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Results of a feasibility randomised controlled trial of osteopathy on neck-shoulder pain in computer users

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ABSTRACT

Background: Computer use is a well-known source of chronic pain, leading to absenteeism and reduced productivity and well-being. This study evaluated the feasibility of conducting a full-scale randomised controlled trial. Several methodological variables defined trial feasibility.
Materials and methods: Thirty adults, daily computer users reporting pain, were recruited. Data collection took place at LABIOMEP. Participants were randomised into 1 of 3 parallel groups and received either osteopathic, sham or no treatment. Only the volunteers were blind to group assignments. The primary objective was to study the feasibility and acceptability of the protocol.
Results: Of 77 participants interested, 30 were included and randomised into three groups of ten. All participants concluded the study, and all the data was analysed. The feasibility outcomes were deemed appropriate. No adverse events or severe side effects were reported or identified.
Conclusion: Studying the efficacy of osteopathic consultation on computer users by conducting an RCT is feasible and safe. With adjustments, a full-scale study can be designed.
Trial registration: ClinicalTrials.gov with the identifier: NCT04501575. Date registered August 06, 2020.

1. Introduction

Computer-based tasks, like typing, represent a significant fraction of the daily occupational profiles [1,2,3]. Several studies have stated the potentially harmful effects of regularly using a computer, proposing physiologic mechanics to develop pain over the neck-shoulder region [46]. This type of problem is often defined as Trapezius Myalgia or Trapezius Muscle Strain and belong to a broader classification of Work-related upper limb and neck disorders (WRULDs). Besides all the adverse effects on individual well-being and personal life, this pain also affects occupational efficiency, affecting productivity levels and causing absenteeism. Moreover, these WRULDs have a significant negative impact on the economy. Its prevention and management do not seem to be improving with current strategies [4]. Therefore, it is urgent to find new approaches to fight the incidence of this and other Musculoskeletal Disorders (MSDs) which result from exposure to occupational physical and emotional stress. According to a report on WRULDs by the European Agency for Safety and Health at Work [5]; the main risks for the neck and shoulder regions include working in positions where part of the body need to be supported (as with elevated arms), prolonged work in static postures (working with a computer) and repeated lifting of the arm or turning head to the side (poor ergonomics). The European Survey of Enterprises on New and Emerging Risks [6] reported that the two better-identified risk factors are repetitive hand or arm movements

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(increased since 2014) and prolonged sitting (new entry on this survey). A report analysing the high prevalence of work-related MSD's emphasised the need for considering psychological factors together with all previously identified [7].

For some time, psychological factors have been identified as predisposing to developing neck pain [8,9]. For instance, there is evidence that patients' expectations predict chronic pain outcomes [10]. As an example, in cervical dystonia, psychological distress and deficits in cognitive and social-cognitive function are distinct features [11]. Psychological evaluation of the impact of work-related MSDs is, however, out of this work scope. Nonetheless, it is an important research area to be considered in future works to understand how these MSD's can be better managed.

Osteopaths are primary contact practitioners who typically manage their consultation timing and dedicate more time and interest [12] to understand the potential causes of the presented problem, identifying predisposing and maintaining factors that may be crucial for the best outcome. It is part of their formal education, some knowledge of ergonomics, and an understanding of the uncertainties of occupational health challenges. In the United States, there is an institution for better preparing osteopaths to intervene in occupational health. It is the American Osteopathic College of Occupational & Preventive Medicine (AOCOPM). Their purpose is to elevate the standards of osteopathic care in public health and preventive medicine. Some international guidelines already recommend manual and spinal manipulation therapies, commonly used by osteopaths, in very common MSDs. Examples are the Orthopaedic Section of the American Physical Therapy Association [13]; the UK's National Institute for Health and Care Excellence [14]; the American College of Occupational and Environmental Medicine [15]; and the American College of Physicians [16]. A systematic review of recommendations for neck and low back pain treatment across Europe showed that high-quality guidelines included reassurance, advice and education, manual therapy combined with other treatments such as exercise therapy [17]. These therapeutic modalities are commonly used in osteopathic consultations. There is growing evidence that osteopathic medicine is effective in several clinical conditions. Its effects also influence the autonomous nervous system [18] and brain activity [19]. Notwithstanding this, there is still scarce quality evidence of its efficacy in occupational settings and profiles.

High-quality, large-scale clinical trials must be conducted to verify whether osteopathy may be a valid option to join the health care force to better respond to WRULDs. Conducting a feasibility study is the recommended action when considering the future design of a large-scale RCT. This type of research ensures that the methodological approach is robust and feasible. It will help identify potential weaknesses and areas for improvement [47]and prevent wasting funds on the more expensive full trials [20]. It mainly tries to answer whether a primary, large-scale study can be done and how it should be conducted [48]. To the authors' knowledge, such an analysis has never been performed concerning the efficacy of osteopathic medicine in occupational contexts. To this end, we investigated the feasibility of conducting a large-scale RCT to analyse the efficacy of an osteopathic consultation on neck-shoulder pain in computer users. The outcomes to assess feasibility included recruitment, adherence, acceptability, adverse events, outcome measures, and the logistics for multicenter trial and retention. Although feasibility results do not necessarily generalise beyond the design's inclusion and exclusion criteria, all data collected was analysed [21]. Another objective was to investigate whether Surface Electromyography (sEMG) is correlated with the pain-measuring tools and assess its practicality. Moreover, we also correlated PPT, NRS and sEMG with demographic, occupational and body composition data.

2. Materials and Methods

2.1. Study design

This study was a triple-armed, single-blinded, parallel-group, single-centred randomised, sham-placebo, and 'usual care' controlled feasibility study. The data collection took five months and was carried out in the Laboratory of Biomechanics of Porto (Labiomep). This study follows the CONSORT statement extension recommendations to randomised pilot and feasibility trials [22] and the CONSORT 2017 update statement for randomised trials of non-pharmacologic treatment [23]. The correspondent checklists are available as supporting information (CONSORT Checklist S1). The main study will follow the CONSORT statement with updated guidelines for parallel reporting group randomised trials [24]. The results of this trial shall inform whether it is feasible to conduct a future powered RCT. This trial was registered on www.ClinicalTrials.gov (identifier: NCT04501575). No changes have been made to the trial protocol since its start.

2.2. Participants

Participants were recruited through an email sent to office workers at the University of Porto. Previous participants also referred to some participants. The recruitment period was set for six months, considered reasonable for a feasibility study. Participation in the study was restricted to adult subjects over the age of 18 and under 65 years old who use a computer as part of their occupational tasks for a daily average of 5 h for at least one year. Eligible participants confirmed by a telephone interview that they experienced pain between their neck and shoulders for a period inferior to 3 months and had no diagnosis or clear onset for that pain. Participants reported the inexistence of neurological, rheumatological, or other medical conditions that may mimic an MSD. At the time of the interview, they were not under the effect of any medication that might have an analgesic effect. Participants were included if they did not report any neurologic symptoms such as paresthesia or hypoesthesia, were using a pacemaker, or were allergic to adhesives. Moreover, the study's participation was limited to individuals who had no experience with osteopathy and no clear understanding of what it is and how an osteopathic consultation works. All participants signed an informed consent form approved by the University of Porto Ethics Committee (82/CEUP/2019), meeting the Declaration of Helsinki's standards.

