


# BMJ Open Single session compared with multiple sessions of education and exercise for older adults with spinal pain in an advanced practice physiotherapy model of care: protocol for a randomised controlled trial

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## ABSTRACT

**Objectives** To assess the effectiveness and cost-effectiveness of a single session compared with multiple sessions of education and exercise for older adults with spinal pain treated conservatively in an advanced practice physiotherapy model of care.

**Methods and analysis** In this pragmatic randomised controlled trial, 152 older adults (≥65 years old) with neck or back pain initially referred for a consultation in neurosurgery, but treated conservatively, will be recruited through the advanced practice physiotherapy neurosurgery CareAxis programme in the Montreal region (Quebec, Canada). In the CareAxis programme, older patients with spinal pain are triaged by an advanced practice physiotherapist and are offered conservative care and only potential surgical candidates are referred to a neurosurgeon. Participants will be randomised into one of two arms: 1—a single session or 2—multiple sessions (6 sessions over 12 weeks) of education and exercise with the advanced practice physiotherapist (1:1 ratio). The primary outcome measure will be the Brief Pain Inventory (pain severity and interference subscales). Secondary measures will include self-reported disability (the Neck Disability Index or Oswestry Disability Index), the Pain Catastrophizing Scale, satisfaction with care questionnaires (9-item Visit-specific Satisfaction Questionnaire and MedRisk), and the EQ-5D-5L. Participants' healthcare resources use and related costs will be measured. Outcomes will be collected at baseline and at 6, 12 and 26 weeks after enrolment. Intention-to-treat analyses will be performed, and repeated mixed-model analysis of variance will assess differences between treatment arms. Cost-utility analyses will be conducted from the perspective of the healthcare system.

**Ethics and dissemination** Ethics approval has been obtained from the *Comité d'éthique de la recherche du CIUSS de l'Est-de-l'Île-de-Montréal* (FWA00001935 and IRB00002087). Results of this study will be presented to different stakeholders, published in peer-reviewed journals and presented at international conferences.

## Strengths and limitations of this study

- This pragmatic randomised controlled trial will provide new data on the clinical and economic effectiveness of two advanced practice physiotherapy approaches.
- This trial has been developed in collaboration with a non-profit organisation named CareAxis that implemented a neurosurgery advanced practice physiotherapy model of care in the greater Montreal area in Quebec, Canada.
- Patients will not be blinded to treatment allocation as the nature of the intervention makes blinding impossible.
- Although this trial will compare two therapeutic approaches in an advanced practice physiotherapy model of care, it does not include a usual medical care control group of participants referred directly to neurosurgeons.

**Protocol version** V.4 August 2021.

**Trial registration number** NCT04868591; Pre-results.

## INTRODUCTION

Musculoskeletal disorders (MSKDs) are the most common cause of long-term pain and physical disability, and they affect hundreds of millions of people around the world.<sup>1</sup> In Canada, the prevalence of MSKDs has increased by more than 25% in the last 10 years and healthcare costs of MSKDs now exceed \$22.3 billion per year.<sup>2</sup> Among MSKDs, spinal pain is highly prevalent with worldwide estimated point prevalence of 5% and 12% for neck and low back pain, respectively.<sup>3 4</sup> The management of neck and low back pain can be complex and costly.<sup>5–8</sup> Although the

majority of patients with spinal pain can be managed effectively in primary care, a relatively large number of patients will still be referred to specialists such as orthopaedic surgeons or neurosurgeons for further assessment and specialised care.<sup>9</sup> Access to specialised care has been especially problematic in the last few decades and there has been a consistent increase in the number of referrals to these two specialties.<sup>10</sup> With the ageing of the Canadian population and the COVID-19 pandemic, the number of referrals is expected to increase, leading to longer wait times.<sup>9 11–14</sup> Evidence shows that longer wait time before seeing a neurosurgeon leads to poorer outcomes in patients with spinal pain.<sup>15</sup> Additionally, the majority of referrals for neurosurgery are ultimately not treated surgically and, instead, are offered conservative medical care by the treating surgeons and often referred to physiotherapy.<sup>16 17</sup>

