

Giornata Precongressuale

21-22-23 GIUGNO 2024 - ROMA

9° Congresso Nazionale ROI

150
ANNI DI
OSTEOPATIA

Nuova professione sanitaria

ERGIFE PALACE

La Completezza del Reporting è Carente nei Trial Clinici Randomizzati Controllati in Ambito Osteopatico: uno studio di Meta-Ricerca con "Call to Action" per la Ricerca Futura in Osteopatia

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Meta-research: Why research on research matters

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Abstract

Meta-research is the study of research itself: its methods, reporting, reproducibility, evaluation, and incentives. Given that science is the key driver of human progress, improving the efficiency of scientific investigation and yielding more credible and more useful research results can translate to major benefits. The research enterprise grows very fast. Both new opportunities for knowledge and innovation and new threats to validity and scientific integrity emerge. Old biases abound, and new ones continuously appear as novel disciplines emerge with different standards and challenges. Meta-research uses an interdisciplinary approach to study, promote, and defend robust science. Major disruptions are likely to happen in the way we pursue scientific investigation, and it is important to ensure that these disruptions are evidence based.

- *Reporting*
- *Riproducibilità*
- *Metodi*
- *Incentivi*



Cosa si intende per Reporting?

- Generalizzabilità?
- Risultati applicabili?

Recovery From Chronic Low Back Pain After Osteopathic Manipulative Treatment: A Randomized Controlled Trial

John C. Licciardone, DO, MS, MBA

Robert J. Gatchel, PhD, ABPP

Subhash Aryal, PhD

Obbiettivo di un report? **Comunicare** design, metodi, risultati...

Innocenti T, Giagio S, Salvioli S, Feller D, Minnucci S, Brindisino F, IJzelenberg W, Ostelo R, Chiarotto A. Completeness of Reporting Is Suboptimal in Randomized Controlled Trials Published in Rehabilitation Journals, With Trials With Low Risk of Bias Displaying Better Reporting: A Meta-research Study.



Come possono gli **autori di RCT** riportare in modo ottimale le informazioni nei loro articoli?





CONSORT checklist

Ogni item è stato descritto come:

- 0: incompleto o mancante
- 1: ben descritto
- 2: non applicabile

		CONSORT Items
<u>Title and abstract</u>		
	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
<u>Introduction</u>		
<u>Background and objectives</u>		
	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
<u>Methods</u>		
<u>Trial design</u>		
	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
<u>Participants</u>		
	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
<u>Interventions</u>		
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
<u>Outcomes</u>		
	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed

