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Effectiveness of pain neuroscience education, motivational interviewing and cognition targeted exercise therapy in patients with chronic neck pain: protocol for a multicentre randomised controlled trial (the COGMO-AP study)

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ABSTRACT

Introduction In primary care, the prevalence of neck pain has increased substantially. Evidence regarding treatment of chronic neck pain (CNP) is scarce, and its effectiveness is not entirely proven in different stages of chronicity, nor for different types of cervical disorders. The goal of this study is to evaluate the effectiveness of a complex intervention (COGMO intervention) compared with usual practice in primary care physiotherapy to improve neck pain intensity, severity and disability in patients with CNP.

Methods and analysis Design: a pragmatic cluster-randomised clinical trial design with a 12-month follow-up. Setting: primary care. Participants: physiotherapists as randomisation unit, and patients as analysis unit. Inclusion criteria: individuals aged 18 to 65 years suffering from moderate to severe CNP. Sample size expected: 142 patients. Recruitment: patients referred from primary care physicians to physiotherapy. Intervention: pain neuroscience education (PNE), motivational interviewing (MI) and cognition targeted exercise therapy (CTE) compared with the standard treatment in primary care. Outcomes: the main variable is reduction in pain intensity; secondary variables include pain severity, conditioned pain modulation, temporal summation, neck disability, fear/avoidance behaviour, kinesiophobia, catastrophising, therapeutic alliance and quality of life. Sociodemographic information and adherence to the intervention will be recorded. Data collection: baseline, and follow-up at 3, 6 and 12 months. Analysis: it will follow intention-to-treat principles, and difference in percentage of subjects achieving success on the primary endpoint at 12 months. A model with multilevel analysis will be adjusted through logistic regression (being the dependent variable pain intensity, and the independent, the intervention).

Ethics and dissemination Ethical approval has been awarded by the Regional Ethics Committee of Madrid (code: COGMO-AP) and the primary health care central commission of research (code: 20210011). The results of the study will be disseminated through international peer-reviewed journals, international conferences, press and social media.

Trial registration number NCT05785455.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The methodology of this research follows a pragmatic approach, taking advantage of the capacities of the Spanish National Health Service.
⇒ The protocol has been validated by four different institutions, serving as a benchmark for addressing challenges in integrating multicomponent complex interventions into primary healthcare, and the methodology has been widely explained to ensure replicability.
⇒ The large number of clinicians involved in this study and the level of proficiency in acquiring the skills to carry out the intervention may introduce variability in the results, potentially influencing the overall future findings.
⇒ Given the nature of the intervention, subjects and clinicians are not blind to the group they belong to.

INTRODUCTION

Neck pain (NP) is defined by the International Association for the Study of Pain (IASP) as pain perceived anywhere in the posterior region of the cervical spine, from the upper nuchal line to the spinous process of the first thoracic vertebra.[1] The prevalence of NP generally increases with age and is typically higher in women than in men.[2] A study conducted in the Community of Madrid in 2007 showed that the prevalence of NP in women was up to 8.4%, and in men 3.2%,[3] having the younger population a better

prognosis for improvement.[2 4] At the European level, it is estimated that chronic pain accounts for more than 300 000 million euros between direct and indirect costs, while in Spain around 3% of the Gross National Product (GNP).[5] NP has become the main reason for consultation in primary care in Spain and one of the most expensive health problems in our society.[6]

Although the aetiology of chronic NP is unclear, it is known to be multifactorial, with a range of factors associated with both biological and psychological problems. Moreover, chronic NP frequently coexists with other musculoskeletal disorders,[7 8] like back, shoulder or multisite pain.[9]

People with chronic neck pain (CNP) present central nervous system changes such as grey matter alterations and features of central sensitisation, and tend to have erroneous beliefs about pain, kinesiophobia, hypervigilance and pain catastrophising, associated with poor treatment outcome.[10–14] It is now accepted that the psychological component may play an important role in the aetiology of CNP and can be used as a very valuable tool for its management by reprogramming harmful behaviours and education of the patient.[15 16] In addition, these conditions have been considered as determinants for the development and perpetuation of NP.[17]

Currently, numerous treatments are used in general practice for the treatment of CNP, including analgesics, rest, physiotherapy and manual therapy.[18] In general, physiotherapy is recognised to be fundamental in the treatment of pain and the prevention of chronic disability within a multimodal approach.[19–21] It includes, among others, passive techniques like manual therapy,[22 23] which have shown to have a short-term hypoalgesic effect,[24 25] and active treatments,[26 27] like exercise therapy which shows very good results with moderate effect sizes in the long term.[28] However, experts conclude that when manual therapy and exercise therapy are applied together, the effects are better and last longer than when applied in isolation.[26 28]

Evidence suggests that the treatment of CNP should focus on getting the individual to return to their normal life, being oriented towards health education (HE), active physiotherapy and increasing the patient's activity level, motivating them to actively participate in controlling their health.[15] For conditions associated with cervical spine disorders, HE is superior to other interventions to reduce pain and disability,[29] but these conclusions are based on heterogeneous HE, including education as part of a multimodal intervention.[30 31] Furthermore, recent studies[15 27] demonstrate the importance of modifying HE programmes, introducing content that explains the neurophysiology of pain and the concept of central sensitisation, since it may improve the patient's symptoms.[29 32–34]

