A streamlined approach to identifying adults suited to orthopedic musculoskeletal physiotherapy management acutely following concussion:

Protocol for a feasibility study

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Background

Concussion or mild Traumatic brain injury is a heterogeneous injury resulting in a diverse range of impairments to both the neurological and musculoskeletal structures of the head-neck complex [1]. Of those sustaining a concussion, as many as 30% go on to experience persistent post-concussion symptoms (PPCS) [2]. The strongest predictor for development of PPCS is acute symptom load [3] Consequently, primary outcomes selected in clinical trials often reflect current understanding that symptom amelioration is an indicator of clinical recovery [4]. This being so, it is reasonable to conclude that optimal acute concussion management would contribute to earlier reduction in symptom load.

To address the heterogeneity of injury phenotypes, multidisciplinary assessment and management is advised [1]. So far, preliminary evidence suggests that treatment of specific domains is effective. However, such results are usually only found in studies where participants are selected based on a comprehensive screening process, and those with impairments specific to the treatment proposed by the study are eligible to participate [5, 6]. Studies which have not identified participants this way have failed to demonstrate treatment effect when interventions to address an injury phenotype was applied [4]. These results

suggest that while treatment to address specific injury phenotypes may be beneficial, implementation of an optimal patient pathways to the most appropriate treatment for individuals post-concussion is not always straight forward.

This may be due to several factors. Firstly, evidence shows that post-concussion symptom profiles are similar regardless of injury phenotype [7]. For e.g., headache, dizziness and neck pain are among the most frequently reported symptoms [8]. However, these symptoms are common across multiple systems that may become impaired following concussion including the oculomotor, vestibular, physiological (migraine), and cervical spine musculoskeletal and sensorimotor systems [9]. Secondly assessment to determine which systems require specific treatment approaches is necessarily broad [10, 11] which is time consuming, expensive, and may result in symptom exacerbation for days afterwards. Thirdly, because it may take review by several health service providers to identify optimal management strategies for a patient, additional costs may be incurred. This may impact accessibility to concussion management services and may mean that not all concussed individuals are treated as quickly or effectively as they could be, while others may not be able to access appropriate treatment due to limited financial or logistical resources. This inaccessibility to appropriate treatment within an expedited time frame may therefore be contributing to the high rate of PPCS.

An urgent need therefore exists to identify ways to streamline the process by which acutely concussed individuals are directed to optimal treatment plans. Any model implemented would however need to fit within the framework of existing local concussion management strategies. Recent cluster and descriptive analyses [9, 12] have identified preliminary evidence for use of a simplified physical exam (SPE) to identify individuals suited to cervical spine Orthopedic Manual Treatment (OMT) and neuromuscular/sensorimotor retraining. Identification is based on positive tests on 2 out of 3 specific cervical spine musculoskeletal outcomes, and at least 1 sensorimotor outcome, as well as an absence of 2 or more positive oculomotor indicators of vestibulo-ocular impairment. Time to perform this SPE is significantly less than that taken for physical exams performed by varying health service providers collectively. This may contribute to expedited plans that effectively manage individual injuries. Additionally, if effective, reductions in risk of developing PPCS and improved equity of access to suitable treatment may be possible.

Study Objectives:

The specific objective of the research project for this application are:

1. To examine feasibility of implementing a simplified physical examination (SPE) aimed at identifying patients suited to cervical spine OMT and neuromuscular/ sensorimotor retraining, within a New Zealand Primary Health Care setting.

2. Based on response to treatment over time, to provide preliminary evidence regarding the

efficacy of the simplified physical examination to accurately identify individuals who may be suited to physiotherapeutic intervention consisting of OMT and neuromuscular/ sensorimotor retraining. Included in this objective will be use of data to validate a clinical objective oculomotor screen to improve clinical utility of the SPE.

We hypothesise that using the SPE will aid in identification of individuals suited to orthopedic manual therapy of the neck. Consequently, primary outcomes including clinician attitude toward using the SPE in a primary health care setting, and participant compliance and satisfaction with the OMT intervention will be positive. Further we anticipate that measurable improvement (objectively assessed neck function and clinical presentation) in response to the selection to neck OMT based on the SPE will be observable over time. Results will therefore support feasibility of using the SPE for acute patient assessment, as well as the clinical efficacy of this approach for managing neck related signs and symptoms following concussion.

