7° CONGRESSO NAZIONALE ROI
NAPOLI

ROI
REGISTRO DEGLI OSTEOPATI D'ITALIA

30 ANNI DI OSTEOPATIA IN ITALIA
SVILUPPO, RICERCA E IDENTITÀ
24 - 25 - 26 GIUGNO 2022

Definizione e classificazione degli eventi avversi nella manipolazione e mobilizzazione vertebrale e degli arti: una Scoping Review

Martha Funabashi (PT, PhD)[1,2], Lindsay Gorrell (MChiroprac, PhD)[3], Katherine Pohlman (DC, PhD)[4], Andrea Bergna (PT, DO)[5], Nicola Heneghan (PT, PhD)[6]

1 Canadian Memorial Chiropractic College, 2 Université du Québec à Trois-Rivières, 3 University of Zürich, 4 Parker University, 5 SOMA Istituto Osteopatia Milano, 6 University of Birmingham

Background

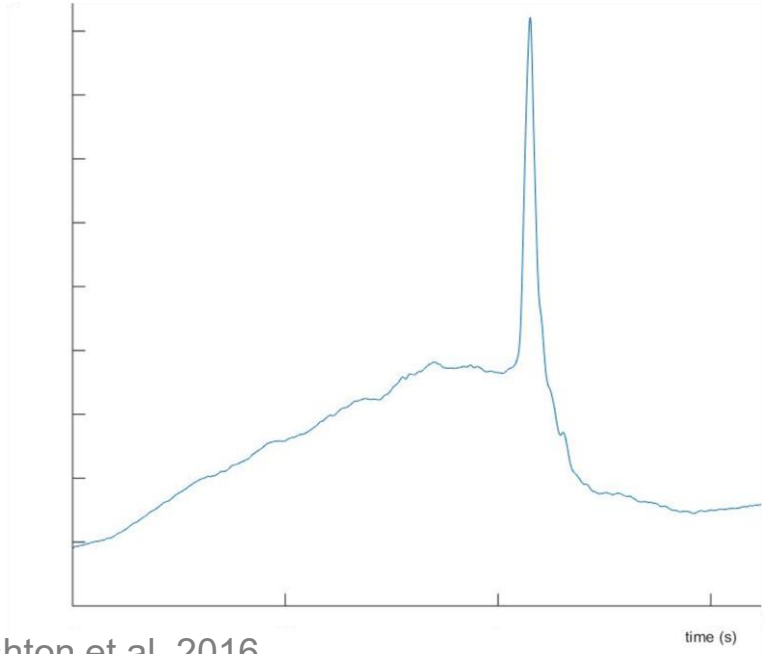
Manipolazione e Mobilizzazione articolare

- Applicate alla colonna vertebrale o alle articolazioni periferiche
- Gestione delle condizioni muscoloscheletriche

Lin et al. 2020; Hawk et al. 2020; National Institute for Health and Care Excellence, 2016

Background

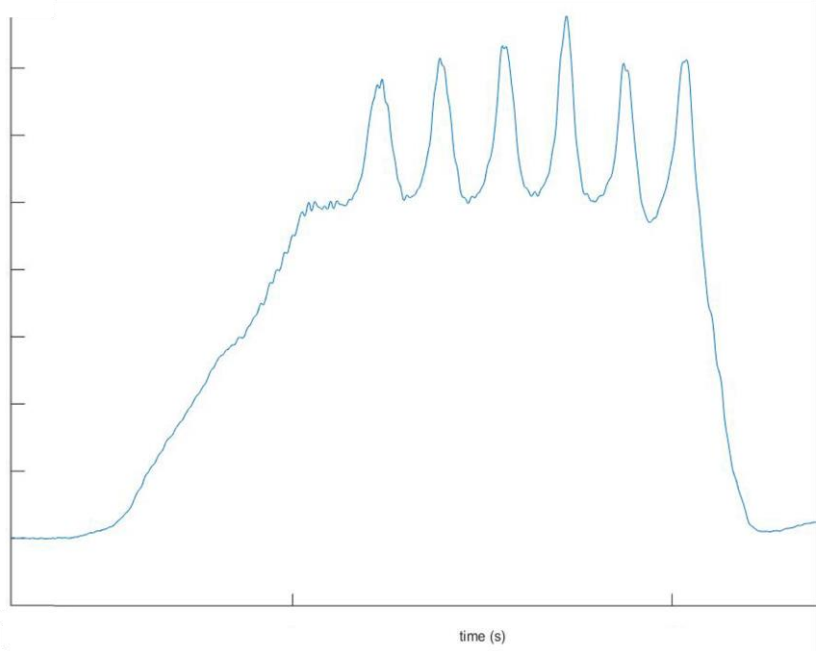
Manipolazione



Rushton et al. 2016

HVLA - Impulso

Mobilizzazione



LVVA - Forza ciclica

Background

Eventi Avversi

Manipolazione & Mobilizzazione

Powell FC et al. 1993

Senstad O et al. 1997

Rubinstein SM et al. 2007

Paciaroni M & Bogousslavsky J 2009

Maiers M et al. 2015

Swait G et al. 2017

Degenhardt BF et al. 2018

ORIGINAL CONTRIBUTION

Characterizing Adverse Events Reported Immediately After Osteopathic Manipulative Treatment

Brian F. Degenhardt, DO; Jane C. Johnson, MA; William J. Brooks, DO; Lisa Norman, BS

From the A.T. Still Research Institute at A.T. Still University (Dr Degenhardt, Ms Johnson, Dr Brooks); the Department of Osteopathic Manipulative Medicine at the A.T. Still University Kirksville College of Osteopathic Medicine (Dr Degenhardt); and Research Support at A.T. Still University (Ms Norman), all in Kirksville, Missouri.

Financial Disclosures: None reported.

Support: The current study was funded by a grant from the American Osteopathic Association (grant no. 11-04-634).

Address correspondence to Brian F. Degenhardt, DO, A.T. Still University, 800 W Jefferson St, Kirksville, MO 63501-1443.

Email: bdegenhardt@atsu.edu

Submitted April 10, 2017; revision received August 10, 2017; accepted August 23, 2017.

Context: Although adverse events in various types of manual therapy have been previously investigated, little is known about the incidence and types of adverse events that occur after osteopathic manipulative treatment (OMT).

Objective: To estimate the incidence and characterize the types of adverse events that patients report after OMT and prior to leaving the office to increase the likelihood of identifying adverse events caused by OMT.

Methods: As part of a prospective study evaluating the use and effectiveness of OMT, patients assessed how they felt immediately after OMT compared with before OMT using a 5-point ordinal rating scale (much better, better, about the same, worse, much worse). For patients who indicated they felt their condition had changed, a follow-up, open-ended question asked them to describe how it had changed. Patients who felt worse or much worse were considered to have experienced an adverse event. Two reviewers independently coded the types of adverse events based on the descriptions provided by the patients. Generalized logistic regression models were used to calculate incidence rates and 95% CIs for the types of adverse events. These models were also used to calculate the ORs and 95% CIs for associations of adverse events with demographic characteristics and with individual OMT techniques after accounting for demographic characteristics.

Results: Immediately after OMT, 884 patients provided data at 1847 office visits (663 [76%] women; 794 [92%] identified as white; mean [SD] age, 51.8 [15.8] years). Patients reported they felt worse or much worse immediately after OMT at 45 office visits; the incidence rate for adverse events was 2.5% (95% CI, 1.3%-4.7%). Pain/discomfort was the most commonly identified type of adverse event (16 [0.9%]; 95% CI, 0.5%-1.6%). Insufficient information was provided to determine the type of adverse event at 20 office visits. Women reported adverse events more frequently than men (OR, 13.9; 95% CI, 1.7-115.6; P=.01).

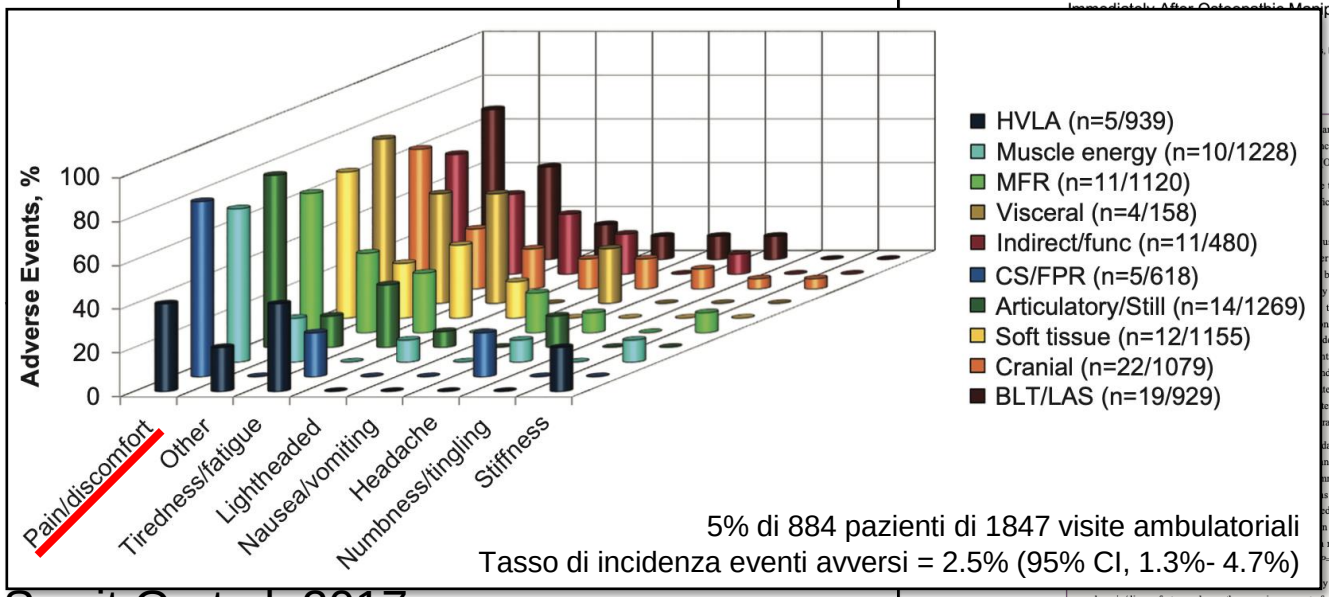
Conclusion: The incidence of adverse events immediately after OMT, most commonly pain/discomfort, was lower than previous reports from other manual medicine disciplines. Larger studies are needed to determine the incidence of serious adverse events and to assess adverse events that occur in the days following OMT.