However, there are no clear conclusions about the efficacy of HE for NP at different stages of chronicity, or for different types of cervical disorder, or at different follow-up periods,[30 35] including counselling on how to contract the muscles, stress-coping strategies or neck exercises.[35 36] Clinical trials support the use of HE in multimodal intervention studies; such education should be based on a theory of learning and skill acquisition,[37 38] and suggest that HE should be used by physiotherapists from a biopsychosocial approach.[23]

In this context, pain neuroscience education (PNE), currently known as 'pain science education',[39] appears as an education strategy used by physiotherapists focused on teaching people suffering from pain about the biological and physiological processes involved in their painful experience.[40 41] It differs from HE as the latter focuses more on anatomy, aetiology and biomechanics to explain the patient's painful experience,[41] which may induce increased fear and anxiety related to the development and maintenance of persistent pain.[42] PNE has been shown to have small effects on pain intensity,[43] fear and avoidance beliefs, pain catastrophising and limitations to movement, decreasing the use of healthcare services.[38 44 45] Nonetheless, PNE is unlikely to generate clinically significant and long-lasting effects when used in isolation.[46]

Motivational interviewing (MI), on the other hand, is a directive therapeutic style to enhance readiness for change by helping patients explore and resolve ambivalence, eliciting their own motivations for change.[47] Conceptually, PNE and MI appear to be interventions with complementary rather than overlapping effects; MI primarily improves cognitive and behavioural awareness and potentially adherence to treatment principles, while PNE potentially increases knowledge and beliefs about pain, such as awareness and willingness to explore psychological factors that are conditionally associated with pain. Therefore, combining PNE with MI could lead to better results with larger and longer-lasting effect sizes.[48] Both strategies together have shown to be effective in the short term (with small effect sizes) for chronic pain management.[48 49] In addition, programmes based on education in the neurophysiology of pain, emotional therapy and at-home training have proven to be effective in the treatment of chronic pain.[26 44]

Just as the re-education of beliefs is important in the improvement of chronic pain, in contemporary pain management approaches, therapeutic exercise (TE) plays a crucial role.[50] Moreover, emphasising the perceptions and knowledge of the patients so that they can understand that the therapeutic exercises applied are not aimed at addressing local neck dysfunctions, but rather at 'retraining the brain', to treat their pain has shown to be effective in reducing pain intensity, biopsychosocial factors and increasing quality of life in patients with chronic spinal pain.[51] This is a combination of PNE with TE, known as 'cognition-targeted exercise therapy' (CTE).[52]

In short, there is a lack of scientific production in terms of multimodal approaches regarding CNP. Current state-of-the-art research suggests exploring the uniqueness and complexities of each patient and how this affects the communication style of the therapist and

the patient-centred content, and that ongoing research needs to explore the effects of diverse PNE approaches and interactions when provided with multiple treatment interventions.[53] Thus, the main objective of this research is to assess the effectiveness of a complex intervention, named 'COGMO Intervention', comprising PNE, MI and CTE compared with routine clinical practice in physiotherapy (exercise and health education), to improve pain intensity, in patients with CNP at 12-month follow-up.

Secondary objectives include assessing the effectiveness of the COGMO intervention versus usual therapy with health education at 3, 6 and 12 months to improve pain intensity, severity, total and distal mechanical hyperalgesia, conditioned pain modulation, pain-free changes in the neck range of motion (ROM), motor control, depressive symptoms, anxiety, kinesiophobia, catastrophism, fear of pain and health-related quality of life, and to describe adherence to COGMO intervention and the degree of patient satisfaction with the therapy received in both groups.

Through the objectives above, we propose a research project that solves these deficiencies found in the usual treatments of chronic pain, promoting the evaluation of a complex and multicomponent intervention in the field of primary care physiotherapy, in a pathology of high prevalence in the working-age population.

The conceptual hypothesis theorises that in patients with CNP, the 'COGMO intervention' performed by primary care physiotherapists will increase the proportion of patients with clinical improvement in pain intensity, compared with a standard programme of health education with exercises, whereas the operational hypothesis is that in patients with CNP, a complex 'COGMO' intervention will achieve an absolute difference in the percentage of patients who achieve clinical improvement of the pain intensity (at least 30 mm on the long-term VAS at 12 months) which will be at least of 25% more participants achieving a 50% reduction in pain in the intervention group compared with the control group.

The present protocol consists of a pragmatic cluster-randomised clinical trial, in which, the randomisation unit is the physiotherapy professional and the analysis unit is the patient. It includes 4 weeks of intervention for two treatment arms, data collection at baseline, and follow-up visits at 3, 6 and 12 months in patients with CNP.

METHODS AND ANALYSIS

The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials guidelines[54] and was registered on ClinicalTrials.gov under the identifier NCT05785455 before the recruitment of participants. Online supplemental appendix 1 holds all elements outlined in the WHO Trial Registration Data Set, while online supplemental appendix 2 addresses all protocol versions.

