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Effectiveness Of Abdominal Massage For Chronic Constipation In The Elderly: A Protocol For A Systematic Review and Meta-analysis

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Effectiveness Of Abdominal Massage For Chronic Constipation In The Elderly: A Protocol For A Systematic Review and Meta-analysis

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ABSTRACT

Introduction Chronic constipation is a health management challenge with high prevalence, difficult treatment, and risk of cardiac and cerebral events in elderly patients. Available laxative medications and lifestyle treatments are ineffective and dependent. Abdominal massage is an economical and effective therapeutic measure to improve chronic constipation in the elderly. The aim of this systematic review and meta-analysis is to evaluate the efficacy and safety of abdominal massage in elderly patients with chronic constipation. An in-depth subgroup analysis will be conducted to explore the factors influencing the efficacy of abdominal massage such as treatment

modality, duration, and frequency to provide credible evidence for future mechanistic studies.

Methods and analysis Electronic searches of clinical randomized controlled trials in Web of Science, PubMed, CINAHL, Cochrane Library, Embase, Airiti Library databases, Chinese National Knowledge Infrastructure Databases (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database (CBM), and Wan Fang Database will be conducted. Relevant data were extracted, and a meta-analysis was performed using Reviewer Manager 5.4. Quality and risk assessments of the included studies were performed, and the outcome indicators of the trials were observed.

Results This meta-analysis will objectively and comprehensively examine the efficacy and safety of abdominal massage in elderly patients with chronic constipation.

Conclusions This review will evaluate abdominal massage as a treatment for relieving symptoms and improving quality of life in the elderly with chronic constipation, and will provide additional insight for clinical treatment and mechanistic studies.

Ethics and dissemination As there will be no collection or generation of raw data, a statement of ethical approval is not required. We will publish the results of our study in peer-reviewed journals.

PROSPERO registration number CRD42023408629

Keywords: Abdominal Massage; Chronic constipation; Elderly patients; Systematic review

Word Count 2865

Strengths and limitations of this study

1. This is the first planned meta-analysis to assess the reliability of the evidence for abdominal massage in the treatment of chronic constipation in the elderly.
2. This study will include elderly patients aged >60 years who meet the diagnostic criteria.
3. Only English and Chinese trials were included, which may lead to an increased risk of bias.
4. There may be a heterogeneity in the different methods of abdominal massage.Introduction

Chronic constipation (CC) is a disease characterized by difficult and hard stools, decreased frequency of bowel movements, and a feeling of incomplete defecation. The main diagnostic criteria are the Rome IV criteria and the patient's self-reported symptoms[1, 2]. The prevalence of chronic constipation was 16% for men and 26% for women aged 65 years and older, and among those aged 84 years and older, the prevalence could be as high as 26% and 34% for men and women, respectively[3]. Aecreased contractile motility of the detrusor and smooth muscle of the colonic, and atrophy of the gastrointestinal mucosa with reduced fluid secretion are the mechanisms that make constipation more common in the elderly[4]. Aging-related changes in dietary and physical activity lifestyle, arthralgia, osteoporosis, and laxative dependence, long-term use of anticholinergic agents, opioid analgesics[5],calcium supplements, and NSAIDs (non-steroidal anti-inflammatory drugs) are all risk factors for chronic constipation in the elderly[6].

Constipation not only seriously affects the quality of life of the elderly, but can also cause many diseases and consume a large amount of health care resources. Fecal retention leads to gut microbiota disorders and the production of harmful flora metabolites inducing cardiovascular, neurocognitive and other diseases[7, 8]. Difficulty in defecation in elderly patients induces cardiovascular and cerebrovascular accidents and increases the risk of sudden death[9]. Meanwhile, CC also serves as a prelude to serious diseases such as colon cancer[10]. The main treatment for CC is the use of laxatives and lifestyle modification[11]. Drug therapy is prone to dependence causing

exacerbation of symptoms or complications. Existing treatments have not completely resolved the suffering of CC patients, thus finding economical and effective treatment methods is urgently needed.

Abdominal massage serves as the most convenient and economical alternative therapy for clinical application[12]. It has potential mechanisms to improve blood circulation in the gastrointestinal tract and stimulate gastrointestinal motility. Several meta-analyses have explored the effectiveness of abdominal massage in digestive function and bowel disorders[13-15]. However, there is still a lack of specific studies on elderly patients with constipation. With the increased prevalence of chronic constipation in the elderly and its specific pathological mechanisms, there is a necessity to explore it in an age-restricted manner.2 Methods and analysis

OBJECTIVES

To evaluate the efficacy and safety of abdominal massage in the treatment of chronic constipation in the elderly.

METHODS

Study registration

This systematic review protocol was registered with PROSPERO 2023(registration number: CRD42023408629). And the protocol report is in the base of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) declaration guidelines[16]. The review will be performed in line with the PRISMA-P declaration guidelines.

Inclusion criteria for study selection

Type of study

All randomized controlled trials (RCTs) that fulfilled the inclusion criteria will be included in this systematic evaluation and meta-analysis to evaluate the safety and

efficacy of abdominal massage therapy for the treatment of chronic constipation in the elderly.

Type of participant

Participants aged 60 years or older diagnosed with chronic constipation will be included regardless of gender, race, education or economic status. The diagnostic criteria for chronic constipation are:

1. Clinical diagnostic criteria (e.g., Rome IV criteria);
2. Diagnostic criteria defined by the authors or defined by the clinician;
3. Participants' self-reported constipation.

The exclusion criteria contain the following items:1) Cognitive disorder;2) Belonged to specific clinical population groups (e.g., pregnant women, ICU patients, post operation patients).

Type of intervention and comparisons.

Abdominal massage, including any type of pressure on the abdominal region, such as Swedish abdominal massage, acupressure, and aromatic abdominal massage. There was no limit to the time or frequency of massage. Comparisons group can include no intervention, placebo intervention, positive control medicine.

Type of outcome measure

The primary outcomes examined were the frequent cy of bowel movements, stool texture and constipation symptoms. Any constipation symptom questionnaire, such as the Demographic Characteristics Questionnaire, the Rome criteria, and the Constipation Assessment Scale, measured constipation symptoms. Secondary outcomes included the influence of constipation on quality of life, laxative use, and adverse events in older patients.

