ABSTRACT

EFFECTS OF SUBOCCIPITAL MYOFASCIAL RELEASE COMPARED TO CERVICAL MOBILIZATION ON CERVICOGENIC HEADACHE IN THE ADULT POPULATION: A META ANALYSIS AND SYSTEMATIC REVIEW

Objective: The purpose of this meta-analysis and systematic review was to compare the effect of suboccipital myofascial release to cervical mobilizations on pain and cervical ROM in individuals with cervicogenic headache.

Data Sources: The following allied health-related databases were searched systematically: PubMed, Science Direct, CINAHL, and Cochrane Library.

Study Selection: Four studies were reviewed and deemed acceptable for this meta-analysis on headache intensity and 3 studies were used in the systematic review to evaluate the effects of suboccipital myofascial release on cervical range of motion.

Data Extraction: The quality of appraisal evaluation of included studies was conducted using the PEDro scale. Subjective perceived level of pain was extracted from the reported measures arranged into their respective sub-groups.

Data Synthesis: Results of the meta-analysis performed on headache intensity reveals homogeneity within the studies. The combined effect size is 2.49 indicating there is a large effect size between suboccipital myofascial release and cervical mobilization.

Conclusion: This study found cervical mobilization was more effective on reducing pain and improving ROM however, suboccipital myofascial release demonstrated significant within group improvements for individuals with CGH.

Jessica Barrows
May 2015
EFFECTS OF SUBOCCIPITAL MYOFASCIAL RELEASE COMPARED TO CERVICAL MOBILIZATION ON CERVICOGENIC HEADACHE IN THE ADULT POPULATION: A META ANALYSIS AND SYSTEMATIC REVIEW

by

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A project submitted in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy in the Department of Physical Therapy College of Health and Human Services California State University, Fresno May 2015
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BACKGROUND

Headaches are an extremely common and widespread condition resulting in frequent debilitating states, decreased quality of life, and limit daily function and participation in social activities.\textsuperscript{1,2} Headaches vary from mild to severe and present in many different forms. One specific type of recurrent headache is cervicogenic headache (CGH), which accounts for 15-20\% of all those who suffer from headaches.\textsuperscript{3-5} According to the International Headache Society, the classification of CGH is associated with pathomechanics of the cervical spine and associated soft tissues.\textsuperscript{6} Characteristics of CGH include neck pain and stiffness, active range of motion (ROM) deficits, dizziness, muscle length changes, and delayed firing and recruitment of appropriate muscles.\textsuperscript{7-9} CGH pain typically presents unilateral and originates from the occipital, suboccipital, and posterior cervical spine with radicular symptoms extending anterior into the forehead as well as the shoulder and arm.\textsuperscript{8,10}

CGH is a term introduced by Sjaastad et al.\textsuperscript{11} in 1983, describing a headache originating from the cervical spine. In efforts to explore the anatomical and pathophysiological mechanism for CGH, Bogduk\textsuperscript{12} suggested symptoms resulted from the convergence of cervical sensory input of cervical facets, musculature, and intervertebral discs with sensory input from vertebral and internal carotid arteries and dura mater of the upper spinal cord upon the trigeminal spinal nucleus. An alternative theory suggests there is an attachment of suboccipital tissues to dura mater at the cervical-cranial junction leading to CGH. It is the connection of these tissues that can then cause traction and movement of the dura resulting in soft tissue restrictions. Pain receptors within the cervical
spine then send pain referral patterns to the occipital region of the head leading to symptoms of a headache.$^{5,13}$

Various diagnostic criteria have emerged in attempts to establish a better understanding of the etiology and pathology associated with CGH. A widely used diagnostic criterion for CGH is the International Classification of Headache disorders. This classification of criteria for CGH was developed in order to assist those in the medical profession with the diagnosis and management of headaches. CGH falls under the “secondary headache” classification attributed to disorder of the neck. $^{6,10,14}$ (see Table 1).

Due to the unknown origin and mechanism by which CGH is diagnosed, treatment for this type of condition is also unclear. Studies have shown that both cervical mobilizations and soft tissue interventions are effective in reducing symptoms for individuals with CGH, however no definitive consensus of treatment intervention exists.$^{9,15}$ For this reason, the purpose of this meta-analysis is to compare the effect of suboccipital myofascial release to cervical mobilizations on pain and cervical ROM in individuals with CGH.

As clinicians, a thorough manual assessment is critical to diagnosing CGH. According to Page$^7$, discrimination between CGH and other headaches can be assessed by palpation of joint dysfunction of the upper cervical spine. Manual assessment of the upper cervical spine has been shown to have good reliability. Upon manual examination, passive mobilization to the cervical spine has been shown to reproduce subjective complaints of pain in 63% of CGH patients.$^{16}$ In addition Zito et al.$^{17}$ found this technique showed a sensitivity of 80%.

Precautions and “red flags” must be reviewed prior to the start of any treatment for individuals with chief complaint of neck pain to help rule out more serious pathologies. This is particularly true for those whose neck pain is
accompanied by complaints of headache. Table 2 provides both red flags for grade five mobilizations and CGH that may indicate underlying conditions (see Table 2).

**Treatment Options and Outcome Measures for Cervicogenic Headache**

Due to the reasonable prevalence of cervicogenic headaches, several treatment options have been considered. These options include but are not limited to, oral medications (e.g. anti-inflammatory drugs, antidepressants, antiepileptics, or muscle relaxants), injection therapy (e.g. botulinum toxin injections, greater occipital nerve blocks, cervical nerve blockades, facet joint injections, epidural steroid injections), and surgical procedures such as cryo-denervation, decompressive neck surgery, ganglionectomy, or denervation of cervical facet joints. For such a vast number of treatment options available, current evidence is limited pertaining to their effectiveness.