Methods

Study Design: This is a mixed methods feasibility study consisting of 3 parts and will investigate clinician and patient response to a ***simplified physical examination (SPE)*** used to inform post-concussion management. Part 1 (Experimental Study a.), a single-group pretest-posttest clinical design will provide preliminary (pilot) evidence of combined effect of assessment and treatment using the SPE to preselect those suited to manual treatment of the neck. Part 2 (Main Feasibility Study) a mixed methods study will consist of a nested qualitative study examining service providers attitudes toward use of the SPE to identify individuals appropriate for neck rehabilitation following concussion (Orthopedic Manual Treatment (OMT) and neuromuscular/ sensorimotor retraining) and utility of this method in the context of current practice. Quantitative exploration of patient compliance, and satisfaction, as well as any adverse reactions to treatment will also contribute to determining overall feasibility of using the SPE. Part 3 (Experimental Study b.), a 3-month follow up will assess long-term effect of treatment selection based on use of the SPE. Combined evidence from these studies will be used to inform development of a future protocol for a pilot randomised, non-inferiority, controlled trial.

Study Procedure and Setting: Participants will take part in one screening session in the Laboratories located at the School of Physiotherapy, University of Otago, Dunedin (referred to as *"screening session"*). Participants identified as eligible to enter the treatment arm of the study will then be invited to participate in further treatment session (referred to as *"treating sessions"*) where they will attend 2 physiotherapy sessions per week for 4 weeks at physiotherapy clinics local to Dunedin. Follow-up assessment (referred to as *"follow up sessions"*) for participants entering the treatment arm of the study will then be conducted 1 week and 3 months following cessation of treatment and will take place at the University of

Otago physiotherapy laboratories. Health care providers (those directly referring to the study, study coordinator, treating physiotherapists) involved in recruitment, screening and treatment of participants will be asked to attend focus groups and individual interviews immediately following completion of treatment sessions by the final participant ("*nested qualitative data collection"*). These will be conducted via zoom or face-to-face depending on any COVID -19 related health restrictions at the time, and also participant preference.

Recruitment:

Procedure: Potential participants will include 160 acutely concussed adults (aged 18-60 years; biological sex: male, female) and are subjects to be considered for this ethics application. Participants for initial screening using the SPE will be recruited via advertisement and or referral (provision of study details) from local primary health care providers.

Local primary health care providers will include but are not limited to Student Health Services, and physiotherapy outpatient, concussion, and balance clinics at the University of Otago, as well as local (Dunedin greater area) physiotherapy clinics specialising in management of concussion. University of Otago electronic and physical notice boards including social media sites (the Researcher's Twitter accounts, School of Physiotherapy Clinics Facebook, University of Otago Instagram accounts) and a research webpage created on the website of the Centre for Health, Activity and Rehabilitation Research (CHARR), School of Physiotherapy will be used for recruitment via advertisement. A link to the Participation Information Sheet will be contained within the social media posts and webpage link to the created research webpage.

"Emergency department (ED) lists of Te Whatu Ora Southern tertiary health care facility, Dunedin Hospital, will be screened on a weekly basis directly by the study Primary Investigator (PI) Dr Olivia Galea. To facilitate this and provide access to contact details only of those meeting injury eligibility criteria based on injury codes, a list of those with appropriate injury codes will be generated weekly. Participants on this list will then be contacted by the PI and provided an opportunity to participate in the study. Contact details for individuals on the list will be retained only during the recruitment process. Participants who are interested to learn more about the study will be directed to the study website and preliminary screening questionnaire where they can enter their contact details for future contact with the study coordinator (SC)."

Volunteers who contact the SC following referral to the study from their health care provider will be screened for inclusion and exclusion criteria. If eligible to participate in the screening session, participants will be forwarded an electronic participant information sheet and consent form and scheduled for the screening session. It is not anticipated that any participants meeting exclusion criteria will be referred from health care providers involved in the study, however if they are, they will be referred back to the referring health care provider

for further care. Participants referred from a health care provider will be required to provide written confirmation of their recent concussion from their treating physician.

