immediately after procedure	9	9.3
	0–1 hour after procedure	4	4.1
	>1–24 hours after procedure	15	15.5
	>24 hours after procedure	4	4.1
	In recovery/at discharge	23	23.7
	After procedure NOS	16	16.5
	Not stated/other	26	26.8
Not stated		105	42.9
	Before procedure	1	1.0
	Immediately after procedure	6	6.2
	0–1 hour after procedure	8	8.2
	>1–24 hours after procedure	6	6.2
	>24 hours after procedure	1	1.0
	In recovery/at discharge	23	23.7
	After procedure NOS	18	18.6
	Not stated	42	43.3

Counts indicate the number of studies with at least one outcome with that time of experience–time of measurement combination. Percentages sum to more than 100 because of studies reporting multiple outcomes.
NOS, not otherwise specified.

multiple electronic databases and searched an additional 15 years of studies published between 2007 and 2022. Our reviews also differed in that the present work emphasised study design regardless of efficacy, while the previous review attempted to identify efficacious interventions.

The findings of this review have implications for future research. Standards should be developed for preferred outcome types and approaches to measurement when investigating interventions to improve patient-reported outcomes of colonoscopy.[42] To aid in this process, generic guidelines have been established to support researchers in selecting outcome measures for 'Core Outcome Sets' in their research domain.[43] Researchers have successfully used these guidelines to develop outcome measure hierarchies outside of colonoscopy, such as for trials of interventions for knee osteoarthritis.[44] Colonoscopy researchers might similarly use these guidelines to develop a set of best practices for measuring patient-reported outcomes of colonoscopy. Such an activity has the potential to reduce heterogeneity in the literature and enable higher-quality evidence syntheses. The design and implementation of guidelines for study design should be complemented with efforts to improve adherence to established reporting guidelines such as the Consolidated Standards of Reporting Trials elaboration for the extension for patient-reported outcomes, which recommends investigators specify and justify the time frames of primary and secondary interest.[45 46] We note the recent development of validated, patient-derived measures of the patient experience of colonoscopy, such as ENDOPREM and the Comprehensive Endoscopy Satisfaction Tool (CEST).[20 21] That these are patient-derived is crucial given that endoscopists and patients differ in how they prioritise different elements of the experience of colonoscopy.[47] These are closely related to the project of harmonising patient-reported outcomes for trials, but their existence does not obviate the need for greater scrutiny of the ways that the some of the constituent patient-reported outcomes can be measured, nor the need to achieve consensus around the optimal measure for use in trials. For example, in the publication describing the CEST, patients are asked to retrospectively evaluate their experience during the procedure in a questionnaire completed between 1 week and 3 weeks after their appointment.[21] The ENDOPREM, on the other hand, was administered before patients left the endoscopy department.[20]

Strengths of our study included the scoping approach chosen to describe the extent and nature of a highly heterogeneous body of literature. Our search strategy was designed in collaboration with an expert information specialist and peer reviewed, and our eligibility criteria were broad. In keeping with our inclusive approach, we charted data from a large number of publications. Included studies were conducted in 39 countries using an array of sedation practices, reflecting global variation in sedation practices and giving our findings international relevance.[12]

This review also has limitations. First, consistent with scoping review methodology, we did not formally evaluate the quality of the literature or the effectiveness of the identified interventions, as this would have required narrowing the scope of the work. While systematic reviews are ideal for research questions focused on identifying unbiased treatment effects from all relevant literature to directly inform practice and policy, scoping reviews are indicated where the research question involves finding knowledge gaps and surveying how research is conducted more broadly.[19] With little empirical evidence of the quantity and characteristics of research that has evaluated non-pharmacological interventions to improve patient-reported outcomes of colonoscopy, it was our priority to generate an understanding of what and how this research has been conducted rather than to make recommendations for practice. Given the suitability of the scoping approach to the questions at hand, we conducted a scoping review to better understand the extent and attributes of the existing literature. Second, we charted the data as reported by the studies. Study participants may have been asked to report maximum pain, but the study may have reported the outcome simply as pain. Without