Search methods for identification of studies

Electronic data sources

The following electronic databases will be searched from their respective inception dates to April 21, 2023: Web of Science, PubMed, CINAHL, Cochrane Library, Embase, Airiti Library databases, Chinese National Knowledge Infrastructure Databases (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database (CBM), and Wan Fang Database. Excluding no language or publication restrictions, randomized clinical trials investigating the effectiveness of abdominal massage on chronic constipation in older adults that met eligibility criteria were investigated.

Searching other resources

The reference lists of potentially missing eligible studies will be scanned ant the relevant conference proceedings will be scanned as well.

Search strategy

The search strategy for PubMed is shown in Table1. The following search keywords will be used: Massage (e.g.,"Tuina" or "Chinese massage" or "Chuna" or "Shiatsu" or "Thai massage" or "Rubbing Abdomen" or " Massage" or "Zone Therapy" or "Therapies, Zone" or "Zone Therapies" or "Therapy, Zone" or "Massage Therapy" or "Massage Therapies" or "Therapies, Massage" or "Therapy, Massage" or "osteopathy" or "Fascial Manipulation); "Constipation" (e.g., "Dyschezia" or "Colonic Inertia" or "Functional Constipation" or "Primary Constipation" or "Chronic Constipation" or "Idiopathic Constipation" or "Slow Transit Constipation" or "Constipated" or "Defecation Disorder" or "Evacuation Disorder*" or "Gastrointestinal Transit" or "Gut Transit" or "Slow Transit" or "Hard Stool*") ; Randomized Controlled trial (e.g., "Controlled clinical trial" or "Random allocation" or "Randomized" or "Randomly" or

Commented [1]: 具体例子

"Double-blind Method" or "Single-blind Method" or "Clinical Trial"). The equivalent search keywords will be used in the Chinese databases.

Search number	Search Details
#1	"Constipation"[MeSH Terms]
#2	"Dyschezia"[Title/Abstract] OR "Colonic inertia"[Title/Abstract] OR "Functional constipation"[Title/Abstract] OR "Primary constipation"[Title/Abstract] OR "Chronic constipation"[Title/Abstract] OR "Idiopathic constipation"[Title/Abstract] OR "Slow transit constipation"[Title/Abstract] OR "Constipated"[Title/Abstract] OR "Defecation disorder"[Title/Abstract] OR "Evacuation Disorder*"[Title/Abstract] OR "Gastrointestinal Transit"[Title/Abstract] OR "Gut Transit"[Title/Abstract] OR "Slow Transit"[Title/Abstract] OR "Hard Stool*"[Title/Abstract] OR "Lumpy Stool*"[Title/Abstract]
#3	#1 OR #2
#4	"Massage"[MeSH Terms]
#5	"Tuina"[Title/Abstract] OR "Chinese massage"[Title/Abstract] OR "Chuna"[Title/Abstract] OR "Shiatsu"[Title/Abstract] OR "Thai massage"[Title/Abstract] OR "Rubbing Abdomen"[Title/Abstract] OR "Massage"[Title/Abstract] OR "Zone Therapy"[Title/Abstract] OR "Therapies, Zone"[Title/Abstract] OR "Zone Therapies"[Title/Abstract] OR "Therapy, Zone"[Title/Abstract] OR "Massage Therapy"[Title/Abstract] OR "Massage Therapies"[Title/Abstract] OR "Therapies, Massage"[Title/Abstract] OR "Therapy, Massage"[Title/Abstract] OR "osteopathy"[Title/Abstract] OR "Fascial Manipulation);
#6	#4 OR #5

#7	"Randomized Controlled Trial" [Publication Type]
#8	"Randomized Controlled Trial"[Title/Abstract] OR "Controlled Clinical Trial"[Title/Abstract] OR "Random Allocation"[Title/Abstract] OR "Randomized"[Title/Abstract] OR "Randomly"[Title/Abstract] OR "Double Blind Method"[Title/Abstract] OR "Single Blind Method"[Title/Abstract] OR "Clinical Trial"[Title/Abstract]
#9	#7 OR #8
#10	#3 AND #6 AND #9

Table 1 Search strategy for the PubMed database.

Data collection and analysis

Selection of studies

The titles and abstracts of all searched studies will be reviewed and screened independently by 2 reviewers (YQ and XYW), aiming at identifying eligible trials and eliminating duplicated or irrelevant studies in line with the criteria. The selected research was imported into the document management software EndNote X9. First, an initial screening based on titles and abstracts will be performed and suitable studies will be selected based on inclusion criteria. Secondly, the full text of all potentially eligible studies will be obtained for re-screening. If there are discrepancies in inclusion and exclusion, discussions with the corresponding authors are planned to resolve the differences. The process will use the PRISMA-P flowchart to show the study selection process in **Figure 1.**.

Figure 1. Flow diagram of study selection process.

Data extraction and management

The following data will be extracted from the selected studies by 2 independent reviewers using a standard data extraction sheet: year of publication, country, general information, participant characteristics, inclusion and exclusion criteria, sample size, randomization, blinding methods, methods, control, outcome measures, results, adverse reactions, conflicts of interest, ethical approval, and other information. The extracted data were entered into the electronic database, and if a difference occurred, it was verified by corresponding authors (HZW and Jl).

Management of missing data

The cause of the missing data will be determined to solve the problem. And if this is not working, the authors will be contacted for the missing part. This will be documented and the available data will be extracted and analyzed if the missing data cannot be obtained.

Risk of bias assessment

The Cochrane Collaboration tool[17] was used to assess the risk of bias in each study, including the following 6 types of bias: random sequence generation, allocation concealment, participant and personal blinding, outcome assessment blinding, incomplete outcome data, selective reporting, and other sources of bias. The quality of the report was divided into 3 levels: low, unclear, and high-risk. Differences were resolved through group discussion.

Statistical analysis

This study will be analyzed using RevMan version 5.3. Relative risk (RR) was used when the results were dichotomous variables with 95% confidence intervals. For continuous variables, we used the standardized mean difference and 95% confidence intervals. The chi-square test and I^2 statistic will be used to confirm heterogeneity. The former checks for heterogeneity, whereas the latter reflects the degree of heterogeneity through a specific value. If I^2 was >50%, there was considerable

heterogeneity between the studies; therefore, a subgroup analysis was performed to investigate the potential causes.

Subgroup analysis

If significant heterogeneity exists, subgroup analyses will be conducted to explore its source. Subgroup analyses were conducted according to the characteristics of the included studies, with respect to the time of publication, the geographical scope of the study, the gender of the participants, and the control interventions. In terms of interventions, the effects of massage modality, duration, and frequency on efficacy will be explored in depth.

