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Supervised *versus* Minimally Supervised Exercises on Pain, Function, and Quality of Life of Individuals with Chronic Non-Specific Neck Pain: A Non-Inferiority Randomized Clinical Trial Protocol

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SUMMARY

Background. Chronic non-specific neck pain (CNSNP) is a prevalent disorder and may be associated with neuromuscular changes. Physical exercises are one of the main non-pharmacological interventions to reduce pain and improve the function of individuals with CNSNP. Although the method of exercise application (*i.e.*, supervised or minimally supervised) may facilitate clinical decision-making by health professionals, it needs to be verified and compared. The aim of this study is to investigate the non-inferiority of a minimally supervised *versus* supervised exercise program (with equal doses of training) on neck disability, pain intensity and quality of life of individuals with CNSNP.
Methods. This randomized controlled trial will include 76 individuals with CNSNP aged 18-50 to perform an eight-week supervised or minimally supervised multimodal exercise program. Outcome measures will be assessed at baseline and after 8 and 16 weeks. The primary outcome will be the neck disability. Secondary outcomes will include pain intensity, neck range of motion, muscle isometric strength, endurance, quality of life, kinesiophobia, catastrophizing, self-efficacy and global perceived effect.
Results. This is the first study to investigate the non-inferiority of a minimally supervised *versus* supervised exercise program (with equal training doses) on neck disability, pain intensity and quality of life of individuals with CNSNP. If successful, the findings of this study will clarify the importance of minimally supervised interventions for CNSNP, providing an additional approach to health professionals.
Conclusions. This clinical trial was designed to able to reproduce an approach as a physiotherapist trained in multimodal exercise program would do.
Study registration. The study has been prospectively registered in the Brazilian Registry of Clinical Trials (RBR-8bbz36g) at https://ensaiosclinicos.gov.br/rg/RBR-8bbz36g.

KEY WORDS
Chronic pain; neck pain; exercise therapy; multimodal exercise program; musculoskeletal chronic pain.

INTRODUCTION

Chronic non-specific neck pain (CNSNP) is a prevalent cause of burden of disease (1, 2) characterized by non-specific pain between the nuchal line and scapular spine or shoulders (1, 3) lasting or recurring for more than three months (4). Moreover, neuromuscular changes (*e.g.*, reduced neck muscle strength and endurance, range of motion, and contraction speed) were observed in individuals with neck pain (5-7). These changes may be caused by an imbalance between the activation of deep and superficial neck muscles and associated with the onset of pain and chronicity (5, 6). Recent guidelines and systematic reviews support physical exercises as one of the main non-pharmacological conservative treatments for CNSNP (8-11). A systematic review

with meta-analysis (8) including ten randomized clinical trials with low risk of bias suggested that specific exercises for the deep neck muscles reduce pain and improve function in individuals with CNSNP. However, clinical decision-making by health professionals may be hindered due to the heterogeneity of protocols and methods of exercise application (*e.g.*, supervised or unsupervised) (12).

Physiotherapists usually supervise exercise programs for CNSNP to avoid possible compensations and improve compliance (12, 13). However, supervision may be hindered in some situations (*e.g.*, COVID-19 pandemic, accessibility, and commute challenges), highlighting the benefits of the minimally supervised approach, which was previously tested for musculoskeletal disorders, such as non-specific chronic low-back pain (14) and temporomandibular disorders (15). Although Evans *et al.* (16) reported lower pain levels after the supervised than minimally supervised exercise for individuals with CNSNP, the exercise dose differed between groups.

In this sense, after confirming that equal doses of exercises are effective for individuals with CNSNP, minimally supervised programs may be an option when supervised exercise cannot be performed. Thus, the aim of this study is to investigate the non-inferiority of minimally supervised *versus* supervised exercise (with equal doses of training) on neck disability and strength, pain, catastrophizing, kinesiophobia, and quality of life of individuals with CNSNP.

METHODS AND ANALYSIS

Study design

This is a two-arm, parallel-group, non-inferiority randomized controlled trial with blinded evaluators and statisticians. This protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (**table I**) (17) and Consolidated Standards of Reporting Trials (CONSORT) recommendations (18) and the Template for Interventions Description and Replication (TIDieR) guidelines (19).

Ethical and dissemination

The study follows the Declaration of Helsinki and was approved by the Research Ethics Committee of the Federal University of Rio Grande do Norte (no. 6,218,685 – date of approval: August 4, 2023). All individuals will sign an informed consent form. All research team will disclose the results to society and academic community through scientific databases and social media. Also, articles will be disseminated in a peer-reviewed journal and at national and international conferences.

Participants

Individuals have been recruited since November 10, 2023 (until completing the sample size) through public announcements and medical records of local or regional orthopedics outpatient clinics.