2.3. Randomisation

Thirty (n = 30) participants were allocated through simple randomisation 1:1:1 ratio into three groups of 10: Group 1- osteopathic consultation, Group 2 - sham osteopathic consultation, and Group 3 control (continued usual management of symptoms but no manual therapy allowed during the trial duration). Randomisation was conducted using a computer-generated order (https://www.random.org/) and presented in sealed, sequentially numbered envelopes. The principal researcher conducted all steps.

2.4. Blinding

Only the participants were blinded to group assignment. For groups 1 and 2, participants were informed they would receive an osteopathic consultation. Group 3, the control group, received no consultation and continued dealing with their pain/symptoms as usual, but without Manual Therapy (MT). After the trial, both groups 2 and 3 were offered free treatments by the principal researcher. Although desirable, the outcome assessor was not possible to blind due to a shortage of staff. It was not possible to blind the osteopath, which provided the treatment. The principal investigator/osteopath collected all data and conducted all the steps.

2.5. Experimental procedure

Before data collection, all participants completed a demographic and occupational questionnaire (S3). In the first visit, their body composition was measured by bioimpedance equipment. Participants were instructed to refrain from smoking and alcoholic drinks 6 h before the data collection and avoid heavy meals and caffeine 2 h before data collection. A clinical neurological examination was performed to verify any suspicion of neurologic deficit. Still, no participant was excluded for this reason. After providing a subjective reporting of the intensity of their pain in both Upper Trapezius (UT) muscles using the Numeric Rating Scale (NRS) and Pressure-Pain Threshold (PPT), participants were instructed to perform a standardised writing task on the computer. It consists of copying from a book for 15 min, similar time used by Kelson et al. [3] and Gonçalves et al. [2]. Participants were asked to adapt the workspace to their usual personal setting and comfort. After a maximum of 1 min of adaptation, they started the task at their average speed. The workspace consisted of a laptop (TOSHIBA TECRA S11-104 15,6″ screen), a desk with a fixed height of 72 cm, a chair with adjustable seat height and backrest (Fig. 1). During the 15 min of the typing task, sEMG data were collected from the UT muscles in four moments, at minutes 1,5,10, and 15, for 30 s each. After completing the task, depending on the allocation group, they received 20 min of an osteopathic consultation, 20 min of a sham osteopathic consultation or were sent home and advised to deal with the pain as they usually would (without using any form of MT). After the intervention, NRS, PPT, and sEMG (15 min of typing) data were again collected from groups 1 and 2. After a short period of 2–4 days of interval, the same procedure was used to collect data in the follow-up visit. In this visit, no interventions were delivered, and NRS, PPT, and sEMG (again, during 15 m of typing task) data were collected. This interval was considered adequate as manual therapy's common benign adverse effects usually resolve within 24 h [49]. One week after the follow-up, a verbal NRS report via telephone was used to collect the last data on pain intensity. An online satisfaction questionnaire (S4) closed data collection. The principal researcher delivered all interventions. An illustration of the protocol is shown in Fig. 2.

2.6. Interventions

Although data was collected on both visits, interventions only took place on the first visit. Due to the pre-determined inclusion criteria, the osteopathic consultation group (Group 1) received 20 min, regularly structured, genuine osteopathic consultation, with reduced time due to the pre-determined inclusion criteria. Osteopathy is a patient-centred healthcare discipline, so no hands-on treatment protocol was followed. Osteopathic assessment and manipulative techniques were performed, being adapted to the patient's characteristics and best interest based on the osteopath's evaluation. Nevertheless, given the similar clinical presentation, the intervention was somewhat comparable for all participants with variations towards their particular morphology and complaints. A fully registered trained osteopathic practitioner with ten years of clinical and academic experience provided the treatment. Techniques were not limited to the participant's symptomatic area but to tissues and body areas interpreted as potentially predisposing or maintaining the complaint. As expected at a consultation of osteopathy, preventive and remedial tailored exercises and ergonomics advice were given. Group 2, the sham osteopathic consultation group, was treated with a placebo protocol, similar to the one used by [50], also performed by the principal researcher. The physical evaluation mimicked the conventional osteopathic assessment without any intention to diagnose. Treatment avoided any possible therapeutic touch in muscles and only using light pressure over different ten bony surfaces for 1 min each. The procedures for both groups are contrasted in Table 1. The patient laid supine and silent during the 20 min. The osteopath counted seconds up to 2 min between the areas where to apply the light touch. Concerning Group 3, the usual care reported from participants, is presented in Table 2.

Fig. 1. Site of data collection with adapted workspace, treatment table, and stand for instruments.

2.7. Outcome measures

2.7.1. Trial feasibility

The items analysed to assess the trial's feasibility were the recruitment, adherence, acceptability, adverse events, outcomes measured, logistics for multicenter trial and retention. The details concerning the recruitment, participant arrangements and consent and retention rates were recorded. Any problems regarding the application of the intervention or measurements were documented.

2.7.1.1. Recruitment, adherence and retention rates. The recruitment rate into the study was tracked, and recruitment success was defined as a minimum of 1 participant per week for six months with a final number not inferior to 30. Adherence and retention rates should be above 80% of the included participants to be considered successful.

2.7.1.2. Acceptability and adverse events. Acceptability was measured by refusal to comply with the interventions; we defined 90% compliance as the minimum acceptable. A minimum average of 'High' in satisfaction with the care provided is the defined criteria for success regarding the satisfaction questionnaire results. Adverse events are not expected, and there should be none.

2.7.1.3. Outcomes measured and logistics for multicenter. Concerning the outcomes of interest, these should quantify pain, correlate with each other, and be minimally disruptive to the recruitment process and to the real-life therapeutic environment.

The logistics for a future multicenter trial was assessed by positive responses to whether the clinical direction and the osteopaths would be interested in participating in such trial. Ten emails were sent, and success was defined as minimum of seven positive responses.

2.7.2. Efficacy in reducing the intensity of pain

The osteopathic consultation efficacy was defined as a statistically significant reduction of the reported pain intensity from PPT for both UTs and C7 (immediate and 2–4 days short-term) and NRS for UTs only (immediate, 2–4 days short-term and 9–11 days short-term) results.

2.7.2.1. Numeric Rating Scale. The 11-point NRS version and the Visual Analogue Scale (VAS) 10 cm are the most used methods for measuring pain intensity by researchers studying the effects of the osteopathic intervention [25]. When comparing NRS with the VAS, Verbal Rating Scale (VRS), and the Faces Pain Scale-Revised (FPS-R), it was considered

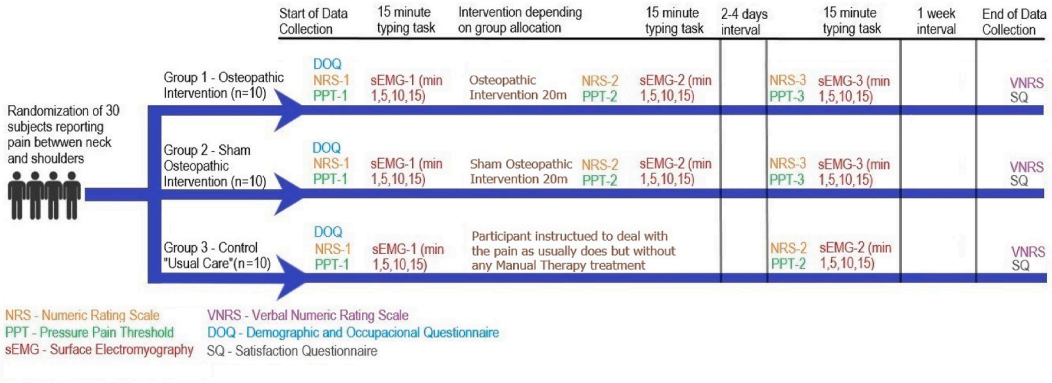


Fig. 2. Illustration of the data collection protocol.