Study design and setting

This study is a pragmatic cluster-randomised clinical trial with a 12-month follow-up. The randomisation unit is the physiotherapy professional, and the analysis unit is the patient. Patients with chronic neck pain under follow-up in primary care will be recruited in Madrid (Spain), from 14 different healthcare centres; they can all be found on the list in online supplemental appendix 3.

Currently, the recruitment of professionals and patients has been completed; the end of the trial and data analysis is expected before May 2025.

Eligibility criteria

In order to participate in the study, the patients must meet the following criteria:

1. Age: between 18 and 65 years.
2. Diagnosed with chronic neck pain, according to the death of the IASP with pain duration of more than 3 months and referred to physiotherapy by their family doctor.[1]
3. Neck Disability Index (NDI) score equal to or greater than 20% (10/50).
4. Pain intensity in the cervical region equal to or greater than 30 mm on the Visual Analogue Scale.
5. Sign informed consent (online supplemental appendix 4).

Potential participants will be excluded when:

1. They have pathologies or comorbidities that may contraindicate the therapies to be applied (severe depression, rheumatological and inflammatory diseases, cancer, fibromyalgia, systemic diseases, serious psychological disorders, neck pain secondary to a traffic accident, cervical radiculopathy or neuropathies)
2. Criteria for referral to surgery or failure of spinal surgery.
3. Inability to read, understand and complete questionnaires; or understand and follow verbal commands.
4. Have received physiotherapy in the last 3 months.
5. Have any legal action pending (eg, injury compensation).

Intervention

Training of professionals (COGMO intervention group)

Prior to the intervention, training of the physiotherapy professionals assigned to the intervention group will be performed. It consists of five training sessions in MI, PNE and CTE. In addition, a manual will be provided to ensure that they can properly carry out what they have learnt. It is expected to have at least 23 physiotherapy professionals (11 per branch) (online supplemental appendix 5). The training has a 2-week duration and a total amount of 25 hours, it will be provided by two experts on the topic with background on MI and psychologically informed physiotherapy, and it will be carried out within the primary healthcare management facilities, giving access to a training aula and providing the necessary materials to implement it. To ensure the homogeneity of the intervention, the supplementary material and the content of

Table 1 Overview of the content of the training provided to physiotherapists

Content overview of the training for physiotherapists			
No. of session	**Duration**	**Topic**	**Content**
1	5 hours	Pain neuroscience education (PNE)	► What is PNE ► Explaining pain neurophysiology ► Factors that influence pain perception ► Metaphors to explain pain neurophysiology ► Practical training of the contents for session 1
2	5 hours	Motivational interviewing (MI)	► What is MI ► Spirit of MI ► Phases of MI (engage, focus, evoke and plan) ► Practical training of the contents of session 1
3	5 hours	Active listening and communication	► Patient-centred model ► Therapeutic alliance ► Empathy ► Active listening ► Open questioning ► Practical training of the contents of session 3
4	5 hours	Integrating MI with PNE and cognition targeted exercise (CTE)	► Change of conduct ► Phases of the change of conduct ► Integrating motivational interviewing with PNE and CTE ► Practical training of the contents of session 4
5	5 hours	Consolidation of acquired knowledge and evaluation	► Solving questions regarding the contents of the training ► Literature reading on the topic ► Solving clinical cases ► Evaluation of the knowledge about the training

the training have been uploaded to the health education database of the primary healthcare 'EPSalud' with restricted access only to the participant therapists in the intervention group. The training will be provided after the recruitment of patients to avoid bias. An overview of the content related to the training can be found in table 1.

Interventions

Both groups of participants will receive the same number of sessions, and with the same frequency (one visit per week) regardless of the group they belong to.

Intervention group: patients will receive a first individual session to assess their beliefs about pain and coping strategies, combining MI and PNE techniques, followed by four group sessions of 60 min, focused on pain neurophysiology and self-efficacy techniques in pain control, emphasising two-way communication. These sessions will be given by physiotherapists with specific training in MI, PNC and CTE (the combination of these three techniques makes up the complex intervention proposed). CTE will consist of a combination of motor control and dynamic exercises and will be applied by working on exercises that the patient understands to be relevant to their pain after and together with PNE, focusing on functionality, according to specific beliefs, targeting movements that are feared or avoided by the patient, and in a personalised way, these exercises should be performed by patients every day during their participation in the study until the end of the study in the last data collection.

Control group: the subjects in the control group will receive a health education programme for five 60 min group weekly sessions (of a minimum of five to six patients), taught by physical therapists with no training in PNE, MI or CTE. The contents of the programmes are the standard practice in primary care in Madrid, which has been validated and approved by the Commission for Validation of Educational Projects of the Community of Madrid. All physiotherapists have access to the health education programme through the health education database of the primary healthcare 'EPSalud', where the guidelines and the materials are stored. It includes sessions about ergonomics, orthopaedics of pain and strengthening and functional exercises. The physiotherapists in this group will not receive any additional training since these group sessions fall within the primary care physiotherapy protocols and routine clinical practice and do not include MI, only routine health education, which also does not include PNE.

