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Manual therapies for pain relief in patients with headache: a systematic review

Terapias manuais no alívio da dor em pacientes com cefaleia: uma revisão sistemática

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RESUMO

Objetivo. O objetivo desta revisão sistemática foi avaliar a eficácia das terapias manuais no alívio da cefaleia. **Método**. Realizou-se uma busca sistemática nas bases de dados MEDLINE, LILACS, Cochrane, CINAHL, Scopus e Web of science por ensaios clínicos randomizados e quasi-randomizados, sem restrição linguística e de ano de publicação. Os descritores foram: 'Headache', 'Headache disorders', 'Musculoskeletal manipulations', além da palavra-chave 'Manual therapy' e seus equivalentes em português. Foram incluídos estudos comparando massagem, manipulação quiroprática, manipulação osteopática e outras manipulações da coluna a grupos sem intervenção, a outras modalidades fisioterapêuticas ou a um grupo sham. **Resultados**. Sete dos 567 artigos avaliados foram selecionados, incluindo pacientes com cefaleia do tipo tensional, cefaleia cervicogênica e migrânea. Não foi possível avaliar o tamanho do efeito do tratamento nos achados desta revisão. As principais limitações foram ausência de randomização e de sigilo de alocação adequados, falta de cegamento dos avaliadores e de análise por intenção de tratar e análise estatística inadequada. **Conclusão**. Não foi possível determinar o tamanho do efeito do tratamento devido à descrição seletiva dos desfechos nos resultados. Devido ao alto risco de viés dos artigos incluídos, as evidências disponíveis sobre a eficácia das terapias manuais no alívio da cefaleia são insuficientes.

Unitermos. Cefaleia, Transtornos da Cefaleia, Manipulações Musculoesqueléticas

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ABSTRACT

Objective. This systematic review aimed to assess the efficacy of manual therapies for headache relief. **Method**. A systematic search in MEDLINE, LILACS, Cochrane, CINAHL, Scopus and Web of Science databases was conducted for randomized and quasi-randomized trials, with no restrictions for language or year of publication. The descriptors were 'Headache', 'Headache disorders' and 'Musculoskeletal manipulations', in addition to the keyword 'Manual therapy' and its equivalents in Portuguese. We included studies that compared massage, chiropractic manipulation, osteopathic manipulation and other spinal manipulation to groups with no intervention, other physiotherapeutic modalities or to a sham group. **Results**. Seven of the 567 articles initially screened were selected, including patients with tension type headache, cervicogenic headache or migraine. It was not possible to assess the magnitude of the treatment effect on the findings of this review. The main limitations were the absence of randomization and adequate allocation concealment, the lack of blinded evaluators and intention-to-treat analysis and inadequate statistical analysis. **Conclusions**. We were unable to determine the size of the treatment effect due to the selective description of findings. Owing to the high risk of bias in the articles included, the available evidence regarding the efficacy of manual therapies for headache relief is insufficient.

Keywords. Headache, Headache Disorders, Musculoskeletal Manipulations

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INTRODUCTION

The different types of headache are commonly treated with medication; however, some patients do not tolerate their use due to the collateral effects or contraindications resulting from associated comorbidities. On the other hand, manual therapies are often recommended as an alternative treatment for patients with headache[1].

The indication of manual therapies for the treatment of headache, based on the interrelationship between cervical musculature and the source of the pain, aims at preventing cervical musculoskeletal alterations from triggering headache[2,3]. However, there are discrepancies in the literature regarding whether pain causes changes in spinal motor control or if musculoskeletal alterations in the spine can trigger pain[4].

Analysis of MEDLINE, Lilacs, CINAHL, and Scopus databases reveals seven systematic reviews[5-12] on the topic. However, they contain important biases. Two reviews[5,12] assessed different physiotherapy techniques, including acupuncture, manipulation, electrotherapy and exercise. Another included case series and reports[11]. Six reviews[5-9,11] assessed the methodological quality of studies by assigning summary scores. However, analysis of these scores may not adequately represent the risk of bias in the articles and they should therefore not be used in systematic reviews. Three of the reviews[8,10,11] imposed language restriction, two[8,11] restricted the year of publication and in one[7] the methodological quality of the studies was not independently assessed by two evaluators.