Volunteers who: respond to advertisement i) using the online screening questionnaire relating to the inclusion/exclusion criteria (primarily whether they have sustained a medically diagnosed concussion within the last 14 days); ii) the study phone; iii) the study email, or who are referred by a health practitioner will be contacted by the study SC. The SC will further screen them for inclusion and exclusion criteria. If eligible to participate in the screening session participants will be forwarded an electronic participant information sheet and consent form and scheduled for the screening session. Individuals contacting the SC in response to advertising who meet exclusion criteria at any stage of the screening process will be provided with names and contact details of primary health services for concussion in Dunedin for follow up if desired. Those recruited via advertisement will be requested to obtain written confirmation of their concussion from their treating physician.

Inclusion criteria: Adults aged 18-60 years, biological sex: male, female, who have sustained a medically diagnosed concussion (mild Traumatic Brain Injury) based on published diagnostic criteria [13-15] and are not more than 14 days since injury [14].

Exclusion criteria: Individuals with past or current history of:

- Moderate to severe TBI as defined by published diagnostic criteria [16]
- Diagnosed concussion with associated trauma related abnormalities apparent on CT or MRI and/ or cervical spine fracture
- Diagnosed concussion due to assault
- Neck pain unrelated to concussion injury(/ies) (requiring treatment)
- Headache disorders (including cervicogenic, migraine (chronic), and tensions type headaches)
- Vestibular, oculomotor, neurological disorders
- Major psychiatric disorders currently being actively treated
- Physical injury that would prevent completion of the screening session

Study power:

Based on previously identified rates of neck impairment post-concussion [9, 17] it is anticipated that screening of **160** participants will be required to identify **60 i**ndividuals who meet inclusion criteria. Allowing for 50% of individuals to decline participation in the trial and a 10% drop-out rate, it is anticipated that data from **n=27** participants (treatment commenced with **n=30**) will be collected at all data collection time points. This group size is consistent with those currently used in randomised control trials investigating outcome following OMT of the

neck post-concussion [18] and with recommendations regarding pilot data sample sizes [19] so is considered adequate for this feasibility study.

Screening and Eligible Participant Identification Process:

Screening session procedure: The screening session will take place at the School of Physiotherapy research laboratories and will be conducted by the PI. Prior to attending the screening session participants will be sent a link by the SC to complete the battery of online questionnaires and asked to complete them 1 day prior to attendance. Included in the battery will be an electronic version of the consent form which participants will be required to sign prior to being able to access the questionnaires.

Questionnaires:

- Rivermead Post-concussion Symptoms Questionnaire (RPQ) [20] *13 Item and 3 Item* – Originally developed to provide an overall symptom severity measure based on symptom reporting following concussion. Participants rate the degree to which each symptom poses more of a problem since their head injury on a 0 to 4-point scale. When divided into three and thirteen item symptom scales construct validity was calculated at 0.83 for the 13-item questionnaire and 0.62 for the 3-item. IRR was 0.89 and 0.72 respectively [21]

- Neck Disability Index (NDI) [22] a 10 item scaled questionnaire. Each question requires the participant to select a response which most accurately reflects the difficulty they experience with specific functional tasks such as driving, reading working or sleeping, and also the extent to which they experience difficulty with function due to headache. It is currently utilised in cervical dysfunction populations including Whiplash Associated Disorder and neck pain to identify functional limitations resulting from either condition. Test-retest reliability has been established at 0.89 [22].

- Dizziness Handicap Index (DHI) [23] lists 25 functional activities. Individuals are asked to rate how much dizziness or unsteadiness affects performance of listed activities in terms of frequency. When summed the greatest resultant total scores for each of the subcategories; functional, emotional, or physical is determined to be the underlying causes for dizziness. Interrater reliability for the DHI has been calculated at 0.97 and internal consistency established between 0.72 and0.85 for each of the categories [23]

- Headache Impact Test – 6 (HIT-6) is a 6-item subjective measure of the impact of headaches, originally based on an existing pool of 54 existing and 35 suggested items [24]. Good internal consistency (Cronbach's $\alpha = 0.89$) and test-re test reliability (0.80) have previously been reported [24]. Sensitivity and Specificity compared to the total HIT scale has been reported at 93.1% and 79.4% respectively [24].