Treatment options differ in physical therapy based on patient presentation and therapist’s philosophies and training. They can vary from modalities, such as low-level laser therapy and transcutaneous electrical nerve stimulation, to manual therapy techniques such as joint mobilizations, muscle stretching, soft tissue mobilization, and therapeutic exercise. Although these interventions are common to physical therapy practice, they may not be advantageous for patients based upon individual age, comorbidities, and other signs and symptoms present, aside from the primary complaint. The most common therapy techniques used for treatment of CGH include spinal mobilizations and soft tissue mobilization. Unfortunately, solid evidence supporting one over the other is lacking.

Joint mobilization is widely used and commonly practiced among physical therapists. The mechanism by which the headache originates suggests joint
dysfunction of the cervical spine indicating cervical mobilization would be an effective treatment option. However, not all patients are candidates for high velocity, low amplitude (HVLA) mobilization, also known as grade five mobilization, and must be evaluated prior to treatment. Six clinical prediction rules were developed in 2006 to help predict a positive response for grade five cervical mobilizations and to predict what would most yield a positive response.

- Initial Neck Disability Index score < 11.50 points
- Bilateral pattern of involvement
- Not performing sedentary work > 5 hours/day
- Feels better while moving the neck
- Does not feel worse while extending the neck
- Diagnosis of spondylosis without radiculopathy

Patients exhibiting 4 or more of these variables have an increased likelihood of experiencing more than 50% pain reduction and greater overall improvement.\(^\text{19}\) It is suggested that mobilization, grades 1 through 4, are also good options for those not suitable for grade 5 mobilization.\(^\text{10}\)

Soft tissue intervention is another common form of treatment for this specific type of headache, however very little evidence exists on its effectiveness. Interestingly enough, soft tissue treatment, myofascial release, and/or suboccipital release were not listed in a 2008 set of published clinical guidelines for neck pain.\(^\text{20}\) Suboccipital myofascial release is one type of soft tissue intervention described as a sustained ventrocranial force on the occiput just caudal to the superior nuchal line performed by the therapist.\(^\text{21}\) Based on the pathomechanics described earlier, cervicogenic headaches originate in the posterior aspect of the superior cervical spine. It is “proposed that this technique might inhibit the muscles inserting into the nuchal line and that it could be used to apply a
distraction to the cervical spine structures.\textsuperscript{21}(p83) This technique has also been referred to as cranial base release, sub-occipital release, trigger point pressure release, ischemic compression, and inhibitive distraction.

Multiple outcome measures exist to indicate a reduction in patient symptoms for individuals with CGH, such as pain scales, frequency and duration of headaches, and cervical ROM. These measures can be assessed with each treatment session. Other outcome measures may include flexion rotation test (FRT), reduction in medication use by the patient, and the Neck Disability Index (NDI) in order to assess changes in functional ability.\textsuperscript{22} These measures can give information regarding improvement or lack thereof, for clients in physical therapy. One study found spinal manipulation therapy was able to reduce patient symptoms by 50\% after treatment.\textsuperscript{13}

Although there are numerous treatment options available for individuals with complaints of CGH, current research doesn’t agree on the optimal treatment approach. Studies show individual effects from both cervical mobilization and suboccipital myofascial release, however no standard program is accepted. Therefore, the purpose of this meta-analysis and systematic review is to compare the effect of suboccipital myofascial release to cervical mobilizations on pain and cervical ROM medically diagnosed with CGH and/or those with chief complaints of headaches. The relative PICO components for this meta-analysis include; individuals between 16 to 60 years of age and presenting with headache that are preferably sited as cervicogenic. The comparative treatments are suboccipital myofascial release to cervical mobilization as measured by increased cervical range of motion and decreased headache intensity as indicated by pain level. It is hypothesized that individuals receiving suboccipital myofascial release will demonstrate increased cervical ROM and greater improvements in subjective pain
compared to those receiving cervical mobilization. The stated null hypothesis is that there would be no change in cervical ROM and subjective pain in individuals receiving suboccipital myofascial release compared to those receiving cervical mobilization.
METHODS

Search Strategy
The following medical and allied health-related databases were searched systematically: PubMed, Science Direct, CINAHL, and Cochrane Library. The following search terms were used: suboccipital release, cranial base release, trigger point release, suboccipital trigger point, cervicogenic headache and physical therapy treatment, inhibitive distraction, cervical mobilization, cervical manipulation, and manual therapy treatment of cervicogenic headache. The search was limited to research published in peer-reviewed journals from 1995 to the present. Search began in August 2014 and was terminated on September 2014.

Eligibility Criteria
Studies appropriate for inclusion into this meta-analysis were level 1 and level 2 research designs. Studies needed to compare suboccipital myofascial release to cervical mobilization. Outcome measures used to monitor progress were required to include the Visual Analog Scale (VAS) or Numeric Pain Rating Scale (NPRS) to assess pain and cervical ROM.

Inclusion and Exclusion Criteria – Study Selection
Studies selected must include both men and women between 16 to 60 years of age and subjective complaints of headache. Additional criteria were subjective report of pain in the posterior cervical region, symptoms consistent with headache (preferably sited as cervicogenic) and decreased cervical ROM. The exclusion criteria for this study included patients with history of neck surgery, trauma to the head and neck within the last year, neurological dysfunction, rheumatoid arthritis, and/or cervical radiculopathy.
**Definitions**

For the purpose of this review, the following pertinent definitions were cited. Grade 5 cervical mobilization will be defined as “a high velocity and low amplitude (HVLA) localized force directed at cervical joint segments.” Grades 1 through 4 cervical mobilization are defined as a “low velocity, small or large amplitude, passive movements within the patient’s range of cervical motion and control.”