New models of care to improve access and efficiency of care for adults with spinal pain are needed. The use of advanced practice physiotherapy (APP) models of care where physiotherapists with an advanced clinical training assess, triage and conservatively treat patients with MSKDs has been proposed as a potential solution to alleviate the growing demand for specialised medical care.<sup>18–23</sup> For adults with spinal pain, APP models of care in the UK, Ireland, Canada, USA, Sweden, and Australia result in comparable pain and disability improvement.<sup>24–26</sup> However, APP models of care have the potential to significantly improve healthcare access by reducing waiting time for initial consultation while maintaining high levels of satisfaction among stakeholders and patients.<sup>16 17 26–33</sup>

In terms of rehabilitation interventions, advanced practice physiotherapists (APPTs) often provide physiotherapy care such as education and exercises to patients with spinal pain, as it is well recognised that patients with neck or low back disorders benefit from these therapeutic interventions.<sup>34 35</sup> Education may include reassurance, advice to stay active, minimise bed rest as well as pain management strategies addressing pain neurophysiology;<sup>34–37</sup> while exercise prescription may include strengthening, neuromuscular control, endurance and functional exercises, stretching, preferential pain-related mobilisations and/or aerobic training.<sup>34 35 38</sup> Several authors also report that rehabilitation should also include strategies to promote adherence to the rehabilitation.<sup>39</sup> Although it could be argued that more rehabilitation may potentially further improve outcomes for patients with MSKDs,<sup>40</sup> little is known about what are the most effective approaches and delivery methods for rehabilitation interventions such as education and exercise.<sup>38</sup> Some authors report that traditional clinic-based rehabilitation is superior to home-based rehabilitation for chronic conditions,<sup>41 42</sup> while others report no significant differences between these two approaches.<sup>43–45</sup> Therefore, the exact types of therapeutic treatment and related dosage for physiotherapy care that include education and exercise prescriptions remain unclear, especially in the context of

an APP model of care for adults referred to neurosurgery for spinal pain.

The aim of this pragmatic randomised controlled trial is to evaluate at 6, 12 and 24 weeks the clinical effectiveness in terms of patient-centred outcomes and the cost-effectiveness of a single session compared with multiple sessions of education and exercise for older adults with spinal pain treated conservatively in an APP neurosurgery model of care.

