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# Combined chiropractic care and Tai Chi for chronic neck pain: A protocol for a pilot randomized trial

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ABSTRACT

*Background:* Neck pain presents a personal and socioeconomic burden globally. Despite increasing prevalence, research on chronic neck pain (CNP) is limited and management relies on generalized approaches. There is growing interest in non-pharmacological interventions, however their efficacy remains uncertain due to the multifactorial etiology of CNP. Two interventions, multimodal chiropractic care (MCC) and Tai Chi, have shown promise individually in managing CNP, and when combined may offer synergistic benefits. This pilot study aims to assess the feasibility of combining these interventions for CNP.

Methods/design: Forty-eight adults, aged 18-65y, with CNP defined as occurring ≥5 days a week for ≥3 consecutive months, severity of ≥3 on the numeric rating scale, and a score of ≥5 on the Neck Disability Index will be recruited. Participants will be randomized 1:1:1 to one of the three treatment groups (MCC plus Tai Chi and Enhanced Usual Care (EUC), MCC plus EUC, or EUC alone). The MCC was validated using a modified Delphi approach. Primary outcomes relate to feasibility (recruitment, retention, and adherence) and secondary outcomes include clinical measures of neck pain severity and disability, health-related quality-of-life, psychosocial well-being, and physical function. Outcomes will be assessed at baseline, 16-weeks (post-intervention), and 24-weeks. Qualitative interviews will be conducted.

*Discussion:* Results of this study will provide preliminary evidence regarding the feasibility and clinical evaluation of pragmatically delivered MCC, alone or in combination with Tai Chi, for individuals with CNP. These data will be used to inform the design of a fully powered, factorial trial evaluating two promising non-pharmacological therapies for CNP.

*Trial registration:* This study is registered in ClinicalTrials.gov (NCT05726331).

## 1. Introduction

Neck pain is a major cause of personal and socioeconomic burden. In developed countries, annual and lifetime prevalence of neck pain is estimated to be 37 % and 49 %, respectively [1], with some evidence of increasing prevalence [2,3]. The vast majority of neck pain is not due to organic pathology, and thus has historically been referred to as "nonspecific." [4] Approximately 50 % of patients experiencing an acute episode of neck pain will continue to have symptoms and/or recurrences and seek healthcare for their symptoms for over a year [5–7]. Chronic neck pain (CNP), typically defined by pain persisting for 3 months or longer [8], is responsible for a significant proportion of direct health care costs, visits to health care providers, sick leave, and related loss of productivity [9,10]. While neck pain sits alongside back pain on the 'top five' list of chronic pain conditions in terms of prevalence and years lost to disability [11], it has received only a fraction of the research attention given to low back pain [4,12].

Lack of neck pain research has resulted in a limited evidence base to guide management, and management strategies often rely on generalizations from studies of chronic low back pain [4,12]. Current guidelines

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for neck pain vary considerably with clinical signs, symptoms, and chronicity [13]. There is growing effort to minimize pharmacological treatment of chronic pain conditions with drugs (including opioids) due to side effects and concerns about long-term addiction [4,13–18]. Consequently, there is a renewed interest in non-pharmacological and non-invasive approaches for managing chronic musculoskeletal pain [17,19], including use of complementary and integrative health (CIH) modalities [20]. In fact, neck pain is among the most common reasons patients use CIH therapies [21–24]. Systematic reviews and meta-analyses indicate varying levels of evidence for individual CIH therapies including chiropractic manipulative therapy, exercise, massage, acupuncture, and mind-body practices, but no one therapy stands out as clearly superior [4,13,14,25–27].

The dearth of research on efficacy of any single unimodal approach may be a consequence of the complexity and heterogeneity of chronic neck pain. Like many other chronic pain conditions, chronic neck pain has a multifactorial etiology and is increasingly viewed as a complex biopsychosocial phenomenon in which anatomical injury interplays with genetic and psychosocial factors, including previous pain experiences, beliefs and fears about CNP, and general health [4,13,25]. Neck pain of nociceptive origin best matches the term "non-specific," while other forms fitting "specific" types (e.g., radicular and nociplastic pain) can occur separately or in combination through physiologically distinct mechanisms. Further, the more comprehensive biopsychosocial nature of chronic neck pain is reflected in the diverse array of co-morbidities and processes it is associated with, including: headaches [28]; anxiety, depression, and perceived stress [29,30]; impaired proprioception, vision, kinesthetic sense, dizziness, balance, and postural control [31–33]; and work-related burnout [13,25,26].

Neck pain is a multidimensional phenomenon involving physical, psychological, emotional, and social dimensions of health that can influence each other [34]. Appreciation for the biopsychosocial nature of CNP has catalyzed a shift toward multimodal and multidisciplinary treatment models, integrating pain management with physical, psychosocial, and behavioral strategies that address a patient's welfare in a more holistic context [35,36]. Recent systematic reviews and individual studies have evaluated unimodal versus multi-modal approaches for chronic musculoskeletal pain [13,14,37]. Although some studies favor multimodal approaches—e.g. spinal manipulation plus exercise, combinations of two or more types exercises, addition of patient education to manual therapy and exercises—other studies suggest no, or only modest incremental, advantages of multimodal approaches. The relative advantages of multimodal versus unimodal approaches specifically for CNP have not been comprehensively evaluated.

This pilot study evaluates the feasibility of pragmatically delivering and clinically evaluating the combined effect of two widely available approaches for managing CNP —multimodal chiropractic care and Tai Chi (TC). We have chosen to evaluate these specific modalities for three reasons. First, both interventions individually show promise in managing CNP. As noted previously, several systematic reviews support the use of spinal manipulation and mobilization delivered by chiropractors as an effective and safe treatment to reduce CNP -related pain and disability [35,38]. However, less is known about the effectiveness of more comprehensive and guideline concordant chiropractic care programs that also integrate manual techniques targeting soft tissues (muscles and fascia), education to foster self-efficacy and improve self-management capacity, and therapeutic CNP -specific exercises [39]. Moreover, few chiropractic studies have utilized pragmatically delivered community-based interventions. TC is also a multimodal intervention which integrates flowing movements, musculoskeletal strength and flexibility training, dynamic and static postural education, and breath instruction, along with training in a variety of cognitive skills including heightened somatic awareness, imagery, and focused mental attention [27,40]. There is a growing body of evidence supporting TC's effectiveness in reducing pain and disability in chronic pain conditions such as low back pain, knee osteoarthritis, and fibromyalgia [41–47].

Second, even though both approaches are independently multimodal, and include mind and body focused therapeutic components, there may be additive or synergistic effects between chiropractic care and TC. As highly trained clinical providers, doctors of chiropractic are well equipped to diagnose the underlying pathophysiology contributing to CNP, and to use targeted manual techniques and prescribed exercises to improve strength, flexibility, mobility and function of relevant anatomy [48]. By comparison, TC training teaches whole-body biomechanically efficient and mindful movement patterns that apply to activities of daily living like walking, lifting or moving objects, and climbing stairs [49]. TC also directly emphasizes heightened interoception, proprioception and kinesthetic awareness[50–52], which likely enhance postural awareness [53].