Sensitivity analysis

Sensitivity analysis will be conducted to test the robustness of the review conclusions if possible. The impacts of sample size, study design, methodological quality, and missing data will be evaluated.

Grading the quality of evidence

The Grading of Recommendations Assessment approach will be used to judge the quality of the evidence for all outcomes. Risk of bias, heterogeneity, indirectness, imprecision and publication bias will be assessed. The assessments will be classified into 4 levels: high, moderate, low, or very low.

Ethics and dissemination

This protocol will not evaluate individual patient information or affect patient rights and therefore does not require ethical approval. Results from this review will be disseminated through peer-reviewed journals and conference reports.

DISCUSSION

This is the first protocol of systematic review and meta-analysis to evaluate the effectiveness and safety of abdominal massage therapy for chronic constipation in elderly patients. Our group will objectively and comprehensively evaluate the therapeutic effects of abdominal massage for constipation in elderly patients. The results of this review will provide physical therapists, gastroenterologists and patients with more information on complementary and alternative treatment options for chronic constipation in the elderly. The credibility of the existing clinical evidence provides new directions for future research.

Ethics and dissemination As there will be no collection or generation of raw data, a statement of ethical approval is not required. We will publish the results of our study in peer-reviewed journals.

Acknowledgements Qiang Yuan, Xiaoyan Wang, Zhou Li contributed equally to this work and share first authorship.

Author Contributions YQ conceived this study and wrote the manuscript. WXY and LZ developed the search strategy. WZH and LJ provided methodological advice. LC, LQW and WHZ revised the manuscript. All authors have reviewed this protocol and approved the final manuscript.

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Competing interests None declared.

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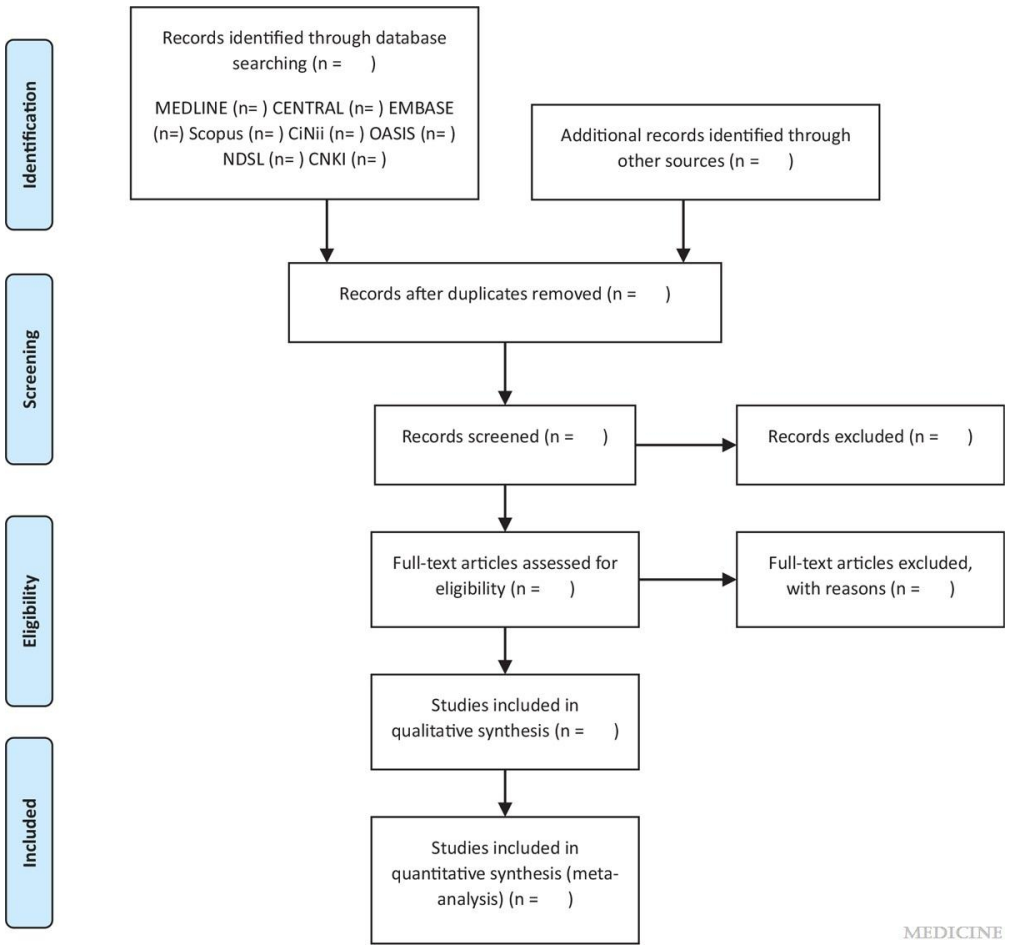

Figure 1. Flow diagram of study selection process.

423x397mm (72 x 72 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NM
Support:			
Sources	5a	Indicate sources of financial or other support for the review	11
Sponsor	5b	Provide name for the review funder and/or sponsor	Not applicable
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Not applicable
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Abdominal Massage for Chronic Constipation in the Elderly: A Systematic Review and Meta-analysis Protocol

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ABSTRACT

Introduction: Chronic constipation is a highly prevalent health challenge, particularly challenging to treat in elderly patients. Although lifestyle guidance and laxative therapy often yield positive outcomes, patients occasionally struggle in maintaining dietary control. Therefore, it is necessary to propose an economical and harmless alternative therapy to the existing treatment methods documented in the international literature. This systematic review and meta-analysis aims to evaluate the efficacy and safety of abdominal massage in elderly CC (Chronic Constipation) patients with chronic constipation. The objective is to investigate an economical and harmless treatment method to provide a basis for future mechanistic research.

Methods and analysis: Electronic searches were conducted to identify clinical randomized controlled trials in various databases, including Web of Science, PubMed, CINAHL, Cochrane Library, Embase, Airiti Library, Chinese National Knowledge Infrastructure Databases (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database (CBM), and Wan Fang databases. Relevant data will be extracted, and a meta-analysis will be conducted using Reviewer Manager 5.4. Quality and risk assessments of the studies included were performed, and the outcome indicators of the trials were observed. This review will evaluate abdominal massage as a treatment option for relieving symptoms and improving quality of life in elderly patients with chronic constipation. Moreover, it will provide additional insights for clinical treatment and mechanistic studies. The search will be performed following the publication of this protocol (estimated to occur on January 1, 2023) and will be repeated one month before the submission for publication of the final review (estimated to be March 1, 2024).