This study will include individuals of both sexes aged between 18 and 50 years, with CNSNP (grade I or II according to Neck Pain Task Force) lasting more than three months, pain intensity ≥ 3 on the Numeric Rating of Pain Scale, and disability ≥ 5 points on the Neck Disability Index (20).

Individuals with previous neck surgery, blood clotting disorders, diffuse idiopathic skeletal hyperostosis, significant infectious diseases, serious disabling health conditions, pregnant or breastfeeding women, or who performed physiotherapy for neck pain or upper dorsal back region in the past eight weeks will be excluded.

All individuals will be assessed for 16 weeks: at baseline (T0), post-intervention (T1), and follow-up period (T2) (**table I**).

Physiotherapists training and treatment reliability

The exercises will be conducted at the Federal University of Rio Grande do Norte. A qualified and experienced musculoskeletal physiotherapist will train all researchers responsible for the exercise program for three days to ensure standardization and focus on elements of the program and home-based exercises, clinical decision-making, and study protocols.

Adherence to the exercise program will be calculated by attendance frequency in the 16 training sessions. All individuals will also be asked to inform about medication use and any adverse events during the exercise period.

Exercise program

Both groups will perform an eight-week program (twice a week) with exercises to improve neck range of motion and motor control. The **supplement** details the exercise program, which will be divided into two stages: week 1 to 4, involving free active movements of the neck and shoulders without any external resistance or load and activation and recruitment of deep neck flexor muscles; and week 5 to 8, involving co-contraction of deep and superficial neck flexor and shoulder complex muscles and their activity in all planes of movement (21-23)

Three sets of ten repetitions (ten seconds each) will be considered for motor control exercises, and five repetitions in each set will be targeted initially for range of motion exer-

Table I. Study schedule according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Timepoint	Study period			
	Screening	Baseline (T0)	Post-intervention (T1)	Follow-up (T2)
	Week -1	Week 0	Week 1-Week 8	Week 16
Enrolment				
Eligibility screening	X			
Informed consent assignment	X			
Allocation		X		
Interventions				
Minimally Supervised group			—	
Supervised group			—	
Assessments				
Neck Disability Index		X	X	X
Numerical Rating Pain Scale		X	X	X
Pressure pain threshold		X	X	X
Neck muscle strength		X	X	X
Craniocervical Flexion Test		X	X	X
Neck range of motion		X	X	X
Quality of life		X	X	X
Kinesiophobia		X	X	X
Pain catastrophizing		X	X	X
Self-efficacy		X	X	X
Global Perceived Effect			X	X

cises, with an increase of two repetitions or more per week, depending on individual tolerance. However, if the increment repetitions increase pain (≥ 2 in the Numerical Rating Pain Scale), the number of repetitions will be maintained, with a new progression attempt in the following session.

Supervised exercise

The supervised group will receive the exercise program and pain neuroscience education (PNE) based on the Retrain Pain Foundation® (24) once a week for approximately 40 to 50 min.

Minimally supervised exercise

The minimally supervised group will be instructed to perform a home-based exercise program regularly. A physiotherapist will guide the program during the first week and reinforce it during visits to the university on weeks 1, 2, 4, 6, and 8. In addition, a digital booklet containing the exercise program will be provided to all individuals with weekly lessons in PNE. Individuals will also be consulted weekly via WhatsApp on adverse events, pain levels, and any requests or difficulties with the exercises.

Outcome measures

A researcher blinded to group allocation will perform all assessments in the morning at T0, T1, and T2, and females will be assessed in the follicular phase of the ovulatory cycle to avoid hormonal interference. Each assessment will last about 90 minutes, with a minimum interval of 48 hours between assessments to avoid possible residual effects of the activation and resistance tests of the deep neck flexor muscles.

Primary outcome

The primary outcome will include the Neck Disability Index (20, 25), translated and adapted to Brazilian Portuguese (26). It has ten items scored on a Likert scale from 0 to 5 points; high scores represent greater disability. Total scores will be classified as no disability (≤ 4 points), mild disability (5 to 14 points), moderate disability (15 to 24 points), severe disability (25 to 34 points), and complete disability (≥ 35 points).

Secondary outcomes

Pain intensity

Pain intensity will be assessed using an 11-point Numeric Rating Scale (20) for the neck region. It ranges from 0 (no pain) to 10 (worst pain imaginable) points, and individuals will also be asked about the minimum, maximum, and average pain in the last seven days.

Pressure pain threshold

The pressure pain threshold is the pressure imposed by the device that causes pain, which will be measured using a digital algometer (Force Ten™, Model FDX, Wagner, Greenwich, EUA). This procedure will be performed on the upper trapezius (27) and levator scapulae muscles and the C5-C6 zygapophyseal joint, and the mean of three measures will be used for statistical analysis.