Finally, national surveys support that patients with chronic pain commonly use more than one CIH therapy [22–24]. TC simultaneously affords group psychosocial support absent in 1:1 chiropractic care, while also emphasizing self-guided practice-based learning which has been shown to enhance self-efficacy [53–55]. Collectively, the more holistic, social, and mindfulness-related attributes of TC training may additively and/or synergistically contribute to benefits derived from chiropractic care. Examples of potential synergy include TC's postural awareness training that can potentially promote longer-lasting benefits following chiropractic care and TC's potential to facilitate both self-efficacy and self-management through improving compliance with chiropractor prescribed therapeutic exercises.

Our long-term goal is to conduct a multi-site, fully powered, factorial trial evaluating both the individual and combined effectiveness of community-based multimodal chiropractic care and TC training to reduce pain and disability in adults with CNP. This pilot study is intended to inform multiple design features for our future trial. In this 3-arm pilot study, we prioritized developing and evaluating the feasibility of delivering the community-based chiropractic care protocol, with and without community-based TC. To use resources efficiently, we did not include a fourth study arm of TC by itself because the feasibility of delivering TC to those with CNP leveraging community-based programs has been evaluated in prior studies [56].

## 2. Materials and methods

### 2.1. Study design, specific aims and hypotheses

This is a three-arm, mixed-methods pilot study. Forty-eight adults with CNP are being recruited and randomized (1:1:1) to receive 1) multimodal chiropractic care (10 sessions delivered over 16 weeks) with concurrent TC training (16 weeks of virtual group training) plus enhanced usual care (EUC); 2) multimodal chiropractic care plus EUC; or 3) EUC alone. Our EUC includes conventional care as well as providing participants with educational materials. Participants randomized to the EUC alone group will receive increased attention in the form of biweekly check-in phone calls. Individuals are followed for 8 weeks after the end of their intervention period to assess longer-term outcomes. The trial flow chart is shown in Fig. 1. This study is registered in ClinicalTrials.gov (NCT05726331) and the protocol was prepared according to SPIRIT guidelines [57] (Supplementary File 1).

The study has three specific aims and associated hypotheses.

Specific Aim 1: To recruit a network of chiropractors and TC instructors, refine our interventions, and assess fidelity of intervention protocols. **Hypothesis 1a.** A pragmatic network of chiropractors and TC instructors in the Greater Boston area can be established. **Hypothesis 1b.** Using a modified Delphi approach, a validated protocol for chiropractic care can be established and implemented, and coordinated with community-based TC interventions. **Hypothesis 1c.** Providers can be trained to deliver established protocols with fidelity. **Hypothesis 1d.** At least 90 % of evaluated chiropractic care visits will use multimodal interventions matching diagnostic categories and corresponding with fidelity checklist items.

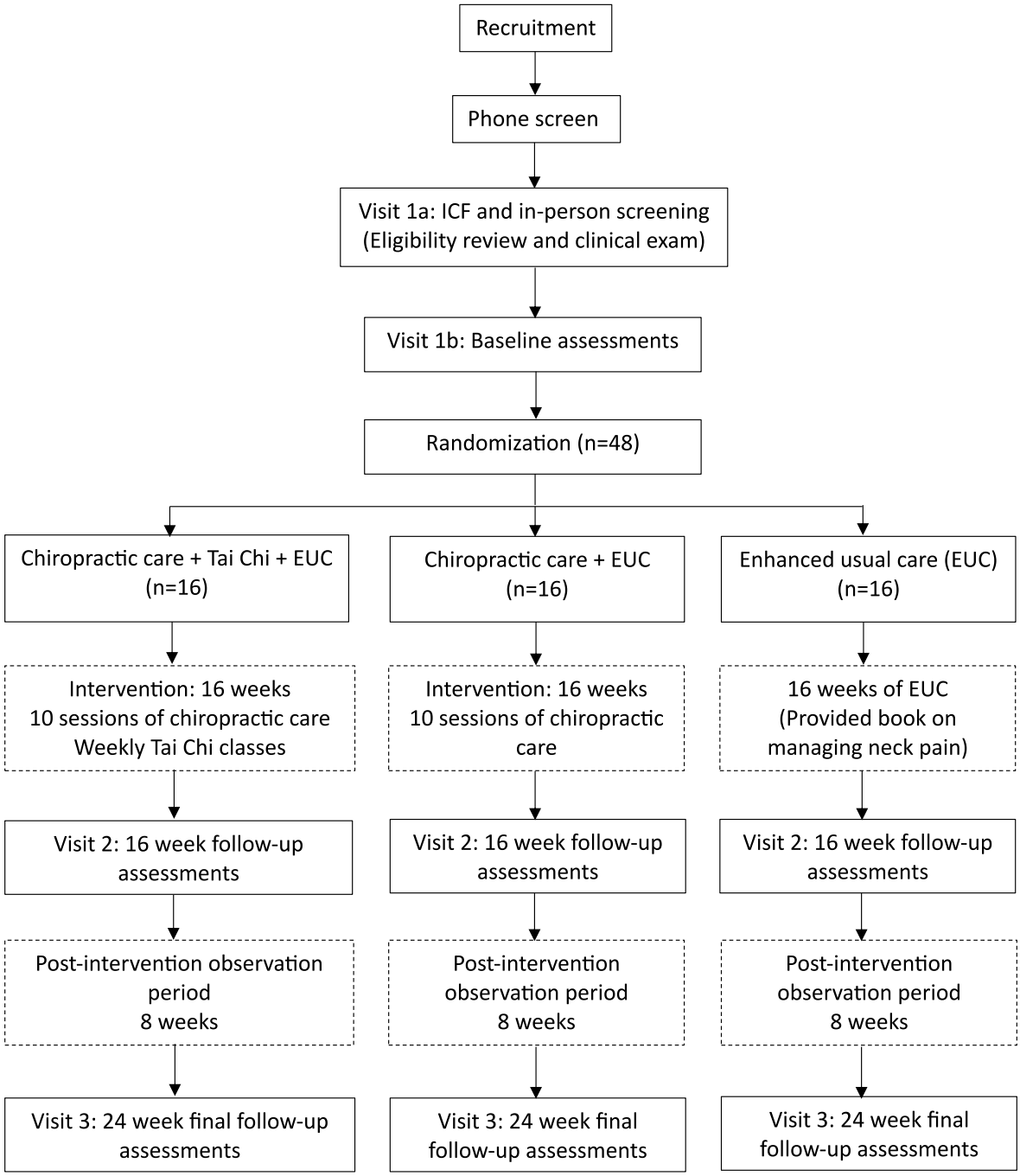


**Fig. 1.** Study schema.

Specific Aim 2: To assess the feasibility of recruiting, retaining, and monitoring the safety of 48 adults with CNP in the 3-armed pilot trial. **Hypothesis 2a**. 48 adults with CNP that meet all study eligibility criteria can be recruited within an 18-month period. **Hypothesis 2b.** Participants in the groups receiving chiropractic care alone or both chiropractic care and TC intervention will attend >70 % of intervention visits/sessions.