Ethics and dissemination: As this is a literature review, ethics approval is not required. We will disseminate the findings of this study to publications in peer-reviewed journals as well as presentations at relevant national and international conferences.

Abbreviations: CC, chronic constipation; NSAIDs, nonsteroidal anti-inflammatory drugs.

Keywords: Abdominal Massage, Chronic constipation, Elderly patients, Systematic review

STRENGTHS AND LIMITATIONS OF THIS STUDY

- All types of Chronic Constipation clinical studies across all elderly age groups will be included without language limitation.
- Adherence to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) and using Cochrane quality assessment tools ensure a rigorous and standardized methodology.
- The systematic review will rely solely on published data, potentially excluding relevant but unpublished studies.

INTRODUCTION

Chronic constipation (CC) is characterized by difficult and hard stools, reduced frequency of bowel movements, and a feeling of incomplete defecation. The main diagnostic criteria are the Rome IV criteria and patient's self-reported symptoms.[1, 2] The prevalence of chronic constipation was 16% for men and 26% for women aged ≥65 years.[3] In individuals aged ≥84 years, the prevalence could be as high as 26% and 34% for men and women, respectively.[4] Decreased contractile motility of the detrusor and smooth muscle of the colon and atrophy of the gastrointestinal mucosa with reduced fluid secretion are the mechanisms that make constipation more common in the elderly.[5] Aging-related changes in dietary and physical activity, lifestyle factors, arthralgia, osteoporosis, laxative dependence, and long-term use of anticholinergic agents, opioid analgesics,[6] calcium supplements, and nonsteroidal anti-inflammatory drugs (NSAIDs) are risk factors for chronic constipation in elderly individuals.[7]

Constipation not only significantly affects the quality of life of the elderly but can also cause many diseases and consume a substantial amount of health care resources. Fecal retention can result in disruptions of gut microbiota and the production of harmful flora metabolites that induce cardiovascular, neurocognitive, and other diseases.[8, 9] The difficulty in defecation experienced by elderly patients may lead to cardiovascular and cerebrovascular accidents, thereby increasing the risk of sudden death.[10] Concurrently, CC also serves as a risk factor for severe conditions such as colon cancer.[11, 12] The main treatment for CC is the use of laxatives and lifestyle modifications.[13] However, drug therapy may occasionally lead to dependency, potentially exacerbating symptoms or causing complications.[13] While existing treatment methods have received positive feedback, it is still necessary to seek safe, effective, and economical treatments due to the high costs, side effects, and, in some cases, ineffectiveness associated with current interventions.

As an auxiliary alternative therapy, abdominal massage is considered a convenient and cost-effective option for clinical use.[14] It has the potential to improve blood circulation in the gastrointestinal tract and stimulate gastrointestinal motility. Previous studies explored the effectiveness of abdominal massage on digestive function and

bowel disorders.[15-17] However, specific studies on elderly patients with constipation are lacking. Given the increased prevalence of chronic constipation in older adults and its specific pathological mechanisms, it is necessary to explore this condition in an age-restricted manner.

METHODS AND ANALYSIS

Study registration

This systematic review protocol was registered in PROSPERO 2023 (registration number: CRD42023408629). The protocol report adhered to the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) declaration.[18] The review was performed in accordance with the PRISMA-P declaration guidelines.

Inclusion criteria for study selection

Type of study

All randomized controlled trials that fulfilled the inclusion criteria were included in this systematic evaluation and meta-analysis to assess the safety and efficacy of abdominal massage therapy for the treatment of chronic constipation among the elderly.

Type of participant

Participants aged 65 years or older diagnosed with chronic constipation will be included, regardless of sex, race, education, or economic status. The diagnostic criteria for chronic constipation were as follows:

1) Clinical diagnostic criteria (e.g., Rome IV criteria);[19]

2) Diagnostic criteria defined by the authors or defined by the clinician;

3) Participants' self-reported constipation.

The exclusion criteria were as follows:

1) Severe cognitive impairment that hinders understanding of the trial;
2) Belonging to specific clinical population groups (e.g., pregnant women, ICU patients, post-operation patients).

Type of intervention and comparisons

Abdominal massage includes any type of pressure applied to the abdominal region, such as Swedish abdominal massage, acupressure (abdominal acupoint massage), and aromatic abdominal massage. There were no limits on the time or frequency of the massages. The comparison group consisted of individuals who received either no intervention, a placebo intervention, or other medicinal treatments, such as osmotic or stimulant laxatives, elobixibat, linaclotide, lubiprostone, mizagliflozin, naronapride, plecanatide, prucalopride, tegaserod, tenapanor, or velusetrag.[20]

Type of outcome measure

The primary efficacy outcomes will be the frequency of bowel movements, related scales, and symptoms of constipation. Constipation symptom questionnaires, such as the Demographic Characteristics Questionnaire, Rome criteria,[19] and related Conk Assessment Scales,[21] were used to measure constipation symptoms. Secondary efficacy outcomes will include the influence of constipation on the quality of life and laxative use. The safety outcomes included the monitoring of adverse events.

Search methods for identification of studies

Electronic data sources

The following electronic databases will be searched from their inception dates up to May 30, 2023: Web of Science, PubMed, CINAHL, Cochrane Library, Embase, Airiti Library, Chinese National Knowledge Infrastructure Databases (CNKI), Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database (CBM), and Wan Fang Database. After excluding language or publication restrictions, we will conduct randomized clinical trials to investigate the effectiveness of abdominal massage on chronic constipation in older adults who meet the eligibility criteria.

Searching other resources

The reference lists of potentially missing eligible studies will be reviewed, and relevant conference proceedings will also be examined.

Search strategy

The search strategy is summarized in Appendix 1. The following search keywords will be used: abdominal massage (e.g., “tuina,” “massage,” “Chinese massage,”); constipation (e.g., “Dyschezia” or “Colonic Inertia”); randomized controlled trial (e.g., “randomized controlled trial,” “controlled clinical trial,” “random allocation,” “randomized,” “randomly,” “double-blind method,” “single-blind method,” or “clinical trial”). Equivalent search keywords were used in Chinese databases. Additional studies will be sought in the reference lists of the selected articles, and the authors will be contacted for any unclear information.