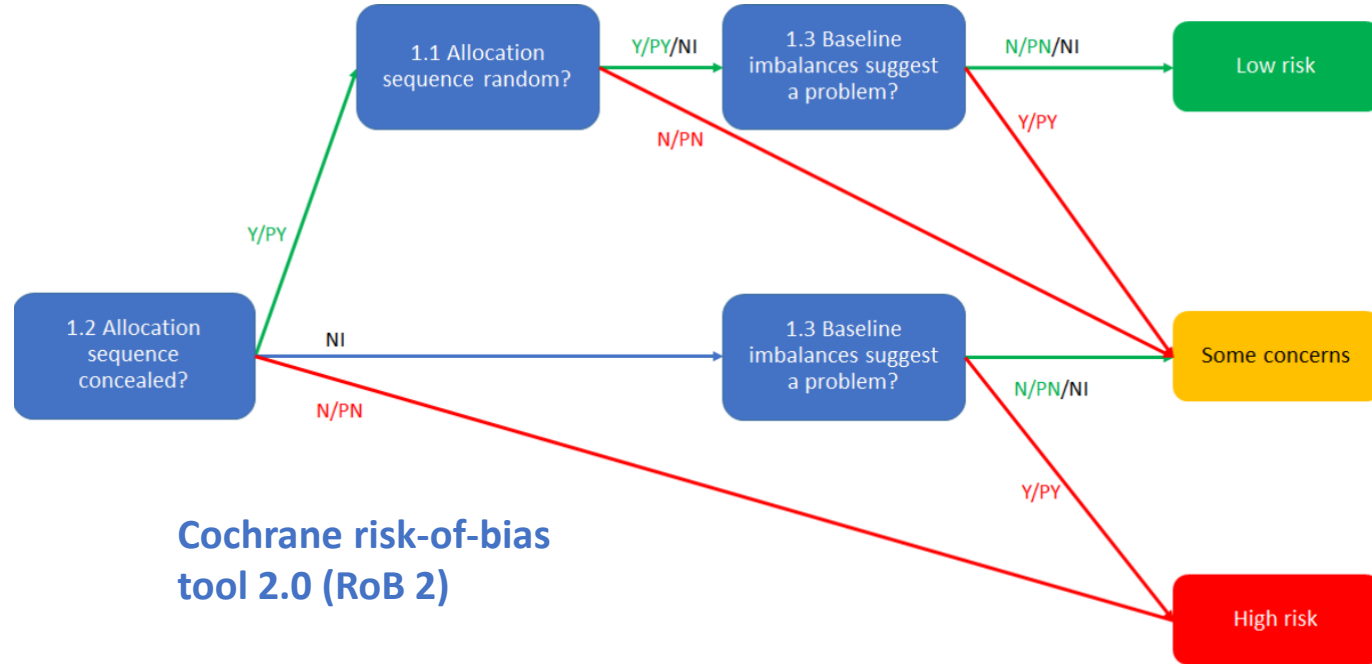


Risk of Bias

5 Domini

Livelli RoB:

- **Alto**
- **Qualche dubbio**
- **Basso**



Cochrane risk-of-bias
tool 2.0 (RoB 2)

Algorithm for suggested judgement of risk of bias arising from the randomization process



Valutazione critica

Difficile da giudicare

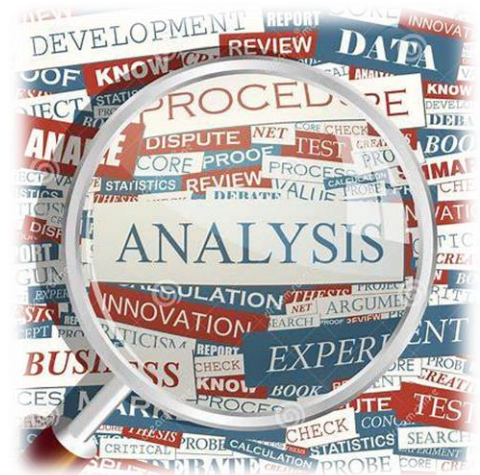
- **Validità interna** → Valutazione RoB
- *Rilevanza clinica*
- *Validità esterna*
- *Consistenza*

potrebbe
influenzare

Report incompleto

☰ *Studi difficili da utilizzare ai fini decisionali*
Linee guida cliniche?

Innocenti T, Giagio S, Salvioli S, Feller D, Minnucci S, Brindisino F, Izzelenberg W, Ostelo R, Chiarotto A. Completeness of Reporting Is Suboptimal in Randomized Controlled Trials Published in Rehabilitation Journals, With Trials With Low Risk of Bias Displaying Better Reporting: A Meta-research Study.





Obiettivi

Primario

- Completezza delle informazioni riportate in RCT Osteopatici

e la possibile
relazione con il

→ ROB

Secondario

- Completezza delle informazioni riportate in RCT Osteopatici

Altre caratteristiche di studi e riviste:

- Anno di pubblicazione
- Registrazione del protocollo
- Quartile
- Opzioni di pubblicazione



Metodi

Criteri di inclusione

- RCT pubblicati in campo Osteopatico
- Design a gruppi paralleli
- 2011-2023

Criteri di esclusione

- Quasi o non-RCT

Osteopathic Manual Treatment and Ultrasound Therapy for Chronic Low Back Pain: A Randomized Controlled Trial

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Conflicts of interest: authors report none.

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ABSTRACT

PURPOSE We studied the efficacy of osteopathic manual treatment (OMT) and ultrasound therapy (UST) for chronic low back pain.

METHODS A randomized, double-blind, sham-controlled, 2 × 2 factorial design was used to study OMT and UST for short-term relief of nonspecific chronic low back pain. The 455 patients were randomized to OMT (n = 230) or sham OMT (n = 225) main effects groups, and to UST (n = 233) or sham UST (n = 222) main effects groups. Six treatment sessions were provided over 8 weeks. Intention-to-treat analysis was performed to measure moderate and substantial improvements in low back pain at week 12 (30% or greater and 50% or greater pain reductions from baseline, respectively). Five secondary outcomes, safety, and treatment adherence were also assessed.