An overview of the contents of both the control and intervention groups can be found in table 2.

Table 2 Overview of the content of the sessions in both arms

Overview of the content in both arms		
Control group	**No. of session**	**Intervention group**
What is neck pain? Neck pain anatomy Explanation of the sessions Advice to do therapeutic exercise In-room supervised exercises	1	Individual session to address patients' beliefs, obstacles and motivation for a change of conduct. Combination of PNE and MI.
Types of neck pain Imaging diagnoses In-room supervised exercises	2	Communication regarding the knowledge acquired in the previous sessions, and going through different stages: 1. Help the patient develop a reason for himself to change. 2. Validate the patient experience. 3. Encourage the patient to further self-exploration. 4. Leave the door open for future conversations in the next sessions. Integrating CTE, PNE and MI: Targeting the deep neck flexors and scapular muscles, including motor control, and dynamic and functional exercises.
Ergonomics Biomechanics of neck movements How to sit and lay down properly Diverse types of pillows Neck braces and orthopaedic collars In-room supervised exercises	3	
Physical activity What is therapeutic exercise? Effects of therapeutic exercise In-room supervised exercises	4	
Locus of control Health determinants Self-care Applying hot or cold packs Recovery stages Active coping Revising and solving doubts In-room supervised exercises	5	

Outcomes

Primary outcome

Improvement in pain intensity (yes/no) at 12 months. It is considered to have improved if there is a decrease ≥30 mm measured according to the visual analogue pain scale. This 30 mm decrease is considered clinically relevant.[55] The visual pain scale is a 100 mm line in which the 'no pain' is represented on the left side of the line and the 'worst pain imaginable' on the right side. The patient marks on the line what the intensity of their pain is.

Secondary outcomes

Secondary outcome variables related to changes in pain intensity, severity, neck disability and quality of life.

Other variables: (a) sociodemographic (age, sex and level of education); (b) clinical: BMI, symptoms of anxiety and depression, perception of fatigue, days with disability; (c) psychosocial: kinesiophobia, pain catastrophising, fear prevention, fear beliefs and/or avoidance; (d) pain: cervical ranges of motion, pain pressure thresholds, temporal summation, conditional pain modulation and endurance of the deep neck flexors, consumption of pain medications; (e) adverse effects; (f) satisfaction.

The variables will be analysed at baseline with three follow-ups, at 3, 6 and 12 months after the intervention; the tools used and timeline can be found in table 3. In addition, variables related to the professional physiotherapists will be recorded (age, sex, years of working experience).

The list of instruments/questionnaires to measure the variables is presented in table 4. These variables have proven to be relevant in the assessment of chronic pain, since psychological and social factors form an interactive complex of biopsychosocial processes that characterise it.[56] Therefore, a comprehensive assessment of the biological aetiology of pain in conjunction with the patient's specific psychosocial and behavioural presentation is necessary, including their emotional state, perception and understanding of symptoms.[57]

To prevent order-of-evidence effects, measurement of measures of self-reported variables shall precede experimental pain testing and clinical testing. In addition, randomisation of the order in which self-reported measures will be carried out. Reasons for withdrawal will also be recorded. The time of enrolment, interventions and follow-up visits can be found in figure 1.

Data collection

Patient information will be obtained through clinical interviews and examinations in physiotherapy clinics by external evaluators, who are physiotherapists with an extensive background in research and knowledge

Table 3 Outcomes and tools

Outcome		Tool	Baseline	Treatment (5 weeks)	3 months	6 months	12 months
Primary variable							
Pain	Pain intensity	VAS	x		x	x	x
Secondary variables							
Pain	Pain severity	CPGS	x		x	X	x
	Pain pressure thresholds	Digital algometer	x		x	x	X
	Temporal summation	Digital algometer	x		x	x	x
	Conditioned pain modulation	Tourniquet test	x		x	x	x
	Consumption of pain medication	eDCN	x		x	x	x
Clinical	Neck disability	NDI	x		X	X	X
	Body mass	BMI	X		X	x	X
	Anxiety	STAI and PASS-20	X		X	X	X
	Depression	BDI-II	X		X	X	X
	Perception of fatigue of the deep neck flexors	VAS-F and DNFR	x		x	X	X
	Quality of life	EQ 5D-5L	X		X	X	X
	Days with disability	eDCN	X		X	X	X
	Central sensitisation	CSI	X		x	X	x
	Cervical range of motion	CROMd	x		X	x	x
Psychosocial	Kinesiophobia	TSK-11	X		X	X	X
	Catastrophising	PCS	X		X	X	X
	Fear beliefs	FPQ-III	X		X	X	X
Interventions	Therapeutic alliance	CAF-P		x			
	Satisfaction to treatment	GRoC		x			
	Adherence to intervention	eDCN		x			
Adverse effects	Adverse effects	eDCN	x		x	X	x

