OSTEOPATHIC CARE COMBINED WITH PHYSIOTHERAPY AND PAIN EDUCATION FOR CERVICOGENIC HEADACHE: STUDY PROTOCOL FOR A THREE-ARM PRAGMATIC RANDOMIZED CONTROLLED TRIAL

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Abstract

Introduction: Cervicogenic headache (CH) is a secondary headache associated with non-traumatic dysfunctions of the cervical region. Osteopathic Care (OC) has shown promising results in reducing pain and disability in patients with migraine, tension-type headaches and CH, but the effectiveness of OC remains scarce, and the studies has low certainty of evidence. **Objective:** To investigate the effectiveness of the OC in the management of headache-related disability in patients with CH 6 weeks and 24 weeks after the intervention compared with sham and control group. **Methods:** This is a three-arm, pragmatic, randomized controlled trial. A total of 120 adult participants with chronic CH will be recruited. Participants must report episodic headache for at least 3 months, occurring at least once per week, present cervical mobility less than 44° on the cervical flexion-rotation test, and exhibit headache during provocative tests at C0, C1, C2, and/or C3. After randomization, the experimental group will receive OC plus Physiotherapy (specific exercises for the cervical spine and Mulligan´s manual therapy) and a pain education booklet. The control group will receive the same Physiotherapy and pain education intervention. The sham group will receive the OC sham combined with Physiotherapy and pain education. Primary outcome will be headache-related disability, assessed by Headache Impact Test (HIT-6). Secondary outcomes will be pain intensity (VAS) and the Perceived Changes Questionnaire (PCQ). Outcome assessment will be carried out at baseline, 6 weeks after the intervention and 24 weeks follow up with an intention-to-treat framework. **Expected Results:** OC combined with Physiotherapy and pain education would be effectiveness in reducing headache-related disability compared to the sham and control groups, 6 weeks after the intervention.

Keywords: Secondary headache disorders, Cervicogenic headache, Musculoskeletal Manipulations, Osteopathic Manipulation, Osteopathic Medicine.

ClinicalTrials.gov Registration: xxxxx

BACKGROUND

Cervicogenic headache (CH) is a secondary headache disorder arising from musculoskeletal dysfunctions in the cervical spine, particularly involving its osseous, discal, or soft tissue structures (Olesen, 2018). CH is a prevalent condition, affecting between 2.2% and 4.1% of the general population (Knackstedt et al., 2010; Sjaastad; Bakketeig, 2008). Beyond physical symptoms, CH imposes a substantial burden on patients' quality of life, often leading to functional disability and increased healthcare costs (Stovner et al., 2022). The diagnosis of CH requires clinical evidence of a temporal and functional relationship between cervical dysfunction and headache symptoms. This includes pain provocation by neck movement and restricted cervical range of motion (Olesen, 2018). While several physical examination tests are used to support the diagnosis by identifying upper cervical mobility deficits (Demont et al., 2022; Hall et al., 2008, 2010; Luedtke et al., 2016; Ogince et al., 2007; Rubio-Ochoa et al., 2016), the clinical management of these patients remains complex, requiring interventions that address both pain and headache-related disability.

Non-pharmacological approaches, such as manual therapy and exercise, are commonly recommended for CH (Cardoso et al., 2022;Patil et al., 2024;Demont et al., 2023; Bini et al., 2022). Recent literature emphasizes that isolated interventions may be insufficient, suggesting that a multimodal approach integrating "bottom-up" (peripheral/hands-on) and "top-down" (central/hands-off) strategies is more effective for chronic conditions (Fernández-De-Las-Peñas et al., 2020). Systematic reviews support this multimodal approach, indicating that combining multiple manual techniques or integrating soft tissue work with therapeutic exercise yields superior outcomes in pain intensity and frequency compared to isolated treatments for CH (Jung et al., 2024; Núñez-Cabaleiro; Leirós-Rodríguez, 2022). Specifically, the addition of Mulligan Concept manual therapy techniques to therapeutic neck exercises, compared to therapeutic exercises alone, has been shown to significantly reduce headache frequency during long-term follow-up (Satpute; Bedekar; Hall, 2024).

Osteopathic Care (OC) has shown promising results in reducing the disability and frequency of primary headaches, such as migraine and tension-type headaches (Cerritelli et al., 2015).