**Data Collection Process**

All data were extrapolated from the results section of each of the studies. Data were collected from post-test tables presented within the research. Results and standard deviations were used to perform statistical analysis. The mean age of the population was calculated based on the average age from each of the studies included in the meta-analysis and systematic review. The sum of the mean age was then divided by the number of studies included in this manuscript.

**Quality Appraisal**

The quality of studies were analyzed using the PEDro scale, an 11-point scale examining the external and internal validity of each study (see Appendix A). The first criterion of the PEDro score examines the applicability of the study however this criterion is not used in the total PEDro score and therefore the total score is based on a 10-point scale. This scale was used as the primary evaluation tool for studies included in both the meta-analysis and systematic review.

**Outcome Measures Studied**

Headache intensity was measured by subjective pain level using either the visual analog scale (VAS) or the numeric pain rating scale (NPRS). The VAS consists of a 0-10 cm line where 0 represents no pain and 10 represents the most
pain a patient can perceive. Similarly, the NPRS is an 11-point scale ranging from 0 to 10 where 0 represents no pain and 10 represents the worst pain imaginable. The patient indicates his or her level of pain by marking a point on the line (VAS) or verbally providing a number (NPRS) that represents his or her severity of perceived pain. The VAS and NPRS have been proven to be both valid and reliable tools.\textsuperscript{24-26} Function, ROM, and pain have been studied in the research using the neck disability index, the flexion rotation test and/or functional disability index. However, mechanisms for measuring ROM include goniometric measurements in degrees and by using a tape measure to assess gains and losses in centimeters.

**Statistical Analysis**

Perceived levels of pain were extracted from the reported measures in each of the studies and arranged into their respective sub-groups, suboccipital myofascial release and cervical mobilization. Individual data from each study were extrapolated. The data were then pooled for statistical comparison based on the number of participants.

For the purpose of the meta-analysis, lower number and/or negative effect size are correlated with improved level of perceived pain. Effect sizes were calculated based on outcome measures and standard deviations. These measures determined the magnitude of the treatment effect. Based on Cohen’s\textsuperscript{27} conventional values, large, medium, and small effect sizes are interpreted as values >0.80, 0.30 – 0.80, and < 0.30 respectively. The Q statistic was calculated to determine statistical homogeneity or heterogeneity of the studies utilized.
RESULTS

Study Selection

The search of PubMed, Science Direct, CINAHL, and Cochrane Library provided 940 total citations. After excluding duplicates, non-peer reviewed articles, and those without physical therapy interventions, 82 articles remained. Of these 82 articles, 68 were excluded secondary to incomparable inclusion and exclusion criteria along with differences in the PICO criteria. The remaining 14 potentially relevant trials were reviewed in greater detail to evaluate the components of the methods and outcome measures along with a review of the statistics. An additional 9 studies were then excluded due to insufficient detail about concerning components of the program and/or inconclusive statistics. Five articles remained and met the inclusion and exclusion criteria. Four of these 5 studies, Youssef and Shanb\textsuperscript{15}, Briem\textsuperscript{21}, Li et al.\textsuperscript{28}, and Jull et al.\textsuperscript{29} were reviewed and deemed acceptable for this meta-analysis. Figure 1 shows all included and excluded trials.

Lin et al.\textsuperscript{9} Youssef and Shanb\textsuperscript{15} and Briem\textsuperscript{21} were used in the systematic review to evaluate the effects of suboccipital myofascial release on ROM. The effects of ROM were necessary to be reviewed systematically. This was done secondary to inconsistent methods of reporting results across the various studies.

PEDro scores for each study were divided by 10 categories and represent the quality of reports included. These criteria assess the strength of each individual study. Of the articles used, PEDro scores ranged from 4 to 8/10 with variation within each study. Criterion most commonly not satisfied by the studies include the blinding of subjects, blinding of therapists, blinding of the assessor, and intention to treat (criterions 4, 5, 6, and 8 respectively). The criterion must be
considered when reviewing statistical results and limitations of studies. Results of PEDro scores are showed as a comparison across studies (Table 3).

**Meta-Analysis – Study Characteristics**

Articles included in the meta-analysis were from the following authors; Youssef and Shanb\(^{15}\), Briem\(^{21}\), Li et al.\(^{28}\), and Jull et al.\(^{29}\) Each of these studies met the PICO criteria and were included based on the study design, subjects involved, level of research, adequate information provided and similar outcome measures. Additional information including level of evidence, study design, and sample size of each study was outlined (Table 4).

Youssef and Shanb\(^{15}\) compared mobilization and massage in a 6-week study and looked at the NDI, ROM along with pain intensity, frequency, and duration of headache attacks. All outcome measures studied showed significant improvement between both groups as compared by paired t-tests. ROM, intensity, frequency, and duration all showed greater improvements with mobilization as compared to suboccipital release. However, the NDI had a greater reduction after massage as compared to mobilization. Therefore, according to this study, mobilizations of the upper cervical spine yields a greater change in overall pain as compared to massage.\(^{15}\)

Briem\(^{21}\) examined immediate effects of inhibitive distraction while looking at the NDI, ROM, pain intensity, frequency, and duration when headache attacks occurred. Patients in the experimental group received inhibitive distraction and patients in the control group received a placebo intervention. All outcome measures were performed prior to treatment and immediately after the interventions were applied. Even though increase in cervical flexion was made in both groups, there was no statistically significant difference between the groups.
Although, the within-group comparisons did achieve statistical significance, \( p=0.046 \). Even though this study did not find clinical significance, a “trend emerged for greater improvements in chronic patients with headaches, lower pain levels, and less pre-intervention active ROM.”\(^{21(p90)}\)