Neck muscle isometric strength

Muscle strength will be assessed using a hand dynamometer (Lafayette Instrument®, IN, USA). Individuals will be instructed to perform maximum strength in the direction of each assessed muscle group, and non-elastic bands will stabilize the device and individual. For neck flexor muscles, individuals will be positioned supine with the neck relaxed and the dynamometer placed in the center of the frontal bone, while for neck extensor muscles, they will be in the prone position with the dynamometer on the occipital protuberance.

After familiarization, three maximum repetitions of five seconds will be performed with 30-second intervals. The highest score will be used for statistical analysis, and the value (kgf) will be divided by the body mass (kg) and multiplied by 100 to normalize peak force, expressed as a percentage.

Neck muscle endurance and motor control

The craniocervical flexion test will measure neck muscle endurance and motor control (28). Individuals will be positioned supine with the occipital region on the Chattanooga® stabilizer inflated to an initial pressure of 20 mmHg (28). They will perform a slow craniocervical flexion without lifting the head (simulating a "yes") to raise the pressure to 22 mmHg and hold it for two to three seconds before relaxing and returning to the initial pressure. Only one repetition will be performed at this level to familiarize and avoid fatigue.

Next, individuals will be instructed to hold each level (22, 24, 26, 28, and 30 mmHg) for ten seconds with 30-second intervals, maintaining a chin tuck without activating the superficial flexor muscles. This phase will end when the individual performs previous compensatory movements or cannot maintain constant pressure. The highest achieved level will be recorded as the activation pressure index (API). Finally, individuals must perform up to ten repetitions at the API. The score of this phase will be calculated as the activation level (2, 4, 6, 8, or 10) multiplied by the number of repetitions (0 to 10). The cumulative performance index will be scored from the level the individual cannot continue (API × repetitions + sum of the maximum scores of previous levels) to match and compare individuals fairly. Thus, the cumulative performance index ranges from 0 to 300.

Neck range of motion

A mobile inclinometer application (Inclinometer® App) will measure the range of motion for flexion, extension, right and left rotation, and lateral bending. For flexion and extension range of motion, individuals will be seated upright with the trunk stabilized and looking straight ahead. The mobile will be positioned vertically over the external auditory canal, and individuals will be instructed to perform maximum neck flexion, extension, and bilateral flexion. For rotation, individuals will be positioned supine with the neck in a neutral position. The mobile will be placed vertically over the top of the head aligned with the sagittal suture, and individuals will be instructed to rotate their neck to the right and left as much as possible (29).

First, the evaluator will demonstrate the movements to the individuals and instruct them to perform without using the thoracic vertebra. Next, individuals will be asked to move

the neck in the three anatomical planes and six directions (30). The mean of three measures will be considered for statistical analysis.

Quality of life

The Short Form-36 questionnaire (31) will assess the self-reported quality of life. It contains 36 items divided into eight domains: functional capacity, physical aspects, pain, general health, vitality, social aspects, emotional aspects, and mental health. The total score ranges from 0 to 100; high scores indicate a high quality of life.

Kinesiophobia

Kinesiophobia will be assessed using the Tampa Scale for Kinesiophobia (32), which has 17 questions on psychosocial aspects. The total score ranges between 17 and 68 points; high scores indicate high levels of kinesiophobia.

Pain catastrophizing

Pain catastrophizing will be assessed using the Pain Catastrophizing Scale, translated and validated to Brazilian Portuguese (33), containing 13 items scored on a Likert scale from 0 to 5 points. The total score is the sum of the items divided by the number of responded items, ranging between 0 and 52 points; high scores indicate a greater presence of catastrophic thoughts.

Self-efficacy

The Chronic Pain Self-Efficacy Scale comprises 22 questions divided into three domains (pain, physical function, and symptom control), with scores ranging from 10 to 100 for each domain. The total score ranges between 30 and 300; high scores indicate greater self-efficacy. This questionnaire has very good validity and reliability in Brazilian Portuguese (Cronbach's alpha: 0.76-0.92) for individuals with chronic pain (34).

Global perceived effect

The global perceived effect (35) will be assessed at T1 and T2 using a five-point Likert scale, classified as helped a lot (1 point), helped (2 points), helped a little (3 points), did not help (4 points), and made things worse (5 points). Also, a form created by the researchers will track symptoms and adverse effects that require additional treatment during the study.

Sample size

The sample size was calculated to estimate non-inferiority between minimally supervised and supervised exercises based on a previous study comparing supervised and home-based exercises (mean score of 19.6 and 14.5 individuals at the end of the protocol, respectively). Considering a non-inferiority margin of 0.75% for the Neck Disability Index and a standard deviation of 9.98, 76 individuals (38 per group) should be included to reach 80% statistical power at a significance level of 5%, with a dropout rate of 15% (36, 37).