Likewise, a recent study investigated the effects of OC in patients with CH, but the two-arm randomized controlled trial compared only OC versus sham OC (Klemm et al., 2026). However, the study did not use the gold standard treatment as control (physiotherapy exercise program plus manual therapy and pain education) or used a validated measure of headache-related disability commonly used in clinical practice (e.g., Headache Impact Test). Hence, OC effectiveness still remains scarce and the studies has low certainty of evidence (Cerritelli et al., 2017).

Despite the growing evidence for combined therapies, no study to date has investigated the effectiveness of OC when combined with physiotherapy and pain education for patients with CH. This study aims to fill this gap by evaluating the effectiveness of OC combined with physiotherapy and pain education compared to sham OC and physiotherapy plus pain education on headache-related disability. We hypothesize that OC combined with physiotherapy and pain education would be effectiveness in reducing headache-related disability compared to the sham and control groups, 6 weeks after the intervention.

METHODS

Patient and public involvement

Participants were not involved in the design of this study. A community survey will be conducted online via Google Forms after the end of the experiment. This survey will aim to promote patient involvement in the discussion of the research. This stage is intended to improve participant engagement and to incorporate the patients' perspectives into the research, helping to enhance its relevance and potential benefits to the community.

Trial design

This is a pragmatic, three-arm, parallel-group, randomized controlled trial with blinded statistical analysis. The study will consist of 6 weeks of intervention followed by 24 weeks of follow-up, totaling 30 weeks (Figure 1).

PLEASE INSERT FIGURE 1 HERE

The study protocol was registered at ClinicalTrials.gov (https://clinicaltrials.gov) under number xxxx and at PRECIS-2 (https://www.precis-2.org/Trials/Details/10881) under number 10881 prior to participant recruitment.

This study protocol is reported in accordance with the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (Chan et al., 2025). The full study will be reported following the Consolidated Standards of Reporting Trials (CONSORT) Statement (Hopewell et al., 2025) and the Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) framework (Loudon et al., 2015). The revised version of PRECIS-2 scores for this trial are: Eligibility = 5; Recruitment = 4; Setting = 5; Organization = 5; Flexibility (Delivery) = 5; Flexibility (Adherence) = 4; Follow-up = 4; Primary Outcome = 5; Primary Analysis = 5 (Figure 2).

PLEASE INSERT FIGURE 2 HERE

Trial setting and recruitment

This study will be conducted at two public healthcare centers providing primary-to-tertiary care (Instituto de Assistência dos Servidores do Estado do Rio de Janeiro and Rodolpho Rocco Municipal Health Center), at Osteopathic Clinic outpatient of Instituto Brasileiro de Osteopatia, both in Rio de Janeiro, RJ, Brazil. Data will be analyzed at the Laboratory of Computational Simulation and Modeling in Rehabilitation at Centro Universitário Augusto Motta, Rio de Janeiro, RJ, Brazil. Participants will be recruited through physician referrals from both centers and through social media.

Eligibility criteria

Participant screening will be conducted by a professional independent of outcome assessment and treatment delivery. Participants of all gender identities, races, religions, sexual orientations, socioeconomic conditions, and with disabilities will be eligible to ensure diversity and equitable treatment.

Eligible participants will include individuals of both sexes who are residents of the city of Rio de Janeiro, RJ, aged over 18 years, and who meet the diagnostic criteria for cervicogenic headache established by the International Classification of Headache Disorders (ICHD-III) (Olesen, 2018). Participants must report episodic headache for at least 3 months, occurring at least once per week, present cervical mobility less than 44° on the cervical flexion–rotation test (CFRT), and exhibit headache during provocative tests at C0, C1, C2, and/or C3.

Participants will be excluded if they are currently undergoing other physiotherapy, osteopathic, orthodontic, or medical treatment; present neurological disorders; have signs of trauma or fracture; report symptoms of vertigo or tinnitus; or have another condition that may be the origin of the headache.

All participants who meet the eligibility criteria will undergo a prior clinical assessment. The evaluator will collect demographic data (sex and age), lifestyle information (dietary habits and physical activity), and sleep quality. Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI) (Bertolazi et al., 2011; Buysse et al., 1989), which evaluates seven components of sleep over the past month. The CFRT will be used to measure cervical range of motion, along with provocative tests (manual joint palpation) at C0, C1, C2 (Ferreira et al., 2022), and C3 (Demont et al., 2022; Luedtke et al., 2016; Ogince et al., 2007; Rubio-Ochoa et al., 2016). The CFRT will be performed using the CROM (Cervical Range of Motion), a validated instrument for measuring cervical mobility (Hall et al., 2008).