## METHODS

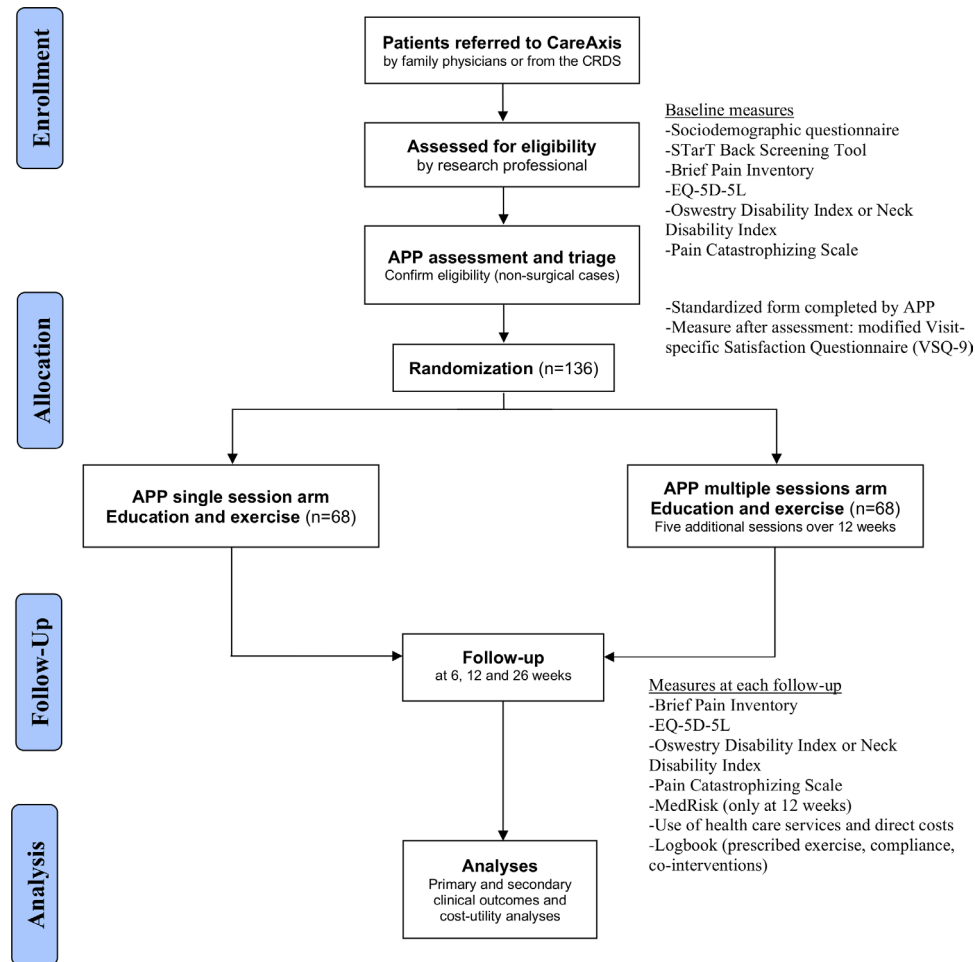
### Study design

This study is a pragmatic randomised controlled trial parallel group with cost-effectiveness analyses. The current protocol is registered on *ClinicalTrials.gov*. This trial will use a pragmatic approach within an existing APP model of care in neurosurgery. Therefore, the rehabilitation intervention in both treatment arms will be offered as they are provided in their current clinical reality (see [figure 1](#) for flow chart).

### Setting and participants

This pragmatic randomised controlled trial will be performed within the CareAxis neurosurgery APP model of care. In 2019, CareAxis, a non-profit organisation, developed and implemented an APP model of care for older patients (65 years and older) with spinal pain referred to neurosurgery in the province of Quebec (Canada). The model was developed in partnership with the Montreal Neurological Institute and Hospital, Montreal, Quebec, Canada. The aim of this model is to reduce wait time to consult a neurosurgeon, more efficiently triage surgical candidates, and improve conservative and rehabilitation care for patients referred to the programme. The current model of care involves a group of trained APPTs, who assess and triage potential surgical candidates, recommend medical care (medication or injection), provide education and prescribe a self-management exercise programme. This is systematically offered to all patients in a 1-hour session. Only patients deemed surgical candidates are then referred to see the neurosurgeon. The programme is funded through health charities and is offered at no costs to older adults with a referral from a family physician.

This study will take place in physiotherapy clinics (n=9) associated with the CareAxis group in Quebec, Canada. Eligible participants will be recruited when referred to the CareAxis model of care, either directly through family physicians or from the *Centre de répartition des demandes de service de Montréal*—the centralised intake system for specialist referrals (including neurosurgery) from primary care in Montreal, Quebec. The eligibility criteria in the current trial are based on the intended clientele to be cared by the APPT within this model of care, representing our pragmatic approach to the definition of our sample. Eligibility criteria: (1) adults consulting for a neck or back condition; (2) aged 65 years



**Figure 1** Flow chart. APP, advanced practice physiotherapy; CRDS, *Centre de répartition des demandes de service*.

old or older; (3) referred for a consultation in neurosurgery to the CareAxis group, either directly by family physicians or from the *Centre de répartition des demandes de service de Montréal* and (4) not considered as a potential surgical candidate based on the initial APPT assessment. Participants referred for a specialist consultation or for an injection, but who are not considered as a potential surgical candidate by the APPT, are eligible to participate in the trial. For patients who decline participation in the project, demographic data, such as age, gender and duration of symptoms, will be collected to calculate participation proportions and establish comparison between participants and non-participants.