J Am Osteopath Assoc. 2018;118(3):141-149
doi:10.7556/jaoa.2018.033

Keywords: adverse events, manual treatment, osteopathic manipulative treatment

Background

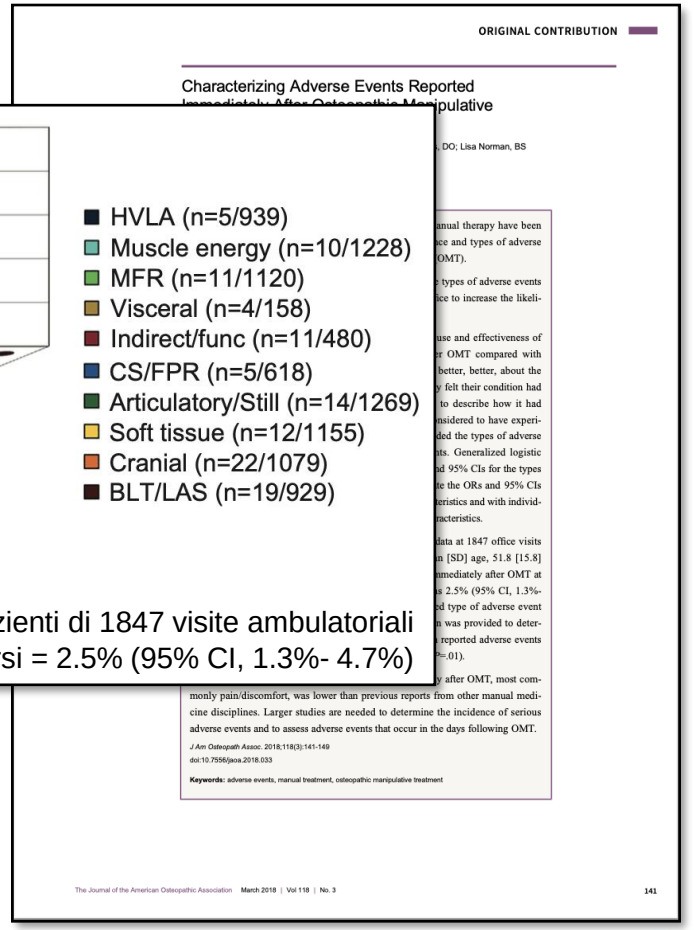
Eventi Avversi



5% di 884 pazienti di 1847 visite ambulatoriali
Tasso di incidenza eventi avversi = 2.5% (95% CI, 1.3%- 4.7%)

Swait G et al. 2017

Degenhardt BF et al. 2018


ORIGINAL CONTRIBUTION

Characterizing Adverse Events Reported Immediately After Osteopathic Manipulative

, DO; Lisa Norman, BS

anual therapy have been ce and types of adverse OMT).

types of adverse events ce to increase the likeli-

se and effectiveness of r OMT compared with better, better, about the felt their condition had to describe how it had nsidered to have experi- ded the types of adverse ts. Generalized logistic d 95% CIs for the types e the ORs and 95% CIs eristics and with individ- racteristics.

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The Journal of the American Osteopathic Association March 2018 | Vol 118 | No. 3

141

Background

Eventi Avversi

Manipolazione & Mobilizzazione

Assistenza sanitaria pazienti

Prevenire e ridurre gli eventi avversi

Background

Eventi Avversi

Il piano OMS d'azione globale 2021-2030 per la sicurezza dei pazienti fornisce un quadro di riferimento per i paesi per sviluppare i rispettivi piani d'azione nazionali sulla sicurezza dei pazienti, nonché per allineare gli strumenti strategici esistenti per migliorare la sicurezza dei pazienti in tutti i settori clinici.

WHO 2021

Background

Eventi Avversi

Gli eventi avversi sono eventi inattesi correlati al processo assistenziale che comportano un danno al paziente, non intenzionale e indesiderabile. I sistemi di reporting di tali eventi rappresentano uno strumento indispensabile per aumentare la conoscenza delle cause e dei fattori contribuenti in base al “principio dell’imparare dall’errore”.

Ministero della Salute 2011

Ministero della Salute

DIPARTIMENTO DELLA QUALITÀ
DIREZIONE GENERALE DELLA PROGRAMMAZIONE SANITARIA,
DEI LIVELLI DI ASSISTENZA E DEI PRINCIPI ETICI DI SISTEMA
UFFICIO III

Linee guida per gestire e comunicare

gli Eventi Avversi in sanità

Roma, Giugno 2011

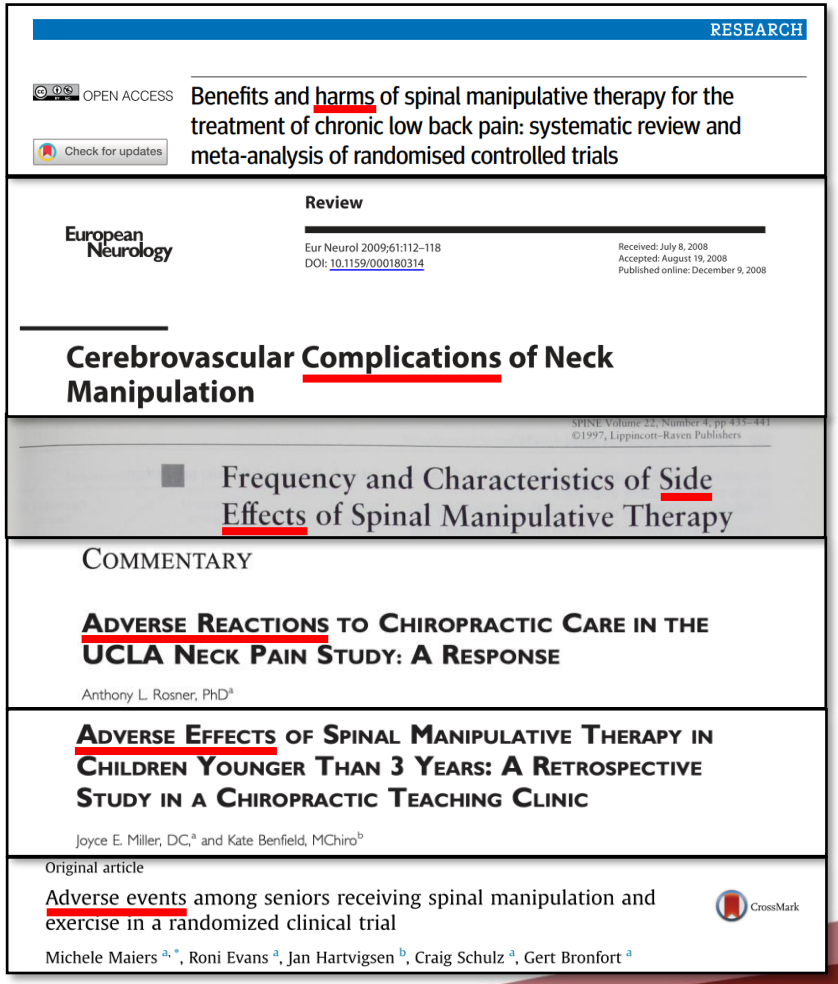
Background

Manipolazione & Mobilizzazione - EA

Termini:

- Danni
- Complicazioni
- Effetti collaterali
- Reazioni avverse
- Effetti avversi
- Eventi avversi

Carlesso et al. 2010, Gorrell et al. 2016, He et al. 2014



RESEARCH

OPEN ACCESS

Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomised controlled trials

Check for updates

Review

European Neurology

Eur Neurol 2009;61:112–118
DOI: 10.1159/000180314

Received: July 8, 2008
Accepted: August 19, 2008
Published online: December 9, 2008

Cerebrovascular Complications of Neck Manipulation

SPINE Volume 22, Number 4, pp 435–441
©1997, Lippincott-Raven Publishers

Frequency and Characteristics of Side Effects of Spinal Manipulative Therapy

COMMENTARY

ADVERSE REACTIONS TO CHIROPRACTIC CARE IN THE UCLA NECK PAIN STUDY: A RESPONSE

Anthony L. Rosner, PhD[a]

ADVERSE EFFECTS OF SPINAL MANIPULATIVE THERAPY IN CHILDREN YOUNGER THAN 3 YEARS: A RETROSPECTIVE STUDY IN A CHIROPRACTIC TEACHING CLINIC

Joyce E. Miller, DC,[a] and Kate Benfield, MChiro[b]

Original article

Adverse events among seniors receiving spinal manipulation and exercise in a randomized clinical trial

CrossMark

Michele Maiers [a,*], Roni Evans [a], Jan Hartvigsen [b], Craig Schulz [a], Gert Bronfort [a]

Background

Manipolazione & Mobilizzazione - EA

Definizione:

L’evento avverso nella manipolazione e nella mobilizzazione è definito come …

Paanalahti et al. 2014, Dougherty et al. 2014, Nielsen et al. 2017

Background

Evento avverso - Causalità

Definizione

Evento avverso: "per indicare un outcome sfavorevole o dannoso che si verifica durante o dopo l'uso di un farmaco o di un altro intervento, ma che non è necessariamente causato da esso".

Effetto avverso: "come un evento avverso per il quale la relazione causale tra l'intervento e l'evento è almeno una possibilità ragionevole".

Peryer et al. 2022 - www.training.cochrane.org/handbook

Background

Evento avverso - Temporalità

Causalità

Il rapporto tra causa ed effetto (EA).

Per stabilire in modo inequivocabile la causalità, si devono utilizzare i seguenti criteri: forza dell'associazione, coerenza, specificità, temporalità, gradiente biologico, plausibilità, coerenza, evidenza sperimentale e analogia.

Temporalità

Lo stato di esistenza o di relazione con il tempo.

Ad esempio, un esito (EA) si verifica dopo un'esposizione.

Rothman KJ & Greenland S 2005, Cartwright N 2010

Background

Manipolazione & Mobilizzazione - EA

Classificazione:

- Gravità
  - lieve, moderata, severa
- Insorgenza
  - durante il trattamento, entro 24-48 ore dal trattamento

Carnes D et al. 2010, Pohlman KA et al. 2014

- Durata
  - transitoria, di breve durata, permanente
- Necessità di ulteriori cure non pianificate
  - cure mediche, visite specialistiche, indagini, ricovero in ospedale
- Evitabilità
- Adeguatezza

Background

Manipolazione & Mobilizzazione - EA

Mancanza di standardizzazione

Varie definizioni e classificazioni

Differenti domini e descrittori

Contents lists available at ScienceDirect

International Journal of Osteopathic Medicine

journal homepage: www.elsevier.com/ijos

Research report

Defining adverse events in manual therapies: A modified delphi consensus study

Dawn Carnes [a,*], Brenda Mullinger [b], Martin Underwood [c]

[a] Institute of Health Sciences Education, Centre for Health Sciences, Barts and The London School of Medicine and Dentistry, 2 Newark St, London E1 2AT, United Kingdom
[b] European School of Osteopathy, Boxley House, Boxley, Maidstone, Kent ME14 3DZ, United Kingdom
[c] Warwick Medical School, Coventry, CV4 7AL, United Kingdom

Contents lists available at ScienceDirect

Manual Therapy

journal homepage: www.elsevier.com/math

Original article

Defining adverse events in manual therapy: An exploratory qualitative analysis of the patient perspective

Lisa C. Carlesso [a,*], John Cairney [b,c], Lisa Dolovich [b], Jennifer Hoogenes [a,d]

[a] Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada
[b] Department of Family Medicine, McMaster University, Hamilton, ON, Canada
[c] Department of Psychiatry and Behavioural Neurosciences, McMaster University, Hamilton, ON, Canada
[d] Department of Biostatistics and Surgery, McMaster University, Hamilton, ON, Canada

Carlesso LC et al. 2010/2011/2013, Carnes D et al. 2010

Background

Manipolazione & Mobilizzazione - EA

- Standardizzazione

➢ Definizione EA

➢ Classificazione EA

- Identificazione, documentazione, segnalazione EA

- Interprofessionale

Obiettivo

Mappare la letteratura scientifica che definisce gli eventi avversi e i rispettivi sistemi di classificazione in seguito a manipolazione e mobilizzazione della colonna vertebrale o delle articolazioni periferiche per condizioni muscoloscheletriche in una popolazione adulta.