Table 1
Contrast of osteopathic and sham intervention in treatment.

Group 1 - Osteopathic Consultation	Group 2 - Sham Osteopathic Consultation
List of techniques used for the hands-on treatment: - Rotation harmonic technique for all spine - Soft-tissue techniques to the UT and peri-scapular muscles - Inhibition technique for a tender area on UT - Posterior-anterior (PA) thrust to a vertebral unit with altered mobility - Traction with flexion of the C0,1 joint - Cervical spine mobilisation - Cervicothoracic junction lift thrust	Light touch on bony prominences bilaterally: - Acromion - Middle point of Clavicle - Medial extremity of Clavicle - Medial end of the spine of Scapula - Mastoid processes - Lateral epicondyles - Anterior-superior iliac spine - Great trochanters - Tibial tuberosity - Lateral malleoli

Table 2
Number of reported items as usual care for this type of pain by participants allocated to Group 3.

Description	Number of participants
Pilates Class	1
Posture Awareness	1
Paracetamol	2
AINEs	2
Movement	3
Stretches	3
Heat	3
Rest	4
Change position that causes pain	5

the most responsive [45]. NRS represents a simple, 1-dimensional measuring instrument for assessing pain intensity (0 = no pain, 10 = unbearable pain). Participants were asked to visualise the quantity of pain they experienced at that precise moment over the shoulder-neck region, both sides.

2.7.2.2. Pressure-Pain Threshold. A Digital Pressure Algometer (Wagner FORCE ONE FDIX 50′, Wagner Instruments, Greenwich, CT, USA) was used on the trapezius muscle, superior fibres, both sides. Other clinical studies have stated its validity and reliability [26–28]. The muscles' exact location for the PPT application was 2 cm above the medial electrode, on both UT muscle fibre directions. The use of PPT was performed before the computer typing task. The algometer pointer was placed perpendicular to the points marked for evaluation, and a vertical compression force was applied. The pressure was continuously increased at a rate of 1 kg/cm2 until the pain was reported. To ensure the maximum reading was obtained, the C-Peak option of the device was enabled. Participants were instructed of the procedures in advance; a simulation on their forearm was performed before the data collection. The participant informed the evaluator that when the pressure sensation becomes pain by saying "STOP", the value was immediately registered. An average of three readings, divided by 10 s, was collected and calculated for each location. All readings are expressed in Kg/cm2.

2.7.3. Other outcomes measures

These outcomes are the UT's electrical activity variation (immediate and 2–4 days after the intervention) and its correlation with the reported pain results.

2.7.3.1. Surface electromyography. sEMG values from both UT muscles were measured using the Biopack NP100A system, and its analysis was performed using the Acknowledge 3.9.1 software (Biopack). According to Kim et al. [29]; static sEMG is reliable and clinically useful to evaluate pain in persons with neck pain. Ag/AgCl 30 mm, disk-shaped surface electrodes were used, two for each muscle and one as reference. The electrodes' positioning in each UT followed the Surface Electromyography for the Noninvasive Assessment of Muscles (SENIAM) recommendation [30]. Before electrode placement, the skin was lightly rubbed with 90% alcohol and shaved if necessary. The EMG signals were acquired at 2000 Hz with a gain of 1100 Hz and 16 bits resolution. The common-mode rejection ratio was 110 dB. The EMG data were filtered using filter Butterworth 1st order bandpass of 20–450 Hz. The Root Mean Square (RMS) of the raw data, with 150 ms windows, was calculated from each reading. Once all participants are symptomatic, and according to Sousa and Tavares [31] and Cid et al. [32]; the Maximal Voluntary Isometric Contraction (MVIC) is not an adequate method for normalising the sEMG signal as pain is likely to influence it. The Reference Voluntary Exertions (RVE) method is used similarly to Kelson et al. [3]. Subjects performed three contraction repetitions for each UT for 3 s alternating with 1 min of rest. Pilot work on healthy subjects used the elevation of the shoulder holding a 0.5 kg weight in hand, setting RVE as 15% of MVC, adapted from the procedures described by Mathiassen et al. [33]. The participants performed these contractions seating in the Biodex Universal Pro T-Base equipment. All data collection took place at Labiomep.

2.7.3.2. Satisfaction questionnaire. One week after the Verbal Numerical Rating Score (VNRS), an email with a weblink to an online questionnaire was sent for each participant. Out of 30 participants, 24 responded. This questionnaire was adapted from the one used by Pflugeisen et al. [34]. It was constituted by several 5-point Likert scales about the facilities, the researcher's performance, and risk explanations. Also, if the subject would accept participating in future studies, if recommends to others and explored the reasons why they agreed to be a participant and why they would not participate again. The questionnaire was made available as supplementary material.

2.7.3.3. Body composition. Body composition was retrieved with the InBody R20 (Biospace Co., Lda. Korea) Bioelectrical Impedance Analysis equipment. Although the InBody equipment seems to produce some degree of individual error, its results are reliable [35]. For each subject, age, sex, and height were entered into the system. Before the analysis, subjects cleaned their hands and feet with antibacterial tissue. Participants stood upright, feet centred on the base electrodes and grasped the hand electrodes with arms wide apart to avoid contact between the arms and torso. As soon as data were collected, participants could step off the device. The variables analysed were weight (kg), muscle mass (kg), fat mass (kg), and body mass index (kg/m).

2.8. Sample size

Thirty participants were recruited, with 10 in each group. Due to the objective of studying the feasibility of conducting a large-scale RCT, a formal sample size calculation was not carried out. This sample followed the recommendation for this type of study. Ten participants were considered adequate to assess its feasibility [36,37]. No interim analysis was performed in this study due to the absence of adverse effects and a small sample.

2.9. Data analysis

Although an intention-to-treat analysis was planned, it was performed according to the original randomisation once there were no dropouts or crossover. Descriptive data are presented as mean and standard deviation (mean ± SD) or numbers and percentages (%). Descriptive statistics were used for feasibility outcomes as participant recruitment, retention, and adherence to the trial, for posterior application in a powered RCT. Distribution was checked for normality and skewness in all variables. As distribution was not normal and there were outliers, an index of the variation before and after interventions was calculated. The index was between 0 and 10 for PPT and 1 and 11 for NRS once there were 0 values. This index was used for the non-parametric Wilcoxon rank-sum test and Kruskal-Wallis rank-sum test to compare the immediate and short-term effects across the randomised groups. When a significant difference in the Kruskal-Wallis test is identified, the *posthoc* analysis was performed for multiple group comparison using the Dunn's Multiple Comparison test with Bonferroni correction. Based on Mangiafico's [38] categorisation, effect sizes were calculated for all tests applied: the r effect for Wilcoxon rank-sum test, the epsilon-squared for Kruskal-Wallis test, and Vargha and Delaney's A, for Dunn test. The relationship between demographic, occupational, body composition variables, PPT, NRS, and sEMG readings was assessed through Spearman's *p* and Point-biserial correlation coefficients. The