Accordingly, the present study aimed to address the afore mentioned flaws and assess the efficacy of manual therapies, such as massage, chiropractic manipulation, osteopathic manipulation and other spinal manipulation, in the relief of headache among adult patients of both sexes.

METHOD

Study selection

In this systematic review studies were selected according to the following inclusion criteria: randomized and non-randomized clinical trials that used manual therapies, such as massage, chiropractic manipulation, osteopathic manipulation and other spinal manipulation, comparing them to a control group with no intervention, other physiotherapy modalities or a sham group, in adult patients of both sexes with cervicogenic headache, tension type headache or migraine. Studies whose participants continued to take medication to guard against recurrent headache were also included.

We excluded studies that compared manual therapies with acupuncture, the use of transcutaneous electrical nerve stimulation, ultrasound, laser, analgesics, biofeedback or other interventions using devices, or those that studied the effect of surgical interventions. Also excluded were studies with pregnant women, participants who underwent other cointerventions in the cervical region during the study period, those who exhibited neuromuscular dysfunctions, rheumatic diseases of the spine, temporomandibular joint dysfunction or both.

The following were considered primary findings: frequency, intensity and duration of pain and quality of life. The secondary findings were gain in cervical mobility, adverse effects of therapy and reduced use of analgesics.

Data sources and searches

We performed a systematic search for articles published in journals indexed in MEDLINE, LILACS, Cochrane, CINAHL, Scopus and Web of Science databases. The descriptors used in the search were in line with the description of MeSH/DeCS terms, as follows: 'Headache', 'Headache disorders' and 'Musculoskeletal manipulations', in addition to the keyword 'Manual therapy' and its equivalents in Portuguese. The terms were combined using the boolean operator AND, with no restriction for language or year of publication. The search was conducted between February and April 2013.

Data extraction and quality assessment

Initially, titles and abstracts were identified and assessed independently by two reviewers (DW and LA) on a computer screen, based on eligibility criteria. The potentially relevant studies that raised doubts were removed for subsequent analysis of the entire text. In cases of disagreement, a third evaluator (DA) took part in the assessment.

Data extraction from the selected studies was carried out independently by two evaluators (DW and LA). The following data were extracted: risk of study bias, eli-

gibility criteria, study population, participant flow, intervention details, measures of findings and results.

Data synthesis and analysis

Assessment of risk of bias was conducted using the 'Cochrane Collaboration Reviewers Handbook, version 5.1.0[13]. Meta-analysis was planned in accordance with the pre-established protocol available to the authors. However, this was precluded by the heterogeneity of the studies.

RESULTS

Of the 567 articles initially selected, 447 were excluded by the title because they did not meet inclusion criteria. Forty of the 110 remaining studies were deemed similar and therefore eliminated, um for being off topic and 22 for having inadequate study designs. Forty-seven studies were selected for more detailed analysis of the abstract, 19 of which were removed for not meeting inclusion criteria. The 28 remaining articles were read and 21 were excluded for not meeting eligibility criteria (Figure 1).

A total of seven studies were included for qualitative synthesis[14-20], one of which14 resulted in two publications[14,20], reporting different findings. Thus, the final number of articles included in review was six[14-19]. Studies included 279 adults (221 women and 58 men), aged between 23 and 59 years, diagnosed with different types of headache.

The population analyzed was composed of participants with tension type headache[14,15,18], cervicogenic headache headache[14,19], and migraine[14,16]. The criteria adopted to establish diagnosis of headache differed among studies, in which only three were based on ICHD (International Classification of Headache Disorders) diagnostic criteria (Table 1)[14,17,18].

The study that resulted in two publications assessed the dose-response of chiropractic manipulation and spinal massage in the relief of cervicogenic headache[14]. One study assessed the effectiveness of massage in the relief of chronic tension type headache and episodic headache[15]. Another study investigated the efficacy of osteopathic manipulation in reducing migraine pain (Table 1)[16].

Two other studies assessed patients with chronic tension type headache[17,18], one analyzing the effects of massage and Cyriax manipulation on headache relief[17], and the other determined the effects of massage on reducing headache[18]. Finally, one study compared the effects of mobilizing the cervical spine and massage on relieving cervicogenic headache (Table 1)[19].