Metodi

5 Fasi Scoping Review

1. Identificare quesito di ricerca

Come vengono definiti in letteratura gli eventi avversi e i rispettivi sistemi di classificazione per gli eventi che si verificano in seguito a manipolazione e mobilizzazione della colonna vertebrale o delle articolazioni periferiche?

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

2. Identificazione studi rilevanti

- Fonti di informazione (febbraio 2021):

MEDLINE Complete · Embase® · CINAHL Available via EBSCOhost · Scopus

Allied and Complementary Medicine Database (AMED) · Index to Chiropractic Literature · PEDro Physiotherapy Evidence Database · Cochrane Library

Open Grey · Open Access Theses and Dissertations

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

2. Identificazione studi rilevanti

- Strategia di ricerca:
  - ➢ assistenza bibliotecario esperto scienze sanitarie
  - ➢ Medical Subject Headings (MeSH), All Fields
  - ➢ operatori Booleani

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

2. Identificazione studi rilevanti

- Criteri di idoneità:
  - ➢ criteri di inclusione
  - ➢ criteri di esclusione

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

2. Identificazione studi rilevanti

- Criteri di inclusione:
  - lingua (inglese, portoghese, italiano)
  - partecipanti (adulti, condizioni muscoloscheletriche)
  - intervento (manipolazione, mobilizzazione, vertebrale e arti; principale e multimodale)
  - outcome (definizione e/o classificazione EA)
  - disegno studio (pubblicazione peer-reviewed)

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

3. Selezione studi

- 5 revisori calibrati
- Controllo indipendente
  - ➢ Titolo e abstract
  - ➢ Full text
- Disaccordo: discussione e consenso

covidence

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

4. Estrazione dati

- Data Extraction Form standardizzato:
  - ➢ caratteristiche studio
  - ➢ caratteristiche intervento
  - ➢ definizione e/o classificazione EA
- Controllo accuratezza: discussione e consenso

Arksey H & O'Malley L 2005

Metodi

5 Fasi Scoping Review

5. Raccolta, riassunto, presentazione dati

- Classificati in:

→ definizione o classificazione diretta

"Gli eventi avversi sono eventi inattesi che si verificano in seguito a un intervento senza evidenza di causalità"

Arksey H & O'Malley L 2005, Kranenburg HA et al. 2017

Metodi

5 Fasi Scoping Review

5. Raccolta, riassunto, presentazione dati

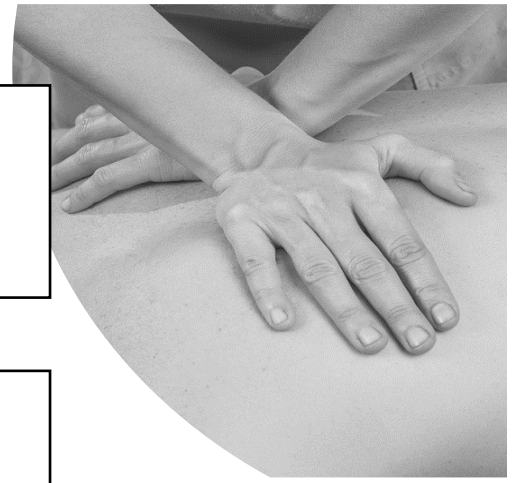
- Classificati in:

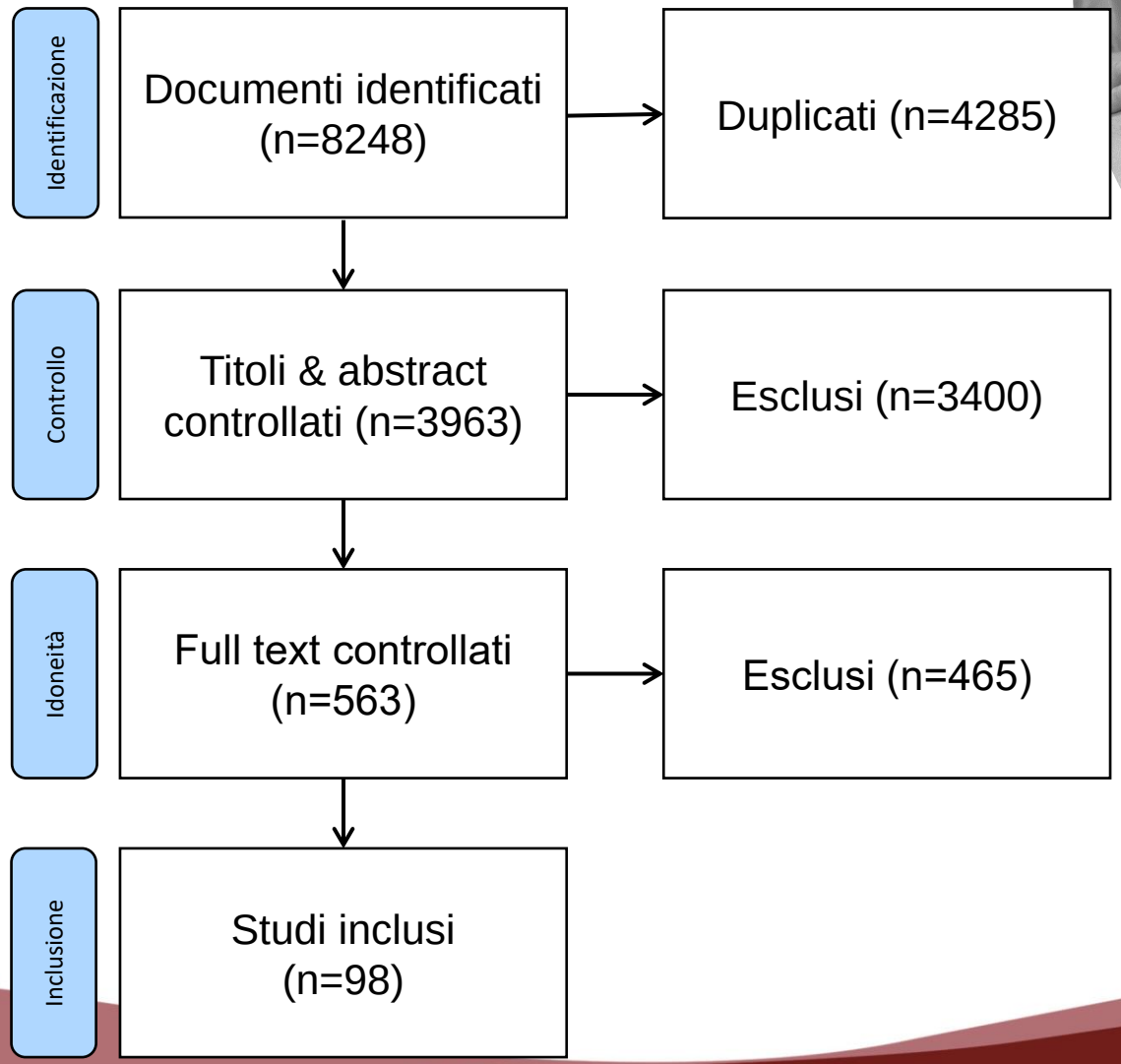
→ definizione o classificazione indiretta

"I suoi sintomi sono peggiorati dopo il trattamento?"

Arksey H & O'Malley L 2005, de Oliveira RF et al. 2013

Risultati




Identificazione
Documenti identificati (n=8248)
Duplicati (n=4285)
Controllo
Titoli & abstract controllati (n=3963)
Esclusi (n=3400)
Idoneità
Full text controllati (n=563)
Esclusi (n=465)
Inclusione
Studi inclusi (n=98)

Risultati

98 studi inclusi

Caratteristiche degli studi

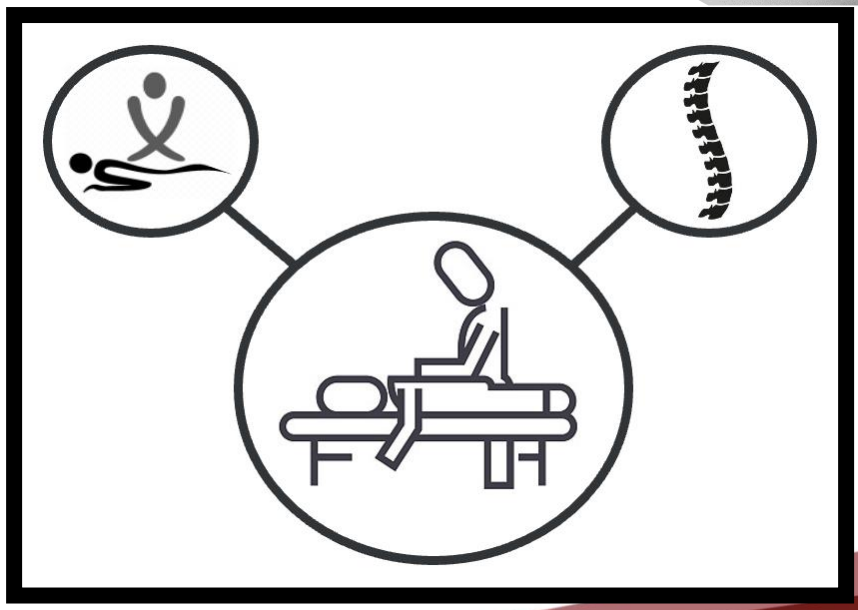
- Pubblicati nel 1993-2021
- Nord America (n=42)
  Europa (n=36)
- Revisioni letteratura (n=21)
  Sondaggi (n=20)
  Studi clinici (n=18)