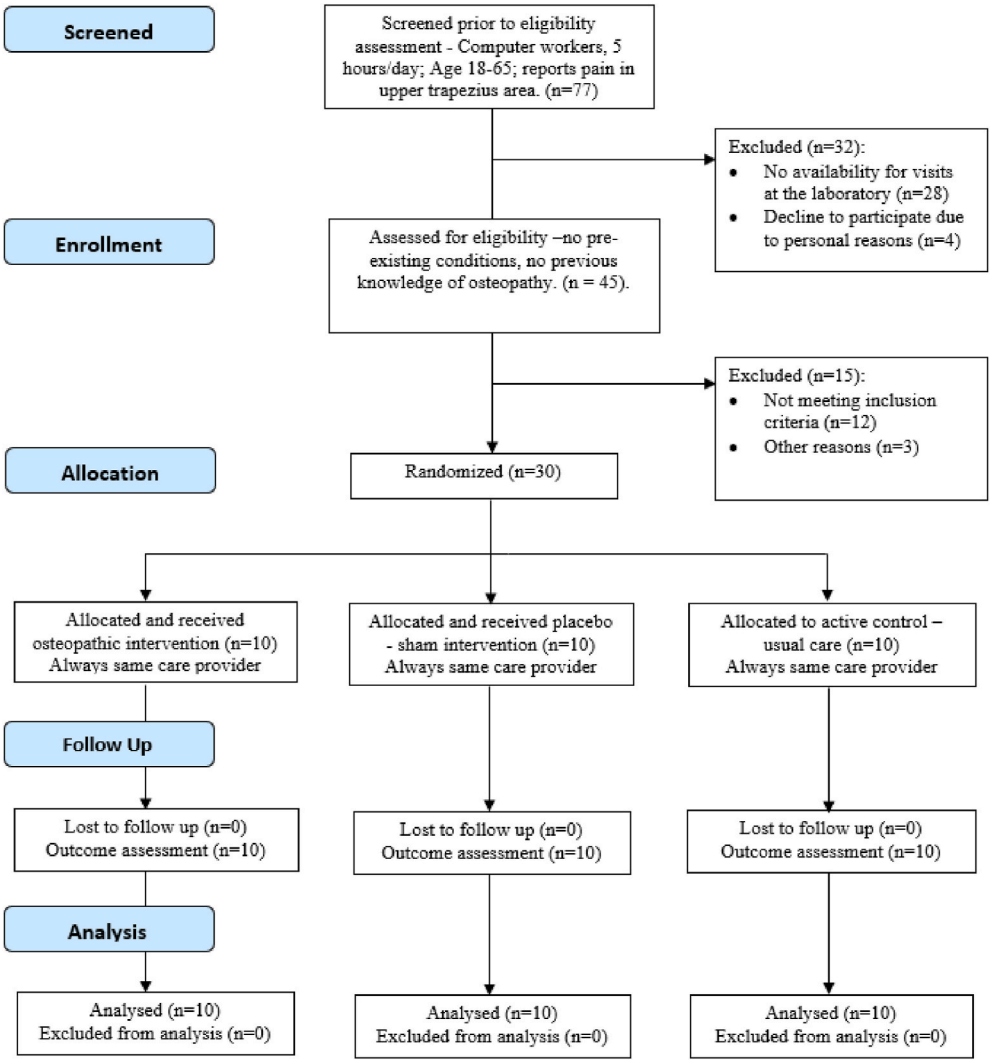


Fig. 3. Flowchart according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials [22] and CONSORT 2017 update extension for non-pharmaceutical trials [23].

influence of sex, hand dominance, computer type, and education within groups was analysed with the Wilcoxon rank-sum test. A statistician performed all analyses, blinded for group allocation and participants, a statistical software package (R Software) was used. A significance level was set at 0.05.

3. Results

From the initial 77 participants, only 30 met all the inclusion criteria and completed the study. Data were collected from September 2019 to February 2020, as planned. After randomisation, no participants were lost to follow up, showing optimal adherence to the study protocol. The flow diagram of participants in all groups through the study is shown in Fig. 3. Demographics, occupational, and body composition characteristics of the participants are described in Table 3.

3.1. Feasibility outcomes

Fourteen methodological items were used to evaluate the protocol's feasibility, as Sosnowski et al. [37] used. Table 4 presents a summary of the findings.

3.2. Safety

No adverse events were registered or reported. At the beginning of the second visit, groups 1 and 2 were asked about any reaction to treatment. Two participants in the intervention group reported having experienced a slight discomfort in the areas where the treatment was applied. They were briefed that it can occur and usually does not last for more than two days, which was the discomfort's reported length. No treatment-related pain or discomfort were reported before follow-up data collection. The most common adverse event is soreness in the muscles and is transient [39].

3.3. Efficacy outcomes

3.3.1. Relation between outcomes

Although this trial does not have statistical power, the analysed data might be acceptable if bias is adequately accounted for and reported [40]. Koes [41] states that the study's validity is a concern of the methodology, and the statistical power is a matter of the precision of the estimation of an effect. Schulz and Grimes [42] state that, although statistical power is essential, a shift of focus from sample size to methodological quality is recommended. For this reason, all the statistical comparisons will be presented.

Table 3
Baseline characteristics of participants.

Participant characteristics (Mean ± SD; min-max) or (%)	Group 1	Group 2	Group 3
Women (%); Men (%)	6 (60); 4 (40)	6 (60); 4 (40)	6 (60); 4 (40)
Age in years	41,6 ± 7,9; (27–54)	37,9 ± 7; (26–46)	39,5 ± 9,6; (26–56)
Level of education: undergraduate (%); graduate (%)	3 (30); 7 (70)	3 (30); 7 (70)	3 (30); 7 (70)
Dominant hand: right (%); left (%)	10 (100); 0 (0)	9 (90); 1 (10)	9 (90); 1 (10)
PC type: desktop (%); laptop (%)	9 (90); 1 (10)	4 (40); 6 (60)	5 (50); 5 (50)
Skeletal Muscle Mass	29,17 ± 5,7; (22,3–37,2)	28,37 ± 7,1; (18,5–42,7)	30,07 ± 6,5; (21,3–38,7)
Body Fat Mass	20,05 ± 8,8; (7,5–34,6)	16,81 ± 9,5; (7,2–40,5)	23,11 ± 10; (11,3–38,8)
Body Mass Index	25,58 ± 3,8; (19,5–32,3)	23,8 ± 5; (18,6–36)	26,66 ± 4,3; (19,1–33,6)

Table 4
Feasibility findings summary.

