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

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074780
Article Type:	Protocol
Date Submitted by the Author:	17-Apr-2023
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Keywords:	Systematic Review, GASTROENTEROLOGY, GERIATRIC MEDICINE, Rehabilitation medicine < INTERNAL MEDICINE, Nursing Care

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1	Effectiveness	Of Abdominal	Massage I	For Chronic	Constipation 1	In The Elderly:
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2 A Protocol For A Systematic Review and Meta-analysis

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- †These authors contributed equally to this work and share first authorship.
- 20 ABSTRACT
- **Introduction** Chronic constipation is a health management challenge with high
- 22 prevalence, difficult treatment, and risk of cardiac and cerebral events in elderly
- 23 patients. Available laxative medications and lifestyle treatments are ineffective and
- 24 dependent. Abdominal massage is an economical and effective therapeutic measure to
- 25 improve chronic constipation in the elderly. The aim of this systematic review and
- 26 meta-analysis is to evaluate the efficacy and safety of abdominal massage in elderly
- 27 patients with chronic constipation. An in-depth subgroup analysis will be conducted
- 28 to explore the factors influencing the efficacy of abdominal massage such as treatment

29	modality,	duration,	and frequ	iency to	provide	credible	evidence	for future	mechanistic
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30 studies.

- 31 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
- 34 Science and Technology Periodical Database (VIP), Chinese Biomedical Literature
- 35 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
- 38 indicators of the trials were observed.
- **Results** This meta-analysis will objectively and comprehensively examine the
- 40 efficacy and safety of abdominal massage in elderly patients with chronic
- 41 constipation.
- 42 Conclusions This review will evaluate abdominal massage as a treatment for
- 43 relieving symptoms and improving quality of life in the elderly with chronic
- 44 constipation, and will provide additional insight for clinical treatment and mechanistic
- 45 studies.
- 46 Ethics and dissemination As there will be no collection or generation of raw data, a
- 47 statement of ethical approval is not required. We will publish the results of our study in

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

- 48 peer-reviewed journals.
- 49 PROSPERO registration number CRD42023408629
- 52 review

- **Word Count** 2865
- 54 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.
- 57 2. This study will include elderly patients aged >60 years who meet the diagnostic
- 58 criteria.
- 59 3. Only English and Chinese trials were included, which may lead to an increased risk
- 60 of bias.

- 4. There may be a heterogeneity in the different methods of abdominal
- 62 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
- 97 constipation in the elderly.

98 METHODS

99 Study registration

- 100 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
- 104 declaration guidelines.

105 Inclusion criteria for study selection

106 Type of study

- 107 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

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

Type of participant

- 112 Participants aged 60 years or older diagnosed with chronic constipation will be
- included regardless of gender, race, education or economic status. The diagnostic
- 114 criteria for chronic constipation are:
- 1. Clinical diagnostic criteria (e.g., Rome IV criteria);
- 116 2. Diagnostic criteria defined by the authors or defined by the clinician;
- 117 3. Participants' self-reported constipation.
- 118 The exclusion criteria contain the following items:1) Cognitive disorder;2) Belonged
- 119 to specific clinical population groups (e.g., pregnant women, ICU patients, post
- operation patients).
- 121 Type of intervention and comparisons.
- 122 Abdominal massage, including any type of pressure on the abdominal region, such as
- 123 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.
- 126 Type of outcome measure
- 127 The primary outcomes examined were the frequent cy of bowel movements, stool
- 128 texture and constipation symptoms. Any constipation symptom questionnaire, such as
- the Demographic Characteristics Questionnaire, the Rome criteria, and the
- 130 Constipation Assessment Scale, measured constipation symptoms. Secondary
- 131 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

- 135 The following electronic databases will be searched from their respective inception
- dates to April 21, 2023: Web of Science, PubMed, CINAHL, Cochrane Library,
- 137 Embase, Airiti Library databases, Chinese National Knowledge Infrastructure
- Databases (CNKI), Chinese Science and Technology Periodical Database (VIP),
- 139 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
- 142 eligibility criteria were investigated.