With respect to controlling patient selection, two studies used a computer as randomization method[14,19], one used a randomization list[15], without supplying data, one used a sealed opaque envelope[18], and the other two did not reveal the randomization method used[16,17]. In relation to allocation concealment, one study did not reveal whether the envelope used to ensure secrecy was opaque[19] and one did not specify which procedure was used to ensure secrecy or whether allocation was performed by an independent individual[14].

There was selective description of the findings in four articles[14,16-18] and one[14] reported different findings in two publications[14,20]. Another articleanalyzed its results[16], comparing the same group before and after intervention. Another studycontained a selective description of the findings[18], since quality of life was only analyzed before treatment. In one investigation the frequency and severity of pain was not reported[17]. None of the articles masked the participants and intent-to-treat analysis was conducted

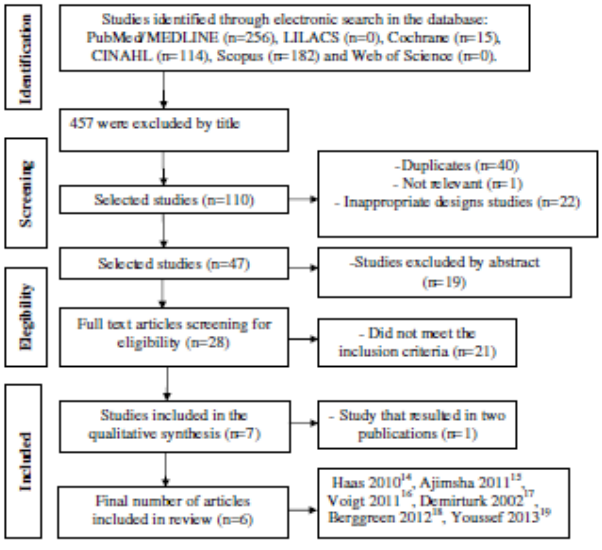

Figure 1. Studies search and selection for systematic review according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

Table 1. Characteristics of included studies.

Author, year (country)	Population	Age (mean)	Diagnosis	Diagnosis criteria	Type of therapy	Intervention protocol
Haas 2010[14] (United States)*	G1: 16 women and 4 men G2: 16 women and 4 men G3: 15 women and 5 men G4: 17 women and 3 men	G1: 38.0±10.0 G2: 35.0±12.0 G3: 37.0±13.0 G4: 34.0±10.0	CC CC+Migraine CC+ TTH CC+Migraine+TTH	ICHD I, 1988	G1 and G2: chiropractic manipulation of the spine G3 and G4: light massage therapy of the cervical and upper thoracic spine	Frequency: G1 and G3 once a week; G2 and G4 twice a week. Duration: 10 minutes. Treatment duration: G1 and G3 8 weeks, total number of 8 sessions; G2 and G4 8 weeks, total number of 16 sessions.
Ajimsha 2011[15] (India)	G1: 15 women and 7 men G2: 14 women and 8 men CG: 7 women and 5 men	G1:43.7±5.6 G2: 44.7±5.2 CG:43.0±5.4	ETTH or CTTH	Headache diary	G1: direct myofascial release of the neck and head G2: indirect myofascial release of the neck and head CG: slow soft stroking on neck and head	Frequency: twice a week Duration: 1 hour, each session separated by 2 days Treatment duration: 12 weeks, total number of 24 sessions
Voigt 2011[16] (Germany)	TG: 21 women CG: 21 women	TG: 47.7±11.3 CG: 42.4±11.0	Migraine with aura Migraine without aura	ICD-10	TG: visceral osteopathic manipulation, cranial osteopathic manipulation, or both depending on the diagnostic CG: without treatment	Frequency: Unknown Duration: 50 minutes Treatment duration: 10 weeks. Unknown total number of sessions
Demirturk 2002[17] (Turkey)	G1: 15 women G2: 15 women	G1: 39.47±12.4 G2: 37.07±10.1	CTTH	ICHD I, 1988	G1: manipulation of the connective tissue and neck massage G2: Cyriax mobilization of the neck and neck massage	Frequency: G1 daily; G2 Massage everyday and Cyriax method three times per week Duration: 30 minutes Treatment duration: 4 weeks, total number of 20 sessions
Berggreen 2012[18] (Denmak)	TG: 19 women CG: 16 women	TG: 38.8±13.7 CG: 42.3±10.2	CTTH	ICHD I, 1988	TG: massage with petrissage, friction and ischemic compression CG:without treatment	Frequency: TG once a week Duration: TG 2-5 min at each myofascial triggerpoint Treatment duration: 10 weeks
Youssef 2013[19] (Egypt)	G1: 8 women and 10 men G2: 6 women and 12 men	G1: 32.4±6.5 G2: 31.0±3.5	CC	International study group on CC	G1: Spinal mobilization techniques of the upper cervical spine G2: massage therapy of the neck region	Frequency: twice a week, each session separated by 48 hours Duration: 30 to 40 minutes Treatment duration: 6 weeks, total number of 12 sessions