Intervention and comparator

Participants in the experimental and sham groups will undergo a comprehensive osteopathic assessment in accordance with the World Health Organization (WHO) benchmarks for osteopathic practice (Giusti, 2017). The osteopath responsible for the interventions holds full training in Osteopathy (Diploma in Osteopathy, D.O.) and has more than 10 years of experience. The musculoskeletal, visceral, and cranial systems will be assessed following the Tissue texture changes, Asymmetry, Restriction of motion, and Tenderness (TART) concept (Chila, 2011; DiGiovanna; Amen; Burns, 2021; Fryer, 2016; Liem, 2016). These participants will have a standardized osteopathic assessment and treatment form used in osteopathy outpatient clinics to ensure transparency regarding identified dysfunctions and the techniques applied.

Experimental Group. Participants will receive OC targeting segments affected by somatic dysfunctions to restore function. All individual treatments will be documented in a table detailing the osteopathic technique applied for each identified somatic dysfunction, including musculoskeletal, visceral, and cranial approaches. Each intervention session will last between 30 and 45 minutes. In addition to OC, participants will also receive the same physiotherapy program and pain education booklet as the control group.

Sham OC Group. Participants will receive sham OC, consisting of light touch, movement arc maneuvers, and simulated osteopathic manipulation, in which the patient is positioned but the final manipulative thrust is not performed (Hage et al., 2025; Hohenschurz-Schmidt et al., 2023a, 2023b; Hohenschurz-Schmidt; Vase; Draper-Rodi, 2025). In addition to sham OC, participants will also receive the same physiotherapy program and pain education booklet as the control group.

Control Group. Participants will be managed by a licensed physiotherapist with over 10 years of experience. They will undergo a physiotherapy program and receive a pain education booklet (Reis et al., 2022). The physiotherapy program consists of specific motor control exercises for the neck and Mulligan Concept manual therapy techniques. Exercises include loaded cervical flexion, scapular retraction in the prone position, passive and static cervical self-stretching, and active cervical mobility exercises. The exercise session will last approximately 30 minutes. Mulligan manual therapy

techniques will be applied according to the patient's symptomatic response for an additional 10 minutes.

The physiotherapist will test each participant to identify which technique provides the greatest reduction in headache intensity during the session. Two techniques will be tested: sustained natural apophyseal glide (SNAG) for headache (performed at the first cervical vertebra) and reverse SNAG (performed at the second cervical vertebra, C2). The first technique capable of reducing pain intensity during the session will be selected. Treatment will be performed once per week for 6 weeks (Satpute; Bedekar; Hall, 2024).

At the end of the study, if the addition of OC to the physiotherapy program demonstrates greater effectiveness than the sham treatment, participants in the CG and SG will receive the same treatment as the EG, in accordance with ethical requirements for research involving human subjects (Novoa, 2014).

Outcomes

The primary outcome will be headache-related disability, measured by Headache Impact Test (HIT-6; score range: 36-78) at 6 weeks post-intervention. Secondary outcomes will include pain intensity measured using the visual analog scale (VAS) and scores on the Perceived Change Scale (PCS) at 6 and 24 weeks.

The HIT-6 consists of six questions assessing the impact of headache on daily, physical, social, and work-related activities. Scores above 60 indicate a very severe impact; scores between 56 and 59 indicate substantial impact; scores between 50 and 55 indicate some impact; and scores below 49 indicate little to no impact (Kosinski et al., 2003; Pradela et al., 2021).

The visual analog scale (VAS) for pain ranges from 0 to 10, where 0–2 indicates mild pain, 3–7 moderate pain, and 8–10 severe pain. Participants will be asked to mark a point on the scale corresponding to their pain intensity (Price et al., 1983).

The Perceived Change Scale consists of 19 items assessing the patient's qualitative perception of changes in their life because of the treatment received. Each item has three response options: 1: worse than before; 2: no change; and 3: better than before. Higher scores indicate a better and more positive perception of improvement from the intervention (Bandeira et al., 2009, 2011).

Participants will complete the visual analog scale for pain intensity and the HIT-6 questionnaire at baseline, at the end of the 6-week intervention, and at 24 weeks of follow-up. The Perceived Change Scale (PCS) will also be administered at the end of the intervention (6 weeks) and at follow-up (24 weeks).