Methodological Items	Findings	Evidence
1. What factors influenced eligibility and what proportion of those approached were eligible?	Ineligibility occurred mainly due to difficulties with setting data collection due to laboratory availability. In other cases, the symptoms reported faded away before data collection. Participants' awareness of osteopathy criteria needs to be revised. Preparation procedures for sEMG created some difficulties and delays.	30 out of 45 (66,6%) agreed to participate and fulfilled the inclusion criteria.
2. Was recruitment successful?	Even that 33,3% were excluded, the recruitment was successful.	The minimum desired sample for each group was achieved.
3. Did eligible participants consent?	Yes, all participants consented to participate.	All participants signed the consent form before data collection.
4. Were participants successfully randomised?	Yes, there were no problems with the randomisation process.	Differences between the 3 groups are shown in Table 2.
5. Were blinding procedures adequate?	No, for this study, only the participant was blinded. For the future RCT, double-blinded procedures (having an outcome assessor) should be implemented.	It was not possible to recruit an assistant nor an outcome assessor. It increases the risk of bias.
6. Did participants adhere to the intervention?	Yes, all participants adhered to the intervention.	There were no objections to the interventions.
7. Was the intervention acceptable to the participants?	The responses to the satisfaction questionnaire measured acceptability.	There were no refusals in complying with the therapy. All participants rated their satisfaction with the care provided as 'very high'.
8. Was it possible to calculate intervention costs and duration?	This study did not include an economic evaluation.	
9. Were outcome assessments completed?	Yes, all procedures were completed as planned.	All data was successfully retrieved and stored.
10. Were outcomes measured those that were the most appropriate outcomes?	sEMG proved to disturb the clinical process's flow. Results were not considered useful for the study's purpose. The other outcomes were deemed valid.	sEMG results were affected by pain variation and did not correlate with validated, pain-measuring tools. For the future RCT, QoL is an outcome of interest.
11. Was retention to the study good?	Yes, all participants completed the study.	There were no dropouts or withdraws from this study.
12. Were the logistics of running a multicentre trial assessed?	Yes, the future RCT should be designed as a multicentered pragmatic trial. Contacts with osteopathic clinics were made with a 90% rate of interest.	Informal contacts with ten clinics providing osteopathy by fully registered practitioners regarding their interest in being partners in a future large-scale RCTreturned nine positive answers.
13. Did all components of the protocol work together?	Mostly yes, the recruitment, intervention, and data collection worked as planned. Laboratory times and sEMG equipment availability were the only issues.	All the planned study processes were completed.
14. Did the feasibility/ pilot study allow a	No, there was no formal calculation of the sample size for the future RCT.	Small sample sizes do not provide a meaningful effect size estimation

(continued on next page)

Table 4 (*continued*)

Methodological Items	Findings	Evidence
sample size calculation for the main trial?		[21]. It would not be advisable to calculate sample size for a full RCT based on the effect size seen in a pilot study [51].

3.3.2. PPT

The application of the protocol to retrieve PPT data showed no problems. The descriptive results are shown in Table 5 and Graphic 1, the statistical difference tests as supplementary material (S2).

Graphic 1 present ranks instead of levels for visual clarity. Regarding the immediate effects, there are significant differences between Groups 1 (Medians - Dominant UT: 1.37; Non-dominant UT: 1.25; C7: 1,11) and 2 (Medians - Dominant UT: 0.80; Non-dominant UT: 0.93; C7:,94), in the Dominant UT ($W = 98$, $p = .0003$, $r = 0.81$), Non-dominant UT ($W = 91$, $p = .0022$, $r = 0.69$) and C7 ($W = 79$, $p = 0{,}0312$, $r = 0.48$). The effect size was considered high for both UT's and medium for C7. Concerning the short-term effects, and for both UTs, PPT measures were significantly affected by interventions (Dominant UT: $H(2) = 13.8$, $p = .001$, $\varepsilon 2 = 0.48$; Non-Dominant UT: $H(2) = 8.4$, $p = .014$, $\varepsilon 2 = 0.29$). But not for C7 ($H(2) = 5.7$, $p = .058$, $\varepsilon 2 = 0.2$). By applying the Dunn test with Bonferroni correction for multiple group comparisons, the analysis focused on comparing the ranks between groups. The PPT variation between Groups 2 and 3 were not significantly different ($p = 1.0000$, $VDA = 0.39$). However, PPT variation in Group 1 was significantly lower than both Group 2 ($p = .0014$, $VDA = 0.89$) and Group 3 ($p = .0144$, $VDA = 0.94$). The effect sizes between Group 1 and 2 and Group 1 and 3 were considered high and between Group 2 and 3 negligible.

Table 5
Description of the PPT results for immediate and short-term effects.

PPT Index in levels	Dominant UT					
	Immediate effects			Short-term effect		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Sample size	**10**	**10**		**10**	**10**	**10**
Minimum	0,98	0,52		0,93	0,57	0,76
Q1	1,07	0,65		1,10	0,67	0,88
Median	1,37	0,80		1,23	0,90	0,96
Average	2,77	0,79		2,63	0,86	0,95
Q3	2,22	0,91		1,72	1,03	1,03
Maximum	14,40	1,07		14,40	1,09	1,15
Std Dev	4,12	0,17		4,15	0,19	0,11
CV	149%	22%		158%	23%	11%
PPT Index in levels	**Non-Dominant UT**					
	Immediate effects			**Short-term effect**		
	Group 1	**Group 2**	**Group 3**	**Group 1**	**Group 2**	**Group 3**
Sample size	**10**	**10**		**10**	**10**	**10**
Minimum	1,02	0,56		0,94	0,62	0,87
Q1	1,10	0,84		1,14	0,71	0,91
Median	1,25	0,93		1,30	0,89	0,94
Average	1,37	0,94		1,31	1,03	1,00
Q3	1,43	1,00		1,49	1,27	1,03
Maximum	2,72	1,39		1,64	1,87	1,39
Std Dev	0,49	0,21		0,21	0,40	0,15
CV	36%	22%		16%	39%	15%
PPT Index in levels	**C7**					
	Immediate effects			**Short-term effect**		
	Group 1	**Group 2**	**Group 3**	**Group 1**	**Group 2**	**Group 3**
Sample size	**10**	**10**		**10**	**10**	**10**
Minimum	0,92	0,72		0,77	0,70	0,61
Q1	1,02	0,85		0,99	0,94	0,79
Median	1,11	0,94		1,13	0,97	0,86
Average	1,15	1,06		1,17	1,14	0,90
Q3	1,29	1,02		1,41	1,06	1,04
Maximum	1,42	2,29		1,50	2,81	1,28
Std Dev	0,17	0,45		0,25	0,59	0,19
CV	15%	42%		22%	52%	21%

3.3.3. NRS

The collection of NRS data was performed according to the protocol, without any concerns being raised. The descriptive results are shown in Table 6 and Graphic 2 and the statistical difference tests as supplementary material (S2).