BDI-II, Beck Depression Inventory-II; BMI, Body Mass Index; CAF-P, Therapeutic Alliance in Physiotherapy Questionnaire-Patients; CPGS, Chronic Pain Gradation Scale; CROM, Cervical Range of Motion device; CSI, Central Sensitization Inventory; DNFR, Deep Neck Flexors Resistance Test; eDCN, electronic Data Collection Notebook; EQ 5D-5L, EuroQol 5 Dimension 5 Level; FPQ-II, Fear of Pain Questionnaire III; GRoC, Global Rating of Change; NDI, Neck Disability Index; PASS-20, Pain Anxiety Symptom Scale Short Form 20; PCS, Pain Catastrophizing Scale; STAI, State-Trait Anxiety Inventory; TSK-11, 11 item Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale; VAS-F, Visual Analogue Scale for Fatigue Severity.

in the measured variables. In addition, to ensure inter-examiner reliability to the best extent possible, the external evaluators have been trained to follow exactly the same measurement protocols for all the study variables. Four visits are contemplated for data collection: baseline visit (which includes verification of inclusion/exclusion criteria and signing of consent), and follow-up visits at 3, 6 and 12 months after the end of the intervention. Primary and secondary outcome measures are recorded in all the visits. The same information will be obtained for the control and intervention groups. All variables will be recorded in an electronic data collection notebook designed ad hoc by visits.

Table 4 Outcomes and tools

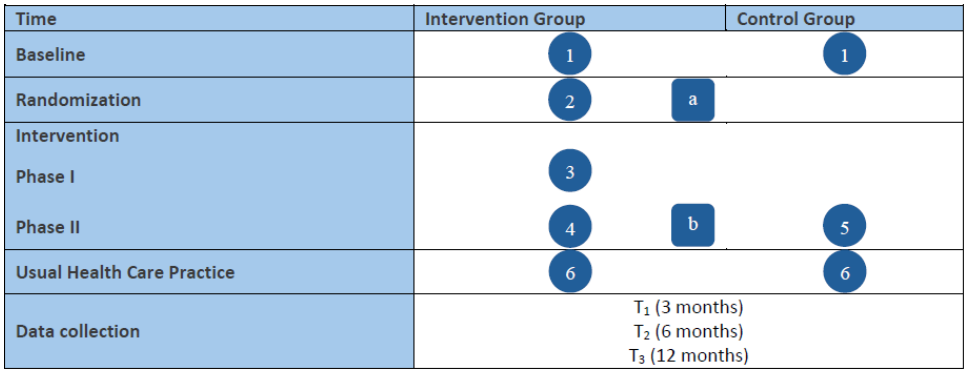
Outcome		Tool
Primary variable		
Pain	Pain intensity	VAS: this is a 100 mm line with 'least possible pain' on the left side of the line and 'worst possible pain' on the right side. The patient marks the intensity of her pain on a flat line, which allows observing the result obtained on the 100 mm line, being able to quantify its pain in this way.[61] A score of less than 30 mm is considered mild pain, between 31 and 54 mm, moderate, and above 55 mm, severe.[62]
Secondary variables		
Pain	Pain severity	CPGS: this scale is divided into two subscales (the first evaluates the intensity of pain and the second the disability perceived with the first subscale). The Spanish version has proven to be valid and reliable for assessing the severity of chronic pain. The total score that can be obtained ranges from 0 to 70 points.[63]
	Pain pressure thresholds	Digital algometer: a digital algometer (FDX 25, Wagner Instruments, Greenwich, Connecticut, USA) will be used, consisting of a rubber head (1 cm^2), attached to a manometer. The measurements were carried out on the upper trapezius as a proximal area and the anterior tibialis as a distal area. The pressure is progressively applied until the patient perceived the pressure as painful.[64 65]
	Temporal summation	Digital algometer: a digital algometer (FDX 25, Wagner Instruments, Greenwich, Connecticut, USA) will be used, consisting of a rubber head (1 cm^2), attached to a manometer. It is elicited with 10 applications of the algometer at pressure pain detection threshold intensity on the dorsal surface of the thumb and at the middle of the right-hand side trapezius belly.[66]
	Conditioned pain modulation	Tourniquet test: provocation of accessory pain will be performed with a pneumatic cuff placed on the arm, inflated until the first sensation of pain, waiting 20 s, and asking the subject to evaluate the level of subjective pain at the moment.[64 67 68]
	Consumption of pain medication	eDCN: the type and average consumption of drugs per week will be recorded in a logbook.
Clinical	Neck disability	NDI: validated version in Spanish of the NDI.[69] It measures the level of disability perceived by the patient as a consequence of their neck pain. It consists of 10 elements, related to functional activities of daily living, pain intensity, concentration capacity, work capacity and headache. The total score ranges from 0 (no activity limitation) to 50 (complete disability). In general, a score between 5 and 14 is considered a mild disability, between 15 and 24 moderate disabilities, and 25 severe disabilities.[70 71]
	Body mass	BMI: it is used to estimate the amount of body fat by using a person's height and weight measurements. The calculation divides an adult's weight in kilograms by their height in metres squared.[72]
	Anxiety	STAI: the Spanish version of the STAI will be used. The total scores for each of the subscales range between 0 and 60 points. Specifically, STAI-E is suitable for assessing state anxiety in a wide variety of clinical situations. In addition, it has good reliability and previously demonstrated validity.[73–75] PASS-20: the Spanish version will be used. It consists of 20 items that measure four anxiety components before pain: fear, escape/avoidance, cognitive anxiety, and physiological anxiety. Patients rate each of the items using a 6-point Likert scale; be 0 never and five always. The total score ranges from 0 to 100.[76 77]
	Depression	BDI-II: it is the most widely used questionnaire to assess depression, the Spanish adaptation will be used. The total score ranges from 0 to 63 points. A score higher than 13 indicates the presence of depressive symptoms. It has been seen that a change of 5 points in the Beck Depression Inventory can be a reasonable estimate of a clinically important difference.[78 79]
	Perception of fatigue of the deep neck flexors	VAS-F: the scale consists of 18 items relating to the subjective experience of fatigue. Each item asks respondents to place an 'X,' representing how they currently feel, along a visual analogue line that extends between two extremes (eg, from 'not at all tired' to 'extremely tired'). The instrument also possesses two subscales: fatigue (items 1–5 and 11–18), and energy (items 6–10).[80] DNFR: the subjects begin in a supine, then are directed to 'tuck the chin' completely and then raise the head. After that time recording starts and is terminated when one of four criteria is met: loss of chin tuck; the subject's head rested for more than 1 s; the head is no longer maintained; or the subject is unwilling to continue. Two measurement scores were averaged, and the result was recorded.[81]
	Quality of life	EQ 5D-5L: the Spanish version consists of five factors: mobility, personal care, daily activities, pain/discomfort and anxiety/depression, with a theoretical range of 1 to 5 in each factor that responds to five levels of severity, in which higher scores represent more serious health conditions. A second element consisting of a vertical VAS with a theoretical range from 0 (the worst imaginable health state) to 100 points (the best imaginable health state). The EQ-5D has presented good psychometric characteristics.[82 83]
	Days of sick leave	eDCN: all days that patients have not been to work and are unable to go to work will be counted to calculate sick leave days, and it will be registered in a logbook.
	Central sensitisation	CSI: this inventory is used to identify symptoms related to central sensitisation. Formed by 25 elements (scores ranging from 0 to 100). The results are interpreted: subclinical from 0 to 29; mild from 30 to 39; moderate from 40 to 49; severe from 50 to 59; and extreme from 60 to 100. The Spanish version will be used.[84–86]
	Cervical Range of Mmotion	CROMd: it consists of three inclinometers attached to a lightweight plastic frame, secured with velcro straps for closure. The protocol used will consist of a sequence of three measurements, with an interval of 30 s between each measurement.[87]