Sample size

The sample size for the present three-group parallel randomized controlled trial was calculated using G*Power software, version 3.1.9.7 (Faul et al., 2007), assuming equal allocation (1:1:1). Based on the 5-point between-group difference (Cerritelli et al., 2015) and a standard deviation of 7.5 points, corresponding to a standardized mean difference of Cohen's $d = 0.67$ and an omnibus effect size of Cohen's $f = 0.31$, with a type I error of 5% ($\alpha = 0.05$) and a type II error of 20% (80% power), a minimum total sample of 102 participants (34 per group) was estimated using a fixed-effects one-way omnibus ANOVA model. To account for a potential 10% loss to follow-up, the target sample size was increased to 114 participants (38 per group), corresponding to 40 participants per group.

Randomization and allocation

Block randomization using Randomizer Software (https://www.randomizer.org) will be used for will be used to allocate participants after eligibility assessment into the experimental, sham or control groups. A block size of 6 (1:1:1 allocation ratio) will be used to ensure balanced group allocation. This procedure will be performed by a professional independent of outcome assessment and treatment delivery.

Blinding

The outcome assessor, the osteopath responsible for the interventions and the physiotherapist delivering the physiotherapy program and pain education will not be blinded to group allocation. However, immediately postintervention, the participants will be asked if they received the sham or active intervention, as a means to confirm the blinding (Lira et al., 2025). The statistician will be blinded to group allocation. The possible answers will be: "sham", "active treatment" or "I don´t know". The "I don't know" response will be assigned proportionally to both groups.

Data collection and Management

Researchers involved in the study will have access to the final clinical trial dataset and may share it for verification and publication purposes upon reasonable request. The principal investigator will be responsible for data management and will ensure that all study data are stored in both physical and digital formats for 5 years after study completion.

The data entry spreadsheet will be updated by the investigator based on collected assessment forms. Study data will be entered into a password-protected database, with access restricted to authorized study personnel. Data quality will be ensured through double-checking of entries and periodic audits. All participant data will be de-identified prior to analysis to ensure confidentiality.

Statistical analysis

Statistical analysis will be conducted by a statistician using coded and de-identified data with the Shiny app RCTapp (https://sciencer.shinyapps.io/RCTapp/**)** (Ferreira AS., 2024). Descriptive statistics will be used for continuous variables, including mean and standard deviation. For non-normally distributed continuous variables, median and interquartile range will be reported.

All participants included in the study will be analyzed according to the group to which they were initially randomized, regardless of protocol deviations, receipt of alternative treatments, adherence issues, or missing outcome data. The analysis will follow the intention-to-treat principle. Additionally, a

sensitivity analysis using a per-protocol approach will be performed to assess the potential impact of incomplete adherence and loss to follow-up.

Continuous variables will be assessed for normality and transformed if necessary. Comparative statistics will be presented as mean differences with 95% confidence intervals. Linear mixed-effects models will be used to examine main and interaction effects of group and time. Baseline outcome values, age, and sex will be included as covariates and evaluated as potential predictors and moderators of treatment effects.

Missing data will be assumed to be missing at random (MAR). Multiple imputation using chained equations will be used to handle missing data, generating 50 imputed datasets. The imputation model will include group, time, and the corresponding outcome variable.

The James Blinding Index (JBI) (James et al., 1996) and Cohen's kappa (Lin et al., 2022) will be used to statistically assess the success of blinding. The JBI is a continuous value between 0 and 1. A JBI score >0.5 suggests adequate blinding (James et al., 1996). For Cohen's kappa, we will consider the following grading to determine the blinding/unblinding as previously described by Lin et al., 2022: up to 0.20 as successful blinding, 0.21 to 0.40 as slightly broken, 0.41 to 0.60 as moderately broken, 0.61 to 1 as severely broken.

Trial monitoring

As part of a risk-based monitoring strategy, all centers will be visited on-site or virtually after enrolment of the first 10-15 patients. Key data will be verified for 100% of patients. Trial sites will then be assessed as being either with or without noticeable findings with respect to the trial protocol, data quality and good clinical practice.

Ethics

This research protocol was approved by the Institutional Research Ethics Committee (No. 96290426.2.0000.5235) prior to its execution, in accordance with National Health Council Resolution

466/2012 and the Declaration of Helsinki. All participants will provide written informed consent after being informed about the nature of the study and the procedures to be carried out.