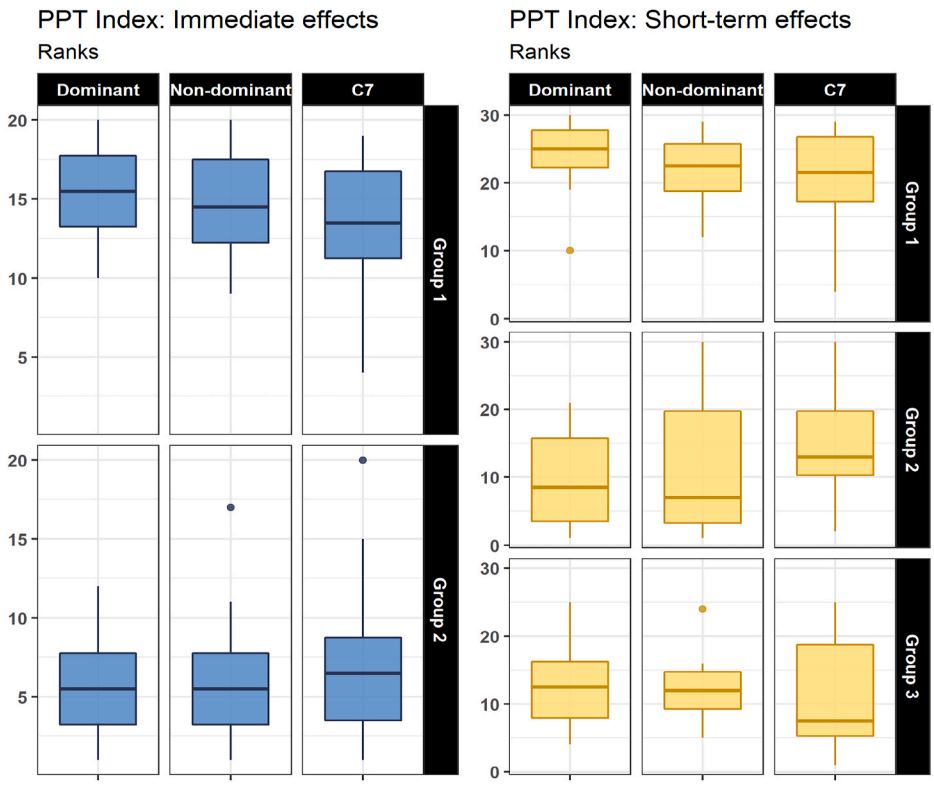
There are significant differences in the immediate effects between Groups 1 (Medians - Dominant UT: 0.37; Non-dominant UT: 0.35) and 2 (Medians - Dominant UT: 1; Non-dominant UT: 1) for the Dominant UT ($W = 7.5$, $p = .0012$, $r = -0.74$) and the Non-dominant UT ($W = 12$, $p = .0025$, $r = -0.69$). The effect size was considered high for both UT's. Regarding the short-term effects (2–4 days), results show that NRS values were significantly affected by interventions (Dominant UT: $H(2) = 12.8$, $p = .0016$, $\varepsilon 2 = 0.44$; Non-Dominant UT: $H(2) = 7.9$, $p = .0191$, $\varepsilon 2 = 0.27$). As in the PPT analysis, the Dunn test with Bonferroni correction for multiple group comparisons was used to compare the ranks between groups. For both UTs, the comparison between Groups 2 and 3 was not significantly different, and the effect size was considered negligible (Dominant UT: $p = 1.0000$, $VDA = 0.42$; Non-Dominant UT: $p = .8989$, $VDA = 0.34$). When comparing Group 1 with the others, although the effect size was negligible for the Dominant UT, the variation was significantly lower than Group 2 ($p = .0124$, $VDA = 0.12$) and Group 3 ($p = .0029$, $VDA = 0.14$). A similar result (negligible) in terms of effect size for the Non-Dominant UT compares Group 1 with the other two groups. For this UT, Group 1 varied significantly lower than Group 3 ($p = .0161$, $VDA = 0.18$) but not Group 2 ($p = .0161$, $VDA = 0.2423$). The last comparison analysis is between NRS readings at baseline and 9–11 days after. Again, results show differences between interventions (Dominant UT: $H(2) = 11.6$, $p = .003$, $\varepsilon 2 = 0.40$; Non-Dominant UT: $H(2) = 11.8$, $p = .0028$, $\varepsilon 2 = 0.41$). After applying the Dunn test with Bonferroni correction, there were only significant differences for both UTs between group 1 and group 3 (Dominant UT: $p = .0025$ $VDA = 0.11$; Non-Dominant UT: $p = .0025$, $VDA = 0.08$). No differences were found between Group 1 and Group 2 (Dominant UT: $p = .00726$, $VDA = 0.17$; Non-Dominant UT: $p = .0546$, $VDA = 0.18$) and between Group 2 and Group 3 (Dominant UT: $p = .829$ $VDA = 0.32$; Non-Dominant UT: $p = .988$, $VDA = 0.36$). All effect sizes were considered negligible.

3.4. Other outcomes

3.4.1. sEMG

Collection and analysis of sEMG data were performed as planned. Still, it raised concerns relative to its disturbance to the therapeutic experience. Table 7 and Graphic 3 present the descriptive results. The statistical difference tests are available as supplementary material (S2).

The immediate effects between Groups 1 (Medians - Dominant UT: 0.87; Non-dominant UT: 0.95) and 2 (Medians - Dominant UT: 1.04; Non-dominant UT: 0.99) resulted non-significant for both the Dominant UT ($W = 45$, $p = .7337$, $r = -0.08$, Non-dominant UT ($49 = 91$, $p = 9698$, $r = -0.02$). The effect size was considered negligible for both UTs. Concerning the short-term effects, for the Dominant UT only, there were differences between the groups measures (Dominant UT: $H(2) = 6.3$, $p = .0043$, $\varepsilon 2 = 0.22$; Non-Dominant UT: $H(2) = 1.1$, $p = .5697$, $\varepsilon 2 = 0.04$). The effect size for the Dominant UT was medium. The Dunn test with Bonferroni correction for multiple group comparisons was used for comparing the ranks between groups. There was a significant difference between Groups 2 and 3 ($p = .0384$, $VDA = 0.20$), but with a negligible effect size.



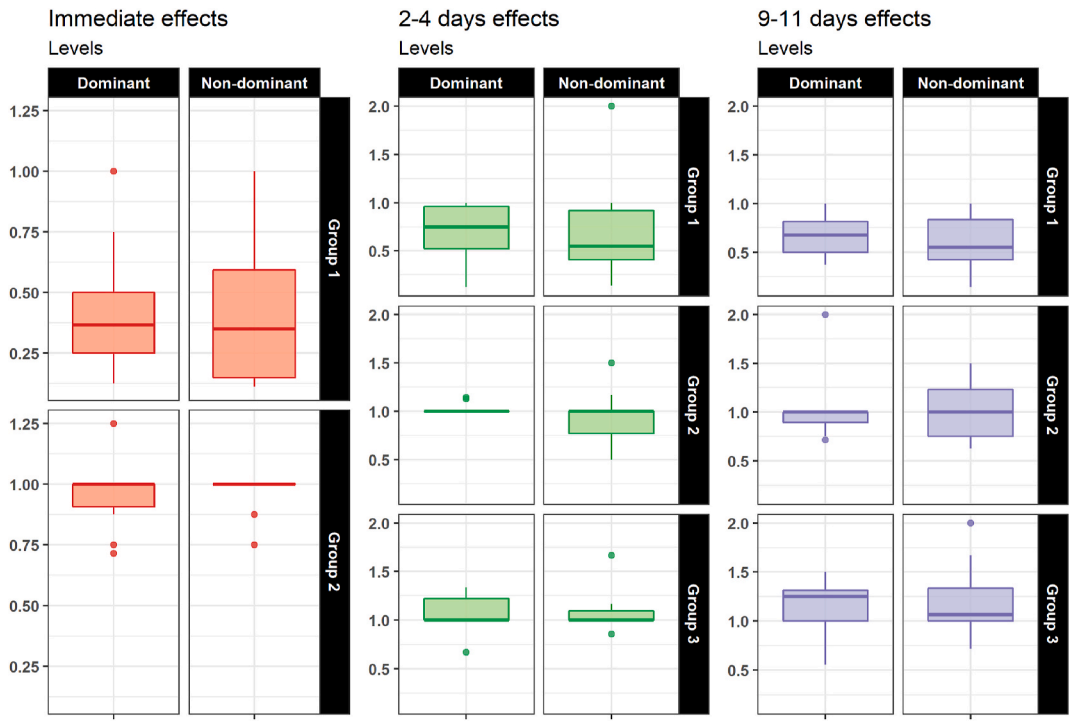
Graphic 1. PPT immediate and short-term effects results.

Table 6
Description of the NRS results for immediate, 2–4 days short-term effects and 9–11 days short-term effects.