Specific Aim 3: To refine data collection procedures and evaluate outcomes for future trials. We will establish data collection procedures integrating functional and patient reported outcomes. We will evaluate a wide battery of biopsychosocially-informative outcomes including metrics of neck pain, neck disability, physical and psychological function, and quality of life. Qualitative interviews conducted at baseline and follow-up will further inform relevant outcomes, as well as facilitators and barriers to participation. **Hypothesis 3a.** Participants will be compliant and complete >85 % of primary outcome assessments.

### 2.2. Ethical oversight

The study has been approved by Mass General Brigham (MGB) institutional review board (IRB) (Protocol #2023P000032). It was registered prospectively on ClinicalTrials.gov (NCT05726331) on January 19th, 2024.

### 2.3. Study population and eligibility criteria

This trial is recruiting adults ages 18–65 years, with CNP which is defined broadly to include neck pain of presumed nociceptive origin (i.

e., "non-specific"), non-surgical neck pain of neuropathic origin (e.g., radicular pain, stable radiculopathy), and nociplastic pain. CNP is further defined as occurring at a frequency of at least 5 days per week for at least 3 consecutive months. CNP severity during the past week must average a rating of 3 or more on the numerical rating scale which ranges from 0 to 10, with 0 described as 'no pain at all' and 10 described as 'worst neck pain imaginable'. Additionally, participants are required to have a Neck Disability Index (NDI) [58] score of 5 or greater. The NDI is a 10-item instrument with scores ranging from 0 to 50; 0 indicates 'no disability' and 50 'complete disability'. Participants must be willing to complete all study procedures, be randomized to any of the three interventions groups, and be fluent in English.

Participants are excluded from the trial if they are currently receiving chiropractic care or have received chiropractic care in the past 12 months; averaged one or more weekly yoga, TC or Qigong sessions in the past 12 months; have any disability precluding exercise; or are currently pregnant. Other exclusion criteria include: any prior cervical spine surgery or any spinal surgery within the previous year; involvement in a disability or accident claim; have signs or symptoms of major systemic illness or unstable medical conditions (e.g. Parkinson's disease, cancer) or psychiatric condition requiring immediate treatment or that could lead to difficulty complying with the protocol; CNP due to a non-neuromusculoskeletal source; inflammatory arthritis; history of stroke, carotid artery dissection, or vertebral artery dissection; presence of neurological disorder; suspected or confirmed pathological hypermobility; or have received interventional pain management to the cervical spine region within the past 4 weeks prior or are scheduled for interventional pain management procedures within the study timeframe. Participants are also excluded if they demonstrate a need for diagnostic imaging at the clinical screening exam or show high risk for adverse events (AEs) to any included treatments.

### 2.4. Recruitment, participant screening, and informed consent

Participants are being recruited from multiple sources. Our primary source of recruitment is through MGB clinical practices including primary care, neurology, pain neurology, orthopedics, physiatry, and physical therapy programs. Additionally, the trial is listed on Rally, a searchable database of ongoing studies within the MGB Healthcare system, which sends out a weekly email to subscribers announcing ongoing trials. Finally, the study recruitment materials are posted in newspapers, online postings, and community bulletin boards. Recruitment from all sources includes specific strategies to ensure adequate enrollment of minority populations. All recruitment procedures follow IRB and Health Insurance Portability and Accountability Act (HIPAA) guidelines.

Interested participants are directed to call study staff, who review the study objectives, protocol, and required commitment for participation, and, after obtaining verbal consent, complete a phone screen to assess initial eligibility. Those eligible at phone screen are then scheduled for an in-person visit at the Osher Clinical Center (OCC) for Integrative Health to confirm eligibility and provide informed consent. A copy of the informed consent form is electronically sent to potential participants to review ahead of time.

The in-person eligibility visit includes an informed consent process performed by a study staff member who describes study procedures and risks before the informed consent form is signed. Eligibility criteria requiring clinical assessment are screened through an exam performed by one of two licensed chiropractors (MK or WB) practicing at the OCC. The exam includes review of participants' health and treatment history, a screening for clinical red flags, and a cervical spine examination including in-office neurologic and orthopedic exam procedures. At the close of the visit, eligible participants are randomly allocated to a study group. For those allocated to receive multimodal chiropractic care, records from the in-person screening exam are provided to the treating community-based chiropractic clinician via a secure file transfer.

### 2.5. Randomization, blinding, and concealment

Participants who are eligible and complete the baseline assessment are randomized 1:1:1 to one of the 3 treatment groups (multimodal chiropractic care plus TC and EUC, multimodal chiropractic care plus EUC, or EUC alone). Group allocation will be implemented using a computer-generated, restricted randomization scheme with random block sizes created by the study biostatistician and uploaded to the randomization module in Research Electronic Database Capture (REDCap) hosted by MGB. Participants, treating chiropractic clinicians, and the study staff are not blinded to treatment group assignment. The blinding for the principal investigator and statisticians will only be broken after the database has been locked and the primary data analysis is complete.

## 3. Study interventions

### 3.1. Chiropractic intervention

Multimodal chiropractic care is characterized by a holistic approach to addressing neuromusculoskeletal conditions. Doctors of Chiropractic, serve as primary spine care practitioners providing non-pharmacological management of these conditions. Care can include manual therapies such as spinal manipulation, education, therapeutic exercise, and other modalities like soft tissue release techniques and lifestyle recommendations. In this trial, chiropractic care is administered according to the protocol developed in Aim 1 and provided by licensed practitioners at participating community-based clinics in the Greater Boston area. The protocol incorporates a practical approach for offering care consistent with clinical practice guidelines and delivered within the scope of chiropractic practice. The protocol also focuses on addressing CNP, offering flexibility to accommodate variations in clinical presentation, and participant preferences within the framework of a defined strategic method.

Participants randomized to a group receiving chiropractic care receive 10 visits over a 16-week period. Initial and follow-up visits are scheduled for approximately 40 and 20 min, respectively. This treatment regimen parallels one used in a prior study of chiropractic care for episodic migraine, and was endorsed by a Delphi expert panel process (see below) [59]. The first chiropractic visit with community-based providers includes a focused history of CNP, assessing for factors to inform an exam, a working diagnosis of pain arising from nociceptive, neuropathic, nociplastic, and/or mixed pain contributors, and a treatment plan. Factors that may pose relative contraindications to care are probed. The clinical history assesses lifestyle factors that may contribute to CNP. The physical examination assesses neurological status with neuro-provocative testing, posture, cervical range of motion, the presence/absence of myofascial trigger points, tenderness, hypertonicity, general muscle imbalance, and related movement restrictions (cervical, temporomandibular, or shoulder). Treating chiropractic clinicians record visit details in an electronic health record using templated visit notes. To facilitate fidelity monitoring, chiropractic records will be electronically transferred to MGB from the respective community clinic using a secure, firewall protected platform.