- Fatigue severity scale (FSS) [25] is a 9-item questionnaire measures level of disabling fatigue over the prior week. The scale has demonstrated good levels of internal consistency (Cronbach's α = 0.89-0.94) and test-retest reliability (ICC 0.751) in patient populations prone to excessive fatigue.

- PROMIS Sleep Questionnaires [26] are two 8-item questionnaires of Sleep Disturbance (SD) and Sleep-related Impairment (SRI) and demonstrated good construct validity when compared to the longer form [27] as well as other outcome sleep related outcome measures.

- International physical activity questionnaire – Short Form [28] measures physical activity of varying intensities over a 1-week period and has demonstrated high test-retest reliability (**α** <0.8)

- EuroQol 5 Dimension (EQ-5D-5L) is a 5-dimension measure of health-related quality of life. The EQ-5D-5L provides general measure of quality of life [29]. Specifically, the scale provides information regarding problems within 5 dimensions of health: anxiety/depression, pain/discomfort, mobility, self-care, and usual activities, and a self-rated health value.

- Sociodemographic questionnaire

Ethical considerations for self-report outcome measures:

As participants will be individuals who are acutely concussed it is possible that increased amounts of screen time and reading may result in a temporary increase in symptoms. However, online questionnaires will be constructed so that is possible to log in and out of the online survey tool to allow response over the 24-hours prior to attending the screening session. Further in line with international recommendations outlining resumption of cognitive activities including symptom limited screen time may commence after 24-48 hours of rest post injury [14], participants will not be required to complete questionnaires within this time post injury. This will be clearly indicated at the start of the questionnaire battery and in the participant information sheet.

At the screening session, the project will first be explained to the potential participants and their questions answered before signing the consent form (Consent form A – Patients). If they do not agree to participate, the electronic questionnaire data will be deleted, and no further use will be made of it. Women will be asked to wear a sports bra or a singlet that exposes the neck region fully. Men will be asked to remove their shirt or wear a singlet that also exposes the neck fully. Anthropometric measures (height, weight, and neck girth) will then be measured.

Simplified Physical Examination:

Measures of cervical spine function: including kinematic assessment [30], neck flexor endurance [31], manual spinal examination [32], joint position sense [33], and global head and eye motion accuracy [34, 35] will be conducted during the screening session and will be used to identify presence of neck impairments [12]. Results indicative of positive findings for each outcome will be based on published criteria [9, 32] . Prior to performance of the measures of cervical spine function a quick safety screen in line with current standards of practice internationally and in New Zealand [36, 37] will be performed for all participants attending the screening session. While it is unlikely individuals medically diagnosed with concussion will present with indicators of serious spinal or vascular pathology of the neck (red flags) precautionary evaluation will be undertaken. In the unlikely event signs or symptoms of serious pathology are evident assessment will cease and the participant will be referred for further medical review according to current standards of practice [36, 37].

Description of cervical spine assessments are as follows:

Neck Kinematic Assessment (including global head motion accuracy) (VR CSp): *The customized neck VR system* - will evaluate cervical spine motion. This system utilizes hardware and software that provides a simple, yet engaging, game monitored via 6-DOF tracking. The hardware includes a head-mounted display and a virtual environment using Unity-pro software, version 3.4.0f5 (http://www.unity3d.com). The neck VR software includes assessment of neck kinematics including active range of motion, velocity, and accuracy of cervical spine motion. Reduced active range of motion has been identified as one of three diagnostic criteria for the classification of cervicogenic headache [38, 39] Reliability of the VR neck system to measure cervical kinematics has been established at good to high 0.84 to 0.93 mostly [40] and sensitivity and specificity to identify neck pain patients has been established at between 85 and 100% accuracy [30].