Data collection and analysis

Selection of studies

The titles and abstracts of all studies retrieved will undergo independent review and screening by two reviewers (YQ and WXY) in order to identify eligible trials and exclude duplicate or irrelevant studies.The selected research was imported into the document management software EndNote X9. The initial screening, based on titles and abstracts, was performed first, and suitable studies were selected based on the inclusion criteria. Subsequently, full texts of all potentially eligible studies were obtained for rescreening. If there are discrepancies between the inclusion and exclusion criteria, discussions with the corresponding authors will be planned to resolve these differences. A PRISMA-P flowchart (Figure 1) was used to illustrate the study selection process.

Data extraction and management

The following data were extracted from the selected studies by two independent reviewers using a standard data extraction sheet: year of publication, country, general information, participant characteristics, inclusion and exclusion criteria, sample size, randomization, blinding methods, methods, controls, outcome measures, results, adverse reactions, conflicts of interest, ethical approval, and other information. The extracted data were entered into an electronic database, and differences were verified by the corresponding authors (LJ and WHZ).

Management of missing data

The cause of missing data was determined to solve this problem. If investigative approach proves unsuccessful, the authors will be contacted to request the missing data. This process will be documented, and in the absence of the missing data, the available data will be extracted and analyzed.

Risk of bias assessment

The Cochrane Collaboration tool will be used to assess the risk of bias in each study, including six types of bias: random sequence generation, allocation concealment, participant and personal blinding, outcome assessment blinding, incomplete outcome data, selective reporting, and other sources of bias.[22] The quality of the reports was divided into three levels: low-, unclear-, and high-risk. Differences were resolved through group discussion.

Statistical analysis

Data were analyzed using RevMan version 5.3. The relative risk was used when the results were dichotomous variables, with 95% confidence intervals. For continuous variables, the standardized mean difference and 95% confidence interval were used. The chi-square test and I^2 statistic were used to confirm heterogeneity. The former checks for heterogeneity, whereas the latter reflects the degree of heterogeneity using a specific value. If I^2 >50%, it indicated considerable heterogeneity among the studies. Consequently, a subgroup analysis was performed to investigate the potential causes.

Subgroup analysis

If significant heterogeneity was observed, subgroup analyses were conducted to explore the sources of heterogeneity. These subgroup analyses were conducted based on the characteristics of the included studies, including the publication time, geographical scope of the study, participant sex, and control interventions. Regarding interventions, we will explore the impact of massage modality, duration, and frequency on efficacy.

Sensitivity analysis

A sensitivity analysis will be conducted to test the robustness of the conclusions, examining the impact of sample size, study design, methodological quality, and missing data.

Grading the quality of evidence

The Grading of Recommendations Assessment approach was used to judge the quality of evidence for all outcomes. Risks of bias, heterogeneity, indirectness, imprecision, and publication bias were assessed. The assessments were classified into four levels: high, moderate, low, or very low.

Ethics and dissemination

This protocol will not evaluate individual patient information or affect patient rights; hence, it does not require ethical approval. The outcomes of this review will be shared through peer-reviewed journals and conference reports.

Patient and public involvement

Patients were not involved in the design, conduct, reporting, or dissemination of this research.

DISCUSSION

This is the first protocol for a systematic review and meta-analysis intended to evaluate the effectiveness and safety of abdominal massage therapy for chronic constipation in elderly patients. Our group aimed to objectively and comprehensively evaluate the therapeutic effects of abdominal massage on constipation in elderly patients. The results of this review will provide physical therapists, gastroenterologists, and patients with additional information on complementary and alternative treatment options for chronic constipation in the elderly population. Furthermore, the credibility of existing clinical evidence provides new directions for future research.

AUTHORS' CONTRIBUTIONS

YQ, WXYand WHZ conceptualised the study.YQ,WXY and ZL wrote the manuscript with support from WHZ and LJ. LQW and LC created the search terms. All authors were responsible for reading and approving this manuscript's final version.

FUNDING STATEMENT

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COMPETING INTEREST

The authors declare that they have no competing interests.

DATA SHARING STATEMENT

All data relevant to the study are included in the article oruploaded as supplementary information.

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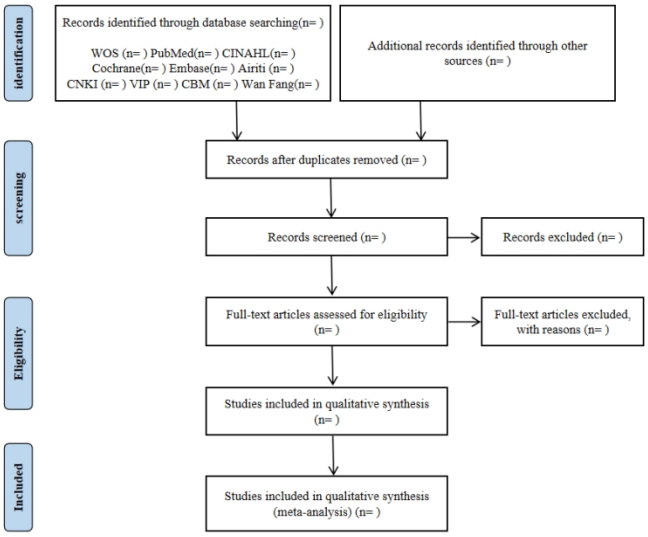
FIGURE LEGEND

Figure 1. Flow diagram of study selection process.

APPENDIX

Appendix 1. Search strategies for databases



Flow diagram of study selection process

190x338mm (120 x 120 DPI)

Appendix 1 Search strategies for databases

Web of Science

#1: TS=("constipation")

#2: TS=("dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation")

#3: TS=("Massage")

#4: TS=("massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings"))

#5: TS=("Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial")

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Pubmed

#1 "constipation"[MeSH Terms]

#2 "dyschezia"[Title/Abstract] OR "colonic inertia"[Title/Abstract] OR "functional constipation"[Title/Abstract] OR "primary constipation"[Title/Abstract] OR "chronic constipation"[Title/Abstract] OR "idiopathic constipation"[Title/Abstract] OR "slow transit constipation"[Title/Abstract] OR "constipated"[Title/Abstract] OR "defecation disorder"[Title/Abstract] OR "evacuation disorder*"[Title/Abstract] OR "gastrointestinal transit"[Title/Abstract] OR "gut transit"[Title/Abstract] OR "slow transit"[Title/Abstract] OR "hard stool*"[Title/Abstract] OR "lumpy stool*"[Title/Abstract] OR "hard feces"[Title/Abstract] OR "straining"[Title/Abstract] OR "incomplete evacuation"[Title/Abstract] OR "infrequent bowel movement"[Title/Abstract] OR "Constipation"[Title/Abstract]