Risultati

98 studi inclusi

Caratteristiche degli studi

Caratteristiche intervento



Risultati

98 studi inclusi

Caratteristiche degli studi

Caratteristiche intervento

Definizione/classificazione EA → 69 studi

29 studi

Risultati

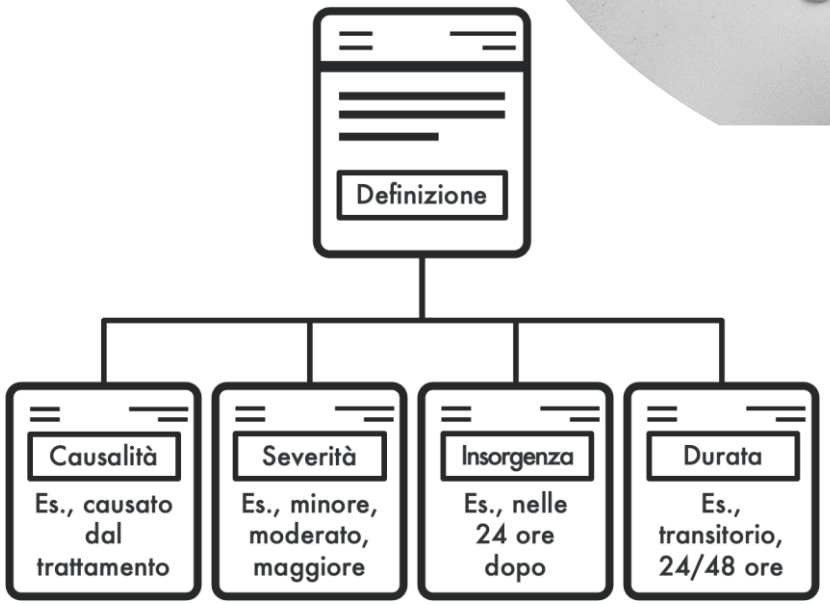
98 studi inclusi

Caratteristiche degli studi

Caratteristiche intervento

Definizione/classificazione EA

→ 69 studi



Risultati

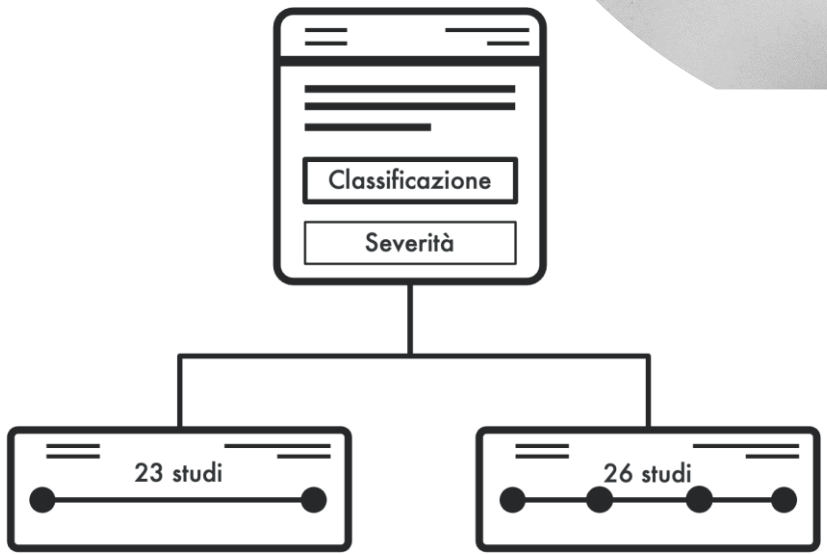
98 studi inclusi

Caratteristiche degli studi

Caratteristiche intervento

Definizione/classificazione EA

→ 69 studi



Risultati

98 studi inclusi

Caratteristiche degli studi

Caratteristiche intervento

Definizione/classificazione EA

→ 69 studi

29 studi

Risultati

98 studi inclusi

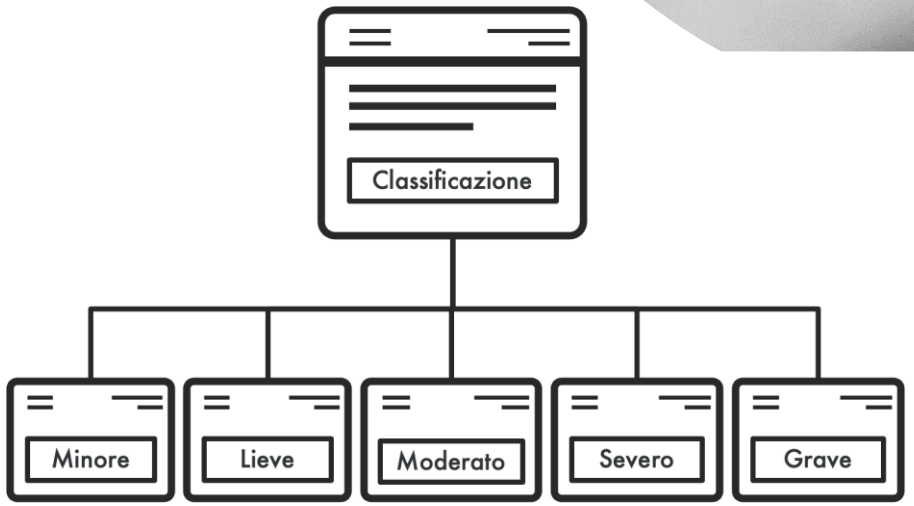
Caratteristiche degli studi

Caratteristiche intervento

Definizione/classificazione EA

→ 69 studi

29 studi



Discussione

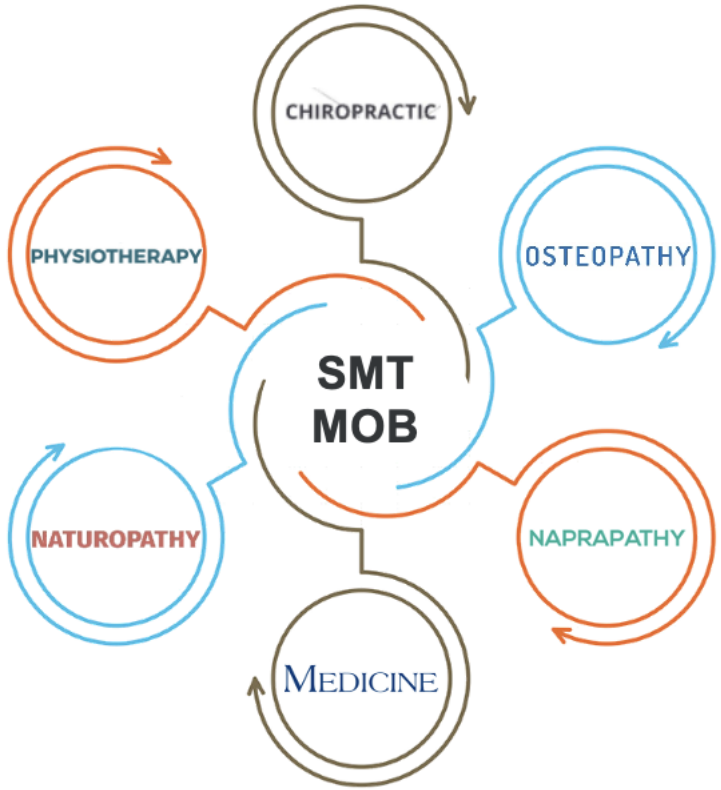
Eterogeneità

- Termini EA
- Definizioni EA
- Sistemi di classificazione EA

Discussione

Eterogeneità

- Multidisciplinarietà
- Localizzazioni geografiche
- Differenze culturali



Limiti

- Termini alternativi non rilevati
- Articoli in lingue differenti non individuati
- Soggettività analisi

Conclusioni

Eterogeneità

- Standardizzazione definizione/classificazione EA necessaria
- Consenso internazionale e interprofessionale

➢Promuovere la sicurezza del paziente

7° CONGRESSO NAZIONALE ROI NAPOLI

ROI REGISTRO DEGLI OSTEOPATI D'ITALIA

Scoping Review

PONE-D-21-35204R2
Definition and classification for adverse events following spinal and peripheral joint manipulation and mobilization: A scoping review

PLOS ONE

Dear Dr. Funabashi:

I'm pleased to inform you that your manuscript has been deemed suitable for publication in PLOS ONE. Congratulations! Your manuscript is now with our production department.

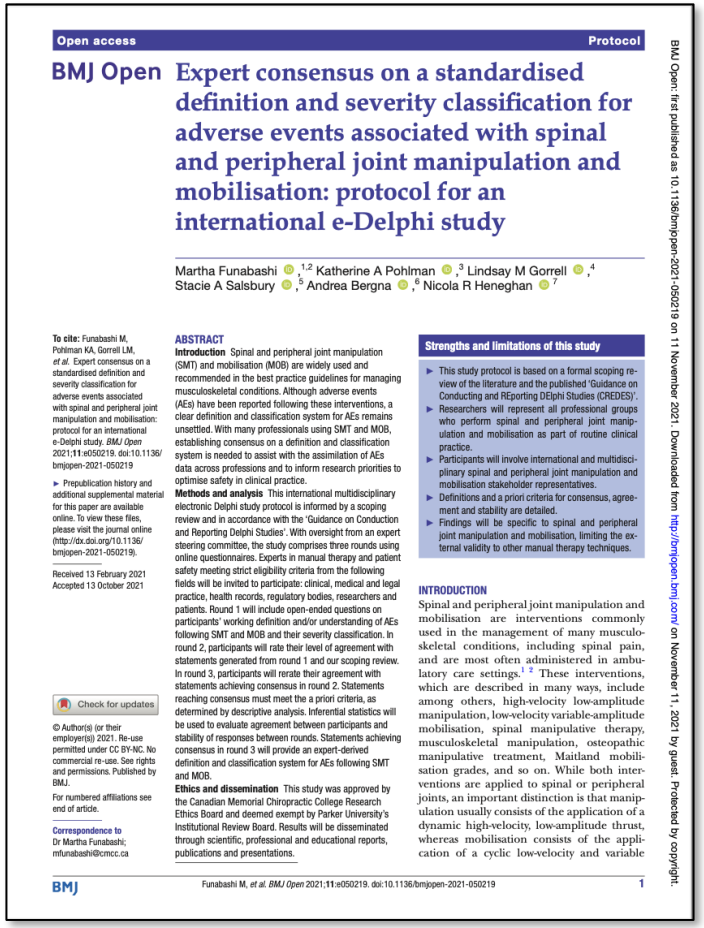
Thursday, June 23, 2022 1:39 PM

Consenso di esperti

e-Delphi internazionale e multidisciplinare

Lo scopo di questo studio e-Delphi è quello di determinare, attraverso un processo di consenso di esperti, una definizione standardizzata e una classificazione della gravità degli eventi avversi a seguito di manipolazione e mobilizzazione, in una popolazione adulta con condizioni muscoloscheletriche, da utilizzare sia nell'assistenza clinica che negli studi di ricerca.

Comitati: direttivo, esecutivo, consultivo



Open access Protocol

BMJ Open

Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study

Martha Funabashi [1,2] Katherine A Pohlman [3] Lindsay M Gorrell [4] Stacie A Salsbury [5] Andrea Bergna [6] Nicola R Heneghan [7]

To cite: Funabashi M, Pohlman KA, Gorrell LM, *et al*. Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study. *BMJ Open* 2021;**11**:e050219. doi:10.1136/bmjopen-2021-050219

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For numbered affiliations see end of article.

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ABSTRACT

Introduction Spinal and peripheral joint manipulation (SMT) and mobilisation (MOB) are widely used and recommended in the best practice guidelines for managing musculoskeletal conditions. Although adverse events (AEs) have been reported following these interventions, a clear definition and classification system for AEs remains unsettled. With many professionals using SMT and MOB, establishing consensus on a definition and classification system is needed to assist with the assimilation of AEs data across professions and to inform research priorities to optimise safety in clinical practice.