### Randomisation

All eligible and consenting patients will be randomly assigned at a 1:1 ratio to either the single session APP arm (no additional care) or the multiple sessions APP arm (five additional sessions with the APPT). A randomisation list will be generated prior to the initiation of the study using an online random number generator. A blocked randomisation will be performed with block sizes of 4, 6 or 8. Randomisation will be stratified for the affected body region (neck or back) and with respect to gender. Allocation will be concealed in opaque and sealed envelopes

that will be sequentially numbered. The randomisation procedure will be performed by an independent research assistant not involved in other aspects of the current trial. The randomisation will occur before the APPT provides any intervention.

### Interventions

Participants will initially consult an APPT of the CareAxis group. In a 1-hour consultation, the APPT will assess and triage surgical candidates, recommend medical care (medication or injection), as well as provide education and prescribe a self-management exercise programme aimed at impairments and functional limitations identified during the initial assessment. Participants randomised to the single session arm will not receive additional care by the APPT while those randomised to the multiple sessions arm will receive five additional consultations with the APPT within a 12-week period. During the follow-up visits, the APPT will reassess the participants, provide further education and recommendations, review and modify the home exercise programme and may provide other rehabilitation interventions. Since this is a pragmatic trial, the interventions in both treatment arms will be offered as they are provided in their current clinical reality and will not be standardised. Information regarding rehabilitation

intervention will be systematically recorded and will be presented in detail in the following publications. Patients will be allowed to take their usual medication and these data will be systematically collected through a diary. Information on other co-interventions during follow-up will also be collected.

### Data collection

Data collection will take place at baseline and at 6, 12 and 26 weeks after the initial evaluation. Prior to being randomised and seen by the APPT, eligible participants will answer a questionnaire regarding sociodemographic characteristics, such as age, sex, gender, education level, household income and living status. Information on clinical variables such as anthropometric data, affected body area (neck or low back), reason for consultation, duration of symptoms and presence of any comorbidities such as arthritis, high blood pressure and diabetes will also be documented. The STarT Back Screening Tool and a modified version for neck pain will be used to evaluate prognosis.<sup>46 47</sup> All data collection will be done through the CareAxis web data collection portal already in use for clinical follow-up of patients and with the *Centre de Recherche de l'Hôpital Maisonneuve-Rosemont* REDCap data collection portal. Both web platforms use Transport Layer Security encryption to secure data.

### Outcome measures

The primary outcome measure will be the Brief Pain Inventory (BPI), short form, pain severity scale and pain interference scale. The BPI is a self-reported questionnaire. The pain severity scale includes four numerical pain rating questions (0–10) related to worst, least, average and current pain intensity, while the pain interference scale includes seven numerical rating questions (0–10) related to the impact of pain on various functional activities. The BPI is valid, reliable and responsive to change in populations with MSKDs, including patients with spinal pain.<sup>48–51</sup>

The secondary outcome measures will include other validated, reliable and responsive to change self-reported questionnaires. Depending on the affected body region, participants will complete the Neck Disability Index for neck-related disorder<sup>52</sup> or the Oswestry Disability Index for back-related disorder.<sup>53</sup> Pain catastrophising will be assessed through the Pain Catastrophizing Scale.<sup>54 55</sup> To assess satisfaction with received care, patients will be asked to complete a modified validated version of the 9-item Visit-specific Satisfaction Questionnaire (VSQ-9) after the initial assessment.<sup>17 19 56</sup> To assess satisfaction following the interventions and follow-up, participants will be asked to complete the MedRisk which was developed to measure patient satisfaction with rehabilitation care.<sup>57</sup> EQ-5D-5L and EQ-VAS will be used to measure health-related quality of life.<sup>58 59</sup> The investigators will also collect healthcare resource use, including medical consultations, diagnostic tests, medication, injections, rehabilitation and surgery using a self-reported questionnaire.

Occurrence of any adverse events will be questioned at each time point.