Li et al.\(^{28}\) studied effects of manipulation on patients with cervicogenic headache. Treatments were performed in sitting, prone, and the supine position. Manipulation were performed 3-5 times per treatment. Treatment was performed for a total of 40 days. The study examined the degree of headache intensity using the numeric rating scale. Results indicated a significant decrease in the numeric rating score with \( p < 0.01 \). This demonstrates manipulation was an effective treatment for individuals with cervicogenic headache. Furthermore, patient’s neck and occipital symptoms were significantly reduced and they were able to return to daily work and life.\(^{28}\)

Jull et al.\(^{29}\) evaluated manipulative therapy for cervicogenic headaches over the course of 6 weeks with follow-up evaluations at 3, 6, and 12 months. The research included a total of 200 participants with CGH. Statistical analysis revealed a statistically significant reduction in headache frequency, intensity and in the neck pain index, immediately after treatment. Changes were still present at the 12-month follow-up. Within the study, 76% of all participants in the treatment group, experienced a 50% or greater, decrease in headache frequency.\(^ {29}\)

Across the 4 studies used in the meta-analysis, 3 were level 1 research studies.\(^{15,21,29}\) These 3 studies achieved a PEDro score ranging from 6-8/10 and all had random allocation of subjects. Three of the 4 studies evaluated the effects of treatment over a course of 4-6 weeks.\(^{15,28,29}\) The fourth study by Briem\(^ {21}\) appraised the results immediately after treatment. Three of the 4 studies found a significant reduction in subjective pain level with mobilization intervention after the
Two of the 4 studies found an improvement in subjective pain level with suboccipital myofascial release, with 1 of the studies showing significant results.\textsuperscript{15,21}

**Meta-Analysis – Synthesis of Results**

Results of the statistical analysis performed on headache intensity reported by subjective pain response per the VAS and NPRS demonstrated homogeneity within the studies ($Q = 3.42$, $p > 0.05$). The combined effect size of 2.49 indicates a large effect between suboccipital myofascial release and cervical mobilization. Effect sizes, standard error of effect size, confidence intervals and combined values for the VAS and NPRS sub group are displayed (Tables 5 and 6). The data were presented as a forest plot (Figure 2).

According to table 5 and 6 along with the forest plot in figure 2 the effect size is positive indicating no reduction of pain with suboccipital myofascial release relative to cervical mobilization. Therefore, the results seem to show individuals receiving the intervention of suboccipital myofascial release do not have an improvement with respect to pain when compared to cervical mobilization.

**Systematic Review – Study Characteristics**

Three articles were reviewed systematically for the variable respect to range of motion comparing cervical mobilizations to suboccipital myofascial release. Each of these articles fit the PICO criteria and the inclusion and exclusion criteria, however, due to lack of commonality between ROM measurements these studies were not included in the meta-analysis. The studies were reviewed systematically based on the following criteria; study characteristics, inclusion/exclusion criteria, description of the intervention, outcome
measurements, statistical analysis, and results of the study. Additional information including level of evidence, study design, and sample size of each study used in the systematic review is outlined (Table 7).

Lin et al.\textsuperscript{9} examined the immediate effects of ischemic compression for individuals with cervicogenic cephalic syndrome (CCS). The study was performed on individuals with CGH who also experienced dizziness as an associated symptom. Lin et al.\textsuperscript{9} introduced the term cervicogenic cephalic syndrome to more comprehensively include these symptoms. This study was a level 3 research case control study conducted in an outpatient clinic at Chang Gung Memorial hospital in Taiwan. Twenty seven subjects were recruited for the experimental group: “Inclusion criteria were (1) subjects who had neck pain for more than 3 months, (2) complaints of at least 1 CCS symptom, including headache, dizziness/vertigo, and disequilibrium, and (3) cervical spine radiograph images that showed kinking, fanning or spondylolisthesis in the anterior-posterior view or lateral views in the neutral, flexion and extension positions. Subjects were excluded if they had any organic lesion of the peripheral ear, nose, throat, eye or central nervous system, any of which can affect the expression of CCS and balance.”\textsuperscript{9(p302)}

Mean age in years of the CCS group is 38.6 ±12.5. Neck ROM included active flexion, extension, right lateral rotation, left lateral rotation and right and left lateral bending measured in degrees of movement by a MicroFET 3\textsuperscript{TM} handheld dynamometer. An intervention of ischemic compression (IC) was applied 5 times over the most significant tender points of the posterior nuchal muscle. After application of intervention the patient was to rest for 10 minutes and was then was re-tested. The results of the study demonstrated ROM increased in all directions (p < 0.05). This study also examined balance and postural stability and found
increased postural stability after the intervention, as measured by a computerized posturography, while performing sensory organization test. 

Briem evaluated the immediate effects of inhibitive distraction on active cervical flexion in a level 1 randomized control trial pilot study. This was a double-blind study, performed by 2 therapists. A sample of convenience including 40 consecutive patients were recruited for this study in Reykjavík, Iceland: “Inclusion criterion was a patient report of pain in the cervical region. […] Exclusion criteria included a history of neck surgery, obesity to the extent that soft tissue approximation might limit cervical flexion, trauma to the head and neck area in the 10 days prior to the study treatment, and diagnoses indicating neurological dysfunction, rheumatoid arthritis, or severe spondylarthrosis.”

Mean age in year of the subjects included in the research was 34.7. Patients were randomly assigned to intervention or placebo treatment.