RESULTS There was no statistical interaction between OMT and UST. Patients receiving OMT were more likely than patients receiving sham OMT to achieve moderate (response ratio [RR] = 1.38; 95% CI, 1.16-1.64; P < .001) and substantial (RR = 1.41, 95% CI, 1.13-1.76; P = .002) improvements in low back pain at week 12. These improvements met the Cochrane Back Review Group criterion for a medium effect size. Back-specific functioning, general health, work disability specific to low back pain, safety outcomes, and treatment adherence did not differ between patients receiving OMT and sham OMT. Nevertheless, patients in the OMT group were more likely to be very satisfied with their back care throughout the study (P < .001). Patients receiving OMT used prescription drugs for low back pain less frequently during the 12 weeks than did patients in the sham OMT group (use ratio = 0.66, 95% CI, 0.43-1.00; P = .048). Ultrasound therapy was not efficacious.

CONCLUSIONS The OMT regimen met or exceeded the Cochrane Back Review Group criterion for a medium effect size in relieving chronic low back pain. It was safe, parsimonious, and well accepted by patients.

Ann Fam Med 2013;11:122-129. doi:10.1370/afm.1468.

INTRODUCTION

Low back pain is primarily responsible for more than 20 million ambulatory medical care visits¹ and \$100 billion in costs² annually in the United States. When low back pain persists for 3 months, it is considered chronic and may cause progressive physical and psychological effects.³ Although practice guidelines recommend considering spinal manipulation for chronic or persistent low back pain,^{4,5} a Cochrane Collaboration review concluded that spinal manipulation is not more effective than sham interventions for short-term relief of chronic low back pain.⁶ The effectiveness of spinal manipulation remains controversial among family physicians.⁷ Osteopathic manual treatment (OMT) is delivered by osteopathic physicians in the United States, and by osteopaths in many other nations. No trial of



Processo di selezione degli studi

1. La ricerca è stata effettuata su *Pubmed, Embase, Cinahl, Cochrane*
 2. Screening di *Titolo e Abstract* degli articoli trovati (due revisori indipendenti in cieco)
 3. Trovati **131** articoli che soddisfavano i criteri di inclusione
 4. Valutazione del *reporting* e del *ROB*
-



Analisi dei dati

Analisi primaria:

- Aderenza % alla CONSORT
- Relazione tra reporting e ROB

$\frac{\text{Item descritti}}{\text{Item applicabili}} \%$

Analisi descrittiva

- Multivariata a regressione lineare tra aderenza CONSORT e singoli domini ROB
- Coefficiente di Spearman tra aderenza CONSORT e Overall RoB

Analisi secondaria:

- Aderenza % alla CONSORT

Altre caratteristiche di studi e riviste:

- Anno di pubblicazione
- Registrazione del protocollo
- Quartile
- Opzioni di pubblicazione