Randomization and allocation

After signing the informed consent form, individuals will be randomly allocated to the experimental (*i.e.*, minimally supervised exercise) or control group (*i.e.*, supervised exercise). An independent researcher will organize an offsite randomization schedule to ensure allocation concealment. This researcher will have no contact with the individuals and not be involved in the recruitment, screening, assessment, enrolment, and treatment process. The randomization will be stored in sequentially numbered sealed opaque envelopes without access for the blinded evaluators.

Individuals with CNSNP will be allocated to the groups up to one week after T0. Only the physiotherapists responsible for the exercise programs will not be blinded to the intervention, and a researcher blinded to group allocation will perform all assessments. All individuals will be instructed not to reveal which group they were allocated to ensure blinding, and all personal data will be maintained confidential before, during, and after the study by encoding the names.

Masking/blinding

Evaluators and statisticians will be blinded to group allocation. Although individuals with CNSNP cannot be blinded due to the study design and the nature of the interventions, they will be instructed not to discuss their experience during the study period with other individuals. Also, the study assessments and interventions will be conducted in separate locations to ensure blinding.

Data management, monitoring, and sharing

All collected data will be compiled electronically, and its integrity and validity will be verified during entry (edit checks). The project manager and research assistant will regularly monitor the study datasets and recommend protocol changes or the end of all or part of the study, if needed.

Individuals data in this study will be shared after blinding (*e.g.*, text, tables, figures, appendices). In addition, the researchers who proposed the methodology will provide the study protocol and clinical trial report (with the planned statistical analysis). Data requests or any form of analysis should be sent via e-mail to Pedro (fisiopedrocastro@gmail.com) or Wouber (hericksonfisio@yahoo.com.br), and requesters will be asked to sign a data access agreement.

Any changes in the protocol will be reported to the research ethics committee using the national website (http://plataformabrasil.saude.gov.br/). Changes will also be included in the clinical trial registry (Brazilian Registry of Clinical Trials).

Statistical analyses

The Levene and Shapiro-Wilk tests will verify homoscedasticity and data normality, respectively. Differences between groups and time points (T0, T1, and T2) will be calculated by analysis of variance (ANOVA) with repeated measures. Data will be presented as mean (standard deviation) or median (interquartile interval), according to the normality of distribution. Mean differences (intra and intergroup) will be presented considering a confidence interval of 95% at a two-sided p-value < 0.05. Intention-to-treat analysis will be conducted (if needed) using the expectation-maximization method for missing data. All analyses will be conducted using the SPSS version 22.0.

DISCUSSION

This study will investigate the efficacy of minimally supervised exercise compared with the same dose of supervised exercise on neck disability, pain intensity and catastrophizing, muscle strength, kinesiophobia, and quality of life of individuals with CNSNP. Although a previous study (16) reported lower pain levels in the supervised exercise than home-based exercise group, a variation in the exercise dose was noted between groups. Minimally supervised exercise may be an alternative for individuals with CNSNP when supervised exercises cannot be implemented. However, its efficacy still needs to be investigated using equal dose protocols.

Literature on the most effective minimally supervised interventions for CNSNP is scarce, and (to our knowledge) this is the first high-quality randomized clinical trial with prospective registration, blinded evaluators, allocation concealment, and an intention-to-treat approach. The sample size was calculated to obtain sufficient statistical power to detect differences in the primary outcome. Also, a two-month follow-up will assess the lasting effects of exercises in individuals with CNSNP.

The findings of this study will clarify the importance of minimally supervised interventions for CNSNP, providing an additional approach to health professionals. However, this protocol has some limitations, including the impossibility of blinding therapists and individuals due to the nature of interventions.

Strengths and limitations of the study

This is the first randomized controlled trial investigating the non-inferiority of a minimally supervised *versus* supervised exercise program (with equal training doses) on neck disability, pain intensity and catastrophizing, muscle strength, kinesiophobia, and quality of life of individuals with CNSNP.

This study is randomized, prospectively registered, with blinded evaluators, allocation concealment, and an intention-to-treat approach, providing a high methodological quality.

Individuals of both sexes will be included, strengthening the external validity of the study.

The main limitation of the study will be the impossibility of blinding the physiotherapists due to the nature of the intervention.

CONCLUSIONS

In summary, this study is designed to investigate the non-inferiority of minimally supervised *versus* supervised exercise (with equal doses of training) on neck disability and strength, pain, catastrophizing, kinesiophobia, and quality of life of individuals with CNSNP. The results of this study may indicate that minimally supervised exercise is an effective treatment for CNSNP, reducing neck disability, pain intensity and catastrophizing, and kinesiophobia and improving muscle strength, quality of life, adherence, and global perceived effect.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author. An agreement could be asked to be signed.

CONTRIBUTIONS

PHMC: conceptualization, data curation, writing – original draft, supervision. WHBV, GADF conceptualization, formal analysis, writing – original draft. All authors: writing – review & editing.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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