Cervical Flexor Endurance Test (CFET): is a measure of synergistic cervical flexor muscle endurance [41]. Participants are positioned in crook lie (supine with knees flexed to 90°) with their occiput resting on the examiners hand. Participants are instructed to look toward their knees, tuck their chin slightly and lift their head just off the supporting surface (examiners hand) to a point where they can no longer feel contact with the examiners hand and hold this position for as long as they can. Reduced cervical spine muscle endurance has previously been identified in neck pain and mTBI populations [12, 42, 43] and inter and intra tester reliability of this test has been identified at 0.83 and 0.85 respectively [41].

Manual Spinal Examination (MSE): Manual examination using postero-anterior Passive Accessory Intervertebral Motion (PAIVM) will be used to assess for the presence of cervical spine facet joint dysfunction. Force is applied to each facet joint (C0/1 to C7/T1 bilaterally)

indirectly via the investigator's thumbs [44-46]. Based on previous studies using this method, [45, 47] determination of the presence of cervical intervertebral joint dysfunction as either "present" or "absent" is based on the presence of at least one joint being found to have all three of the following: 1/abnormal displacement, 2/abnormal tissue resistance to displacement (6-7/7 on a Likert scale) [44, 45, 48]) 3/ pain provocation reported (≥3/10 on a NRS) during the testing procedure [45, 48-50]). This criteria has previously been identified as an accurate indicator of cervical facet joint dysfunction in cervical spine disorders (sensitivity 71-100% and specificity 96-100%) [45, 47] and cervicogenic headache (sensitivity 80%) [32]. Intra and interrater reliability of manual assessment to identify individual cervical spine facet joint dysfunction is established at 0.63 to 0.85, and 0.79 to 0.96 respectively [44].

Joint Position Error (JPE): is generally considered a primary measure of proprioceptive capability of the cervical spine [51]. Participants are positioned in sitting with a low-level laser light attached to their head and centered on the middle of a target 90cm in front of them. Participants turn their head to the right and left and attempt to return as accurately as possible to their original start point while their eyes are closed. The use of laser beam to assess JPE of the neck is a common technique used by clinicians for patients with whiplash or neck pain and poses very minimal risks to the subjects. Significant difference between whiplash associated disorders D and control subjects has been identified with the cervical spine positioned to start in neutral [52]. Sensitivity for this test has been established in head neutral position at 78% and specificity at 85% in a neck pain cohort and interrater reliability at 0.68 [53].

Smooth Pursuit/ Neck Torsion: The patient is seated comfortably with the head positioned in neutral and is asked to follow a slow-moving target approximately 40° (20° to the right and to the left). The patient is instructed to keep the head still while observing the target. This is repeated in neutral and in cervical torsion (rotation of the trunk to the left or right underneath the head, rather than turning the head left or right). Differences in eye motion are noted with differences between neutral and cervical torsion being associated with cervical sensorimotor disturbance, as opposed to vestibulo-ocular impairment which may be more apparent in neutral [54].

Ethical considerations for clinical measures of neck function and head movement control: There is a risk of symptomatic aggravation such as increased dizziness or nausea, or soreness in the neck muscles following assessment based on previous participant reports, however all symptoms have been short-lived and (dizziness usually settles with a short break following test performance). Muscle endurance tests have the potential risk of mild muscle strain or post exercise soreness. However, there is minimal likelihood of injury as testing is performed within the participants tolerance levels. Any muscle discomfort or soreness associated with the endurance test is usually short lived and resolves within 24-48 hours. Participants will also

be offered a short break if required during testing to allow time for symptoms to settle.

***Measures of vestibulo-ocular performance**:* will be used to identify individuals with evidence of vestibulo-ocular impairment [55]. Vestibulo-ocular assessment will commence with oculomotor screen of eye movement to determine presence or absence of baseline oculomotor paresis or palsy [56] which may unduly influence VOS results. This will be followed by completion of the oculomotor and vestibular testing suite (recorded as present/ absent: nystagmus, saccades, strabismus, canalith disorders, vestibulo-ocular reflex function impairment [gain]) on the ICS Chartr 200 VNG System (Otometrics; Taaastrup; Denmark). Two or more positive tests will identify individuals with evidence of vestibulo-ocular impairment [57, 58].