### 3.2. Delphi validation process

The chiropractic care protocol was formally assessed and finalized using a modified Delphi based approach, incorporating current literature and expert panel member's opinions about effectiveness and translatability into practical clinical care. As in prior Delphi studies, we used a four-phase iterative process. Phase I involved drafting an initial protocol led by two senior chiropractic clinicians (MK and RV), with input from other members of the study team. General sections of the protocol included clinical evaluation, diagnostic categorization, consent, and a multi-modal treatment approach. Phase II involved

developing a baseline survey for review by a panel of chiropractic experts. The panel was then asked to review the initial draft and answer questions assessing the level of agreement with 12 statements addressing different aspects of the protocol. These statements focused on how well the clinical protocol mirrored a comprehensive and evidence-based chiropractic approach for CNP, the ease with which the average chiropractor could grasp and implement the protocol without extensive additional training, the adequacy of the clinical approach in addressing the most probable clinical scenarios, and the convenience, safety, efficacy, and suitability of the clinical protocol for the trial cohort. Agreement with each statement was rated with a 7-point numeric rating scale and prompts were included for open-ended narrative comments.

In Phase III both quantitative scoring and qualitative comments from the survey were synthesized, and blinded data was shared with the panel. A virtual group conference was then held to review survey scoring and feedback, focused on clarifying questions and consensus building for protocol components with the lowest levels of agreement. Study team facilitators (MK, RV, and PW) led the discussion and gathered suggestions for improving clarity. Phase IV involved revising the protocol based on feedback from the panel, followed by a second panel member review and survey.

### 3.3. Delphi validation process results

The expert panel was composed of 11 Doctors of Chiropractic (36 % female) with an average of 26 years of clinical experience. Five of the 11 had research experience. Table 1 lists the items included in the validation questionnaire, and expert panel scores before and after the integration of the suggested modifications.

### 3.4. Final chiropractic protocol

An outline of the final chiropractic care protocol validated by the Delphi process is summarized in Table 2. The interventions are not exhaustive. Rather, they represent examples of those commonly used and which match working diagnostic categories (nociceptive pain, neuropathic pain, nociplastic pain, mixed). Care plans are individually developed.

Chiropractic care consists of 4 main components: 1) Manipulation or mobilization may be applied manually or with the aid of instrumented tables; 2) Instrumented and/or manually applied soft-tissue therapies are used to improve flexibility, circulation, relax hypertonic tissue, and disrupt or stretch presumed fibrous adhesions; 3) Active care includes postural, strengthening, and conditioning exercises; and 4) Education includes reassurance, helping participants understand a condition, promoting self-monitoring and self-management activities, and learning about activities and factors that modulate symptoms. For this trial chiropractic care comprises all 4 components, though each component is not required on every visit and participants may opt out of any component.

#### 3.4.1. Identification of treating chiropractic clinicians

Three groups of community-based chiropractic care providers working in private practices in the Greater Boston area were identified. Eligibility criteria for treating chiropractic clinicians were developed by MK and RV and reviewed with the investigative team. Criteria for treating chiropractic clinicians included a minimum of 5 years of full-time (or full-time equivalent) practice experience in treating CNP and using evidence-based treatments included in the developed protocol including spinal manipulative techniques, soft-tissue treatments, myofascial strengthening and motor control techniques, postural correction and rehabilitative exercises, and education. Postgraduate clinical training was preferred, though not specifically required.

#### 3.4.2. Clinical training

Prior to participant recruitment, treating chiropractic clinicians were trained as in prior studies [60,61]. Six hours of training with members of the investigative team were completed. Training included standardized evidence-based evaluation protocols and the finalized, expert-validated treatment protocol developed with the modified Delphi process. Training also included developing and documenting care plans using therapeutic approaches informed by working diagnoses. Treating chiropractic clinicians were certified to treat participants in the trial after demonstrating the ability to consistently support working diagnoses with evidence-informed rationale and developing aligned treatment plans including the 4 mandatory components using example case descriptions. Training included discussion of trial logistics (e.g., visit scheduling, records transfer processes), fidelity monitoring, and systematic screening for and documentation of serious AE data and discussion of potential risks associated with therapeutic procedures. During the first 6-months after trial launch, investigators will meet with treating chiropractic clinicians every 1–2 months to address any noted challenges related to fidelity, documentation clarity, logistics, and communication with participants. Questions from treating chiropractic clinicians will also be addressed and training materials used during initial training will be available during the trial.

### 3.5. Tai Chi intervention

TC instruction is highly pragmatic, such that participants randomized to the group participating in TC follow the existing curriculum at the recruited school of their choice [49,62]. Schools were selected from a pre-existing network of TC studios that met *a priori* defined eligibility criteria including long-standing programs; senior instructors with >10 years training and experience working with people who have chronic medical conditions; 2 or more entry level virtual classes per week; English language instruction; and programs following one of the more traditional TC training systems (i.e., Yang, Wu, Sun, Chen styles). Participants randomized to this group attend at least one class per week over the 16-week intervention period, offered virtually. Of note, recent studies support that even when taught via virtual platforms, participation in group classes provides significant perceived social support [63,64]. They are also asked to practice a minimum of 30 min on their own, at least 3 additional days per week. Selected schools provide online digital or digital versatile disc (DVD) materials to facilitate home practice.

### 3.6. Enhanced usual care

Participants in this study receive usual medical care from their own provider. Usual medical care for CNP generally includes medications (non-narcotic analgesics, non-steroidal anti-inflammatory drugs, muscle relaxants) and self-care exercises which are monitored and recorded in

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**Table 1**
Summary scores for chiropractors' responses to 12 questions regarding the clinical protocol. Responses were solicited twice through the Delphi method.

| Survey Question | Round | Survey Responders (1–11) | | | | | | | | | | | Median | Mean | SD |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | | | |
| 1. The protocol is reflective of an evidence-informed chiropractic approach for managing CNP. | 1 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6.73 | 0.47 |
| | 2 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 6.82 | 0.40 |
| 2. The protocol is feasible to carry out by chiropractors without additional post-graduate training. | 1 | 3 | 7 | 6 | 5 | 7 | 6 | 3 | 7 | 7 | 5 | 7 | 6 | 5.73 | 1.56 |
| | 2 | 5 | 7 | 7 | 5 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 6.55 | 0.82 |
| 3. The protocol represents a practical approach for managing CNP. | 1 | 5 | 7 | 7 | 6 | 3 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6.18 | 1.25 |
| | 2 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6.73 | 0.47 |
| 4. There are additional chiropractic treatment approaches that should be included in the treatment protocol. | 1 | 7 | 7 | 7 | NR | 1 | 7 | 6 | 6 | 6 | 5 | 4 | 6 | 5.5 | 1.84 |
| | 2 | 3 | 7 | 6 | 6 | 7 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 6.27 | 1.19 |
| 5. The protocol lacks an evidence-based component that should be included. | 1 | 7 | 6 | 6 | 6 | 7 | 7 | 6 | 6 | 6 | 6 | 7 | 6 | 6.45 | 0.52 |
| | 2 | 7 | 7 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6.82 | 0.40 |
| 6. The protocol includes components that are not evidence based. | 1 | 5 | 7 | 6 | 6 | 7 | 7 | 6 | 6 | 6 | 6 | 7 | 6 | 6.27 | 0.65 |
| | 2 | 5 | 7 | 6 | 6 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6.45 | 0.69 |
| 7. The treatment protocol offers the flexibility needed to individualize care for patients with CNP. | 1 | 7 | 7 | NR | 7 | 4 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 6.60 | 0.97 |
| | 2 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6.82 | 0.40 |
| 8. The protocol is manageable with respect to time constraints and support staff in most clinical settings (e.g., private solo practice, multidisciplinary practice, hospital-based). | 1 | 5 | 7 | 6 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 6.45 | 0.69 |
| | 2 | 6 | 7 | 6 | 6 | 7 | 7 | 6 | 6 | 6 | 7 | 7 | 6 | 6.45 | 0.52 |
| 9. The treatment protocol should help reduce neck pain frequency, severity, and/or duration in the majority of cases. | 1 | 7 | 6 | 4 | 6 | 6 | 4 | 6 | 6 | 7 | 7 | 7 | 6 | 6.00 | 1.10 |
| | 2 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 6.55 | 0.69 |
| 10. The frequency and duration of care is sufficient to assess if the protocol is effective | 1 | 7 | 5 | 6 | 6 | 7 | 2 | 6 | 7 | 6 | 7 | 5 | 6 | 5.82 | 1.47 |
| | 2 | 7 | 7 | 6 | 6 | NR | 6 | 7 | 6 | 7 | 7 | 7 | 7 | 6.60 | 0.52 |
| 11. The treatment protocol appears safe. | 1 | 7 | 7 | 6 | 6 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 6.64 | 0.67 |
| | 2 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6.91 | 0.30 |
| 12. The study eligibility criteria represent a group of patients likely to respond to the treatment protocol. | 1 | 5 | 6 | 6 | 6 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 6.27 | 0.65 |
| | 2 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6.64 | 0.67 |