Methods and analysis This international multidisciplinary electronic Delphi study protocol is informed by a scoping review and in accordance with the 'Guidance on Conduction and Reporting Delphi Studies'. With oversight from an expert steering committee, the study comprises three rounds using online questionnaires. Experts in manual therapy and patient safety meeting strict eligibility criteria from the following fields will be invited to participate: clinical, medical and legal practice, health records, regulatory bodies, researchers and patients. Round 1 will include open-ended questions on participants' working definition and/or understanding of AEs following SMT and MOB and their severity classification. In round 2, participants will rate their level of agreement with statements generated from round 1 and our scoping review. In round 3, participants will rerate their agreement with statements achieving consensus in round 2. Statements reaching consensus must meet the a priori criteria, as determined by descriptive analysis. Inferential statistics will be used to evaluate agreement between participants and stability of responses between rounds. Statements achieving consensus in round 3 will provide an expert-derived definition and classification system for AEs following SMT and MOB.

Ethics and dissemination This study was approved by the Canadian Memorial Chiropractic College Research Ethics Board and deemed exempt by Parker University's Institutional Review Board. Results will be disseminated through scientific, professional and educational reports, publications and presentations.

Strengths and limitations of this study

- This study protocol is based on a formal scoping review of the literature and the published 'Guidance on Conducting and REporting DElphi Studies (CREDES)'.
- Researchers will represent all professional groups who perform spinal and peripheral joint manipulation and mobilisation as part of routine clinical practice.
- Participants will involve international and multidisciplinary spinal and peripheral joint manipulation and mobilisation stakeholder representatives.
- Definitions and a priori criteria for consensus, agreement and stability are detailed.
- Findings will be specific to spinal and peripheral joint manipulation and mobilisation, limiting the external validity to other manual therapy techniques.

INTRODUCTION

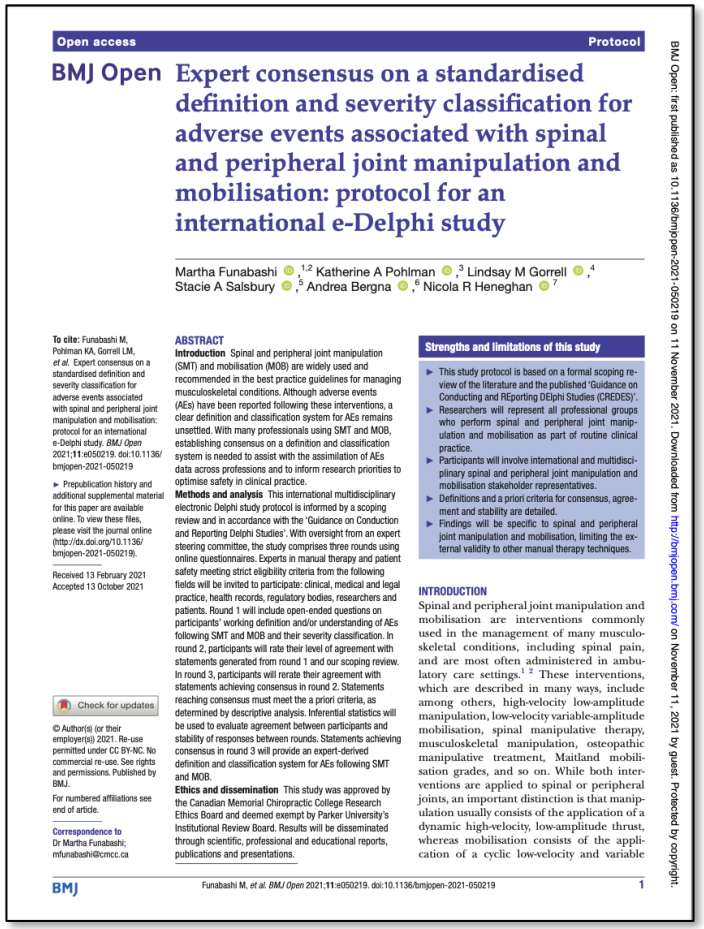
Spinal and peripheral joint manipulation and mobilisation are interventions commonly used in the management of many musculoskeletal conditions, including spinal pain, and are most often administered in ambulatory care settings.[1 2] These interventions, which are described in many ways, include among others, high-velocity low-amplitude manipulation, low-velocity variable-amplitude mobilisation, spinal manipulative therapy, musculoskeletal manipulation, osteopathic manipulative treatment, Maitland mobilisation grades, and so on. While both interventions are applied to spinal or peripheral joints, an important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust, whereas mobilisation consists of the application of a cyclic low-velocity and variable

Consenso di esperti

Professioni: Chiropratica, Fisioterapia, Medicina, Naprapatia, Naturopatia, Osteopatia

Esperti: ricercatori, clinici terapie manuali e manipolative, pazienti, medici, studenti terapie manuali e manipolative, rappresentanti di organismi di regolamentazione professionale, rappresentanti di assicurazioni, avvocati o giudici, analisti di dati, informatici, responsabili di cartelle cliniche elettroniche

215 partecipanti: 1 rappresentante per ogni ambito di esperienza, 1 rappresentante per continente



Open access Protocol

BMJ Open

Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study

Martha Funabashi [1,2] Katherine A Pohlman [3] Lindsay M Gorrell [4] Stacie A Salsbury [5] Andrea Bergna [6] Nicola R Heneghan [7]

To cite: Funabashi M, Pohlman KA, Gorrell LM, *et al*. Expert consensus on a standardised definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilisation: protocol for an international e-Delphi study. *BMJ Open* 2021;**11**:e050219. doi:10.1136/bmjopen-2021-050219

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ABSTRACT

Introduction Spinal and peripheral joint manipulation (SMT) and mobilisation (MOB) are widely used and recommended in the best practice guidelines for managing musculoskeletal conditions. Although adverse events (AEs) have been reported following these interventions, a clear definition and classification system for AEs remains unsettled. With many professionals using SMT and MOB, establishing consensus on a definition and classification system is needed to assist with the assimilation of AEs data across professions and to inform research priorities to optimise safety in clinical practice.

Methods and analysis This international multidisciplinary electronic Delphi study protocol is informed by a scoping review and in accordance with the 'Guidance on Conduction and Reporting Delphi Studies'. With oversight from an expert steering committee, the study comprises three rounds using online questionnaires. Experts in manual therapy and patient safety meeting strict eligibility criteria from the following fields will be invited to participate: clinical, medical and legal practice, health records, regulatory bodies, researchers and patients. Round 1 will include open-ended questions on participants' working definition and/or understanding of AEs following SMT and MOB and their severity classification. In round 2, participants will rate their level of agreement with statements generated from round 1 and our scoping review. In round 3, participants will rerate their agreement with statements achieving consensus in round 2. Statements reaching consensus must meet the a priori criteria, as determined by descriptive analysis. Inferential statistics will be used to evaluate agreement between participants and stability of responses between rounds. Statements achieving consensus in round 3 will provide an expert-derived definition and classification system for AEs following SMT and MOB.

Ethics and dissemination This study was approved by the Canadian Memorial Chiropractic College Research Ethics Board and deemed exempt by Parker University's Institutional Review Board. Results will be disseminated through scientific, professional and educational reports, publications and presentations.

Strengths and limitations of this study

- This study protocol is based on a formal scoping review of the literature and the published 'Guidance on Conducting and REporting DElphi Studies (CREDES)'.
- Researchers will represent all professional groups who perform spinal and peripheral joint manipulation and mobilisation as part of routine clinical practice.
- Participants will involve international and multidisciplinary spinal and peripheral joint manipulation and mobilisation stakeholder representatives.
- Definitions and a priori criteria for consensus, agreement and stability are detailed.
- Findings will be specific to spinal and peripheral joint manipulation and mobilisation, limiting the external validity to other manual therapy techniques.

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Spinal and peripheral joint manipulation and mobilisation are interventions commonly used in the management of many musculoskeletal conditions, including spinal pain, and are most often administered in ambulatory care settings.[1 2] These interventions, which are described in many ways, include among others, high-velocity low-amplitude manipulation, low-velocity variable-amplitude mobilisation, spinal manipulative therapy, musculoskeletal manipulation, osteopathic manipulative treatment, Maitland mobilisation grades, and so on. While both interventions are applied to spinal or peripheral joints, an important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust, whereas mobilisation consists of the application of a cyclic low-velocity and variable

Consenso di esperti

- Recruitment (8 weeks)
- Development round 1 questionnaire

← Reviewed by Steering Committee

Round 1 (6 weeks)
- Demographic information
- Open-ended questions on adverse event definition and severity classification

Reclutamento >> n=215

Round 1 >> n=180 (83,72%)

- Round 1 data analysis (two independent reviewers)
- Development of round 2 statements based on round 1 responses and results from scoping literature review

← Reviewed by Steering Committee

Round 2 (6 weeks)
- Feedback from round 1
- Statements of adverse events definitions and severity classification following spinal/joint manipulation and mobilization

Round 2 >> n=163 (75,81%)

- Round 2 data analysis (two independent reviewers)
- Round 2 statements not achieving consensus removed
- Development of round 3 statements based on round 2 responses

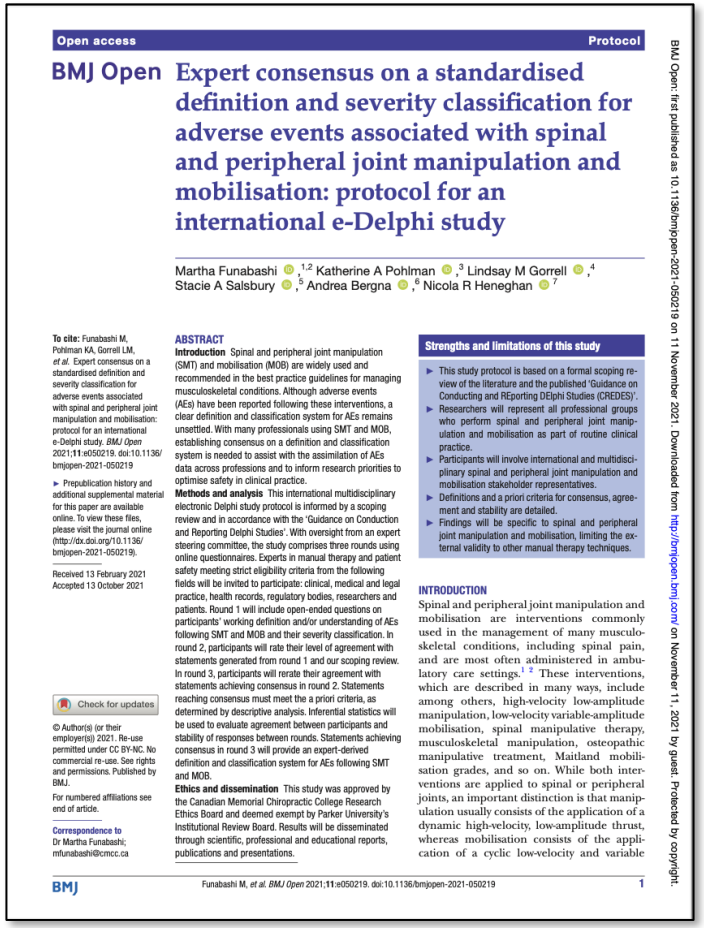
← Reviewed by Steering Committee

Round 3 (6 weeks)
- Feedback from round 2
- Statements of adverse events definitions and severity classification following spinal/joint manipulation and mobilization

Round 3 >> n=? (?%)

- Round 3 data analysis (two independent reviewers)
- Round 3 statements not achieving consensus removed

← Reviewed by Steering Committee



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ABSTRACT

Introduction Spinal and peripheral joint manipulation (SMT) and mobilisation (MOB) are widely used and recommended in the best practice guidelines for managing musculoskeletal conditions. Although adverse events (AEs) have been reported following these interventions, a clear definition and classification system for AEs remains unsettled. With many professionals using SMT and MOB, establishing consensus on a definition and classification system is needed to assist with the assimilation of AEs data across professions and to inform research priorities to optimise safety in clinical practice.