143 Searching other resources

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

Search strategy

- 147 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
- 153 "Functional Constipation" or "Primary Constipation" or "Chronic Constipation" or
- 154 "Idiopathic Constipation" or "Slow Transit Constipation" or "Constipated" or
- "Defecation Disorder" or "Evacuation Disorder*" or "Gastrointestinal Transit" or "Gut
- 156 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

search keywords will be used in the Chinese databases.

Search	Search Details
number	
#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.**.

173 Figure 1. Flow diagram of study selection process.

174 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 JI).

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
This is the first protect of systematic ferrors and mote unarysis 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.

- 232 Ethics and dissemination As there will be no collection or generation of raw data, a
- 233 statement of ethical approval is not required. We will publish the results of our study in
- 234 peer-reviewed journals.
- 235 Acknowledgements Qiang Yuan, Xiaoyan Wang, Zhou Li contributed equally to this
- work and share first authorship.
- 237 Author Contributions YQ conceived this study and wrote the manuscript. WXY and
- LZ developed the search strategy. WZH and LJ provided methodological advice. LC,
- 239 LQW and WHZ revised the manuscript. All authors have reviewed this protocol and
- approved the final manuscript.
- Funding This study was supported by Professor Luo Caigui's "Emei injury therapy"
- spinal manipulation inheritance research project (Chengdu University of Traditional
- 243 Chinese Medicine Foundation No. CCYB2022004) and clinical efficacy study of Luo's
- 244 manipulation combined with wax therapy based on shear wave elastography for the
- 245 treatment of postpartum low back pain with cold and dampness (Sichuan Provincial
- 246 Administration of Traditional Chinese Medicine No. 2021MS075).
- 247 Competing interests None declared.

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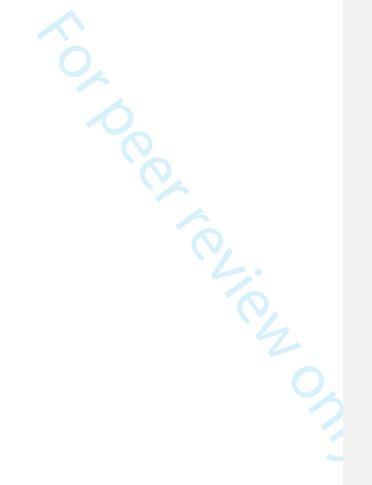
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 Preferred reporting items for systematic review and meta-analysis protocols

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(PRISMA-P) 2015: elaboration and explanation. Bmj 2015, 350: g7647. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Bmj 2011, 343: d5928.



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Identification

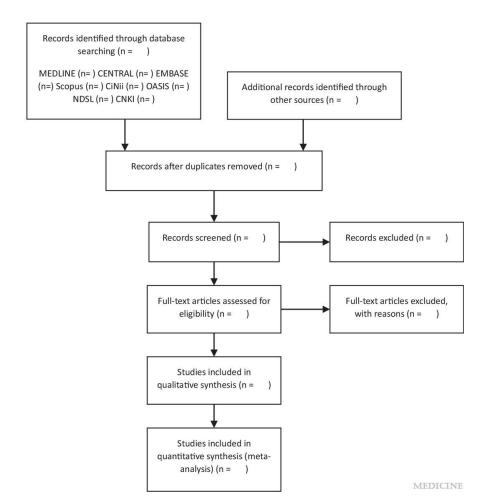


Figure 1. Flow diagram of study selection process.