ICHD I = The International Classification of Headache Disorders; ICD-10 = International Classification of Diseases and Related Health Problems; G1, G2, G3, and G4 = Groups of treatment; GT = Treatment group; GC = Control group; CC = cervicogenic headache; TTH = Tension-type headache; CTTH = Chronic tension-type headache. * The study of Haas 201014 resulted in two publications (Haas 201014 and Haas 201020).

in only two[14,18]. Two articles mentioned intent-to-treat analysis execution, albeit without explaining the process in their results[14,16]. Results of risk of bias are described in Figure 2.

With respect to the findings, all the studies used valid instruments for reproducible assessment of pain except one[17], which does not contain data on the frequency or severity of pain. However, in this study the data are presented as headache index, which corresponds to the product of headache frequency and pain severity[17]. Only one study evaluated pain duration[19], expressed as mean hours per week (group 1: 1.3±0.23 and group 2: 1.62±0.51), and anotheranalyzed pain severity[17], but did not provide any values. Moreover, a headache diary was only used in four of these articles[15,17-19]. Two studies presented the results of pain frequency obtained from the diary[15,20]. Only one study analyzed the use of analgesics[19]. Another important aspect is that the studythat resulted in two publications assessed the intensity and frequency of pain, showing different results (Table 2)[14].

In relation to quality of life, three studies assessed this finding[14,16,18]. However, one of them only assessed quality of life before treatment[14] and the other did not present any data because it found no significant intergroup difference after treatment[18]. One article evaluated quality of life using Modified Von Korff scales[14], while the otherused the Short Form 36 Health Survey[18]. Another investigation used the Migraine Disability Assessment and Short Form 36 Health Survey questionnaires[16]. This study found a significant difference in quality of life between the intervention and control groups on both questionnaires[16]. However, the authors did not provide the standard deviation in their results and statistical analysis was conducted between groups[16]. On the other hand, this was the only study that used a valid instrument designed for patients with headache[16].

Only two studies assessed cervical mobility[17,19] and two others analyzed the reduced use of analgesics (Table 2)[14,18]. Moreover, no adverse effects resulted from the therapies used in any of the studies.

In regard to the protocols used, two articles did not provide a detailed description of the intervention groups, types of therapy or how they were applied[14,16]. The repercussions of the data for clinical practice, types of therapy, protocols used, comparison groups and main outcomes are described in Table 1.

The sample was calculated in only two studies[14,18] and only two[14,16] reported sample losses, but did not include them in results analysis. Only one investigations considered the difference clinically important in pain assessment[14]. Furthermore, only one article showed conflicts of interest, since participants were paid to take part in the research[14].

DISCUSSION

Due to the heterogeneity of the clinical trials in terms of types of headache, participant characteristics, interventions and comparison groups, the efficacy of manual therapies for pain relief in migraine, tension type headache and cervicogenic headache remains unclear. In addition, most of the studies analyzed some of their outcomes based on statistical significance, but it was not possible to calculate the magnitude of the treatment effect[14,16-18].