NRS Index in levels	Dominant UT							
	Immediate effects		2–4 days effects			9–11 days effects		
	Group 1	Group 2	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Sample size	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Minimum	0,13	0,71	0,13	1,00	0,67	0,38	0,71	0,56
Q1	0,24	0,84	0,48	1,00	1,00	0,48	0,83	0,95
Median	0,37	1,00	0,75	1,00	1,00	0,68	1,00	1,25
Average	0,43	0,96	0,70	1,03	1,06	0,67	1,03	1,13
Q3	0,56	1,00	1,00	1,03	1,25	0,88	1,00	1,33
Maximum	1,00	1,25	1,00	1,14	1,33	1,00	2,00	1,50
Std Dev	0,27	0,15	0,29	0,06	0,19	0,23	0,36	0,29
CV	63%	16%	42%	6%	18%	34%	35%	25%
NRS Index in levels	**Non-Dominant UT**							
	Immediate effects		**2–4 days effects**			**9–11 days effects**		
	Group 1	**Group 2**	**Group 1**	**Group 2**	**Group 3**	**Group 1**	**Group 2**	**Group 3**
Sample size	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Minimum	0,11	0,75	0,14	0,50	0,86	0,14	0,63	0,71
Q1	0,14	0,97	0,34	0,75	1,00	0,34	0,75	1,00
Median	0,35	1,00	0,55	1,00	1,00	0,55	1,00	1,06
Average	0,44	0,96	0,69	0,95	1,08	0,59	1,01	1,22
Q3	0,70	1,00	1,00	1,04	1,14	0,89	1,27	1,42
Maximum	1,00	1,00	2,00	1,50	1,67	1,00	1,50	2,00
Std Dev	0,35	0,08	0,55	0,27	0,22	0,31	0,29	0,38
CV	79%	9%	79%	28%	20%	52%	29%	31%

3.4.2. Analysis of the influence of demographic and occupational data

No statistical difference was found between the sexes for immediate effects. Still, there were differences in Group 2 for the PPT short-term effects in the Dominant UT ($p = .0428$) and in Group 3 and PPT short-term effects in C7 ($p = .0142$). The same analysis concerning differences between education levels showed a statistical difference in Group 3 for PPT short-term effects in the Dominant UT ($p = .0402$). Statistically significant differences were found in the analysis of dominance and computer type. However, the categories' distribution is not equivalent (only two left-handed and only one laptop user in Group 1) and cannot be interpreted. There is a statistical difference for computer type for PPT on the Dominant UT for Group 2. These relationships need a larger sample and participant heterogeneity, as desired in the future RCT. All tests are available at the supplementary material (S2).



Graphic 2. NRS immediate, 2–4 days short-term, and 9–11 days short-term days effects results.

Table 7
Description of the sEMG results for immediate and short-term effects.

NRS Index in levels	Dominant UT					Non-Dominant UT				
	Immediate effects		Short-term effects			Immediate effects		Short-term effects		
	Group 1	Group 2	Group 1	Group 2	Group 3	Group 1	Group 2	Group 1	Group 2	Group 3
Sample size	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Minimum	0,46	0,62	0,45	0,53	0,55	0,65	0,73	0,21	0,24	0,58
Q1	0,64	0,82	0,74	0,55	0,79	0,74	0,82	0,62	0,55	0,73
Median	0,87	1,04	1,13	0,6	1,71	0,95	0,99	0,85	0,96	1,06
Average	1,29	0,99	1,32	0,89	2,99	0,96	0,96	1,34	1,09	1,21
Q3	1,25	1,1	1,54	1,06	5,54	1,17	1,1	1,21	1,47	1,64
Maximum	5,07	1,35	3,53	2,44	9,51	1,28	1,15	6,04	2,74	2,16
Std Dev	1,36	0,21	0,88	0,6	3,1	0,23	0,15	1,69	0,76	0,54
CV	106%	22%	67%	68%	104%	24%	16%	126%	70%	44%

3.4.3. Correlations

The comparison between the variation of the PPT, NRS, and sEMG measurements resulted in a strong correlation between NRS and PPT. For immediate effects in Dominant UT ($p = .001$) and Non-Dominant UT ($p = .016$) and for short-term effects Dominant ($p = .009$) and Non-Dominant ($p = .041$). sEMG was not significantly correlated with PPT or NRS. Concerning the immediate effects, age was correlated with sEMG in the Dominant UT ($p = .048$) and NRS ($p = .012$) for the Non-Dominant UT. For the short-term effects, there is a significant correlation between age and PPT ($p = .028$). All details are available in the supplementary material (S2).

3.4.4. Satisfaction questionnaire

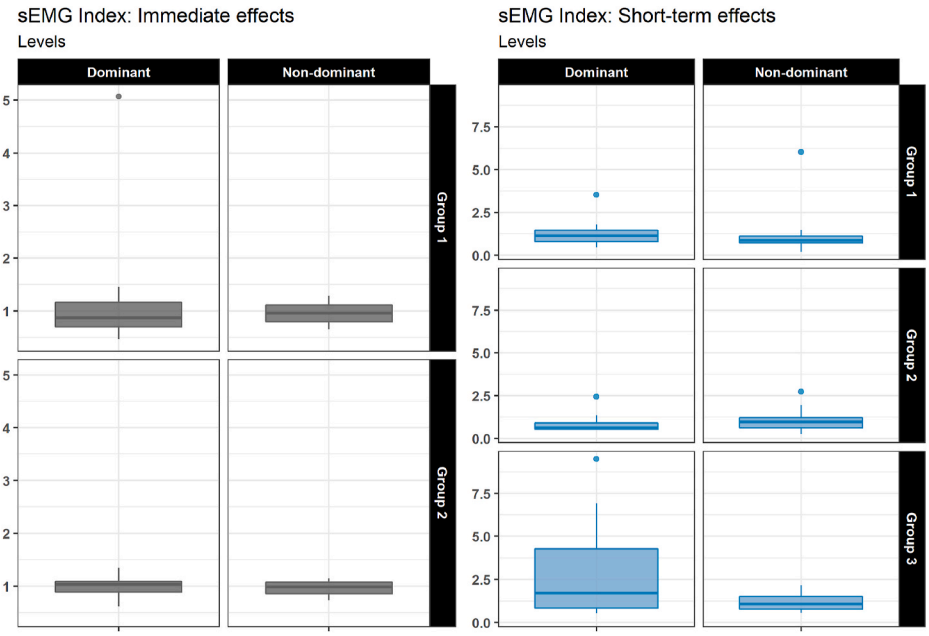
Completion rates were 80% (24/30) for this online questionnaire. Their appreciation of the waiting time, explaining all the procedures, being aware of the risks and benefits, and the investigator's care was 'very good' (5/5) on the 5-point Likert scale. Regarding the location and the data collection environment, only under 60% rated 'very good'. A qualitative question on what could be improved, only 4% responded and complained of the laboratory noise and lack of privacy, which might have influenced their experience. About 80% of the responders declared that they enjoyed participating and would most certainly participate and encourage friends and relatives to participate in future trials.

4. Discussion

To our knowledge, this is the first feasibility study for assessing the viability of running a large-scale RCT comparing the effects of the osteopathic consultation with placebo (sham osteopathic consultation) and active control (usual care) on pain intensity within an occupational profile.