Abbreviations: Chronic neck pain (CNP); not rated (NR); standard deviation (SD).

**Table 2**
Final chiropractic clinical protocol quick reference guide.

| Diagnostic Categories | Diagnostic Criteria (Unless indicated, all criteria are not necessary) | Component 1: Manipulation or Mobilization | Component 2: Soft tissue therapy | Component 3: Active care | Component 4: Education |
|---|---|---|---|---|---|
| Nociceptive pain | • Clear proportionate mechanical/ anatomical nature to symptoms<br>• Pain in proportion to trauma/ pathology<br>• Pain in area of injury/dysfunction with/without referral<br>• Resolving consistent with expected tissue healing time<br>• Usually intermittent and sharp with movement/mechanical provocation<br>• Pain in association with other symptoms of inflammation | • Thrust/non-thrust joint manipulation to spinal and/or extraspinal joints | • Compress-stretch techniques<br>• Muscle/soft tissue stretching<br>• Trigger point therapy<br>• Instrumented friction therapy | • Postural correction exercise<br>• Diaphragmatic breathing<br>• Rehabilitative exercise (e.g., for motor deficit, motor control, and/or imbalance)<br>• Muscle strengthening and/or conditioning exercise<br>• Directional preference exercise | • Condition specific advice to reduce tissue stress/ strain<br>• Symptom interpretation to learn safe vs harmful movements/activities<br>• Information about basic mechanisms of available treatment(s)<br>• Information and advice about self-monitoring activities |
| Radicular pain (Neuropathic pain) | • Lancinating travels along narrow (dermatomal) region<br>• Pain extending beyond the spine<br>• Episodic, recurrent, or paroxysmal | • Thrust/non-thrust joint manipulation to spinal and/or extraspinal joints<br>• Passive neural mobilization | • Neurodynamic stretching<br>• Muscle/soft tissue stretching<br>• Trigger point therapy<br>• Active release<br>• Instrumented friction | • Mindfulness and/or meditation<br>• Active neural mobilization | • Condition specific ergonomic advice (e.g., body positioning techniques)<br>• Pain education as indicated[a]<br>• Explanation or interpretation of diagnostic findings and medical terminology surrounding condition |
| Radiculopathy (Neuropathic pain) | • Objective findings of nerve root conduction loss in the distribution of a spinal nerve (e.g., reduced deep tendon reflex, motor strength, sensation, and/ or nerve conduction velocity of a corresponding nerve root) | | | | |
| Nociplastic pain | <u>Must have all 4 criteria</u><br>• Pain for at least 3 months<br>• Regional rather than discrete pain distribution<br>• Pain not entirely be explained by nociceptive or neuropathic mechanisms<br>• Clinical signs of pain hypersensitivity such as static or dynamic mechanical allodynia, heat or cold allodynia, in the region of pain | • Thrust/non-thrust joint manipulation to spinal and/or extraspinal joints<br>• Passive movements using a graded approach | • Compress-stretch techniques<br>• Muscle/soft tissue stretching<br>• Trigger point therapy<br>• Instrumented friction therapy | • Graded exercise to improve endurance, self-efficacy, resilience, and symptom interpretation<br>• Graded exercise to reduce pain, fear, and pain-related anxiety | |

[a] Pain education: Explaining pain neurobiology using simple metaphors. Pain education addresses biological, psychological, social, environmental, and emotional influences on pain. Pain education is appropriate for people with chronic musculoskeletal pain, when nociplastic pain is suspected, and/or when patients exhibit fear-avoidance behaviors, catastrophizing thoughts, poor self-efficacy, and difficulty coping. Pain education explains pain neurobiology using simple metaphors to help reduce pain, improve understanding of how treatments and other factors influence pain, to help people improve symptom interpretation, and to support self-management capability.[1–5]

all 3 study arms. All participants are given a neck pain self-care book [65]. that explains common causes and management strategies for neck pain, and that has been used as a control intervention in prior large-scale trials of CNP [66,67]. We also provide participants in the EUC only group with increased attention in the form of biweekly calls from the study research assistants. Participants in the EUC group who complete the study are offered up to 5 free chiropractic sessions with our chiropractic clinicians.

## 4. Outcomes

### 4.1. Overview of outcomes

Outcomes to be evaluated in this study are outlined in Table 3. Given the pilot nature of this study, the primary outcomes center on the assessment of protocol safety as well as the feasibility of participant recruitment, retention, and adherence to all aspects of the protocol. Secondary outcomes include clinical measures of neck pain severity and neck pain related disability, health-related quality of life, psychosocial well-being, and physical function. All outcomes will be assessed at baseline, post-intervention (16 weeks), and eight weeks after the conclusion of the intervention period (24 weeks) to evaluate the longer-term stability of outcomes.

Weekly surveys will be administered via a secure and unique link through REDCap across the three groups to assess adherence to the respective treatments and to monitor AEs experienced by the participants. Collectively, feasibility and clinical outcomes, in combination with qualitative interview data conducted at baseline and 16-weeks, will be used to inform the design of a future full-scale powered trial.

### 4.2. Feasibility

Feasibility will be evaluated with respect to three attributes: recruitment, retention, and adherence.

*Recruitment* will be evaluated by tracking the recruitment source of participants, the number of participants enrolled per month overall and by site, the reasons that screened individuals were not eligible, and the number of individuals deciding not to be screened, or if screened, why they are not interested in enrolling in the pilot trial.

*Retention* will be quantified by the proportion of participants who complete all outcome assessments listed above at the end of the intervention period and at 8 weeks post-intervention.