Based on their initial assessment, the APPTs will complete a standardised form, indicating their diagnosis, suggestion for additional medical imaging or laboratory tests (if relevant), treatment plan (eg, conservative treatment options, medication, injections or physiotherapy care) and referral to other specialists, if relevant. For the multiple sessions arm, APPTs will document patients' progress, change in the exercise plan and all treatments provided.

### Statistical analyses

Descriptive statistics will be used to present the participants' characteristics. Participants withdrawing from the study and reasons for withdrawal will be analysed. Characteristics of participants and non-participants will be compared. Baseline demographic data will be compared across groups to establish the comparability across intervention arms. If important differences are observed, statistical models will be adjusted accordingly. Descriptive statistics will be computed for all outcome measures at the different measurement times. Intention-to-treat analyses will be performed. As secondary analyses, the proportion of responders (percentage of participant with a clinically important response) and the number needed to treat for the two groups will be calculated. Furthermore, per-protocol analyses will also be performed. Primary analyses will include all participants regardless of the involved region (neck and back). Stratified analyses (per region and sex/gender) will also be reported as secondary analyses. Missing data will be handled with multiple data imputation. A repeated mixed-model analysis of variance (ANOVA) will be used to determine whether outcomes differ between treatment arms across time points. Separate analyses will be conducted on each of the primary and secondary outcomes. In particular, if a difference (interaction) between groups is detected ( $p < 0.05$ ), individual effects will be examined. Sphericity will be tested with Mauchly's test.<sup>60</sup> If sphericity is rejected (variances of the difference are not equal), correction will be used to determine if repeated measures ANOVA test is statistically significant. If  $\epsilon > 0.75$ , the Huynh-Feldt correction will be used and if  $\epsilon \leq 0.75$ , the Greenhouse-Geisser correction will be used.<sup>61</sup> Differences in proportions of adverse events, co-interventions (medication, injections or any other treatment), satisfaction scores (VSQ-9 at initial assessment and MedRisk at 12 weeks) between treatment arms will be calculated using  $X^2$  tests or Student's  $t$ -tests. Alpha levels will be set at 0.05. All analyses will be carried out using the SPSS software (IBM Corp Released 2019. IBM SPSS Statistics for Windows, V.26.0) and the Excel software (Microsoft Corporation. 2018. Microsoft Excel for Windows).

### Economic evaluation

A cost-utility analysis comparing both arms will be conducted. The analysis will be from the perspective of



the publicly funded healthcare system. Secondary analyses including publicly and privately healthcare system costs will also be performed. Costs and outcomes will be assessed within the follow-up period of the trial. Data on services used and the efficacy of each approach will be obtained from the concurrent trial. Health utility value will be derived from the EQ-5D-5L using the Canadian validated algorithm.<sup>62</sup> Quality-adjusted life years (QALYs) will be estimated using the total area under the curve method.<sup>63</sup> Unit costs for each healthcare resource, such as physician visits, hospitalisations, medications and emergency department visits, will be obtained from *Régie de l'assurance maladie du Québec*. Costs will be expressed in 2021 Canadian dollars.

Results of the cost-utility analysis will be presented as incremental cost per QALY gained. The statistical analysis will be conducted in accordance with current guidelines for a cost-effectiveness analysis alongside randomised controlled trials.<sup>64 65</sup> The incremental cost and incremental outcome will be estimated using generalised estimating equations with appropriate links and distributions to account for repeated nature of the trial data. The incremental cost-effectiveness ratio will be obtained through the difference in the mean costs of the two approaches divided by the difference in the mean value of QALYs for the two arms as denoted by the coefficient of the intervention indicator variables. Uncertainty in the analysis will be addressed by estimating 95% CIs using a non-parametric bootstrapping method. For this study, 10 000 estimates of costs and outcomes will be obtained for both arms. Results from the bootstrapping exercise will also be used to show cost-effectiveness acceptability curves,<sup>66</sup> which represent the probability of each APP approach being cost-effective over a range of willingness to pay values that the health system may be willing to pay for an additional unit of QALY. A series of sensitivity analyses will be undertaken to examine the robustness of the trial findings. For example, we will examine the effects of conducting a complete case-only analysis and of varying costs of APPTs.