explicit description of how questions were asked, it is difficult to rule out this possibility. This reinforces the importance of transparent and precise reporting of outcome measurement methods. Third, we limited our search to studies published in English. Metaepidemiological evidence suggests that, at least for systematic reviews, language restrictions do not change the conclusions of reviews.[48] Fourth, we did not make an explicit attempt to identify studies using comprehensive, patient-derived experience measures. As a result, the outcomes we identified may better represent outcomes of greatest concern to endoscopists rather than outcomes of greatest concern to patients, which previous research has demonstrated differ in some respects.[47] Nonetheless, given the novelty of these patient-derived measures (a 2019 British Society of Gastroenterology position statement noted that, at the time, 'there are no patient-derived validated tools to assess patient experience'[49]), our review likely remains an accurate representation of research conducted in this domain to date. Finally, we did not differentiate between outcome measures that were described as validated or unvalidated. Some studies claiming to have used validated scales included citations that did not lead to any validation study, and other studies aggregated 'validated' subscores into a summary score which was not itself validated, making the distinction of questionable utility in practice.[49]

CONCLUSION

In this scoping review of non-pharmacological interventions to improve patient-reported outcomes of colonoscopy, we found existing research efforts to be unevenly distributed across types of non-pharmacological intervention. Variation in study design and suboptimal reporting around patient-reported outcomes pose barriers to evidence synthesis. Future efforts to investigate non-pharmacological interventions to improve patient-reported outcomes of colonoscopy should focus on understudied interventions of potential value. To reduce research waste and facilitate evidence synthesis of research in this domain, researchers should prioritise the development and implementation of consensus guidelines to harmonise study design, particularly with respect to outcome measures.

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Supplemental Table 1. PRISMA-ScR reporting checklist.

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	7
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7-8
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	8
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplement
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	7-8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	8-9
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8-9
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	Click here to enter text.
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	9
RESULTS			

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9, Figure 1
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	9, Table 1
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	Click here to enter text.
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	9-11, Table 2-3, Figure 2
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	9-11, Table 2-3, Figure 2
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	11-15
Limitations	20	Discuss the limitations of the scoping review process.	15-16
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	16
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	3, Table 1

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Supplement: Search strategies