In this respect, the absence of data on outcomes is a relevant bias in the estimate of the treatment effect[13], characterizing a selective description of findings. This type of bias occurs because studies with positive results tend to be published more often than those with negative results. For this reason the authors should provide data

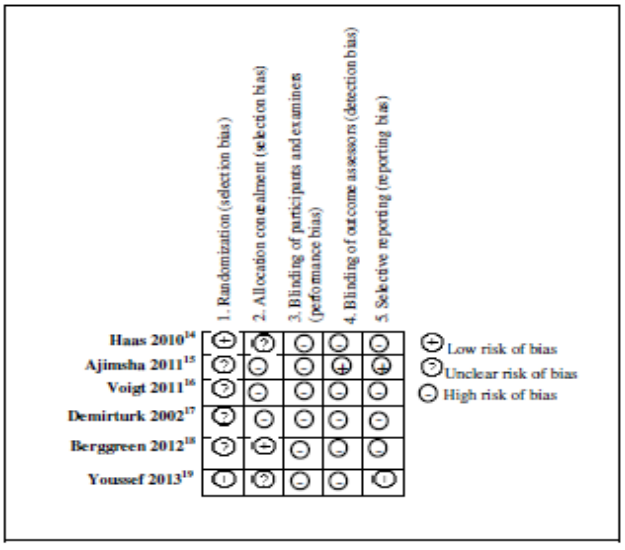

Figure 2. Risk of bias assessment according to Cochrane Collaboration Reviewer's Handbook (version 5.1.0).

Table 2. Outcomes assessment.

Author, year	Outcome assessment	Pain intensity (instrument)	Pain Frequency (instrument)	Medicine consumption	Neck mobility (instrument)
Haas 2010[14]*	12th and 24th week of treatment	G1: 33.3±19.7 points (MVK) G2: 27.8±26.7 points (MVK) G3:41.5±18.2 points (MVK) G4: 48.6±21.4 points (MVK)	G1: 7.2±5.3 days (MVK) G2: 6.6±8.2 days (MVK) G3: 8.7±7.6 days (MVK) G4: 10.7±7.5 days (MVK)	G1: 8.1±8.5mg G2: 7.0±8.6mg G3: 12.1±12.3mg G4: 11.7±9.5mg	Not assessed
	4th, 8th, and 12th week of treatment	G1: 30.8±20.0 points (MVK) G2: 29.6±23.7 points (MVK) G3:42.0±20.6 points (MVK) G4: 49.4±19.0 points (MVK)	G1: 5.8±4.8 days (MVK) G2: 6.4±6.8 days (MVK) G3: 9.8±6.7 days (MVK) G4:12.9±8.8 days (MVK)	Not assessed	Not assessed
Ajimsha 2011[15]	Between weeks 1st-4th and weeks 17 th -20 th	Not assessed	G1: 7.1±2.6 days (Headache diary) G2: 6.7±1.81 days (Headache diary) CG: 1.6±0.5 days (Headache diary)	Not assessed	Not assessed
Voigt 2011[16]	Before and after 6 months of treatment	TG: 53.8 (MIDAS). SD not reported CG: 62.6 (MIDAS). SD not reported TG: 51.5 (GPQ). SD not reported CG: 64.7 (GPQ). SD not reported	TG: 19.2 days (MIDAS). SD not reported. GC: 18.7 days (MIDAS). SD not reported.	Not assessed	Not assessed
Demirturk 2002[17]	Before, at the end of treatment and one month after treatment ends	Not assessed	Value was not reported (Headache diary)	G2: 42.5±3.8cm (goniometer)	G1: 44.9±3.0cm (goniometer)
Berggreen 2012[18]	Pain: assessment 4 weeks before the intervention, during the intervention and 4 weeks after the intervention. Quality of life: assessment before and after treatment	GT: 16.2±11.8 points (VAS) GC: 24.9±14.5 points (VAS)	Not assessed	TG: 64.1±94.0mg CG: 84.6±9.0mg	Not assessed
Youssef 2013[19]	Before treatment and one week after the end of intervention	G1: 2.2±0.7 points (VAS) G2: 4.3±0.7 points (VAS)	G1: 1.9±0.6 days (Headache diary) G2: 3.9±0.5 days (Headache diary)	Not assessed	Cervical flexion (tape measure): G1: 3.9±0.4cm; G2: 3.5±0.5cm Cervical extension (tape measure): G1: 2.9±0.3cm; G2: 0.6±0.4cm

G1, G2, G3, and G4 = Groups of treatment; TG = Treatment group; CG = Control group; GPQ = German pain questionnaire; VAS = Visual Analogue Scale; MVK = Modified Von Korff scales; MIDAS = Migraine Disability Assessment; SD = Standard deviation. * The study of Haas 201014 resulted in two publications (Haas 201014 and Haas 201020).

on post-treatment outcomes and analyze intervention groups, avoiding comparison before and after treatment in the same group.