*Adherence* will be judged by the number of visits attended by participants for the assigned interventions.

Fidelity assessment for chiropractic care will be completed by 2 authors (MK, RV) through independent review of clinical records against a fidelity checklist. Key items include: 1) confirming regular screening for serious AEs, 2) care plans containing 4 main components, and 3) assessing consistency between clinical evaluations, diagnostic categories, and care plans. A second monitoring process includes video recording of approximately 10 % of randomly selected study visits. Video review will focus on assessing consistency with the care documented in clinical records. Fidelity assessment for TC will be completed by 2 authors (PW, DL) for a minimum of 3 classes at each school within the first 3 months using a fidelity checklist to confirm that all practices fall within training guidelines.

**Table 3**
Primary and secondary outcomes at timepoints and throughout study.

| Outcome | Timepoint | | | |
|---|---|---|---|---|
| | Baseline | 16-week | 24-week | Through study completion[b] |
| Recruitment rate[a] | | | | X |
| Retention rate[a] | | | | X |
| Intervention adherence[a] | | | | X |
| Medical history | X | | | |
| Physical examination | X | | | |
| Pain intensity | X | X | X | |
| Neck disability index | X | X | X | |
| Pain on movement | X | X | X | |
| PROMIS-29 | X | X | X | |
| Self-efficacy | X | X | X | |
| Postural awareness | X | X | X | |
| Pain catastrophizing | X | X | X | |
| Kinesiophobia | X | X | X | |
| Interoceptive awareness | X | X | X | |
| Gait health | X | X | X | |
| Treatment perception | X | X | | |

Abbreviations: Patient reported outcomes measurement system (PROMIS-29).
[a] Primary outcomes for pilot study.
[b] Average of 18 months.

### 4.3. Clinical outcomes

At baseline, 16-weeks, and 24-weeks participants will be asked to complete the following questionnaires:

Pain intensity will be measured using a single item 11-point numerical rating scale (NRS) with 0 indicating "no pain at all" and 10 indicating "worst neck pain imaginable" [68]. Neck pain related disability will be measured using the NDI. This 10-item questionnaire determines how participants see their neck pain affecting their daily activities, with a maximum score of 50 (0 = no disability, 50 = complete disability) [58]. Pain on Movement (POM) will be assessed using a previously validated and reliable protocol where participants are asked to flex, extend, laterally flex, and laterally rotate their necks to the left and right. In each movement, any evoked pain is measured on an 11-point NRS and an average POM score is then calculated [69]. Pain Interference will be measured using the 4 validated questions included in the Patient-Reported Outcomes Measurement Information System (PROMIS-29) [70]. Bothersomeness of Pain (BOP) in the past 7 days will be assessed using a single item 11-point NRS [71].

PROMIS-29 is a widely used and validated measure of patient-reported health status for physical, mental, and social well-being. In addition to pain intensity and pain interference, this set of measures includes physical function, fatigue, depressive symptoms, anxiety, ability to participate in social roles and activities, and sleep disturbance [72–74]. Self-efficacy will be assessed using the General Self-Efficacy Scale (GSES) which measures a participant's confidence in their ability to respond to environmental demands and challenges. The scale consists of 10 items with a 4-point Likert response scale ranging from 1 ("not at all true") to 4 ("exactly true") with higher summed scores indicating greater self-efficacy to complete the task [75].

Postural Awareness will be measured using the Postural Awareness Scale (PAS) which includes 12 items that describe the awareness of body posture and postural control [53]. Pain Catastrophizing Scale (PCS) will be used to assess catastrophic thinking associated with pain [76]. This instrument consists of 13 items that measure rumination, magnification, and helplessness related to pain [77]. Fear of Movement will be measured using the Tampa Scale for Kinesiophobia (TSK) consisting of 17 items that measure pain-related fear [78]. Interoceptive awareness, the sensitivity toward stimuli originating from within the body, will be measured using the Multidimensional Assessment of Interoceptive Awareness Scale (MAIA), which consists of 40 items resulting in eight separate dimensions of interoceptive awareness; higher scores represent higher awareness [79].

Gait and balance will be assessed during standing and walking using the Zeno™ Walkway, developed by ProtoKinetics (https://www.protokinetics.com). Gait data is collected by simply walking across an electronic gait mat. Participants are asked to walk the length of the electronic walkway two times under four different conditions (quiet walking at a preferred speed, completing a cognitively distracting task (i.e., counting aloud backwards from five-hundred in intervals of 7) at a

preferred speed, turning their head over their right and left shoulders at a preferred speed, and walking at a fast speed). Gait parameters calculated by Zeno™ include walking speed, stride characteristics (e.g. stride time, stride time variability, swing time, double support percentage, cadence), left to right leg ratio, center of pressure through the gait cycle, and gait variability index.

### 4.4. Qualitative evaluation

Qualitative interviews will be employed to probe participants' perceptions of chiropractic care with and without the addition of TC training, focusing on a) understanding facilitators and barriers to participation in a pragmatic trial utilizing community-based practitioners, and b) patient-centered experiences that might inform outcome measures to use in our future trial. A convergent mixed-methods approach will be used to inform quantitative findings [80]. All participants will be interviewed before randomization. Each interview will last approximately 30–45 min. At baseline, questions will focus on participants' CNP histories and types of treatments previously used; reasons for joining the study; and their knowledge of, prior experience with, and expectations for improvement with chiropractic care and TC. At follow-up visits, questions will focus on participants' overall experience with the trial, facilitators and barriers to their participation, perceptions of treatment on physical and psychological dimensions of CNP, and whether they believed the intervention to be effective. Interviews will be digitally recorded and transcribed.

## 5. Safety monitoring

### 5.1. Adverse events monitoring and classification

AEs will be proactively monitored in all groups. Participants will be instructed to report any symptoms of concern in their weekly REDCap surveys, and to contact investigators if serious symptoms occur. Participants in the chiropractic groups will be queried about serious AEs at every chiropractic visit. If a participant reports adverse symptoms, study staff will gather information about the relatedness, expectedness, and severity. If an event is graded as unexpected and possibly re lated to any study intervention, it will be reported to the IRB, the Data Safety and Monitoring Board, and the sponsor National Center for Complementary and Integrative Health, National Institutes of Health (NCCIH/NIH). All AEs will be recorded and submitted for Continuing Review to the IRB.

### 5.2. Risks of chiropractic care

The risks of AEs, and especially serious AEs associated with chiropractic care are generally believed to be very low. Table 4 summarizes both common and rare side effects or AEs that have been reported to emerge in the course of chiropractic treatment. A 2009 systematic review of chiropractic publications (primarily case reports and observational studies) concluded that most AEs reported are benign and transitory. However, there are reports of complications that are rare and life threatening, such as arterial dissection and epidural hematomas [81]. One recent trial prospectively evaluated the occurrence of AEs in 70 people with migraine (83 % women, avg age 40y+/−) randomly exposed to real and placebo (low velocity, low amplitude sham maneuver) chiropractic spinal manipulation therapy (CSMT) [82]. A total of 73/355 CSMT sessions versus 29/348 placebo sessions resulted in a reported AE. The most common attributable AEs were local tenderness and tiredness on the day of treatment, which were moderately higher in the CSMT group. No severe or serious AEs were observed.