A cervical goniometer was used to measure cervical flexion. The intervention was described as inhibitive distraction preformed by a therapists while the patient rested supine on a treatment table. The therapists fingertips were just caudal to the superior nuchal line as they produced a sustained force in a ventrocranial direction. The intervention was applied then released slowly for a total of 3 to 3.5 minutes. One therapist was utilized to apply the intervention and one was used to measure the effects. Results of the study showed that the average pre-to post- intervention increases were 2.4 degrees with a standard deviation of +/- 6.2 degrees for the experimental group which was not statistically significant with p < 0.05. However, a statistically significant negative correlation was found between subject age and pre-intervention active ROM. The results showed these individuals along with patients experiencing lower levels of pain, those whom were experiencing headaches, and those who had pain for 6 months or greater
showed a larger change and greater improvement in active ROM compared to others.\textsuperscript{21}

Youssef and Shanb\textsuperscript{15} performed a study comparing mobilizations to massage therapy as a treatment for cervicogenic headache in a level 1 research study. A total of 38 patients were recruited from Kaser El-Eini hospital with age range in years from 18 to 40 who have recurrent headaches and neck pain for 2 months prior. “Inclusion criteria included symptoms of CGH, (1) unilaterality of pain, (2) reduction in the range of neck movement, (3) ipsilateral shoulder discomfort and, (4) ipsilateral arm discomfort, (5) mechanical precipitation of exacerbations/attacks by awkward neck positions or external pressure against sensitive occipital structures. Subjects were excluded from the study if they had migraine, cluster, headache, cervical radiculopathy, entrapment neuropathy, myelopathy, rheumatoid arthritis, or previous surgery of the cervical spine, pregnancy, whiplash trauma, or if they had received therapeutic treatment for neck pain or headache during the previous 6 months.”\textsuperscript{15(p19)} Subjects were randomly assigned to each treatment group. Active ROM measurement was performed using a tape measure. Measurements included flexion, extension, rotation, and lateral flexion. Treatment was applied 2 sessions per week for 6 weeks. Group 1 intervention included low velocity, high amplitude mobilizations to the upper cervical spine. Group 2 intervention included myofacial release, manual cervical traction, trigger point therapy, stretching techniques and effleurage of the cervical region. Active cervical ROM was significantly increased in both group 1 and group 2 with p < 0.05. The study revealed while both groups showed improvements with ROM, group 1 had greater gains. This indicated mobilization techniques were more effective for increasing cervical ROM in individuals with CGH.\textsuperscript{15}
Across the 3 studies used in the systematic review, 2 of the 3 evaluated the immediate effects of suboccipital myofascial release. The third study evaluated the effect of suboccipital myofascial release compared to cervical mobilization after a 6-week intervention. All 3 studies reviewed systematically found an increase in cervical ROM after suboccipital myofascial release, with 2 of the 3 studies finding significance. Although significant improvement was found after suboccipital myofascial release, Youssef and Shanb found a greater improvement of cervical ROM in the cervical mobilization treatment group.
DISCUSSION

The purpose of this meta-analysis and systematic review was to present and evaluate current evidence-based research comparing suboccipital myofascial release to cervical mobilizations for the treatment of CGH. Although both interventions have shown benefit for the treatment of CGH, one treatment has not been shown more effective than the other. This discussion will review the meta-analysis results for subjective pain level, appraise the results from the systematic review on cervical ROM changes, and discuss the clinical implications of the intervention for various patient populations.

Combined results from both the meta-analysis and the systematic review reject the alternative hypothesis. Individuals receiving suboccipital myofascial release did not fare better than those receiving mobilizations. Specifically, subjects did not demonstrate increased cervical ROM or greater improvements in subjective pain compared to those subjects who received cervical mobilization.

**Meta-Analysis on Headache Intensity**

The meta-analysis alone demonstrated that cervical mobilizations are more effective than suboccipital myofascial release to reduce headache intensity for individuals with CGH. The studies revealed homogeneity indicating similarity between the studies that were pooled to produce the effect size. The results also revealed a large effect size (greater than 0.80). Unfortunately, the large effect size was in the positive direction and according to the hypothesis, a negative number would signify a reduction in pain level. This large effect size indicates a considerable difference between suboccipital myofascial release and cervical mobilization. The results from the meta-analysis show that suboccipital myofascial
release is not as effective of a treatment when compared to cervical mobilization to reduce pain.

Multiple studies all report a significant reduction in subjective pain level for individuals receiving cervical mobilization.\textsuperscript{15,28,29} Another study performed by Nilsson et al.\textsuperscript{30} which should not be incorporated in this meta-analysis because of insufficient detail in statistics, also found a statistically significant change in headache intensity in a group of 28 individuals participating in a prospective randomized controlled trial over a 5-week period. These studies provide evidence that cervical mobilization is effective for patient populations studied.

In this meta-analysis suboccipital myofascial release did not show a positive effect on pain level when compared to mobilization. However, it may not be that the effect of suboccipital myofascial release does not exist, rather it is lost when matched against the very large treatment effect of cervical mobilization. For example, if suboccipital myofascial release had been compared against another type of treatment not shown to be as effective as mobilization (such as therapeutic exercise, low-level laser therapy or transcutaneous electrical nerve stimulation) a larger, positive effect for suboccipital myofascial release would most likely have been seen.

\textbf{Systematic Review on Cervical ROM}

Three studies were reviewed systematically in regards to cervical ROM for individuals with CGH. Studies were compared systematically secondary to inconsistent measurement units for outcome measures between the studies. Two studies examined the effect of suboccipital myofascial release. Both studies examined the immediate effects of the intervention.\textsuperscript{9,21} The third study compared suboccipital myofascial release to cervical mobilizations for long-term effects (6
weeks). Of the 3 experimental groups receiving suboccipital myofascial release, Youssef and Shanb and Lin et al. showed significant improvements in cervical ROM, and the third study by Briem, also demonstrated improvements however, results were not significant compared to baseline.