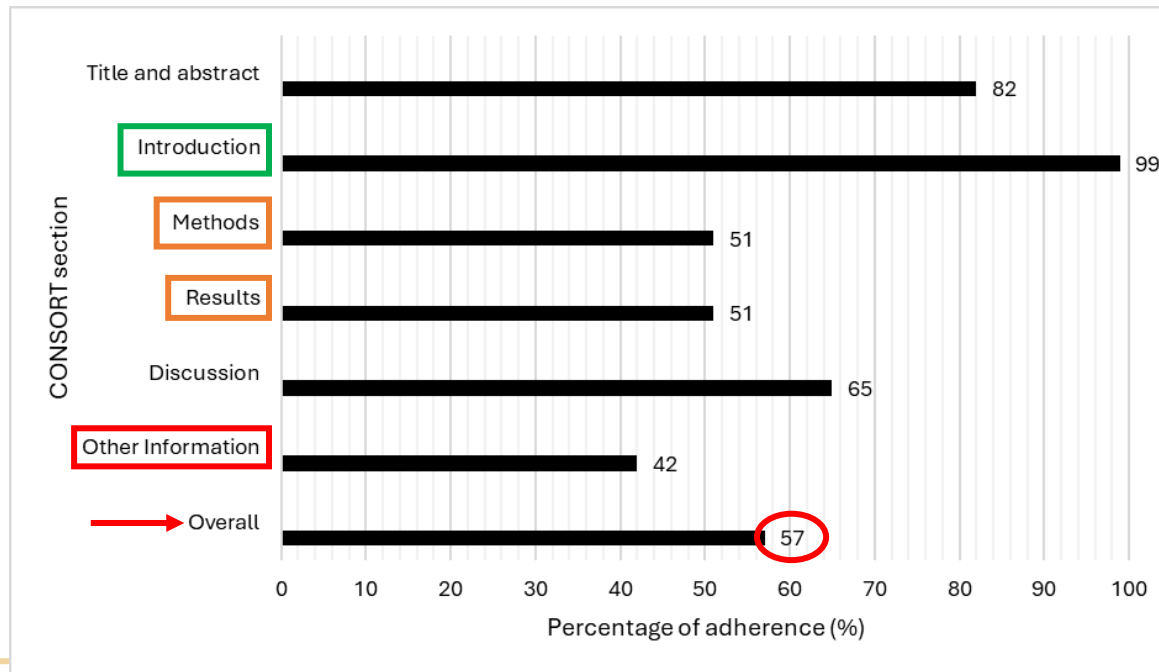
Multivariata a regressione lineare



Risultati

- 57% (18% to 97%)

- L'aderenza media varia tra item e sezioni





Risultati

Relazione tra aderenza alla CONSORT e singoli domini RoB

	<i>B</i>	<i>P</i>	<i>Lower</i>	<i>Upper</i>
* <i>D1</i>	12.368	<u><0.001</u>	8.901	15.835
* <i>D2</i>	7.218	<u>0.001</u>	2.848	11.589
* <i>D3</i>	4.007	<u>0.044</u>	0.117	7.898
<i>D4</i>	0.798	0.650	-2.671	4.266
* <i>D5</i>	10.836	<u><0.001</u>	7.267	14.405



Risultati

Coefficiente di correlazione di Spearman tra aderenza alla CONSORT e Overall RoB

Coefficiente di correlazione di Spearman (r_s)

$$r_s = 0.24327$$

Valore p

$$p \text{ (2-tailed)} = 0.00511$$

Correlazione positiva debole ma significativa tra aderenza complessiva degli studi alla **CONSORT** e overall **RoB**



Risultati

Relazione tra aderenza alla CONSORT e altre caratteristiche degli studi / riviste

	<i>B</i>	<i>P</i>	<i>Lower</i>	<i>Upper</i>
Anno di pubblicazione	0.169	0.605	-0.475	0.812
* Quartile	4.667	<u>0.001</u>	1.909	7.425
* Opzioni di pubblicazione	-6.402	<u>0.006</u>	-10.920	-1.884
* Registrazione protocollo	21.137	<u><0.001</u>	16.448	25.826



Call to Action

Panoramica della qualità della ricerca osteopatica alla nascita della nuova professione sanitaria

- Fisioterapia? 65%
- Gli **autori** di **RCT** dovrebbero **seguire** dettagliatamente la **CONSORT checklist**
- Le **riviste** dovrebbero **implementare diversi step** al fine di aumentare l'aderenza alle checklist
- **Intelligenza artificiale?**

Altman DG. Better reporting of randomized controlled trials: the CONSORT Statement. BMJ 1996;313:570-1.



Punti di forza

- **Metodologia** utilizzata
- **Cochrane risk-of-bias tool 2.0** ben strutturato e validato

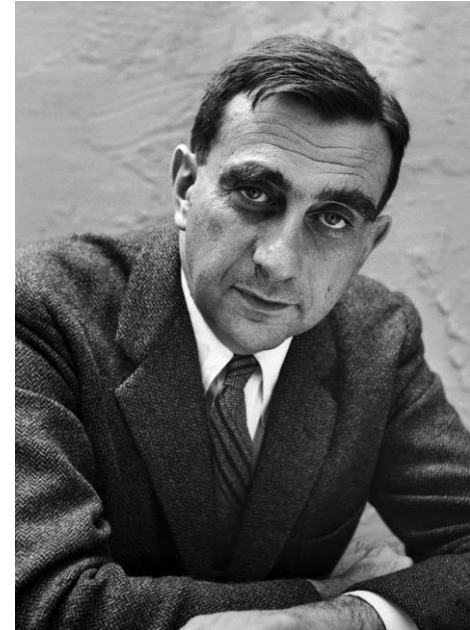
Limitazioni

- La **CONSORT** non è una griglia di valutazione per la qualità del reporting



"Il successo nella scienza arriva non con la ricerca della perfezione, ma con la continua correzione dei nostri errori."

- Edward Teller





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