One rare yet serious potential AE reportedly associated with chiropractic manipulation is cervical arterial dissection (CD) which may lead to stroke in some individuals. Published reports on the association of chiropractic care and risk of CD and stroke due to CD vary greatly and are debated [83–88]. A scientific statement from the American Heart Association/American Stroke Association (AHA/ASA) published in 2014 summarized the existing literature on the association between CD and cervical manipulative therapy (CMT) [89]. Among younger individuals, those who received chiropractic care had a 3.1–6.6-fold increase in risk of experiencing a stroke associated with CD (particularly vertebral artery) compared to those who did not receive chiropractic care. However, there are limitations and potential biases inherent in the available data including the observational nature of all studies and potential for recall or interview bias. Additionally, due to the very low incidence of CD in the general population (~2.6–2.9 per 100,000 population), most studies had small sample sizes and wide confidence intervals [90,91]. The AHA/ASA scientific statement explicitly states that it is not clear whether this association is causal or "due to lack of recognition of pre-existing CD in these patients." [89] The authors conclude: "although the incidence of CMT-associated CD in patients who have previously received CMT is not well established, and probably low, practitioners should strongly consider the possibility of CD as a presenting symptom, and patients should be informed of the statistical association between CD and CMT prior to undergoing manipulation of the cervical spine." Further questioning a causal association between CMT-associated CD are data from studies demonstrating equivalent associations with CD following primary care practitioner visits [83,87,92–95]. The long-theorized causal mechanism of carotid and/or vertebral artery damage from overstretching or kinking, which leads to CD, thrombus formation, and stroke is now far less plausible given current observational research and several biomechanical studies that demonstrate CMT causes significantly less arterial strain than normal range of motion [96–98].

All participants in our study will be informed of the potential risk of CD during the informed consent process using language that is included in Table 4.

**Table 4**
Common and rare side effects or AEs that have been reported to emerge in the course of chiropractic treatment.

Common
- Neck or upper back soreness or stiffness that occurs within one day of treatment and self-resolving
- Tiredness/fatigue (short duration, self-resolving)
- Headache occurring within one day of treatment (short duration, self-resolving)
- Exam procedures may cause neck or upper back stiffness or soreness usually resolving within a few minutes and rarely lasting 1–2 days.
- Radiating discomfort from the neck or upper back (short duration, self-resolving)

Rare
- Light-headedness or dizziness within 1 day following treatment and self-resolving
- Nausea/vomiting (short-duration, self-resolving)
- Blurred or impaired vision (short-duration, self-resolving)
- Ringing in ears (short-duration, self-resolving)
- Arm or leg weakness (short-duration, self-resolving)
- Confusion or disorientation (short-duration, self-resolving)
- Injury to a blood vessel in the neck (Cervical or Vertebral Artery Dissection) that could lead to a stroke

Abbreviations: Adverse Events (AEs).

### 5.3. Risks of Tai Chi

TC is a safe exercise practice for adults [99,100]. The risks involved are minimal, and comparable to everyday activities. Participants may experience some muscle soreness, shortness of breath, or dizziness if they have not exercised for a long time. There is also some risk of falling for those who have difficulty with balance. Participants are instructed, both for formal online classes and individual home training and practice, to not over-exert themselves and to take breaks whenever necessary. The TC protocol for this study excludes specific TC practices contraindicated for CNP (e.g. use of heavy weapons or two-person martial practices).

## 6. Analysis plan

The primary purpose of this study is to evaluate various components of trial feasibility, which are organized around 3 broad specific aims as follows. Specific Aim 1: To recruit a network of chiropractors and TC instructors, refine our interventions, and assess fidelity of intervention protocols. In line with *Hypothesis 1a*, and as described above, we successfully recruited and established a pragmatic network of chiropractors and TC instructors in the Greater Boston area. *Hypothesis 1b*, centered around the Delphi validation process, has also been completed as described above. For *Hypotheses 1c and 1d*, we developed and employed a fidelity checklist and protocol (described above), and results will be published at the conclusion of the trial.

Specific Aim 2 will "Assess the feasibility of recruiting, retaining, and monitoring the safety of 48 adults with CNP in the 3-armed pilot trial". Descriptive statistics will be used to report recruitment, with respect to rate of enrollment (target 48 individuals within 18 months), (*Hypothesis 2a*), and retention, quantified by the proportion of participants who complete all outcome assessments listed above at the end of the intervention period (i.e. 16 weeks) and at 8-week post-intervention (i.e. 24 weeks) (*Hypothesis 2b*). We will consider future testing of our interventions if the expected proportion of participants to have completed primary outcome assessments is at least 85 %.

Additionally, adherence will be judged by the number of visits attended by participants for the assigned interventions. For those randomized to chiropractic care + EUC, adherence will be calculated as the proportion of participants who attend at least 70 % of the chiropractic care visits. For those randomized to chiropractic care + TC + EUC, adherence will be calculated as the proportion of participants who attend at least 70 % of the chiropractic care visits and 70 % of TC classes. We will consider future testing of our interventions if the expected proportion of participants judged to be adherent to the intervention is at least 85 %.

We will tabulate the AEs for each treatment group by organ system according to the Medical Dictionary for Regulatory Activities and classify each AE with its degree of relatedness to the intervention (unrelated, possibly related, related), grade (mild, moderate, severe, or serious), and expectedness. These data will be used to evaluate feasibility of consistently collecting AEs and reporting it according to the trial's Data and Safety Monitoring Plan.

Specific Aim 3 is to "Refine data collection procedures and evaluate outcomes for future trials". Descriptive statistics will be used to calculate the proportion of participants who complete at least 85 % of primary outcome assessments (*Hypothesis 3a*).

### 6.1. Clinical study endpoints

We will summarize the baseline characteristics of those randomized to each of the three groups using means and standard deviations or medians and interquartile ranges for continuous variables and counts and percentages for categorical variables.

Our primary clinical outcome will be change in pain intensity recorded by participants from the baseline study visit through post-intervention (16 weeks), and eight weeks after the conclusion of the intervention period (24 weeks), with the 16-week being the primary endpoint. Secondary outcomes will include changes in additional patient reported outcome measures including NDI, POM, BOP, PROMIS-29, GSES, PAS, PCS, TSK, MAIA and measures of gait and balance from baseline to 16 and 24 weeks. Analyses will be conducted using an intention-to-treat sample to estimate the effectiveness in preparation for a future trial. We will estimate effectiveness and variability by modeling the outcomes with a linear mixed-effects regression over baseline, 16-weeks and 24-weeks. The model will have fixed effects for time and random effects for participants over time using an unstructured covariance matrix. We will report estimated mean changes within and between groups with 95 % confidence intervals based on these models. Secondary models will adjust for baseline characteristics (i.e. age and sex) to explore whether results are robust to any chance imbalances at baseline.