Continued

Table 4 Continued

Outcome		Tool
Psychosocial	Kinesiophobia	TSK-11: it allows to know the degree of fear of movement or reinjury. The validated Spanish version of the 11-item scale has a score range from 11 to 44 points. It counts with subscales for activity avoidance, and harm. This scale has been shown to have good validity and reliability.[88 89]
	Catastrophising	PCS: it consists of 13 elements that evaluate catastrophic cognitive-emotional processes with respect to pain and collect the three main dimensions of catastrophism (rumination, helplessness and magnification). They are evaluated on a Likert scale. The total score range is between 0 and 52. The Spanish version of the PCS has shown good internal consistency.[90 91]
	Fear beliefs	FPQ-III: it is used to evaluate the emotional components of pain, the fears and apprehensions of an individual in the face of a varied nature of stimuli and situations that can cause pain. The total score of the questionnaire fluctuates between 30 and 150 points. The Spanish version will be used.[92 93]
Interventions	Therapeutic alliance	CAF-P: the Spanish version will be used. It is a 14-item scale in which each is assessed on a 3-item Likert-like scale from totally disagree (2 points), partially disagree (1 point), neither agree nor disagree (0 points), partially agree (3 points), and totally agree (4 points). Reaching a maximum of 56 points means excellent therapeutic alliance and 0 points being the minimum, meaning no alliance.[94]
	Satisfaction to treatment	GRoC: it involves a single question that asks the patient to rate their change with respect to a particular condition from the time they began treatment until the time they answered the question. The rating is based on a 15-point self-report scale (from –7 to 7), where a '–7' indicates 'a very great deal worse,' '0' indicates 'about the same,' and '+7' indicates 'a very great deal better'.[95]
	Adherence to intervention	eDCN: patient's attendance to treatment sessions. Attending 3 of the five sessions is considered adequate adherence. Adhesion will be calculated as the ratio of the number of treatment sessions that were carried out in relation to the number of sessions prescribed. It will be registered in a logbook.[96]
Adverse effects	Adverse effects	eDCN: the participants will be asked about all the possible adverse effects, they will be recorded in a logbook that will be collected from the patients after receiving the different treatments, and serious adverse effects will be reported to the research committee of the healthcare centres.