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BMJ Funabashi M, *et al*. *BMJ Open* 2021;**11**:e050219. doi:10.1136/bmjopen-2021-050219 1

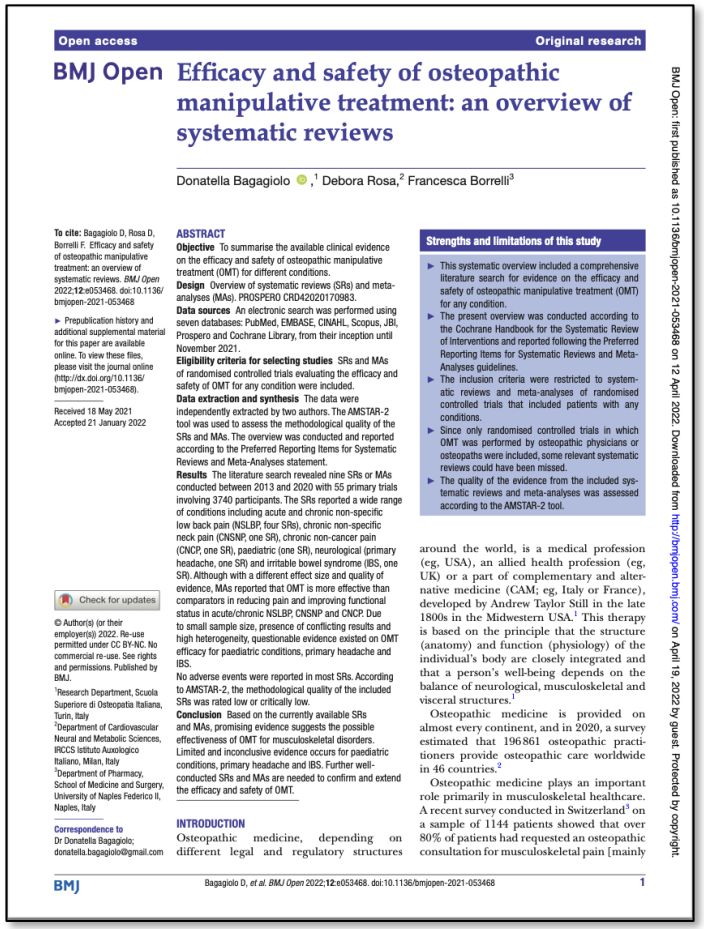
>> Standardizzazione

Standardizzazione in osteopatia

Eventi avversi

Dopo il trattamento manipolativo osteopatico non si sono verificati eventi gravi con disturbi muscoloscheletrici, neurologici, viscerali o pediatrici.

Solo due delle sette revisioni sistematiche incluse hanno riportato la definizione utilizzata per misurare gli eventi avversi. L'idea che le terapie manuali siano sicure può essere dimostrata solo se gli eventi avversi vengono definiti e valutati in ogni studio clinico. In particolare, gli autori dovrebbero riportare in modo adeguato e dettagliato l'approccio utilizzato per misurare gli eventi avversi, che devono essere definiti utilizzando una tassonomia appropriata.



Open access Original research

BMJ Open

Efficacy and safety of osteopathic manipulative treatment: an overview of systematic reviews

Donatella Bagagiolo ,[1] Debora Rosa,[2] Francesca Borrelli[3]

To cite: Bagagiolo D, Rosa D, Borrelli F. Efficacy and safety of osteopathic manipulative treatment: an overview of systematic reviews. *BMJ Open* 2022;**12**:e053468. doi:10.1136/bmjopen-2021-053468

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ABSTRACT

Objective To summarise the available clinical evidence on the efficacy and safety of osteopathic manipulative treatment (OMT) for different conditions.

Design Overview of systematic reviews (SRs) and meta-analyses (MAs). PROSPERO CRD42020170983.

Data sources An electronic search was performed using seven databases: PubMed, EMBASE, CINAHL, Scopus, JBI, Prospero and Cochrane Library, from their inception until November 2021.

Eligibility criteria for selecting studies SRs and MAs of randomised controlled trials evaluating the efficacy and safety of OMT for any condition were included.

Data extraction and synthesis The data were independently extracted by two authors. The AMSTAR-2 tool was used to assess the methodological quality of the SRs and MAs. The overview was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.

Results The literature search revealed nine SRs or MAs conducted between 2013 and 2020 with 55 primary trials involving 3740 participants. The SRs reported a wide range of conditions including acute and chronic non-specific low back pain (NSLBP, four SRs), chronic non-specific neck pain (CNSNP, one SR), chronic non-cancer pain (CNCP, one SR), paediatric (one SR), neurological (primary headache, one SR) and irritable bowel syndrome (IBS, one SR). Although with a different effect size and quality of evidence, MAs reported that OMT is more effective than comparators in reducing pain and improving functional status in acute/chronic NSLBP, CNSNP and CNCP. Due to small sample size, presence of conflicting results and high heterogeneity, questionable evidence existed on OMT efficacy for paediatric conditions, primary headache and IBS.

No adverse events were reported in most SRs. According to AMSTAR-2, the methodological quality of the included SRs was rated low or critically low.

Conclusion Based on the currently available SRs and MAs, promising evidence suggests the possible effectiveness of OMT for musculoskeletal disorders. Limited and inconclusive evidence occurs for paediatric conditions, primary headache and IBS. Further well-conducted SRs and MAs are needed to confirm and extend the efficacy and safety of OMT.

Strengths and limitations of this study

- This systematic overview included a comprehensive literature search for evidence on the efficacy and safety of osteopathic manipulative treatment (OMT) for any condition.
- The present overview was conducted according to the Cochrane Handbook for the Systematic Review of Interventions and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.
- The inclusion criteria were restricted to systematic reviews and meta-analyses of randomised controlled trials that included patients with any conditions.
- Since only randomised controlled trials in which OMT was performed by osteopathic physicians or osteopaths were included, some relevant systematic reviews could have been missed.
- The quality of the evidence from the included systematic reviews and meta-analyses was assessed according to the AMSTAR-2 tool.

INTRODUCTION

Osteopathic medicine, depending on different legal and regulatory structures around the world, is a medical profession (eg, USA), an allied health profession (eg, UK) or a part of complementary and alternative medicine (CAM; eg, Italy or France), developed by Andrew Taylor Still in the late 1800s in the Midwestern USA.[1] This therapy is based on the principle that the structure (anatomy) and function (physiology) of the individual's body are closely integrated and that a person's well-being depends on the balance of neurological, musculoskeletal and visceral structures.[1]

Osteopathic medicine is provided on almost every continent, and in 2020, a survey estimated that 196 861 osteopathic practitioners provide osteopathic care worldwide in 46 countries.[2]

Osteopathic medicine plays an important role primarily in musculoskeletal healthcare. A recent survey conducted in Switzerland[3] on a sample of 1144 patients showed that over 80% of patients had requested an osteopathic consultation for musculoskeletal pain [mainly

Standardizzazione negli studi

Eventi avversi

CONSORT

Standard consolidati di rendicontazione degli studi

Estensione per la segnalazione degli esiti dei danni o degli effetti indesiderati

Table 2. **Checklist of Items To Include When Reporting Harms in Randomized, Controlled Trials***

Standard CONSORT Checklist: Paper Section and Topic	Standard CONSORT Checklist: Item Number	Descriptor	Reported on Page Number
Title and abstract	1	If the study collected data on harms and benefits, the title or abstract should so state.	
Introduction			
Background	2	If the trial addresses both harms and benefits, the introduction should so state.	
Methods			
Participants	3		
Interventions	4		
Objectives	5		
Outcomes	6	List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardized and validated definitions, and description of new definitions). Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent).	
Sample size	7		
Randomization			
Sequence generation	8		
Allocation concealment	9		
Implementation	10		
Blinding (masking)	11		
Statistical methods	12	Describe plans for presenting and analyzing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures, and any statistical analyses).	
Results			
Participant flow	13	Describe for each arm the participant withdrawals that are due to harms and their experiences with the allocated treatment.	
Recruitment	14		
Baseline data	15		
Numbers analyzed	16	Provide the denominators for analyses on harms.	
Outcomes and estimation	17	Present the absolute risk per arm and per adverse event type, grade, and seriousness, and present appropriate metrics for recurrent events, continuous variables, and scale variables, whenever pertinent.†	
Ancillary analyses	18	Describe any subgroup analyses and exploratory analyses for harms.†	
Adverse events	19		
Discussion			
Interpretation	20	Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalizability, and other sources of information on harms.‡	
Generalizability	21		
Overall evidence	22		

* This proposed extension for harms includes 10 recommendations that correspond to the original CONSORT checklist.
† Descriptors refer to items 17, 18, and 19.
‡ Descriptor refers to items 20, 21, and 22.

7° CONGRESSO NAZIONALE ROI
NAPOLI

ROI REGISTRO DEGLI OSTEOPATI D'ITALIA

Standardizzazione in osteopatia

Valutazione osteopatica

Conferenza di consenso per lavorare alla coerenza, alla plausibilità, alla generalizzabilità, alla rilevanza e all'applicabilità prevista della **disfunzione somatica.**

healthcare MDPI

Review

International Overview of Somatic Dysfunction Assessment and Treatment in Osteopathic Research: A Scoping Review

Marco Tramontano [1,*], Federica Tamburella [1], Fulvio Dal Farra [2], Andrea Bergna [2,3], Christian Lunghi [4], Mattia Innocenti [5], Fabio Cavera [5], Federica Savini [5], Vincenzo Manzo [5] and Giandomenico D'Alessandro [4,5]

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Abstract: Background: Osteopathic manipulative treatment (OMT) is a patient-centred, whole-body intervention aimed at enhance the person's self-regulation. OMT interventions are focused on somatic dysfunctions (SD) that can be defined as an altered regulative function associated with inflammatory signs palpable in the body framework in different body regions. The conceptual model that sustains SD, as well as its usefulness for the osteopathic profession, is still being discussed by the osteopathic community. Understanding the role and the application of SD is the aim of this scoping review. Methods: A literature search was carried out through the main biomedical databases: Pubmed (Medline), Cochrane, Central (Cochrane), Embase, PEDro and Scopus. Grey literature was considered via Google Scholar and the Osteopathic Research Web. The review was prepared by referring to the "Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews" (PRISMA-ScR). Results: A total of 37,279 records were identified through database searching and other sources. After the duplicates were removed, 27,023 titles and abstracts were screened. A total of 1495 full-text articles were assessed for eligibility. The qualitative synthesis included 280 studies. Conclusions: Treating SD is an important part of osteopathic practice that varies from country to country. SD should be considered as a clinical value that assists in the clinical assessment and guides the decision-making process of osteopathic practitioners. Further studies should be designed to better understand why and how to choose the different assessment and intervention modalities to approach SD and to evaluate new osteopathic models.