DISCUSSION

Evidence supporting physiotherapy interventions for headache is growing (Fernández-De-Las-Peñas et al., 2020;Núñez-Cabaleiro; Leirós-Rodríguez, 2022; Jung et al., 2024), however, the effectiveness of osteopathic care (OC) when added to a multimodal physiotherapy program and pain education remains unclear. A recent randomized controlled trial investigated OC in patients with cervicogenic headache but compared OC with sham OC without integrating these interventions into a physiotherapy program (Klemm et al., 2026). Moreover, that trial used the Neck Disability Index (NDI) as its primary outcome, which primarily assesses neck-related disability, whereas the present trial uses the Headache Impact Test (HIT-6) to specifically assess headache-related impact. The three-arm design of the present study addresses this gap by comparing OC plus physiotherapy and pain education, sham OC plus the same physiotherapy and pain education, and physiotherapy and pain education alone. This design will allow assessment of whether adding OC to physiotherapy provides benefits beyond physiotherapy alone and whether any observed effects exceed those associated with a sham hands-on intervention.

Strengths of this protocol include its three-arm pragmatic randomized controlled design and the evaluation of interventions that can be integrated into physical rehabilitation practice. The inclusion of both a sham OC group and a physiotherapy-only control group allows the specific effects of OC to be distinguished from potential contextual effects associated with additional hands-on care. The inclusion of a 24-week follow-up will also enable assessment of the longer-term effects of the interventions beyond the immediate post-intervention period. Additional procedures intended to reduce potential threats to internal validity include blinding of the statistician, computer-generated block randomization, standardized intervention procedures, and the use of valid and reliable instruments to assess study outcomes.

Several limitations should also be acknowledged. The eligibility criteria, including the exclusion of participants with neurological disorders and signs of trauma, may limit the external validity and generalizability of the findings to broader populations with headache. Attrition and non-compliance may also be higher than anticipated, particularly given the duration of the intervention and follow-up. Furthermore, although the sham OC intervention is intended to control for contextual and hands-on effects associated with OC, complete participant blinding may be difficult to achieve. Treatment expectations are not formally assessed; therefore, their potential influence on the study outcomes cannot be directly evaluated.

This paper presents the protocol for a three-arm pragmatic randomized controlled trial designed to evaluate the effectiveness of adding OC to a multimodal physiotherapy program and pain education in patients with cervicogenic headache. By comparing OC with both sham OC and a physiotherapy-only control condition, the trial will determine whether the addition of OC provides benefits for headache-related disability at 6 and 24 weeks and whether these benefits exceed those associated with a sham intervention. The findings are expected to address an important gap in the literature regarding the added value of OC within a multimodal rehabilitation approach for cervicogenic headache.

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Declaration of competing interest

None to declare.