With respect to controlling patient selection, not all studies used adequate randomization methods and valid allocation concealment. However, it is known that these aspects of methodological control are important, given that randomization and allocation concealment minimize the risk of selection bias, avoiding overestimating the treatment effect[21,22]. Furthermore, random allocation of study participants balances the characteristics of the group, avoiding confounding factors in the analysis of post-treatment results[23]. Therefore, the efficacy of manual therapy may be even lower in studies where randomization and allocation concealment were inadequate.

None of the studies masked participants. However, even though it was not possible to prevent patients from knowing they were receiving manual therapy, the studies exhibited detection bias[14-19]. Moreover, the lack of masking interferes in the results and, in the case of the outcomes analyzed in this systematic review, the interference was even greater since outcomes were subjective, representing a risk of bias. Although it was feasible to mask examiners and evaluators from outcomes in all the studies analyzed, only one investigation did so[15]. Even though masking is not always possible, it prevents execution and measuring bias, minimizing investigator and patient interference[22].

Another failure among the studies was the sample calculation, that is important in clinical trials, and necessary for the study to have sufficient power to demonstrate intergroup difference, if they exist[8]. Moreover, it is also important to conduct intent-to-treat analysis, applied to reduce overestimated interference in treatment effects caused by sample losses[24], which was not observed in most studies.

Regarding the accurate diagnosis of headache, the ICHD diagnostic criteria was not used in all studies. These criteria were established by professionals with experience in diagnosing headaches and their use should be encouraged. One of the main reasons for recommending the use of ICHD diagnostic criteria is the existence of various types of headache, whose characteristics can be quite similar, leading to flawed diagnoses. Thus, a patient could be given a false positive or false negative diagnosis, indicating inconsistencies in three clinical trials[15,16,19] involving other forms of diagnosis[25].

Furthermore, in cases of headache, it is recommended that a self-report diary be used to characterize pain in terms of intensity, frequency, duration and severity, in addition to analgesics in the case of headache crises[26]. The pain diary or headache diary is an instrument that shows the relationship between the occurrence, intensity and frequency of pain in patients[26]. Despite the importance, because not all studies used this resource and none of them provided all diary results, it was not possible to determine the difference between groups or the magnitude of the treatment effect among the groups.

In addition to pain, another relevant aspect in the treatment of patients with headache is the perception of quality of life, that was not assessed in all studies. Moreover, most of them presented a selective description of their findings, since they did not provide post-treatment results or analyzed outcomes within the same group, before and after treatment, not providing sufficient data to calculate differences between the intervention and control groups.

With respect to protocols, there was significant heterogeneity, without detailed description of the interventions[14,16]. One study used visceral or cranial osteopathic maneuvers or both in patients with headache[16]. However, the choice of maneuver varied according to the participant's diagnosis, and the technique was not clearly described, precluding its reproduction. Another study applied connective tissue manipulation sessions, neck massage and cervical mobilization using the Cyriax method, without specifying whether the protocol in different intervention groups was applied for the same duration and number of sessions[17]. The protocol used in other study involved chiropractic manipulation and light massage of the cervical spine and upper thorax[14]. However, the techniques employed were not detailed, making them irreproducible.

None of the studies demonstrated the possible adverse effects of the techniques. Knowing the results of these investigations is necessary in order to determine the beneficial and harmful effects of a given treatment and be able to recommend future interventions.

CONCLUSION

In the present systematic review the efficacy of manual therapies for pain relief in migraine, tension type headache and cervicogenic headache remains unclear. Based on the data observed, it can be concluded that there is high risk of bias in available studies, precluding making recommendations regarding the use of techniques applied in the protocols analyzed.

Thus, it is suggested that new randomized controlled trials be designed with greater methodological rigor and sample power, using ICHD diagnostic criteria and controlling allocation concealment, evaluator masking and losses. These future trials should also provide adequate data in order to analyze the magnitude of the treatment effect on the main outcomes. Moreover, protocols must be detailed and reproducible.

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