Keywords: osteopathic manipulative treatment; somatic dysfunction; manual therapy; osteopathic techniques

check for updates

Citation: Tramontano, M.; Tamburella, F.; Dal Farra, F.; Bergna, A.; Lunghi, C.; Innocenti, M.; Cavera, F.; Savini, F.; Manzo, V.; D'Alessandro, G. International Overview of Somatic Dysfunction Assessment and Treatment in Osteopathic Research: A Scoping Review. *Healthcare* **2022**, *10*, 28. https://doi.org/10.3390/healthcare10010028

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1. Introduction

Osteopathic manipulative treatment (OMT) is a patient-centred, whole-body intervention. It is aimed at enhancing the person's self-regulation and favor the structure-function-environment relationship by applying five models as a guide for the osteopathic approach to diagnosis and treatment [1,2]. Osteopathy is recognised and regulated differently throughout the world [3]. In fact, in the USA there is an ongoing process to establish osteopathic principles to fulfill osteopathic recognition standards [4]; many countries, for example, Italy [5], are struggling to spread a shared benchmark for standardized core curriculum and core competence. In many European countries, efforts are being made to have osteopathy confirmed as a healthcare profession by identifying distinctive osteopathic competencies and producing evidence. As recently reported in a bibliometric analysis,

7° CONGRESSO NAZIONALE ROI NAPOLI

ROI REGISTRO DEGLI OSTEOPATI D'ITALIA

Standardizzazione in osteopatia

Trattamento manipolativo osteopatico

L'estrema variabilità dei protocolli degli studi inclusi rende impossibile, di fatto, ogni tipo di generalizzazione. La variabilità è stata osservata nei diversi approcci manipolativi, anche all'interno della stessa tipologia di intervento: dosaggio, durata delle sedute, durata del periodo "in care", trattamenti semi- o non standardizzati, scelta delle tecniche, grado e livelli di esperienza degli operatori.

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journal homepage: www.elsevier.com/locate/ctim

Effectiveness of osteopathic interventions in chronic non-specific low back pain: A systematic review and meta-analysis

Fulvio Dal Farra [a,*], Roberta Giulia Risio [a], Luca Vismara [a,b,c], Andrea Bergna [a]

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[b] Division of Neurology and Neurorehabilitation, IRCCS Institute Auxologico Italiano 28824, Piancavallo-Verbania, Italy
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ARTICLE INFO

Keywords:
Chronic low back pain
Osteopathic manipulative treatment
Manipulation
Myofascial release
Systematic review

ABSTRACT

Background: Chronic low back pain (CLBP) is a frequent cause of disability and it represents a medical, social and economic burden globally. Therefore, we assessed effectiveness of osteopathic interventions in the management of NS-CLBP for pain and functional status.
Methods: A systematic review and meta-analysis were conducted. Findings were reported following the PRISMA statement. Six databases were searched for RCTs. Studies were independently assessed using a standardized form. Each article was assessed using the Cochrane risk of bias (RoB) tool. Effect size (ES) were calculated at post-treatment and at 12 weeks' follow up. We used GRADE to assess quality of evidence.
Results: 10 articles were included. Studies investigated osteopathic manipulative treatment (OMT, n = 6), myofascial release (MFR, n = 2), craniosacral treatment (CST, n = 1) and osteopathic visceral manipulation (OVM, n = 1). None of the study was completely judged at low RoB. Osteopathy revealed to be more effective than control interventions in pain reduction (ES: -0.59; 95% CI: -0.81, -0.36; P < 0.00,001) and in improving functional status (ES: -0.42; 95% 95% CI: -0.68, -0.15; P = 0.002). Moderate-quality evidence suggested that MFR is more effective than control treatments in pain reduction (ES: -0.69; 95% CI: -1.05, -0.33; P = 0.0002), even at follow-up (ES: -0.73; 95% CI: -1.09, -0.37; P < 0.0001). Low-quality evidence suggested superiority of OMT in pain reduction (ES: -0.57; 95% CI: -0.90, -0.25; P = 0.001) and in changing functional status (ES: -0.34; 95% CI: -0.65, -0.03; P = 0.001). Very low-quality evidence suggested that MFR is more effective than control interventions in functional improvements (ES: -0.73; 95% CI: -1.25, -0.21; P = 0.006).
Conclusion: Results strengthen evidence that osteopathy is effective in pain levels and functional status improvements in NS-CLBP patients. MFR reported better level of evidence for pain reduction if compared to other interventions. Further high-quality RCTs, comparing different osteopathic modalities, are recommended to produce better-quality evidence.

1. Introduction

Low back pain (LBP) is one of the most common musculoskeletal health problem with the highest prevalence in the adult population; globally, it represents a relevant cause of medical, social and economic burden.[1,2] Non-specific chronic low back pain (NS-CLBP) is defined as lumbar pain persisting for longer than three months, in absence of a suspected pathology (red flag conditions such as e.g. tumor, infection or fracture). Patients typically report physical disabilities and psychological distress concurrently with the pain.[3] Prevalence varies from 4% to 20%, increasing linearly from the third decade until the 60 years of age and stabilizing in the seventh decade; it is more relevant in women (approximately 1,5:1).[4]

Since NS-CLBP pathophysiology remains partially unclear, several authors tried to explain it considering the problem as a result of interactions of biological, psychological, and social factors. [5] Central sensitization is considered one of the key-aspects in the NS-CLBP[6]; neuroimaging research showed how some brain areas, activated by nociception stimuli, can also be influenced by emotions and behaviors. This process could induce mood alterations, depression and maladaptive coping.[7] These findings probably explain the reason why pharmacological treatments (NSAIDs, steroids and opioids) are not particularly

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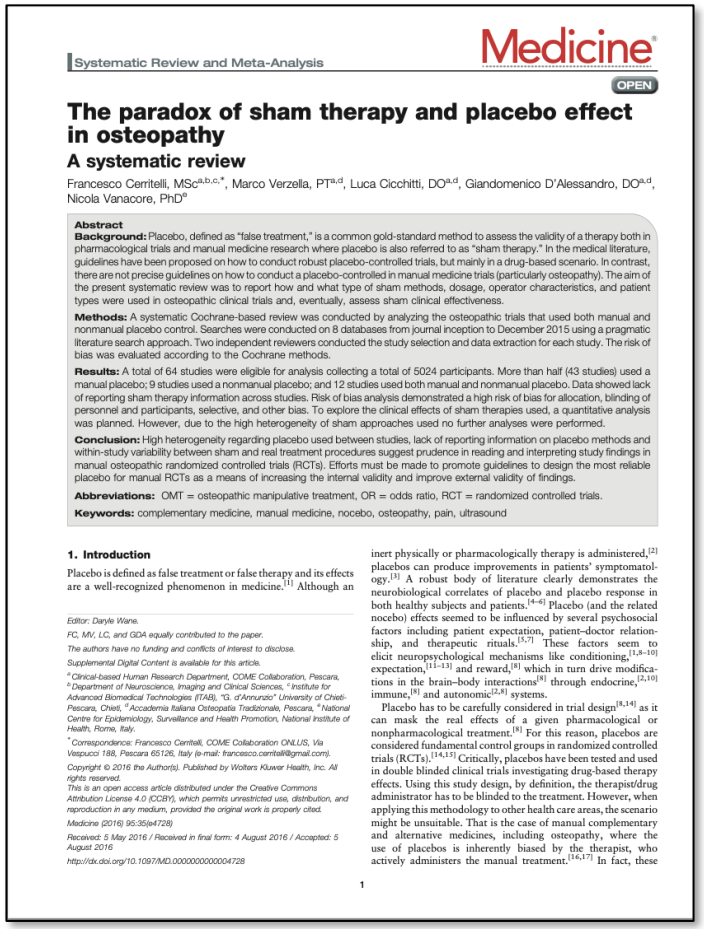
Available online 13 November 2020
0965-2299/

Standardizzazione in osteopatia

Trattamento sham

L'elevata eterogeneità tra gli studi suggerisce di impegnarsi per promuovere linee guida che consentano di progettare il placebo più affidabile per gli RCT nelle terapie manuali come mezzo per aumentare la validità interna e migliorare la validità esterna dei risultati.



Systematic Review and Meta-Analysis

Medicine

OPEN

The paradox of sham therapy and placebo effect in osteopathy

A systematic review

Francesco Cerritelli, MSc[a,b,c,*], Marco Verzella, PT[a,d], Luca Cicchitti, DO[a,d], Giandomenico D'Alessandro, DO[a,d], Nicola Vanacore, PhD[e]

Abstract

Background: Placebo, defined as "false treatment," is a common gold-standard method to assess the validity of a therapy both in pharmacological trials and manual medicine research where placebo is also referred to as "sham therapy." In the medical literature, guidelines have been proposed on how to conduct robust placebo-controlled trials, but mainly in a drug-based scenario. In contrast, there are not precise guidelines on how to conduct a placebo-controlled in manual medicine trials (particularly osteopathy). The aim of the present systematic review was to report how and what type of sham methods, dosage, operator characteristics, and patient types were used in osteopathic clinical trials and, eventually, assess sham clinical effectiveness.

Methods: A systematic Cochrane-based review was conducted by analyzing the osteopathic trials that used both manual and nonmanual placebo control. Searches were conducted on 8 databases from journal inception to December 2015 using a pragmatic literature search approach. Two independent reviewers conducted the study selection and data extraction for each study. The risk of bias was evaluated according to the Cochrane methods.

Results: A total of 64 studies were eligible for analysis collecting a total of 5024 participants. More than half (43 studies) used a manual placebo; 9 studies used a nonmanual placebo; and 12 studies used both manual and nonmanual placebo. Data showed lack of reporting sham therapy information across studies. Risk of bias analysis demonstrated a high risk of bias for allocation, blinding of personnel and participants, selective, and other bias. To explore the clinical effects of sham therapies used, a quantitative analysis was planned. However, due to the high heterogeneity of sham approaches used no further analyses were performed.