Youssef and Shanb compared suboccipital myofascial release to cervical mobilization and found that both groups experienced significant improvements in cervical ROM. Despite these observed changes, subjects receiving cervical mobilization showed greater overall improvement. This indicates for some patient populations, e.g. those similar to the one in this study, mobilizations appear to be more clinically relevant compared to suboccipital myofascial release.

**Clinical Implications of Meta-Analysis Combined with Systematic Review**

The systematic review parallels the findings of the meta-analysis in that cervical mobilizations have a greater effect on pain and ROM in certain patient populations that exhibit CGH. Even though suboccipital myofascial release can decrease subjective pain level and improve objective ROM, cervical mobilizations showed more effective results with greater improvements. Given these findings, physical therapists treating individuals between 16 to 60 years of age, properly diagnosed with CGH should consider cervical mobilization as the primary treatment approach for these individuals.

However, as physical therapists, one must first and foremost recognize which of our patients with CGH are candidates for grade 5 mobilizations and thus properly rule out those with contraindications. Individuals with contraindications represent a large patient population frequently identified in physical therapy practices. These individuals who are not candidates for mobilizations would
include patients who present with red flags. Other treatment options need to be explored for patients in which mobilizations are contraindicated.

The meta-analysis showed a large effect size on reducing patient pain levels with cervical mobilization, however, this effect size is misleading. After analyzing the results, a negative effect size was expected, indicating a reduction in pain and headache intensity with suboccipital myofascial release. However, according to the forest plot, the effect size is positive indicating no reduction of pain with suboccipital myofascial release relative to cervical mobilization. In fact it appears the individuals receiving this intervention have an increase in pain. The results mask the treatment effect of suboccipital myofascial release because cervical mobilization has such a large treatment effect. This is a logical deduction because Youssef and Shanb’s\textsuperscript{15} study examining suboccipital myofascial release found a clinically minimal detectable significant difference of 2.5 decrease in pain levels, from pre- to post- test score. Therefore, a consistent within group treatment effect from pre to post-test means of the suboccipital myofascial release group is present.

However, when suboccipital myofascial release is placed back into the PICO question and is compared to cervical mobilization, it appears the treatment effect is lost due to such a large effect size of cervical mobilization. The results erroneously make it appear as if individuals receiving the intervention of suboccipital myofascial release get worse with respect to pain. When in reality, individual group means consistently show an improvement in pain scores.

A significant decrease of 2.5 on the pain scale, reported by Youssef and Shanb\textsuperscript{15} is considered a minimally clinically important difference.\textsuperscript{25,31} This is an important consideration as it gives clinicians an alternative treatment to mobilization that still yields a clinically relevant change for those not appropriate for mobilization. Although the treatment effect of suboccipital myofascial release
is lost when compared to cervical mobilization, a 2.5 decrease of pain is still significant and should not be negated due to the relevant treatment effect.

For those individuals not suitable to receive grade 5 mobilization due to changes associated with advancing age, such as poor integrity of ligament or bony structures, osteoporosis, herniated disc, and/or rheumatoid arthritis, suboccipital myofascial release presents as an effective alternative. The study performed by Briem\textsuperscript{21} evaluating the effects of suboccipital myofascial release, found an interesting correlation between age and pain level. The study included individuals with a mean age of 34.7 years with the most advanced age being 48 years. Within this study, the results from the suboccipital myofascial release group were subdivided based on characteristics into 3 categories: pain level, age, and those suffering from headache. Comparatively, they found, those who were older and experiencing a lower level of pain had a greater increase in ROM, and those suffering from headaches that had discomfort for 6 months or more had a greater increase in ROM. This indicates a correlation may exist between those with advancing age and positive effect of suboccipital myofascial release treatment.

Cervicogenic dizziness is a characteristic identified with CGH. Due to the pathology and origin of the headache, cervical afferent inputs can become irritated and leads to dizziness.\textsuperscript{9} Lin et al.\textsuperscript{9} were able to demonstrate a reduction of cervicogenic dizziness with suboccipital myofascial release. Cervicogenic dizziness is another symptom and characteristic of CGH due to a dysfunction of the cervical mechanoreceptor associated with neck pain and cervical pathology. Lin et al.\textsuperscript{9} stated the cervical proprioception becomes impaired due to fatigue of these muscles. The results showed an increase in postural stability, a relief of fatigue, and an improvement in local circulation secondary to suboccipital myofascial release.\textsuperscript{9}
Within this meta-analysis and systematic review, it was identified CGH must be properly diagnosed and CGH is best treated by cervical mobilizations to improve ROM and reduce pain. For the population of individuals with CGH who are not candidates for mobilizations, studies have shown that suboccipital myofascial release is a good alternative treatment with significant results of improved cervical ROM and reduced pain level. These manual techniques have been developed and made efficacious for patients by studying the anatomy of the neck and the origin of CGH. Because CGH are recurrent-type headaches, emphasis on home exercise program also needs to be examined to help prevent individuals with CGH from constantly coming back to physical therapy. An additional manual therapy technique that has been considered is the Mulligan Concept. This approach was developed by Brian Mulligan and was titled the Mulligan Concept. The concept is described as “simultaneous application of therapist applied accessory mobilizations and patient generated active movement.” The goal of this type of treatment is to increase function and decrease pain directly after treatment. The Mulligan Concept developed into a self-managed approach for articular dysfunction of the neck. The approach for the neck was called a C1-C2 self-sustained natural apophyseal glide (SNAG) and combines accessory motion with spinal active movement used to restore cervical ROM and improve function. This concept emphasizes C1-C2 rotation using the self-SNAG strap targeting the same dysfunction observed in individuals with CGH.