#3 #1 OR #2

#4 "Massage"[MeSH Terms]

#5 "massage"[Title/Abstract] OR "tuina"[Title/Abstract] OR "tui na"[Title/Abstract] OR "chinese massage"[Title/Abstract] OR (("rubbed"[Title/Abstract] OR "rubbing"[Title/Abstract] OR "rubbings"[Title/Abstract])

#6 #4 OR #5

#7 "Randomized Controlled Trial" [Publication Type]

#8 "randomized controlled trial"[Title/Abstract] OR "controlled clinical trial"[Title/Abstract] OR "random allocation"[Title/Abstract] OR "randomized"[Title/Abstract] OR

"randomly"[Title/Abstract] OR "double blind method"[Title/Abstract] OR "single blind method"[Title/Abstract] OR "clinical trial"[Title/Abstract]

#9 #7 OR #8

#10 #3 AND #6 AND #9

CINAHL-Plus with full text（EBSCOhost Research Databases ）

#1: MH "Constipation"

#2: "dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: MH "Massage"

#4: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#5: PT "Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Cochrane library

#1: MeSH descriptor: [Constipation]

#2: "dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: MeSH descriptor: [Massage]

#4: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#5: "Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Embase(Ovid)

#1: "constipation"/exp

#2 :"dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: #1 OR #2

#4: "Massage"/exp

#5: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#6: #4 OR #5

#7: "Randomized Controlled Trial"/exp

#8:"randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#9: #7 OR #8

#10: #3 AND #6 AND #9

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NM
Support:			
Sources	5a	Indicate sources of financial or other support for the review	11
Sponsor	5b	Provide name for the review funder and/or sponsor	Not applicable
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Not applicable
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Abdominal Massage for Chronic Constipation in the Elderly: A Systematic Review and Meta-analysis Protocol

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Date Submitted by the Author:	08-Dec-2023
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Primary Subject Heading:	Complementary medicine
Secondary Subject Heading:	Gastroenterology and hepatology, Complementary medicine
Keywords:	COMPLEMENTARY MEDICINE, GASTROENTEROLOGY, Nursing Care

Abdominal Massage for Chronic Constipation in the Elderly: A Systematic Review and Meta-analysis Protocol

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ABSTRACT

Introduction: Chronic constipation (CC) is a highly prevalent health challenge that is particularly challenging to treat in elderly patients. Although lifestyle guidance and laxative therapy often yield positive outcomes, patients occasionally struggle with maintaining dietary control. Therefore, identifying an economical and safe alternative therapy to the existing treatment methods documented in the international literature is necessary. This systematic review and meta-analysis aims to evaluate the efficacy and safety of abdominal massage in elderly patients with CC to provide a basis for future mechanistic research.

Methods and analysis: Electronic searches will be conducted to identify clinical randomized controlled trials in various databases, including Web of Science, PubMed, Cumulated Index to Nursing and Allied Health Literature, Cochrane Library, Embase, Airiti Library, Chinese National Knowledge Infrastructure Databases, Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database, and Wan Fang Data. Relevant data will be extracted, and a meta-analysis will be conducted using Reviewer Manager 5.4. Quality and risk assessments of the included studies will be performed, and the outcome indicators of the trials will be observed. This review will evaluate abdominal massage as a treatment option for relieving symptoms and improving quality of life in elderly patients with CC. Moreover, it will provide additional insights for clinical treatment and mechanistic studies. The search will be performed following the publication of this protocol (estimated to occur on December 30, 2023).

Ethics and dissemination: As this is a literature review, ethics approval will not be required. We will disseminate the findings of this study to publications in peer-reviewed journals as well as presentations at relevant national and international conferences.

Abbreviations: CC, chronic constipation

Keywords: Abdominal Massage, Chronic Constipation, Elderly Patients, Systematic Review

STRENGTHS AND LIMITATIONS OF THIS STUDY

- All types of clinical studies on chronic constipation across all elderly age groups will be included without language limitations.
- The use of Cochrane quality assessment tools will ensure rigorous and standardized methodology.
- The systematic review will rely solely on published data, potentially excluding relevant although unpublished studies.

INTRODUCTION

Chronic constipation (CC) is characterized by difficult to pass and hard stools, reduced frequency of bowel movements, and a feeling of incomplete defecation. The main diagnostic criteria are the Rome IV criteria and self-reported symptoms.[1, 2] The prevalence of CC is 16% for men and 26% for women aged ≥65 years.[3] In individuals aged ≥84 years, the prevalence is reportedly as high as 26% and 34% for men and women, respectively.[4] Decreased contractile motility of the detrusor and smooth muscle of the colon and atrophy of the gastrointestinal mucosa with reduced fluid secretion are the mechanisms that make constipation more common in the elderly.[5] Aging-related changes in diet and physical activity, lifestyle factors, arthralgia, osteoporosis, laxative dependence, and long-term use of anticholinergic agents, opioid analgesics,[6] calcium supplements, and nonsteroidal anti-inflammatory drugs are risk factors for CC in elderly individuals.[7]

Constipation not only significantly affects the quality of life of the elderly but can also cause many diseases and consume a substantial amount of health care resources. Fecal retention can result in disruptions of gut microbiota and the production of harmful flora metabolites that induce cardiovascular, neurocognitive, and other diseases.[8, 9] The difficulties with defecation experienced by elderly patients may lead to cardiovascular and cerebrovascular accidents, thereby increasing the risk of sudden death.[10] Concurrently, CC also serves as a risk factor for severe conditions such as colon cancer.[11, 12] The main treatments for CC are laxative use and lifestyle modifications.[13] However, drug therapy may occasionally lead to dependency, potentially exacerbating symptoms or causing complications.[13] Although existing treatment methods have received positive feedback, identifying safe, effective, and economical treatments is necessary due to the high costs, side effects, and, in some cases, the ineffectiveness of current interventions.

As an auxiliary alternative therapy, abdominal massage is considered a convenient and cost-effective option in clinical practice.[14] Abdominal massage has the potential to improve blood circulation in the gastrointestinal tract and stimulate gastrointestinal motility. Previous studies explored the effectiveness of abdominal massage on digestive

function and bowel disorders.[15-17] However, specific studies on elderly patients with constipation are lacking. Given the increased prevalence of CC in older adults and its specific pathological mechanisms, exploring this condition in an age-restricted manner is necessary.