### 6.2. Qualitative data analysis

Through systematic analysis, a minimum of two researchers will search for meaningful categories and potential patterns across interviews. Potential explanations will be developed, using the constant comparative method of analysis for generating themes [101–103]. The qualitative researchers will iteratively return to the original transcripts to look for contrasting evidence to the emerging theories and search for exemplar quotes illustrative of the identified themes. Quantitative data on the number of participants who mentioned a given theme will also be tracked. Before finalizing analyses, qualitative researchers will also discuss potential theories with the larger research team. Bias and validity will be addressed through random selection of transcripts for analysis, having each transcript independently coded by two authors who had not taken part in the original interviews, having a third author act as arbiter in cases where there was disagreement, utilizing a multi-disciplinary analysis team, and documenting all analysis and decision points in detail [104].

### 6.3. Sample size

As a pilot study, there is not a plan to test for efficacy but rather to obtain information on the feasibility of this design. Thus, power calculations were not performed. The sample size of 48 participants (16 per treatment group) was chosen as we anticipate this will be a sufficient sample enabling us to have adequate data to estimate recruitment rates from various sources, to assess issues and solutions to using community chiropractic clinics and estimate variability of outcome measures to inform sample size calculations for a full-scale trial. This sample size will also allow us to adequately assess the fidelity of intervention delivery and achieve data saturation for qualitative analysis.

## 7. Data management

Study data will be entered by participants directly into REDCap tools hosted at MGB. REDCap provides a secure, web-based interface for validated data entry with auditing features for data management, as well as exporting data for statistical analysis and data importation from external data sources. All clinical notes conducted by chiropractors during any given week will be uploaded in PDF format to a secure Dropbox folder at the end of each week.

## 8. Discussion

While there is a growing call for the use of conservative, scalable, non-pharmacological and non-invasive approaches for the treatment of CNP, evidence to guide this strategy is very limited. Results of this study will provide critical preliminary evidence regarding the feasibility of pragmatically delivered chiropractic care, alone or in combination with TC, for individuals with CNP. These data will be used to inform the

design of a fully powered, full factorial trial evaluating two promising and widely available non-pharmacological therapies for managing CNP.

There are a number of novel design features and noteworthy strengths of this study. First, while prior studies have evaluated the use of spinal manipulation or mobilization delivered by chiropractors in the treatment of CNP [35,38], less is known about the effectiveness of more comprehensive chiropractic care programs that also integrate manual techniques targeting soft tissues (muscles and fascia), education to foster self-efficacy, and therapeutic CNP -specific exercises [61]. Of note, our multimodal intervention which includes substantial practitioner-patient interaction, likely include non-specific therapeutic psychosocial effects, in addition to specific treatment effects related to manual and educational components [105,106]. Second, this is the first study we are aware of evaluating the combined effect of chiropractic care and TC. While both chiropractic care and TC include potentially overlapping therapeutic elements, each also has unique therapeutic components that could results in additive or synergistic effects.

Third, this study utilizes community-based practitioners to pragmatically deliver both interventions. Guided by a detailed, Delphi-validated treatment manual that affords a standardized, yet flexible approach, chiropractic care will be delivered by experienced community-based Doctors of Chiropractic. Similarly, TC will be delivered by established instructors within existing virtual community-based classes. Systematic monitoring of both sets of practitioners will assure fidelity of intervention delivery. Pragmatic use of community-based programs to deliver both interventions enhances the generalizability of this and future study findings, and also informs eventual scalability of implementing this approach nationally [107].

Fourth, the study combines both quantitative and qualitative methods. As we have done in prior studies[108–110], there is an opportunity for methodological triangulation, where findings from both classes of data inform each other. Such mixed-methods approaches are particularly informative in pilot studies where outcomes, mechanisms, and more general behavioral responses are poorly understood.

This study also has limitations. First, while this pilot study aims to inform a future, fully factorial design evaluating the independent and combined effect of chiropractic care and TC, for practical cost reasons, this pilot study did not include a fourth independent TC arm. This fourth factorial arm was not considered essential for this pilot study as prior studies by our group have already demonstrated that TC delivered by itself is effective for CNP [56,111], that it can be delivered pragmatically [49,62,107] and is adaptable to virtual delivery [63,64]. The absence of this fourth arm in this pilot study eliminates the opportunity for estimating some feasibility parameters and the magnitude of treatment synergistic and interactive effects that would inform a future trial design. Second, while the use of pragmatic interventions that allow for modest adaptability based on both patient characteristics and provider preferences affords high external validity, this approach reduces internal validity and makes mechanistic causal links between exposure and outcomes more difficult. Moreover, this intervention heterogeneity may necessitate larger samples in future trials to assure to statistical power [112].

In conclusion, this pilot trial emphasizes rigorously developing protocols, assessing feasibility, and refining data collection procedures which will lay the foundation for a future more definitive trial that addresses chronic neck pain and assesses novel and promising non-pharmacological pain treatment strategies.

## CRediT authorship contribution statement

**Peter M. Wayne:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Robert Vining:** Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Cynthia R. Long:** Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Wren M. Burton:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation. **Daniel Litrownik:** Writing – review & editing. **Jacqueline Guzman:** Writing – review & editing, Investigation, Data curation. **Karen Kilgore:** Writing – review & editing. **Thomas J. Hagan:** Writing – review & editing. **Pamela M. Rist:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization, Romy Lauche, Writing – review & editing, Funding acquisition, Conceptualization. **Matthew H. Kowalski:** Writing – review & editing, Methodology, Funding acquisition, Data curation, Conceptualization.

## Ethics approval and consent to participate

Ethics approval was provided by the Mass General Brigham Institutional Review Board on February 24th, 2023 (Protocol ID: #2023P000032). Informed consent will be obtained from all participants.

## Consent for publication

Not applicable.

## Availability of data and materials

All data generated or analyzed during the current study will be included in future published articles.

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## Declaration of competing interest

Peter Wayne is the founder and sole owner of the Tree of Life Tai Chi Center. Dr. Wayne's interests were reviewed and are managed by Mass General Brigham in accordance with their conflict of interest policy. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgements

There are no acknowledgements to disclose.

## List of Abbreviations:

AE(s) – Adverse event(s)
AHA – American Heart Association
ASA – American Stroke Association
BOP – Bothersomeness of Pain
CD – Cervical artery dissection
CIH – Complementary and integrative health
CMT – cervical manipulative therapy
CNP – Chronic neck pain

CSMT – Chiropractic spinal manipulation therapy
DVD – Digital versatile disc
EUC – Enhanced usual care
GSES – General Self-Efficacy Scale
HIPAA – Health insurance portability and accountability act
IRB – Institutional Review Board
MAIA – Multidimensional Assessment of Interoceptive Awareness Scale
MGB – Mass General Brigham
NCCIH/NIH – National Center for Complementary and Integrative Health, National Institutes of Health
NDI – Neck Disability Index
NRS – Numeric Rating Scale
OCC – Osher Clinical Center
PAS – Postural Awareness Scale
PCS – Pain Catastrophizing Scale
POM – Pain on Movement
PROMIS-29 – Patient Reported Outcomes Measurement Information System
REDCap – Research Electronic Database Capture
RPDR – Research Patient Data Registry
TC – Tai Chi
TSK – Tampa Scale for Kinesiophobia

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2025.101482.

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