### Sample size calculation

The sample size required is based on the primary outcome measure, the BPI short form. The BPI interference scale and the severity scale have estimated minimum clinically important difference of 1 point.<sup>67–70</sup> To estimate the SD, we used the mean SD at 3-month to 6-month follow-up in three studies using the BPI in adults with spinal pain.<sup>69 71 72</sup> The estimated SDs are, respectively, 2.03 and 2 for the BPI interference and severity scales. The considered parameters are 0.05 for a type I error ( $\alpha$ ) with a power of 0.80 ( $1-\beta$ ). For an ANOVA two-sided, the sample size required is 76 participants per group for the BPI interference (74 for the BPI severity). This sample also accounts for a potential 15% loss to follow-up at 6 months. The total sample will be 152 participants and will provide adequate power. Sample size calculation was performed with the

Excel software using the sample size formula as described by Zhong.<sup>73</sup>

### Patient and public involvement

The CareAxis steering committee involves one patient with chronic low back pain who is seeking physiotherapy care. This patient has been involved in decision-making with the CareAxis organisation, notably to develop the APP model of care for older adults with back and neck pain. This patient expresses the potential need for patients to receive additional physiotherapy care. This patient will not be involved in the recruitment of participants nor in the analysis of the results but will comment the manuscript and potential implications.

### Protocol amendments

Protocol amendments will be described in the final manuscript and will be detailed on *ClinicalTrials.gov*.

## ETHICS AND DISSEMINATION

### Ethics

Ethics approval has been obtained from the *Comité d'éthique de la recherche du CIUSS de l'Est-de-l'Île-de-Montréal* (FWA00001935 and IRB00002087).

### Consent

Detailed information about the nature and objectives of the research project and regarding the experimental procedures will be provided to all participants before the signature of the information and consent form. Participants will need to sign the information and consent form before enrolment in the current trial. The information and consent form is available in online supplemental material.

### Confidentiality

All research team members will respect patients' data confidentiality, in agreement with current regulations. Patients' names will be coded to keep their identity confidential. The key to the code linking their name to their research file will be kept by the principal investigator of this research project in a password-protected file. All information collected during the study, including test results, will be treated as anonymous. It will not be possible to identify patients in the coming publications. Deidentified individual participant data that underlie the results reported in the primary study manuscript will be made accessible.

### Dissemination

This project will use the Canadian Institute of Health Research's integrated approach to research and knowledge translation based on the knowledge to action framework.<sup>74</sup> Results of this study will be presented to the different stakeholder groups such as members of the CareAxis group and of the department of neurosurgery at the Montreal Neurological Hospital. Other usual means of dissemination will include communications in



international conferences and in scientific publications in peer-reviewed medical journals in the field of neurosurgery, rehabilitation or health service organisation.

This is the first study to compare two therapeutic approaches in an APP model of care comparing single and multiple sessions of education and exercise for older adults with spinal pain. This pragmatic randomised controlled trial will provide key data on the clinical effectiveness and economic efficiency of these approaches. Evidence-based development of APP models of care has the potential to profoundly impact access and quality of care for Canadians and may alleviate increasing health-care demands in an efficient manner.

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**Contributors** SL contributed to study design and preparation of the procedures and data collection and he will conduct the recruitment of participants, perform data analyses and the interpretation and writing of the manuscripts. CS, KP, BB, DF, LJH and JF contributed to study design and will contribute to data interpretation and reviewing and editing the manuscripts. KT contributed to study design and preparation of the procedures and will oversee the conduct and the interpretation of the economic data and reviewing and editing the manuscripts. FD led study design, the preparation of the procedures and will supervise overall data collection and interpretation and writing and reviewing of the manuscripts.

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**Competing interests** CS declares being the Chief Medical Officer for CareAxis, a non-profit organisation involving an APP model of care for adults with spinal pain, and being a consultant for Medtronic and for Stryker, two medical devices and technology firms.

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