Use of Generative Artificial Intelligence in Scientific Writing

During the preparation of this work, the authors used a large language model-based tool (ChatGPT, OpenAI) to revise the translated version from Portuguese. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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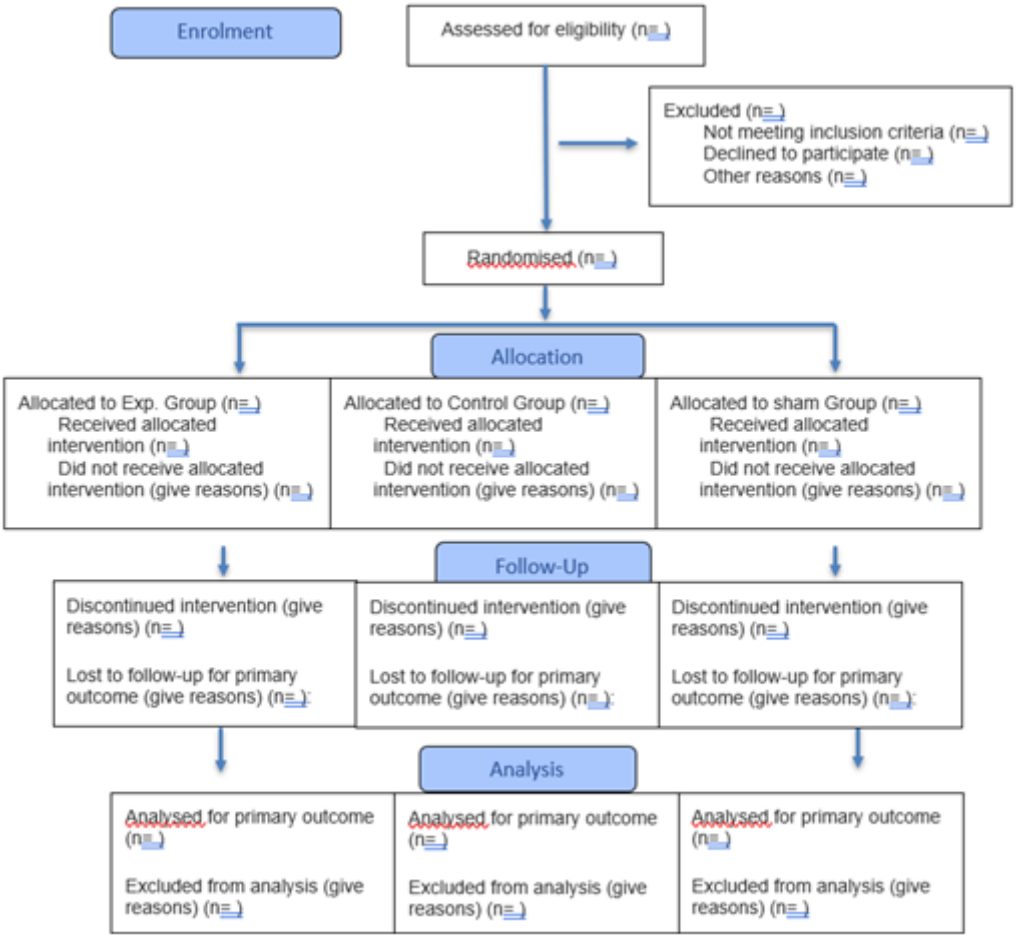


Figure 1. Study flowchart.

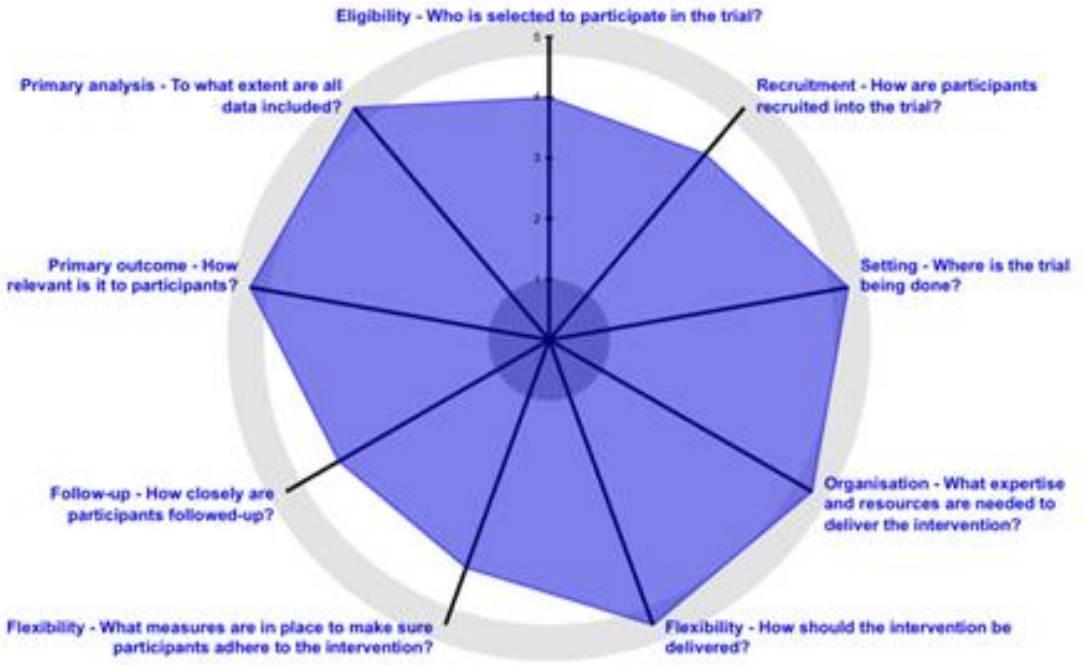


Figure 2. PRagmatic-Explanatory Continuum Indicator Summary (PRECIS-2) scores for this trial.