423x397mm (72 x 72 DPI)

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

Section and topic	Item No	Checklist item Checklist item	Reported on Page #
ADMINISTRATIV	E INF	ORMATION E E E	
Title:		Identify the report as a protocol of a systematic review	
Identification	1a		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:		and and	
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mathematical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical affiliation authors.	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:		THE SECOND SECON	
Sources	5a	Indicate sources of financial or other support for the review Provide name for the review funder and/or sponsor	11
Sponsor	5b	Provide name for the review funder and/or sponsor	Not applicable
Role of sponsor or funder	5c	Indicate sources of financial or other support for the review Provide name for the review funder and/or sponsor Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
INTRODUCTION		imila	
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		9 ies	
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, trail 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

by copyright,

Study records:		7.4780 include	
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review on the second	8
Selection process	11b	(that is corresping clicibility and inclusion in moto 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	Dist and define all variables for which data will be sought (such as PICO items, funding sources) and simplifications	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and a the same of the	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether the bias 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 combining data from studies, including any planned exploration of consistency (such as I ² , Kendal's section of consistency).	`9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regrestion)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Not applicab
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective regorting within studies)	10
victa bias(cs)			
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10
Confidence in cumulative evidence * It is strongly recomthe items. Amendment	17 mende	Describe how the strength of the body of evidence will be assessed (such as GRADE) d that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite where available) for important clereview protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is the PRISMA-P Group	larification on
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BMJ Open

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

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074780.R1
Article Type:	Protocol
Date Submitted by the Author:	01-Nov-2023
Complete List of Authors:	yuan, qiang; Hospital of Chengdu University of Traditional Chinese Medicine, Department of Tuina Wang, Xiaoyan; Hospital of Chengdu University of Traditional Chinese Medicine, Oncologe Department Li, Zhou; Hospital of Chengdu University of Traditional Chinese Medicine, Oncologe Department Li, Chuan; Chengdu University of Traditional Chinese Medicine School of Acupuncture and Tuina Lu, Qunwen; Hospital of Chengdu University of Traditional Chinese Medicine, Tuina Department Wang, Haozhong; Chengdu University of Traditional Chinese Medicine, Luo, Jian; Hospital of Chengdu University of Traditional Chinese Medicine, Tuina Department
Primary Subject Heading :	Complementary medicine
Secondary Subject Heading:	Gastroenterology and hepatology
Keywords:	COMPLEMENTARY MEDICINE, GASTROENTEROLOGY, Nursing Care

SCHOLARONE™ Manuscripts

1	Abdominal Massage for Chronic Constipation in the Elderly: A Systematic
2	Review and Meta-analysis Protocol
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22	

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 peerreviewed journals as well as presentations at relevant national and international conferences.

- **Abbreviations:** CC, chronic constipation; NSAIDs, nonsteroidal anti-inflammatory
- 53 drugs.
- Keywords: Abdominal Massage, Chronic constipation, Elderly patients, Systematic

55 review

- 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 \geq 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

95	bowel disorders.[15-17] However, specific studies on elderly patients with constipation
96	are lacking. Given the increased prevalence of chronic constipation in older adults and
97	its specific pathological mechanisms, it is necessary to explore this condition in an age-
98	restricted manner.
99	
100	METHODS AND ANALYSIS
101	Study registration
102	This systematic review protocol was registered in PROSPERO 2023 (registration
103	number: CRD42023408629). The protocol report adhered to the guidelines outlined in
104	the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol
105	(PRISMA-P) declaration.[18] The review was performed in accordance with the
106	PRISMA-P declaration guidelines.
107	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

125	Abdominal massage includes any type of pressure applied to the abdominal region,
126	such as Swedish abdominal massage, acupressure (abdominal acupoint massage), and
127	aromatic abdominal massage. There were no limits on the time or frequency of the
128	massages. The comparison group consisted of individuals who received either no
129	intervention, a placebo intervention, or other medicinal treatments, such as osmotic or
130	stimulant laxatives, elobixibat, linaclotide, lubiprostone, mizagliflozin, naronapride,
131	plecanatide, prucalopride, tegaserod, tenapanor, or velusetrag.[20]
132	Type of outcome measure
133	The primary efficacy outcomes will be the frequency of bowel movements, related
134	scales, and symptoms of constipation. Constipation symptom questionnaires, such as
135	the Demographic Characteristics Questionnaire, Rome criteria,[19] and related Conk
136	Assessment Scales,[21] were used to measure constipation symptoms. Secondary
137	efficacy outcomes will include the influence of constipation on the quality of life and
138	laxative use. The safety outcomes included the monitoring of adverse events.
139	Search methods for identification of studies
140	Electronic data sources
141	The following electronic databases will be searched from their inception dates up to
142	May 30, 2023: Web of Science, PubMed, CINAHL, Cochrane Library, Embase, Airiti
143	Library, Chinese National Knowledge Infrastructure Databases (CNKI), Chinese
144	Science and Technology Periodical Database (VIP), Chinese Biomedical Literature
145	Database (CBM), and Wan Fang Database. After excluding language or publication
146	restrictions, we will conduct randomized clinical trials to investigate the effectiveness
147	of abdominal massage on chronic constipation in older adults who meet the eligibility
148	criteria.
149	Searching other resources
150	The reference lists of potentially missing eligible studies will be reviewed, and
151	relevant conference proceedings will also be examined.
152	Search strategy