BDI-II, Beck Depression Inventory-II; BMI, Body Mass Index; CAF-P, Therapeutic Alliance in Physiotherapy Questionnaire-Patients; CPGS, Chronic Pain Gradation Scale; CROM, Cervical Range of Motion device; CSI, Central Sensitization Inventory; DNFR, Deep Neck Flexors Resistance Test; eDCN, electronic Data Collection Notebook; EQ 5D-5L, EuroQol 5 Dimension 5 Level; FPQ-II, Fear of Pain Questionnaire III; FVAS, Fatigue Visual Analogue Scale; GRoC, Global Rating of Change; NDI, Neck Disability Index; PASS-20, Pain Anxiety Symptom Scale Short Form 20; PCS, Pain Catastrophizing Scale; STAI, State-Trait Anxiety Inventory; TSK-11, 11 item Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale.



1	Patient recruitment, signing informed consent. Baseline visit (T_0) Data collection by external evaluators.
T_0	Collection of variables related to: pain; clinical and psychosocial manifestations; and adverse effects.
2	5 training sessions about MI, PSE, CTE to the physiotherapists randomized in the intervention group.
a	Manual and protocol given to the physiotherapists to ensure homogeneity.
3	COGMO: 1 individual session combining MI and PSE (1h).
4	COGMO: 4 group sessions combining MI, PSE, and CTE (1h/session).
5	Usual physiotherapy care, 5 group sessions combining health education and exercise (1h/session).
b	Selfcare guidance, pain management, stress control, physical activity and return to work.
6	Usual care: Patients receive the visits with their general practitioner, nursing and physiotherapy professionals.
T_1, T_2, T_3	Collection of variables related to: pain; clinical and psychosocial manifestations; interventions; and adverse effects.

Figure 1 Enrolment, interventions and assessments. Graphical method for depicting randomised trials of complex interventions.[97]

Sample size

According to two systematic reviews, chronic neck pain with manual physiotherapy treatment improved by 11% (in the first review) and 29% (in the second) compared with the control group.[18 22] Expecting to find a difference in percentages of patients achieving a clinically significant decrease in pain (at least 30 mm on the visual scale), of 25% more patients in the COGMO intervention group than in the control group, for a 95% confidence level and 80% potency, 58 subjects would be needed in each group. Considering that the average cluster size of patients per physiotherapist is 6 patients, and for an intercalary correlation coefficient of 0.02 the design effect will be 1.1 [(ED=1+(6−1)×0.02=1.1, (58+58)×ED(1.1)], the sample size required will be 128 patients; overestimating due to possible losses of 10%, the final size is 142 patients (71 per branch).

Sampling

Consecutive sampling of patients included in the waiting list of patients referred to the physiotherapy unit in each health centre.

Recruitment

Professionals: the intervention in both arms will be performed by physiotherapists belonging to each primary care health centre. For this project, the recruitment of professionals has been performed through the research team, which already has an associated clinical group of 29 physiotherapists.

Patients: to avoid selection bias, the recruitment of patients will be carried out prior to physiotherapists' randomisation. The Primary Care Health Service of the Community of Madrid will provide the list of people who are on the waiting list of each participating healthcare centre. After reviewing the list, each physiotherapist will consecutively offer participation to patients who already meet the inclusion criteria, until a minimum of five to six subjects per physiotherapist is completed. When the patient agrees to participate, the physiotherapist will inform in detail about the study and confirm inclusion/exclusion criteria and the patient's acceptance with the signing of the informed consent. If the patient does not accept, data on age, sex and reason for rejection will be collected.

The patient recruitment period is estimated at 1 year and the follow-up of each patient lasts 12 months from the completion of the COGMO or regular intervention.

Allocation and randomisation

The unit of randomisation is the physiotherapists who will participate in the study and the unit of analysis is the patients. It will be carried out using the module for assigning subjects to the treatment of the Epidat V.4.1 program, considering the intervention to be studied as COGMO as treatment and the health education and exercises project as a control. In order to obtain an equal number of professionals in each group (intervention and control), the balanced groups option will be used. Once the physiotherapist has been assigned to a study group, all patients recruited by him/her will be included in that arm. The assignment will be carried out with the central randomisation system of the Research Support Unit of the Healthcare Management of Primary Care in Madrid. It will be carried out after each physiotherapist has included and selected patients and the external evaluators have collected the variables of the baseline visit. Subsequently, each one will receive the information of the study group to which they have been assigned. To avoid bias, physiotherapists who coincide in the same centre and work shift will carry out their treatment at the time when the colleague completes the weekly consultation sessions, which will be held in a different room.

The physiotherapists assigned to the intervention group will receive training in the intervention and those in the control group will access the project. At the end of the trial, the physiotherapists in the control group concerned will be able to receive training in the COGMO intervention.

Blinding

Due to the characteristics of the study, it is not possible to blind the physiotherapists who will provide the COGMO intervention or control. Evaluators of outcome variables will be blinded. In addition, at the end of each assessment, the evaluator will be examined for blinding success by asking the assessor to indicate the participant's group assignment, including the percentage of certainty (50% certainty equals pure guess). The people in charge of the analysis of results will be blinded to group assignment.[58]

Data management plan and safety

The data to be collected are individual patient variables that will be collected after inclusion in the study and signing of the informed consent. The information will be collected through clinical interviews and complementary quantitative sensory testings.