4.1. Interpretation

The feasibility study objectives were met. Results showed that after addressing some identified problems, a future large-scale RCT is feasible. This assumption is made based on the successful recruitment strategy and randomisation, the optimal retention rate of 100% after the allocation, consent received from all participants, most of the protocol components worked well together, and completion of all outcome measures. These were the main items to be identified in feasibility studies, according to Shanyinde et al. [43]. Also, the absence of



Graphic 3. Electrical activity for immediate and short-term effects results.

side-effects and encouraging answers to the satisfaction questionnaire showed that a future RCT is feasible to be conducted. Some aspects need to be revised, as the criteria about previous knowledge of osteopathy. It needs to be stricter and prevent participants from looking up how a consultation of osteopathy is and what they should expect. Nowadays, that information is widely available and easily accessible online through a range of pages by any browser search. After all other inclusion criteria are met, the future strategy involves asking several questions regarding previous experience with manual therapy application by different professions. The participant would choose from a list of healthcare professions commonly using manual therapy. The future participant would be included if they only report experiences with other professions and not osteopathy.

Conducting a future trial at a laboratory with 'ideal' conditions was verified as not desirable. This is mainly due to the lack of real osteopathic clinical setting conditions, which can also introduce bias for being distant from real-world situations. An osteopathic consultation's laboratory setting was considered disturbing for the osteopath and participants because it lacked a clinical environment. Also, as noted by participants, other researchers use the laboratory. There was very little privacy as it is a site for classes, which disrupts the therapeutic process. It is also the principal researcher's opinion. Other laboratories can offer better conditions but are probably never similar to a real clinical setting [44]. Contacts with clinics offering osteopathy services were made for a future multicenter trial, most stated being interested. That will change the recruitment strategy only slightly. The participant will choose from various clinics, increasing consultation date and time and geographical flexibility and potentially preventing dropouts. Another issue is the sEMG data collection. This requires setting equipment, preparing the participant's skin, potentially restricting participants' habits, and running normalisation procedures. All this involves time and effort from the participant, which is in pain, increasing the chance of aggravating it and influencing the sEMG signal [3,31]. sEMG was removed from the future RCT's intended outcomes.

Regarding the PPT results, we can observe that the osteopathic consultation significantly increases the pain threshold to applied pressure (reduced sensitivity to pressure) compared to both sham osteopathic consultation and usual care. This was verified for both UTs in immediate and short-term effects but only for immediate effects for C7. Additionally, the sham osteopathic consultation had no significant effect on PPT over usual care.

NRS results for both UTs show that the osteopathic consultation significantly decreases the reported intensity of pain, compared to usual care for the immediate, 2–4 days short-term and the 9–11 days short-term measures. Compared with the sham-osteopathic consultation, there was a significant decrease in the reported intensity of pain after the osteopathic consultation for immediate effects for both UTs and 2–4 days short-term effects for the dominant UT only. All other results were not significant.

The osteopathic consultation did not significantly change the electrical activity pattern of the UT muscles. The sham-osteopathic consultation seemed to decrease the electrical activity when compared to the usual care group.

These results align with Galindez-Ibarbengoetxea et al. [27]; who analysed the effects of manipulative treatment for chronic cervical pain. This study used PPT, Visual Analogue Scale (VAS), and sEMG to collect data before and after the intervention. However, according to Kim et al. [29]; sEMG was found to be reliable when correlated with VAS and PPT for neck pain participants. More studies should investigate the inter-reliability of these measuring tools.

In summary, after the osteopathic consultation, the reported intensity of pain, measured by both PPT and NRS, was significantly reduced compared with sham-osteopathic treatment and usual care. The comparison between the measurement tools' variation showed a significant, positive correlation between NRS and PPT, potentially meaning that these two types of pain measurement are inter-reliable. sEMG was not correlated with PPT or NRS. There were no significant results regarding correlations between the measurement tools and demographic (sex, age), occupational (dominant UT, type of computer), and body composition variables (skeletal muscle mass, body fat mass, body mass index).

4.2. *Applicability*

The methods used for this feasibility study can generally be applied to a future RCT. Changes to the outcomes include removing sEMG, as discussed, and using a Quality of Life (QoL) questionnaire. The use of more than one primary outcome decreases the risk of type I errors. The demographic and occupational questionnaires were considered appropriate, as well as the collection of the body composition. The recruitment

strategy might differ in future RCT. It was identified as a weakness and source of bias conducting the trial in a laboratory. The intervention and data collection should happen in real osteopathic practices with a minimum deviation from an osteopathic consultation's expected everyday experience. Feasibility studies have a more flexible design, and changes to future RCT are common. A pilot study should be planned with the final design [51].

4.3. Limitations

Some methodological limitations were identified. The main researcher provided all interventions and collected all the data, affecting the internal validity by increasing the risk of bias. External validity is also influenced as laboratory-based osteopathic consultation results cannot be expected to be found in a real clinical osteopathic environment. Groups of participants were not similar in terms of their body composition or type of PC. All data relative to participants' health were self-reported, and no medical records were accessed. sEMG analysis was only performed in the time domain. Outcomes are only concerned with the reported intensity of pain and not its interference. Efficacy outcomes do not have statistical power due to the small sample.

5. Conclusions

Computer use's negative impact on neck-shoulder pain impacts a large community, potentially growing, affecting well-being and productivity. We can assert that a large-scale RCT to study the osteopathic consultation's efficacy on reducing neck-shoulder pain intensity in computer workers will be feasible with adjustments. Such RCT results should be helpful for healthcare policymakers to evaluate the possibility of considering integrating osteopathy in the occupational health task force, preventing and managing this type of WRULDs.

Declarations of interest

None.

Author's contribution

Rui José Santiago: Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Visualization. **Jorge Eduardo Esteves**: Methodology, Writing - review & editing. **João Santos Baptista**: Validation, Resources, Supervision. **André Magalhães**: Conceptualization, Validation, Formal analysis. **José Torres Costa**: Writing - review and editing, Supervision, Project administration.

Additional files

CONSORT checklists - S1.
(DOC)
Statistical Analysis - S2.
(DOC)
Demographic and Occupational questionnaire (in Portuguese) - S3.
(PDF)
Satisfaction questionnaire (in Portuguese) - S4.
(PDF)

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Availability of data and materials

All data and material are available from the corresponding author.

Ethics approval and consent to participate

Ethics approval was granted by the Porto University Ethics Committee (82/CEUP/2019), meeting the standards of the Declaration of Helsinki.

Written informed consent was obtained at baseline from the participant. Verbal consent from the participant was again received at each follow-up data collection visit.

This trial was registered at ClinicalTrials.gov with the identifier: NCT04501575. Date registered August 06, 2020.

Conflicts of interest

None declared.
Use of colour in Print.
No, online only.

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Abbreviations

WRULDs	Work-related upper limb and neck disorders
MSDs	Musculoskeletal Disorders
MSK	Musculoskeletal
UT	Upper Trapezius
NRS	Numeric Rating Scale
PPT	Pressure-Pain Threshold
sEMG	Surface Electromyography
RCT	Randomised Controlled Trial
BMI	Body-Mass Index
MT	Manual Therapy
SENIAM	Surface Electromyography for the Noninvasive Assessment of Muscles
RMS	Root Mean Square
MVIC	Maximal Voluntary Isometric Contraction
RCT	Randomised Controlled Trial
RVC	Relative Voluntary Contraction
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale
FPS-R	Faces Pain Scale-Revised
SD	Standard Deviation
QoL	Quality of Life;

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2021.101507.

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