Research was performed by Hall et al. in 2007, to determine the efficacy of C1-C2 self-SNAG intervention for individuals with CGH. The study was a double blind, randomized, placebo-controlled trial design evaluating both immediate change and long-term self-reported change. The intervention includes a
“thin rubber-covered strap positioned on the posterior arch of C1 and drawn horizontally forward across the face.”33 The results showed significant improvement in headache symptoms and ROM increase, both immediately after treatment and maintained at 1-year follow-up. The idea behind the intervention is “stimulation of mechanoreceptors within the joint capsule and surrounding tissues causes an inhibition of pain at the spinal cord.”33(p106) It is also theorized that end range rotation at C1-C2 via self-SNAG technique may engage pain-inhibitory systems within the periaqueductal gray matter to further reduce pain and discomfort.33

Although the Mulligan Concept is an additional intervention, and not directly compared to either cervical mobilizations or suboccipital myofascial release, it brings about an interesting concept of similar anatomical theories combining both interventions for improving the symptoms and objective dysfunctions of CGH. The Mulligan concept may be appropriate for all populations however further investigation needs to be researched to help identify the red flags and contraindications of treatment.

Despite the numerous studies performed on cervicogenic headache, the evidence available does not show consistency or provide thorough outcome measures. Short-term versus long-term effects of suboccipital myofascial release were not possible to evaluate, nor was frequency, and duration of headaches due to lack of measurement consistency in the available research. Future research should evaluate consistency of cervical ROM measurements, short-term versus long-term effects, and available treatment options for individuals who cannot undergo mobilizations due to red flags and contraindications. This population of individuals with CGH needs to be studied. There is also inconsistency in diagnosing CGH with several different diagnostic criteria and theories. Proper diagnosis of these
individuals is of upmost importance to allow for more effective and efficient treatment that will resolve CGH symptoms.

Limitations
This study has several limitations. The available research on suboccipital myofascial release is extremely limited and does not have strong PEDro scores further limiting the quality of the study. Randomization and intention-to-treat is lacking in several of the articles which could possibly lead to bias within the study or miscalculation of the treatment effect. There is very little consistency in diagnostic criteria for CGH leading to poor outcome measures and lack of regularity in type of measurement. Studies vary from long term to short term effects, which may cause differences in overall results of treatment.

Conclusion
This meta-analysis revealed homogeneity among the studies with a large effect size indicating suboccipital myofascial release is not as effective in reducing pain for individuals with CGH as compared to cervical mobilization. However, combined with the systematic review, the composite picture shows although cervical mobilization was more effective on reducing pain and improving ROM, suboccipital myofascial release demonstrated significant within group improvements for individuals with CGH. This means that suboccipital myofascial release may be an alternative treatment to cervical mobilizations and be effective for individuals who are not candidates for mobilization. Implications for future research needs to include the effectiveness of suboccipital myofascial release for individuals who are not candidates for mobilization, consistency in diagnosing CGH, and standardized outcome measures. Frequency and duration of headache should be tracked on a weekly basis, headache intensity should be reported by
perceived level of pain on a standardized 11-point scale, ROM needs to be measured in degrees of change, and neck disability index should be performed as a functional outcome measure in all individuals with CGH.
REFERENCES
REFERENCES


Table 1. Diagnostic Criteria for Cervicogenic Headache (According to the International Classification of Headache Disorders)

<table>
<thead>
<tr>
<th>Description</th>
<th>Headache caused by a disorder of the cervical spine and its component bony, disc and/or soft tissue elements, usually but not invariably accompanied by neck pain</th>
</tr>
</thead>
</table>
| Diagnostic criteria | A. Any headache fulfilling criterion C  
B. Clinical, laboratory and/or imaging evidence of a disorder or lesion within the cervical spine or soft tissues of the neck,  
C. Evidence of Causation demonstrated by at least 2 of the following  
1. Headache has developed in temporal relation to the onset of the cervical disorder or appearance of the lesion  
2. Headache has significantly improved or resolved in parallel with improvement in or resolution of the cervical disorder or lesion  
3. Cervical range of motion is reduced and headache is made significantly worse by provocation maneuvers  
4. Headache is abolished following diagnostic blockage of cervical structure or its nerve supply  
D. Not better accounted for by another ICHD-3 diagnosis |

Adapted from International Classification of Headache Disorders, 3rd Edition (beta Version)
## Table 2. Red Flags for Cervicogenic Headache and Manipulation

<table>
<thead>
<tr>
<th>Red Flags for Manipulations&lt;sup&gt;34&lt;/sup&gt;</th>
<th>Red Flags for Cervicogenic Headache&lt;sup&gt;7&lt;/sup&gt;</th>
<th>Absolute Contraindications for Manipulation&lt;sup&gt;34&lt;/sup&gt;</th>
<th>Precautions to Manipulation&lt;sup&gt;34&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Significant trauma</td>
<td>• Headaches that are getting worse over time</td>
<td>• Lack of indications</td>
<td>• Osteoporosis</td>
</tr>
<tr>
<td>• Weight loss</td>
<td>• Sudden onset of severe headache</td>
<td>• Poor integrity of ligamentous or bony structures</td>
<td>• Herniated disc with radiculopathy</td>
</tr>
<tr>
<td>• History of cancer</td>
<td>• Headaches associated with high fever</td>
<td>• Vertebral basilar insufficiency</td>
<td>• Signs of spinal instability</td>
</tr>
<tr>
<td>• Fever</td>
<td>• Stiff neck or rash</td>
<td>• Use of anticoagulant medication</td>
<td>• Rheumatoid arthritis</td>
</tr>
<tr>
<td>• IV drug use</td>
<td>• Headache after head injury</td>
<td></td>
<td>• Pregnancy</td>
</tr>
<tr>
<td>• Steroid use</td>
<td>• Problems with vision or profound dizziness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient &gt; 50 yo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Severe nighttime pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pain that worsens on lying down</td>
<td></td>
<td></td>
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</table>
Table 3. Results of Individual Studies