Conclusion: High heterogeneity regarding placebo used between studies, lack of reporting information on placebo methods and within-study variability between sham and real treatment procedures suggest prudence in reading and interpreting study findings in manual osteopathic randomized controlled trials (RCTs). Efforts must be made to promote guidelines to design the most reliable placebo for manual RCTs as a means of increasing the internal validity and improve external validity of findings.

Abbreviations: OMT = osteopathic manipulative treatment, OR = odds ratio, RCT = randomized controlled trials.

Keywords: complementary medicine, manual medicine, nocebo, osteopathy, pain, ultrasound

1. Introduction

Placebo is defined as false treatment or false therapy and its effects are a well-recognized phenomenon in medicine.[1] Although an inert physically or pharmacologically therapy is administered,[2] placebos can produce improvements in patients' symptomatology.[3] A robust body of literature clearly demonstrates the neurobiological correlates of placebo and placebo response in both healthy subjects and patients.[4–6] Placebo (and the related nocebo) effects seemed to be influenced by several psychosocial factors including patient expectation, patient–doctor relationship, and therapeutic rituals.[5,7] These factors seem to elicit neuropsychological mechanisms like conditioning,[1,8–10] expectation,[11–13] and reward,[8] which in turn drive modifications in the brain–body interactions[8] through endocrine,[2,10] immune,[8] and autonomic[2,8] systems.

Placebo has to be carefully considered in trial design[8,14] as it can mask the real effects of a given pharmacological or nonpharmacological treatment.[8] For this reason, placebos are considered fundamental control groups in randomized controlled trials (RCTs).[14,15] Critically, placebos have been tested and used in double blinded clinical trials investigating drug-based therapy effects. Using this study design, by definition, the therapist/drug administrator has to be blinded to the treatment. However, when applying this methodology to other health care areas, the scenario might be unsuitable. That is the case of manual complementary and alternative medicines, including osteopathy, where the use of placebos is inherently biased by the therapist, who actively administers the manual treatment.[16,17] In fact, these

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Standardizzazione in osteopatia

Ragionamento clinico osteopatico

Identità professionale

Modelli osteopatici di valutazione e trattamento

Pratica clinica osteopatica centrata sulla persona e la relativa complessità

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Models and theoretical frameworks for osteopathic care – A critical view and call for updates and research

A health profession often owns its identity by the originality and relevance of therapeutic models it defends [1]. Historically, part of the success of osteopathic care among patients may be explained by the innovative approaches that emerged in the first 100 years of its existence. During this time, osteopathic models and principles defended concepts that were to become central across health disciplines in the 21st century. In Western medicine, osteopathy was indeed among the first medical disciplines to emphasise the importance of person-centred care [2]. Notwithstanding this pioneering role in person-centred care, inherited from traditional medicine principles [3], some of the profession's conceptual bases are no longer regarded as unique but have progressively been incorporated in the entire medical field, especially in general medicine, and are now widely recommended as best practice. In fact, in the specific case of musculoskeletal care, Caneiro and colleagues [4] have recently argued that it is time to move beyond 'body region silos' to manage musculoskeletal pain, and fully embrace a person-centred active approach to treating musculoskeletal pain and disability with a critical thinking approach. Thus, what osteopaths have traditionally claimed to be their unique selling points, are now regarded as mainstream healthcare according to the scientific evidence available.

Despite the claimed person-centredness of osteopathic care, clinicians have traditionally mainly focused on a biomedical model of care [5]. Central to this traditional approach to osteopathic evaluation and treatment, and still adopted by many practitioners, is the diagnosis of somatic dysfunction [6]. For those who still consider somatic dysfunction as a relevant clinical entity, the concept focuses on ways to detect and resolve objective structural signs at the origin of the patient's symptoms, function and general health and is typically treated using manipulative procedures [6,7]. The conceptual basis of somatic dysfunction implies the reliance on a simple cause-effect model of osteopathic care. Whilst causality is clinically attractive, human behaviour is inherently complex and influenced by an array of factors at many different levels; therefore, establishing clinical causality in complexity is either extremely difficult or impossible to achieve [8]. Although clinical phenomena associated with somatic dysfunction may be biologically plausible, the concept fails to integrate social and psychological aspects, and the relationship between somatic dysfunction and health status has not been established [9]. Moreover, the concept reflects outdated theories from the early 20th century that reinforces the belief in a structural cause of pain [6]. Faced with these ongoing challenges, research in the field of osteopathy has recently started to investigate the importance of other aspects of care such as practitioner-person interactions [10], affective touch [11], interoception [12,13], contextualisation [14,15] and placebo [16].

Scholars and academics from the field are now openly expressing their difficulties in understanding, explaining, defending, and justifying central models of osteopathic care [6,17–21]. We would argue that incoherence within models, lack of theoretical and empirical support, oversimplification, pseudoscience, and absence of consensus over the validity of the profession's conceptual framework are some of the challenges osteopathic education and research are facing.

There is an overall scientific consensus on the importance of having a robust theoretical framework for complex health interventions such as osteopathic care [22]. Traditional or innovative theoretical models are more likely to be accepted and implemented if they provide guidance on the process of care, clearly frame their intent and level of application, are logically plausible and consistent, are backed up by a rational documented understanding of the change process including causal relationships among the constructs, are testable, are supported by empirical observations, show good explanatory power, and are generalisable to different settings and subpopulations [23]. Unfortunately, in osteopathic education, taught models largely depend on tradition and political priorities rather than scientific standards. An example of this is the "Five osteopathic models" of care agreed upon by policymakers during the elaboration of the WHO report [24]. The model sets five alternative views through which a patient's musculoskeletal condition can be evaluated, understood and treated; the biomedical-structural model, the respiratory-circulatory model, the metabolic-nutritional model, the neurological model, and the behavioural-psychosocial model. The overall model does not provide any testable components of any underlying theory. It does not, therefore, meet expected standards for a theoretical model on many points [20] and is largely insufficient to justify the profession's identity in higher education programmes [25,26]. The "Five osteopathic models" approach has nevertheless been broadly adopted nationally and institutionally by many countries and training institutions, arguably without the required level of critical analysis [7,27]. Robust assessment, revision, and consensus of theoretical models in osteopathy are still lacking and require clearer views on what to expect from theoretical models (Table 1).

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Eventi avversi

Rischi trattamento manipolativo cervicale

Alta probabilità di associazione tra la terapia manipolativa della colonna vertebrale cervicale e le relative complicanze (dissecazione arteria vertebrale).

Anamnesi, esame fisico e tecniche diagnostiche adeguate.

Valutare le comorbidità, la terapia in corso, identificare le red flags ed eventuali controindicazioni.

Diagnosi differenziale bilanciando sempre l'efficacia terapeutica con i rischi potenziali.

Informare il paziente sull'associazione tra manipolazione cervicale ed eventi avversi, insieme all'acquisizione del consenso informato, dovrebbe diventare una prassi comune prima di eseguire la manipolazione.

diagnostics

MDPI

Systematic Review

Cervical Spine Manipulations: Role of Diagnostic Procedures, Effectiveness, and Safety from a Rehabilitation and Forensic Medicine Perspective: A Systematic Review

Andrea Bernetti [1,2], Raffaele La Russa [3], Alessandro de Sire [2,4,*], Francesco Agostini [1], Stefania De Simone [3], Giacomo Farì [5], Giorgia Viola Lacasella [6], Gabriele Santilli [7], Stefania De Trane [8], Michele Karaboue [3], Pierangela Ruiu [1], Massimiliano Mangone [1], Massimiliano Leigheb [9], Valter Santilli [1] and Pietro Fiore [2,3,8]

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Abstract: Background: Cervical spine manipulations (CSM) have been performed for centuries and are a widely practiced intervention to manage cervical spine musculoskeletal disorders. We aimed to perform an overview of the literature concerning the effects and the adverse events of CSM in the Physical and Rehabilitation Medicine (PRM) field with a forensic medicine perspective. Methods: A search in the scientific literature (PubMed, Google Scholar, PEDro and Cochrane) was carried out from inception until October 2020. Results: Fourteen articles were included in this narrative summary. The possible development of side effects requires a careful mandatory balance of benefits and risks even when there is an indication for this approach. Moreover, a qualified professional is essential to perform CSM–a non-invasive therapeutic procedure that can be potentially harmful. Conclusions: In conclusion, it is essential to perform the diagnosis, to treat, and to manage complications within the PRM field, both for the reduction of malpractice claims and, most importantly, for the safety of the patient.

Keywords: cervical spine manipulations; manipulative therapy; cervical artery dissection; spine; side effects; rehabilitation; forensic medicine

1. Introduction

According to the World Health Organization, spinal manipulative therapy "includes all procedures where the hands or mechanical devices are used to mobilize, adjust, manipulate, apply traction, massage, stimulate, or otherwise influence the spine and paraspinal tissues with the aim of influencing the patient's health" [1].

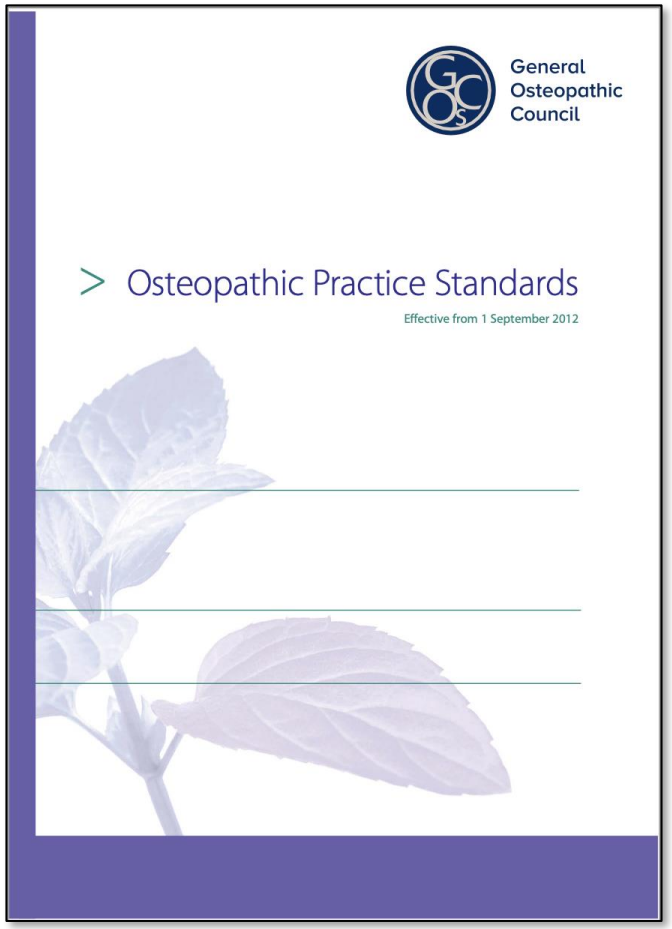
Comunicazione e accordo con il paziente

Consenso informato

Il paziente deve comprendere la natura, lo scopo e i rischi dell'esame o del trattamento proposto.

Il paziente deve quindi essere libero di accettare o rifiutare l'esame o il trattamento proposto.

GOC 2012, Vogel S 2012, Leach J 2011



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