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

182	The cause of missing data was determined to solve this problem. If investigative
183	approach proves unsuccessful, the authors will be contacted to request the missing
184	data. This process will be documented, and in the absence of the missing data, the
185	available data will be extracted and analyzed.
186	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

210	A sensitivity analysis will be conducted to test the robustness of the conclusions,
211	examining the impact of sample size, study design, methodological quality, and
212	missing data.
213	Grading the quality of evidence
214	The Grading of Recommendations Assessment approach was used to judge the
215	quality of evidence for all outcomes. Risks of bias, heterogeneity, indirectness,
216	imprecision, and publication bias were assessed. The assessments were classified into
217	four levels: high, moderate, low, or very low.
218	Ethics and dissemination
219	This protocol will not evaluate individual patient information or affect patient rights;
220	hence, it does not require ethical approval. The outcomes of this review will be shared
221	through peer-reviewed journals and conference reports.
222	Patient and public involvement
223	Patients were not involved in the design, conduct, reporting, or dissemination of this
224	research.
225	research.
226	DISCUSSION
227	This is the first protocol for a systematic review and meta-analysis intended to
228	evaluate the effectiveness and safety of abdominal massage therapy for chronic
229	constipation in elderly patients. Our group aimed to objectively and comprehensively
230	evaluate the therapeutic effects of abdominal massage on constipation in elderly
231	patients. The results of this review will provide physical therapists,
232	gastroenterologists, and patients with additional information on complementary and
233	alternative treatment options for chronic constipation in the elderly population.
234	Furthermore, the credibility of existing clinical evidence provides new directions for
235	future research.
236	
237	AUTHORS' CONTRIBUTIONS

238	YQ, WXYand WHZ conceptualised the study.YQ,WXY and ZL wrote the manuscript
239	with support from WHZ and LJ. LQW and LC created the search terms. All authors
240	were responsible for reading and approving this manuscript's final version.
241	
242	FUNDING STATEMENT
243	This project was financially supported by the Program of Sichuan Provincial
244	Administration of Traditional Chinese Medicine (No. 2021MS075 and No.
245	2023MS534) and the Project of the Key Research Base for Humanities and Social
246	Sciences in the Universities of Sichuan Province- the Coordinated Development of
247	Traditional Chinese Medicine Culture in Sichuan Province (No. 2023XT105)
248	
249	COMPETING INTEREST
250	The authors declare that they have no competing interests.
251	
252	DATA SHARING STATEMENT
253	All data relevant to the study are included in the article oruploaded as supplementary
254	information.
255	

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25	297		review of clinical and experimental studies from 1990 to 2021. Complement
26 27	298		Ther <i>Med</i> 2022 , 70 : 102861.
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30 31	300		massage on enteral nutrition complications in adult critically ill patients: A
32 33	301		systematic review and meta-analysis. Complement Ther Med 2022, 64:
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Figure 1. Flow diagram of study selection process.