The information collected will be incorporated by the external evaluators into an electronic data collection notebook (eDCN), which will assign a unique code to each patient, and in which there will be no reference to the identity of the subjects. Each evaluator will keep the list of their patients included, with the link between code and affiliation in a secure place. Limited access to the eDCN will be ensured using a user ID and password and will be hosted on the research/innovation server of the Foundation for Research, and Bio sanitary Innovation in the Primary Health Care of the Community of Madrid (FIIBAP).

The data will be collected by two external evaluators hired through the Foundation for Bio sanitary Innovation and Research in Primary Care (FIIBAP), and they will not know at any time to which group the assigned patients belong. The data will be taken through clinical interviews and physical examination in a room setup in each primary healthcare centre and will be entered into

the electronic data collection programme. Anonymised data will be available from the authors upon reasonable request and with the permission of the project's principal investigators in future publications.

Statistical methods

Description of baseline characteristics: qualitative variables will be presented with absolute and relative frequency. The quantitative variables with their mean and SD (or median and IQR if the distribution is not normal: Kolmogorov-Smirnov test). The losses and the reasons for the loss will be described. A comparison of baseline characteristics (descriptive and adjustment variables) will be made of the intervention group and the control group with bivariate analysis (Student's T or χ^2 according to the type of variable).

Primary effectiveness analysis: it will be done on an intention-to-treat basis. The percentage of subjects that achieve success in the primary endpoint will be calculated (yes/no success: decrease ≥30 mm on the Visual Scale Analogue (VAS) of pain intensity) in the intervention group and the control group with their 95% CI. Additionally, as a secondary approach, proportions achieving ≥15%, ≥30%, ≥50% and ≥70% pain reduction will be analysed to illustrate the pain treatment effects.

A model with multilevel analysis will be adjusted (patient: first level, professional: second level) through a logistic regression in which the dependent variable will be the improvement in pain intensity and the independent variable will be the intervention. The variables of the patient and the professional physiotherapist will be considered as fixed effects, and the random effect is the grouping by physiotherapist.

As for the secondary outcomes, the same analysis will be carried out by comparing the values of the secondary outcome at 3, 6 and 12 months compared with baseline. Effectiveness analyses will also be conducted with respect to other outcome variables: mean difference in change in pain intensity (decrease in mm in VAS), severity according to the EGDC and NDI, and quality of life (Euro-QoL: utilities and Euro-Qol: EVA). This analysis will also be carried out among groups comparing baseline with visits at 3, 6 and 12 months. The level of statistical significance will be set at $p<0.05$. The STATA statistical package will be used.

Limitations of this study

Given the nature of the intervention, subjects are not blind to the treatment they receive. Similarly, the possibility of contamination between patients cannot be ruled out. However, to control this risk, patients will be instructed to limit their communication with subjects from the other group in the healthcare centres, and appointments with their clinicians will be scheduled at different times whenever possible.

Another limitation is that, due to the type of intervention and the fact that it will be carried out by different physiotherapists, there may be some variability in its implementation. To address this, and the potential practitioner effect, thorough training sessions will be held to reinforce the procedure for carrying out the intervention.

Moreover, the validity of the conclusions derived from the results of this study may be affected by the highly demanding intervention, in which the patients are required to perform the exercises proposed until the last measuring time.

In addition, pragmatic trials with long time commitment as the one proposed are often constrained by insufficient sample sizes and potentially high dropout rates; we have tried to approach this by a robust statistical analysis that can enhance the interpretation of the results.

Finally, participation in trials may lead to observational bias (Hawthorne effect).

Fidelity measures

All processes of the research have been explained in detail in the protocol and have been planned reducing bias to the biggest extent possible. In addition, treatment adherence, and direct observation have been used to assess fidelity of the intervention itself, trying to ensure homogeneity.[59]

Patient and public involvement

The research presented in this protocol is to be carried out in the Primary Health Care Centers of the Public National Health Service of Spain; in this case, the clinicians (as the public) have taken part in when to carry out the methodology and how to adapt the project in the primary care according to their experience. The list of participating clinicians can be found in online supplemental appendix 5.

Ethics and dissemination

This project will be carried out under the guidelines of the Declaration of Helsinki[60] and the standards of Good Clinical Practice. The study has already been approved by the Regional Research Ethics Committee of the Community of Madrid (code: COGMO-AP) and the Central Commission of Primary Care Research of the Community of Madrid (code: 20210011). All participants will be informed about the objectives and requirements to participate and written informed consent will be required before starting the research. The data obtained will be confidential and treated following current legislation on data protection and the processing, communication and transfer of your data will be carried out in accordance with the provisions of the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and the Organic Law on the Protection of Personal Data and Guarantee of Digital Rights 3/2018 of 5 December, which confers on you the rights of access, rectification, cancellation and opposition of your data. The right to confidentiality will also be held at the time of publication and dissemination of results. The study has been registered with the US Clinical Trials Registry (https:// clinicaltrials.gov) (code: NCT05785455).

The results will be disseminated in scientific forums, congresses, scientific publications and the media, maintaining the confidentiality and rights of the participants. Under no circumstances will data that allows them to be identified will be published. To maximise access to, and reuse of scientific data generated by the project, the results and the anonymised database will be published openly, always within the framework of legal regulations.

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