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Meta-Analysis</th>
<th>Systematic Review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Youssef and Shanb$^{15}$</td>
<td>Briem$^{21}$</td>
</tr>
<tr>
<td>1. Random allocation of subjects</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2. Allocation concealment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3. Similar groups at baseline</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4. Subjects blinded</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5. Therapists administering treatment blinded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Assessors blinded</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>7. Key outcome obtained</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>8. ‘Intention to treat’ used for analysis of one key outcome</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>9. Between-group statistics for one key outcome reported</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>10. Point measures and measures of variability</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Total Score</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Study</td>
<td>Level of Evidence</td>
<td>Sample Size</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Jull et al. 29, 2002</td>
<td>Level 1 RCT</td>
<td>n=48</td>
</tr>
<tr>
<td>Li et al. 28, 2007</td>
<td>Level 2</td>
<td>n=36</td>
</tr>
<tr>
<td>Youssef and Shanb 15, 2013</td>
<td>Level 1</td>
<td>n=38</td>
</tr>
<tr>
<td>Briem 21, 2007</td>
<td>Level 1</td>
<td>n=20</td>
</tr>
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### Table 5. Effect Size and Confidence Interval for Headache Intensity

<table>
<thead>
<tr>
<th>Experimental</th>
<th>Control</th>
<th>Effect Size (ES)</th>
<th>Standard of Error of ES</th>
<th>CI Lower</th>
<th>CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Briem²¹</td>
<td>Jull et al.²⁹</td>
<td>2.39</td>
<td>0.33</td>
<td>1.73</td>
<td>3.04</td>
</tr>
<tr>
<td>Youssef and Shanb¹⁵</td>
<td>Youssef and Shanb¹⁵</td>
<td>2.96</td>
<td>0.48</td>
<td>2.01</td>
<td>3.90</td>
</tr>
<tr>
<td>Briem²¹</td>
<td>Li et al.²⁸</td>
<td>2.12</td>
<td>0.34</td>
<td>1.45</td>
<td>2.79</td>
</tr>
<tr>
<td>Youssef and Shanb¹⁵</td>
<td>Jull et al.²⁹</td>
<td>2.88</td>
<td>0.37</td>
<td>2.16</td>
<td>3.61</td>
</tr>
<tr>
<td>Briem²¹</td>
<td>Youssef and Shanb¹⁵</td>
<td>2.35</td>
<td>0.42</td>
<td>1.52</td>
<td>3.17</td>
</tr>
</tbody>
</table>

### Table 6. Combined Effect Size and Confidence Interval for Headache Intensity

<table>
<thead>
<tr>
<th>Stats Labels</th>
<th>Data</th>
</tr>
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<tbody>
<tr>
<td>ES Combined</td>
<td>2.49</td>
</tr>
<tr>
<td>SE Combined</td>
<td>0.17</td>
</tr>
<tr>
<td>CI Lower</td>
<td>2.16</td>
</tr>
<tr>
<td>CI Upper</td>
<td>2.82</td>
</tr>
<tr>
<td>Study</td>
<td>Level of Evidence</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Youssef and Shanb(^{15}) 2013</td>
<td>Level 1</td>
</tr>
<tr>
<td>Lin(^{9}) 2012</td>
<td>Case Control Study Level 3</td>
</tr>
<tr>
<td>Briem(^{21}) 2007</td>
<td>Level 1</td>
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</tbody>
</table>
FIGURES
Figure 1. Study selection of all included and excluded trials
Figure 2. Forrest Plot on effect size of compared studies for headache intensity measured by subjective pain level
APPENDIX A: PEDRO SCALE
PEDro scale

1. eligibility criteria were specified  
   no [ ] yes [ ] where:  

2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)  
   no [ ] yes [ ] where:  

3. allocation was concealed  
   no [ ] yes [ ] where:  

4. the groups were similar at baseline regarding the most important prognostic indicators  
   no [ ] yes [ ] where:  

5. there was blinding of all subjects  
   no [ ] yes [ ] where:  

6. there was blinding of all therapists who administered the therapy  
   no [ ] yes [ ] where:  

7. there was blinding of all assessors who measured at least one key outcome  
   no [ ] yes [ ] where:  

8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups  
   no [ ] yes [ ] where:  

9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”  
   no [ ] yes [ ] where:  

10. the results of between-group statistical comparisons are reported for at least one key outcome  
    no [ ] yes [ ] where:  

11. the study provides both point measures and measures of variability for at least one key outcome  
    no [ ] yes [ ] where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP et al 1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41). The list is based on “expert consensus” not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (i.e. RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or “generalisability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999
Notes on administration of the PEDro scale:

All criteria **Points are only awarded when a criterion is clearly satisfied.** If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.

Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

Criterion 2 A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.

Criterion 3 **Concealed allocation** means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.

Criterion 4 At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.

Criteria 4, 7-11 **Key outcomes** are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

Criterion 5-7 **Blinding** means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

Criterion 8 This criterion is only satisfied if the report explicitly states both the number of subjects initially allocated to groups and the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.

Criterion 9 An **intention to treat** analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.

Criterion 10 A **between-group** statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group x time interaction). The comparison may be in the form hypothesis testing (which provides a “p” value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.

Criterion 11 A **point measure** is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. **Measures of variability** include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
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Jessica Barrows

Type full name as it appears on submission

- May 4, 2015

Date