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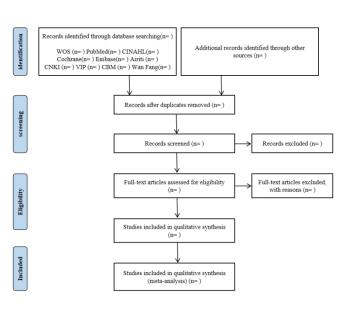
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APPENDIX 333

strategies 1. Appendix 1. Search strategies for databases

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Flow diagram of study selection process $190x338mm (120 \times 120 DPI)$

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

"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 peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

#7: #3 OR #4

#8: #5

#9: #6 AND #7 AND #8

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#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"

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#10: #3 AND #6 AND #9

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Study records: Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8
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Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independent and duplicate), any	9
Data items	12	Dist and define all variables for which data will be sought (such as PICO items, funding sources) and simplifications	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and and and and and and and and and an	5
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Abdominal Massage for Chronic Constipation in the Elderly: A Systematic Review and Meta-analysis Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-074780.R2
Article Type:	Protocol
Date Submitted by the Author:	08-Dec-2023
Complete List of Authors:	yuan, qiang; Hospital of Chengdu University of Traditional Chinese Medicine, Department of Tuina Wang, Xiaoyan; Hospital of Chengdu University of Traditional Chinese Medicine, Oncologe Department Li, Zhou; Hospital of Chengdu University of Traditional Chinese Medicine, Oncologe Department Li, Chuan; Chengdu University of Traditional Chinese Medicine School of Acupuncture and Tuina Lu, Qunwen; Hospital of Chengdu University of Traditional Chinese Medicine, Tuina Department Wang, Haozhong; Chengdu University of Traditional Chinese Medicine, Luo, Jian; Hospital of Chengdu University of Traditional Chinese Medicine, Tuina Department
Primary Subject Heading :	Complementary medicine
Secondary Subject Heading:	Gastroenterology and hepatology, Complementary medicine
Keywords:	COMPLEMENTARY MEDICINE, GASTROENTEROLOGY, Nursing Care

SCHOLARONE™ Manuscripts

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

22	Introduction: Chronic constipation (CC) is a highly prevalent health challenge that is
23	particularly challenging to treat in elderly patients. Although lifestyle guidance and
24	laxative therapy often yield positive outcomes, patients occasionally struggle with
25	maintaining dietary control. Therefore, identifying an economical and safe alternative
26	therapy to the existing treatment methods documented in the international literature is
27	necessary. This systematic review and meta-analysis aims to evaluate the efficacy and
28	safety of abdominal massage in elderly patients with CC to provide a basis for future
29	mechanistic research.
30	Methods and analysis: Electronic searches will be conducted to identify clinical
31	randomized controlled trials in various databases, including Web of Science, PubMed
32	Cumulated Index to Nursing and Allied Health Literature, Cochrane Library, Embase,
33	Airiti Library, Chinese National Knowledge Infrastructure Databases, Chinese
34	Science and Technology Periodical Database (VIP), Chinese Biomedical Literature
35	Database, and Wan Fang Data. Relevant data will be extracted, and a meta-analysis
86	will be conducted using Reviewer Manager 5.4. Quality and risk assessments of the
37	included studies will be performed, and the outcome indicators of the trials will be
88	observed. This review will evaluate abdominal massage as a treatment option for
39	relieving symptoms and improving quality of life in elderly patients with CC.
10	Moreover, it will provide additional insights for clinical treatment and mechanistic
1	studies. The search will be performed following the publication of this protocol
12	(estimated to occur on December 30, 2023).
13	Ethics and dissemination: As this is a literature review, ethics approval will not be
14	required. We will disseminate the findings of this study to publications in peer-
15	reviewed journals as well as presentations at relevant national and international
16	conferences.
17	Abbreviations: CC, chronic constipation

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

- 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

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

METHODS AND ANALYSIS

93 Study registration

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

Inclusion criteria for study selection

- 101 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.
- 106 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;
- 114 2) Belonging to specific clinical population groups (e.g., pregnant women, 115 intensive care unit patients, post-operation patients).