METHODS AND ANALYSIS

Study registration

This systematic review protocol is registered with the International Prospective Register of Systematic Reviews (registration number: CRD42023408629). The reporting of this protocol adheres to the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement.[18] The review will be reported in accordance with the PRISMA-P guidelines.

Inclusion criteria for study selection

Type of study

All randomized controlled trials that fulfill the inclusion criteria will be included in this systematic evaluation and meta-analysis to assess the safety and efficacy of abdominal massage therapy (performed by nurses, nurses aids, caregivers, or doctors) for the treatment of CC among the elderly.

Type of participant

Participants aged 65 years or older diagnosed with CC will be included, regardless of sex, race, education, or economic status. The diagnostic criteria for CC are as follows:

1) Clinical diagnostic criteria (e.g., Rome IV criteria);[19]

2) Diagnostic criteria defined by the authors or defined by the clinician;

3) Participants' self-reported constipation.

The exclusion criteria are as follows:

1) Severe cognitive impairment that hinders understanding of the trial;
2) Belonging to specific clinical population groups (e.g., pregnant women, intensive care unit patients, post-operation patients).

Type of intervention and comparisons

Abdominal massage includes any type of pressure applied to the abdominal region, such as Swedish abdominal massage, acupressure (abdominal acupoint massage), and aromatic abdominal massage. No limits will be placed on massage time or frequency. The comparison group consists of individuals who received either no intervention, a placebo intervention, or other medicinal treatments, such as osmotic or stimulant laxatives, elobixibat, linaclotide, lubiprostone, mizagliflozin, naronapride, plecanatide, prucalopride, tegaserod, tenapanor, or velusetrag.[20]

Type of outcome measure

The primary efficacy outcomes will be the frequency of bowel movements, related scales, and symptoms of constipation. Constipation symptom questionnaires, such as the Demographic Characteristics Questionnaire, Rome criteria,[19] and related Conk Assessment Scales,[21] will be used to measure constipation symptoms. Secondary efficacy outcomes will include the influence of constipation on the quality of life and laxative use. The safety outcomes include the monitoring of adverse events.

Search methods for identification of studies

Electronic data sources

The following electronic databases will be searched from their inception dates up to December 30, 2023: Web of Science, PubMed, Cumulated Index to Nursing and Allied Health Literature, Cochrane Library, Embase, Airiti Library, Chinese National Knowledge Infrastructure Databases, Chinese Science and Technology Periodical Database (VIP), Chinese Biomedical Literature Database, and Wan Fang Data. After excluding publication restrictions, we will review randomized clinical trials to investigate the effectiveness of abdominal massage on CC in older adults who meet the eligibility criteria.

Searching other resources

The reference lists of potentially missing eligible studies will be reviewed, and relevant conference proceedings will also be examined.

Search strategy

The search strategy is summarized in Appendix 1. The following search keywords will be used: abdominal massage (e.g., "tuina," "massage," "Chinese massage,"); constipation (e.g., "Dyschezia" or "Colonic Inertia"); and randomized controlled trial (e.g., "randomized controlled trial," "controlled clinical trial," "random allocation," "randomized," "randomly," "double-blind method," "single-blind method," or "clinical trial"). Equivalent search keywords were used in Chinese databases. Additional studies will be identified from the reference lists of the selected articles, and the authors will be contacted for any unclear information.

Data collection and analysis

Selection of studies

The titles and abstracts of all retrieved studies will undergo independent review and screening by two reviewers (YQ and WXY) to identify eligible trials and exclude duplicate or irrelevant studies. The selected studies will be imported using the document management software EndNote X9 (Clarivate, London, UK). The initial screening, based on titles and abstracts, will be performed, and suitable studies will be selected based on the inclusion criteria. Subsequently, full texts of all potentially eligible studies will be obtained for rescreening. In case of discrepancies between the inclusion and exclusion criteria, discussions with the corresponding authors will occur to resolve these differences. A PRISMA-P flowchart (Figure 1) will be used to illustrate the study selection process.

Data extraction and management

The following data will be extracted from the selected studies by two independent reviewers (QY and XW) using a standard data extraction sheet: year of publication, country, general information, participant characteristics, inclusion and exclusion criteria, sample size, randomization, blinding methods, methods, controls, outcome measures, results, adverse reactions, conflicts of interest, ethical approval, and other

information. The extracted data will be entered into an electronic database, and differences will be verified by the corresponding authors (JL and HW).

Management of missing data

The cause of missing data will be determined to solve this problem. If this investigative approach proves unsuccessful, the authors will be contacted to request the missing data. This process will be documented, and in the absence of the missing data, the available data will be extracted and analyzed.

Risk of bias assessment

The Cochrane Collaboration tool will be used to assess the risk of bias in each study, including six types of bias: random sequence generation, allocation concealment, participant and personal blinding, outcome assessment blinding, incomplete outcome data, selective reporting, as well as other sources of bias.[22] The quality of the reports will be divided into three levels: low, unclear, and high risk. Differences will be resolved through group discussion.

Statistical analysis

Data will be analyzed using RevMan version 5.3 (The Cochrane Collaboration, London, England). The relative risk will be used to evaluate dichotomous variables, with 95% confidence intervals. The standardized mean difference and 95% confidence interval will be used to evaluate continuous variables. The chi-square test and I^2 statistic will be used to confirm heterogeneity. The former checks for heterogeneity, whereas the latter reflects the degree of heterogeneity using a specific value. I^2 >50%, will indicate considerable heterogeneity among the studies. Consequently, a subgroup analysis will be performed to investigate the potential causes.

Subgroup analysis

If significant heterogeneity is observed, subgroup analyses will be conducted to explore the sources of heterogeneity. These subgroup analyses will be conducted

based on the characteristics of the included studies, including the publication time, geographical scope of the study, participant sex, and control interventions. Regarding interventions, we will explore the impact of massage modality, duration, and frequency on efficacy.

Sensitivity analysis

A sensitivity analysis will be conducted to test the robustness of the conclusions, examining the impact of sample size, study design, methodological quality, and missing data.

Grading the quality of evidence

The Grading of Recommendations Assessment approach will be used to judge the quality of evidence for all outcomes. Risks of bias, heterogeneity, indirectness, imprecision, and publication bias were assessed. The assessments were classified into four levels: high, moderate, low, or very low.