MEDLINE Search strategy

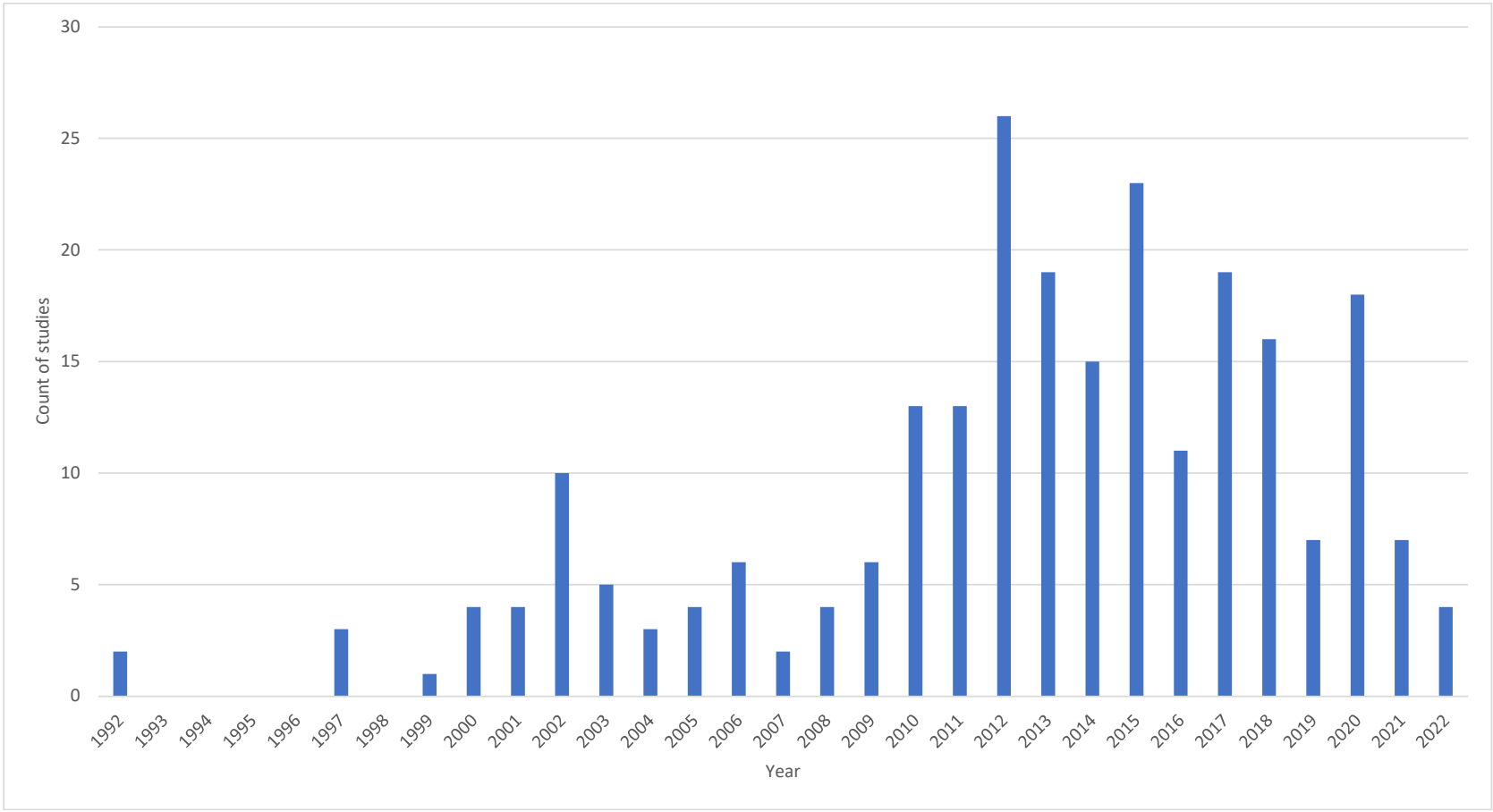
Medline

1 exp Colonoscopy/ 33241
2 exp Colonoscopes/ 1370
3 colonoscop*.tw,kf. 34274
4 coloscop*.tw,kf. 521
5 sigmoidoscop*.tw,kf. 4869
6 proctosigmoidoscop*.tw,kf. 307
7 ileocolonoscop*.tw,kf. 684
8 (endoscop* adj5 (colon* or bowel* or intestine* or anus or anal or rectum or rectal* or colorect*)).tw,kf. 12443
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 57616
10 exp Patient Satisfaction/ 97127
11 personal satisfaction/ 22247
12 Patient Comfort/ 569
13 Pain Management/ 39044
14 Pain Measurement/ 92842
15 Pain/ 142340
16 Pain, Procedural/ 703
17 Anxiety/ 97049
18 (satisf* or preference* or comfort*).ti,kf. 85366
19 (patient* adj2 (satisf* or preference* or comfort*)).ab. 79907
20 (dissatisf* or unsatisf* or discomfort* or uncomfortab*).ti,kf. 6950
21 (patient* adj2 (dissatisf* or unsatisf* or discomfort* or uncomfortab*)).ab. 8968
22 pain.tw,kf. 710068
23 (anxiet* or anxious* or nervous*).tw,kf. 581795
24 willing*.tw,kf. 50682
25 (patient* adj2 experience*).tw,kf. 113814
26 (patient adj2 perception*).tw,kf. 6255
27 (patient adj2 (reported or perspective* or complaint* or feedback or evaluation*)).tw,kf. 73709
28 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 1699627
29 9 and 28 7136
30 ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or randomised.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (exp animals/ not humans.sh.) 4643657 [Modified Cochrane search filter for RCTs, https://libraryguides.mcgill.ca/epib629/rct-filters]
31 29 and 30 2266

OpenGrey Search strategy

(colonoscop* OR sigmoidoscop* OR proctosigmoidoscop* OR ileocolonoscop* or endoscop*) and (satisf* OR comfort* OR pain* OR anxiety OR anxious* OR nervous* OR willing* OR preference OR satisf* OR comfort* OR discomfort* OR uncomfort* OR experience* OR perception* OR complaint* OR feedback OR evaluation*) and ("randomized controlled trial" OR "controlled clinical trial" OR random* OR placebo OR randomly OR trial* OR groups)

Supplement 3. Count of studies by calendar year.



Supplement 4. Geographic distribution of study country of origin.

Country	n
Australia	2
Austria	1
Brazil	1
Canada	11
China	29
Czech Republic	5
Denmark	1
Ecuador	1
Germany	4
Hong Kong	7
India	5
Indonesia	3
Iran	4
Ireland	2
Israel	2
Italy	13
Japan	25
Korea	6
Malaysia	1
Mexico	1
Netherlands	1
New Zealand	1
Norway	10
not stated	1
Philippines	1
Poland	3
Portugal	2
South Korea	9
Spain	7
Sri Lanka	1
Sweden	3
Switzerland	3
Taiwan	24
Thailand	1
The Netherlands	2
Turkey	10
UK	8
United States	34