116	Type of intervention and comparisons
117	Abdominal massage includes any type of pressure applied to the abdominal region,
118	such as Swedish abdominal massage, acupressure (abdominal acupoint massage), and
119	aromatic abdominal massage. No limits will be placed on massage time or frequency.
120	The comparison group consists of individuals who received either no intervention, a
121	placebo intervention, or other medicinal treatments, such as osmotic or stimulant
122	laxatives, elobixibat, linaclotide, lubiprostone, mizagliflozin, naronapride,
123	plecanatide, prucalopride, tegaserod, tenapanor, or velusetrag.[20]
124	Type of outcome measure
125	The primary efficacy outcomes will be the frequency of bowel movements, related
126	scales, and symptoms of constipation. Constipation symptom questionnaires, such as
127	the Demographic Characteristics Questionnaire, Rome criteria,[19] and related Conk
128	Assessment Scales,[21] will be used to measure constipation symptoms. Secondary
129	efficacy outcomes will include the influence of constipation on the quality of life and
130	laxative use. The safety outcomes include the monitoring of adverse events.
131	Search methods for identification of studies
132	Electronic data sources
133	The following electronic databases will be searched from their inception dates up to
134	December 30, 2023: Web of Science, PubMed, Cumulated Index to Nursing and
135	Allied Health Literature, Cochrane Library, Embase, Airiti Library, Chinese National
136	Knowledge Infrastructure Databases, Chinese Science and Technology Periodical
137	Database (VIP), Chinese Biomedical Literature Database, and Wan Fang Data. After
138	excluding publication restrictions, we will review randomized clinical trials to
139	investigate the effectiveness of abdominal massage on CC in older adults who meet
140	the eligibility criteria.
141	Searching other resources
142	The reference lists of potentially missing eligible studies will be reviewed, and
143	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

171	information. The extracted data will be entered into an electronic database, and
172	differences will be verified by the corresponding authors (JL and HW).
173	Management of missing data
174	The cause of missing data will be determined to solve this problem. If this
175	investigative approach proves unsuccessful, the authors will be contacted to request
176	the missing data. This process will be documented, and in the absence of the missing
177	data, the available data will be extracted and analyzed.
178	Risk of bias assessment
179	The Cochrane Collaboration tool will be used to assess the risk of bias in each study,
180	including six types of bias: random sequence generation, allocation concealment,
181	participant and personal blinding, outcome assessment blinding, incomplete outcome
182	data, selective reporting, as well as other sources of bias.[22] The quality of the
183	reports will be divided into three levels: low, unclear, and high risk. Differences will
184	be resolved through group discussion.
185	Statistical analysis
186	Data will be analyzed using RevMan version 5.3 (The Cochrane Collaboration,
187	London, England). The relative risk will be used to evaluate dichotomous variables,
188	with 95% confidence intervals. The standardized mean difference and 95%
189	confidence interval will be used to evaluate continuous variables. The chi-square test
190	and I^2 statistic will be used to confirm heterogeneity. The former checks for
191	heterogeneity, whereas the latter reflects the degree of heterogeneity using a specific
192	value. $I^2 > 50\%$, will indicate considerable heterogeneity among the studies.
193	Consequently, a subgroup analysis will be performed to investigate the potential
194	causes.
195	Subgroup analysis
196	If significant heterogeneity is observed, subgroup analyses will be conducted to
197	explore the sources of heterogeneity. These subgroup analyses will be conducted

198	based on the characteristics of the included studies, including the publication time,
199	geographical scope of the study, participant sex, and control interventions. Regarding
200	interventions, we will explore the impact of massage modality, duration, and
201	frequency on efficacy.
202	Sensitivity analysis
203	A sensitivity analysis will be conducted to test the robustness of the conclusions,
204	examining the impact of sample size, study design, methodological quality, and
205	missing data.
206	Grading the quality of evidence