Ethics and dissemination

Because this study is based exclusively on published literature, ethics approval and informed consent will not be required. The outcomes of this review will be shared through peer-reviewed journals and conference reports.

Patient and public involvement

Patients will not be involved in the design, conduct, reporting, or dissemination of this research.

DISCUSSION

This is the first protocol for a systematic review and meta-analysis intended to evaluate the effectiveness and safety of abdominal massage therapy for CC in elderly patients. We aim to objectively and comprehensively evaluate the therapeutic effects of abdominal massage on constipation in elderly patients. The results of this review will provide physical therapists, gastroenterologists, and patients with additional

information on complementary and alternative treatment options for CC in the elderly population. Furthermore, the credibility of existing clinical evidence provides new directions for future research.

AUTHORS' CONTRIBUTIONS

QY, XW, and HW conceptualized the protocol. QY, XW, and LZ wrote the manuscript with support from HW and JL. QL and CL created the search terms. All authors were responsible for reading and approving the final version of the manuscript.

FUNDING STATEMENT

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COMPETING INTEREST

The authors declare that they have no competing interests.

DATA SHARING STATEMENT

All data relevant to the study are included in the article or as supplementary material.

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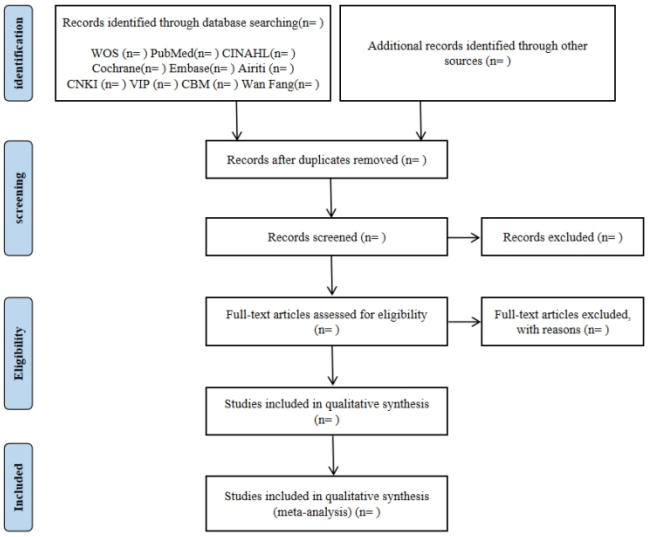
FIGURE LEGEND

Figure 1. Flow diagram of study selection process

SUPPLEMENTARY MATERIAL

Appendix 1. Search strategies



Flow diagram of study selection process

190x338mm (120 x 120 DPI)

Appendix 1 Search strategies for databases

Web of Science

#1: TS=("constipation")

#2: TS=("dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation")

#3: TS=("Massage")

#4: TS=("massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings"))

#5: TS=("Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial")

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Pubmed

#1 "constipation"[MeSH Terms]

#2 "dyschezia"[Title/Abstract] OR "colonic inertia"[Title/Abstract] OR "functional constipation"[Title/Abstract] OR "primary constipation"[Title/Abstract] OR "chronic constipation"[Title/Abstract] OR "idiopathic constipation"[Title/Abstract] OR "slow transit constipation"[Title/Abstract] OR "constipated"[Title/Abstract] OR "defecation disorder"[Title/Abstract] OR "evacuation disorder*"[Title/Abstract] OR "gastrointestinal transit"[Title/Abstract] OR "gut transit"[Title/Abstract] OR "slow transit"[Title/Abstract] OR "hard stool*"[Title/Abstract] OR "lumpy stool*"[Title/Abstract] OR "hard feces"[Title/Abstract] OR "straining"[Title/Abstract] OR "incomplete evacuation"[Title/Abstract] OR "infrequent bowel movement"[Title/Abstract] OR "Constipation"[Title/Abstract]

#3 #1 OR #2

#4 "Massage"[MeSH Terms]

#5 "massage"[Title/Abstract] OR "tuina"[Title/Abstract] OR "tui na"[Title/Abstract] OR "chinese massage"[Title/Abstract] OR (("rubbed"[Title/Abstract] OR "rubbing"[Title/Abstract] OR "rubbings"[Title/Abstract])

#6 #4 OR #5

#7 "Randomized Controlled Trial" [Publication Type]

#8 "randomized controlled trial"[Title/Abstract] OR "controlled clinical trial"[Title/Abstract] OR "random allocation"[Title/Abstract] OR "randomized"[Title/Abstract] OR

"randomly"[Title/Abstract] OR "double blind method"[Title/Abstract] OR "single blind method"[Title/Abstract] OR "clinical trial"[Title/Abstract]

#9 #7 OR #8

#10 #3 AND #6 AND #9

CINAHL-Plus with full text（EBSCOhost Research Databases ）

#1: MH "Constipation"

#2: "dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: MH "Massage"

#4: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#5: PT "Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Cochrane library

#1: MeSH descriptor: [Constipation]

#2: "dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: MeSH descriptor: [Massage]

#4: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#5: "Randomized Controlled Trial" OR "randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#6: #1 OR #2

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

Embase(Ovid)

#1: "constipation"/exp

#2 :"dyschezia" OR "colonic inertia" OR "functional constipation" OR "primary constipation" OR "chronic constipation" OR "idiopathic constipation" OR "slow transit constipation" OR "constipated" OR "defecation disorder*" OR "evacuation disorder*" OR "gastrointestinal transit" OR "gut transit" OR "slow transit" OR "hard stool*" OR "lumpy stool*" OR "hard feces" OR "straining" OR "incomplete evacuation" OR "infrequent bowel movement" OR "Constipation"

#3: #1 OR #2

#4: "Massage"/exp

#5: "massage" OR "tuina" OR "tui na" OR "chinese massage" OR ("rubbed" OR "rubbing" OR "rubbings")

#6: #4 OR #5

#7: "Randomized Controlled Trial"/exp

#8:"randomized controlled trial" OR "controlled clinical trial" OR "random allocation" OR "randomized" OR "randomly" OR "double blind method" OR "single blind method" OR "clinical trial"

#9: #7 OR #8

#10: #3 AND #6 AND #9

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NM
Support:			
Sources	5a	Indicate sources of financial or other support for the review	11
Sponsor	5b	Provide name for the review funder and/or sponsor	Not applicable
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Not applicable
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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