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

225	information on complementary and alternative treatment options for CC in the elderly
226	population. Furthermore, the credibility of existing clinical evidence provides new
227	directions for future research.
228	
229	AUTHORS' CONTRIBUTIONS
230	QY, XW, and HW conceptualized the protocol. QY, XW, and LZ wrote the
231	manuscript with support from HW and JL. QL and CL created the search terms. All
232	authors were responsible for reading and approving the final version of the
233	manuscript.
234	
235	FUNDING STATEMENT
236	This work was supported by the Program of Sichuan Provincial Administration of
237	Traditional Chinese Medicine, grant numbers 2021MS075 and 2023MS534 and the
238	Project of the Key Research Base for Humanities and Social Sciences in the
239	Universities of Sichuan Province-the Coordinated Development of Traditional
240	Chinese Medicine Culture in Sichuan Province, grant number 2023XT105.
241	
242	COMPETING INTEREST
243	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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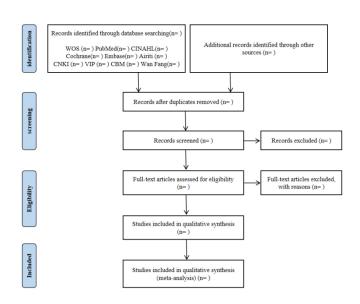
310 FIGURE LEGEN

Figure 1. Flow diagram of study selection process

SUPPLEMENTARY MATERIAL

Appendix 1. Search strategies





Flow diagram of study selection process $190 \times 338 \text{mm} (120 \times 120 \text{ DPI})$

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

"rand method #9 #7 #10 #

CIN #1: M
#2: "c

"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 peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

#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 carecellist: recommended items to address in a systematic review protocol*

Item No	Checklist item Checklist item	Reported on Page #
E INFO	ORMATION COMMATION	
	202 gne att	
1a	Identify the report as a protocol of a systematic review	1
1b		1
2	If registered, provide the name of the registry (such as PROSPERO) and registration number $\Xi = \Xi$	2
	eric	
3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mathematical mathematical affiliation, e-mail address of all protocol authors; provide physical mathematical address of corresponding author	1
3b	Describe contributions of protocol authors and identify the guarantor of the review	1
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
	Tr. S	
5a	Indicate sources of financial or other support for the review	11
5b		Not applicable
5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Not applicable
	imila	
6	Describe the rationale for the review in the context of what is already known	3
7	Provide an explicit statement of the question(s) the review will address with reference to participants, Interventions, comparators, and outcomes (PICO)	3
	9025	
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
9	Describe all intended information sources (such as electronic databases, contact with study authors, tradit registers or other grey literature sources) with planned dates of coverage	6
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
	1a 1b 2 3a 3b 4 5a 5b 5c 6 7	Identify the report as a protocol of a systematic review If the protocol is for an update of a previous systematic review, identify as such If registered, provide the name of the registry (such as PROSPERO) and registration number If the protocol is for an update of a previous systematic review, identify as such Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mathematical author Describe contributions of protocol authors and identify the guarantor of the review 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 Indicate sources of financial or other support for the review Indicate sources of financial or other support for the review Provide name for the review funder and/or sponsor Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol Describe the rationale for the review in the context of what is already known Provide an explicit statement of the question(s) the review will address with reference to participants, comparators, and outcomes (PICO) 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 Describe all intended information sources (such as electronic databases, contact with study authors, tradit registers or other grey literature sources) with planned dates of coverage Describe all intended information sources (such as electronic databases, including planned limitige such that it could be

by copyright,

management Selection 1 process	11a	0 -	
process		Describe the mechanism(s) that will be used to manage records and data throughout the review on the second	8
Data collection 1		State the process that will be used for selecting studies (such as two independent reviewers) through the phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
process		Describe planned method of extracting data from reports (such as piloting forms, done independent in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	processes for obtaining and confirming data from investigators List and define all variables for which data will be sought (such as PICO items, funding sources)	8
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and and an outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether the swall be done at the outcome or study level, or both; state how this information will be used in data synthesis	9
Data synthesis 1		Describe criteria under which study data will be quantitatively synthesised	9
1	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of combining data from studies, including any planned exploration of consistency (such as I², Kendall's 10.	9
1	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regrestion)	10
	15d		Not applicab
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective regorting within studies)	10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10
		I that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite where available) for important clereview protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) in head by the PRISMA-P Group	
distributed under a Crea	ative	Commons Attribution Licence 4.0.	
	her L), Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferr e d re x orting items for systemation	c review and
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