Description of the vestibulo-ocular assessment is as follows:

Video Nystagmography (VNG) Vestibulo-ocular Assessment: This includes various tests where the participant while wearing a pair of goggles with an implanted video camera (GN Otometrics ICS Impulse® video nystagmography unit), will be asked to focus their eyes on certain positions on a blank wall 1m in front of them while their head is moved by the assessor, or they move it independently. Additionally, the subject's eyes will be covered momentarily for some tests. These clinical assessments are commonly used to assess for any dysfunction which may indicate the presence of disturbance to usual eye reflexes [59, 60]. In this case the addition of the VNG goggles allows results to be quantified, increasing diagnostic utility of the measures [61]

Dix Hallpike manoeuvre and Head-roll tests currently used clinically to assess for the presence of BPPV will also be performed using the VNG goggles. The manoeuvre is performed with the individual sitting on a plinth with legs extended and head turned to the side by about 45 degrees. The individual is then quickly assisted into a lying position by the tester, with the head and neck fully supported and remaining rotated and in approximately twenty degrees of extension. Onset of involuntary eye movement is then observed (specialised goggles which black out the room, also often used clinically, will be used for observational purposes) to determine the presence of BPPV [62]. Sensitivity and specificity for this are established [62]. Currently accepted testing procedure requires the performance of the test once for accurate diagnosis. The eyes are covered throughout the test so that visual fixation on an object by the participant does not occur.

Vestibular Oculomotor Screen: The Vestibular Ocular Motor Screen (VOMS) [63] is a test designed for use with individuals aged 9-40, interpretation of abnormal results in individuals outside this age range may vary. While interpretation of results is based on symptom reproduction, abnormal movements of the eyes should also be recorded. Where oculomotor (OM) movements seem abnormal and so it seems you have detected OM or vestibular

impairment appropriate referral should be made. It is important to remember that performance of the VOMS requires a substantial amount of head on neck motion, therefore consideration should be given to the cervical spine as a potential source of increase in symptom reporting. This is especially the case where cervical sensorimotor assessment appeared to indicate the presence of dysfunction.

Ethical considerations for vestibular dysfunction measures: There is a risk of symptomatic aggravation such as increased dizziness or nausea following assessment based on previous participant reports, and the potential to identify the presence of BPPV, oculomotor and vestibular disorders of a central origin unrelated to concussion. However, all reported symptoms have been short-lived and (generally dizziness has settled with a short break following test performance). Permission will also be sought from participants so share information related to findings of the assessment with their physician. Participants will also be offered a short break if required during testing to allow time for symptoms to settle.

Order of testing will be performed to minimise symptom exacerbation and influence of preceding outcomes on those to follow and therefore will not be randomised and will be performed consistently in the same order.

Following completion of the screening session participants identified as eligible for entry to the treatment arm of the study will be provided with activity monitors (ActiGraph activity monitors [GT3x, GT9x]).

Physical Activity Levels and Sleep: Participants will be asked to wear ActiGraph activity monitors (GT3x, GT9x) on their waist/ hip and wrist to measure physical activity during the first 7 days following the screening session. Both ActiGraph activity monitors are tri-axial and solid state accelerometers [64, 65], and have been validated for use in adult populations [66, 67]. Participants will be asked to complete a day time activity log (including time when monitors are removed for personal care activities, when vigorous activity was performed etc.) for interpretation of data collected by the activity monitors, and a sleep log to evaluate sleep quality of the previous night's sleep [68, 69]. The sleep log will be manually completed in the morning in relation to the previous night's sleep.

Eligibility for Entry to Treatment Arm:

Participants identified as eligible for entry to treatment arm: will include those participants who demonstrate positive findings for a minimum of 3 cervical spine musculoskeletal and or sensorimotor outcome [12] as well as an absence of 2 or more positive oculomotor indicators of vestibulo-ocular impairment [55, 57]

Participants identified as ineligible for entry to treatment arm: identified due to an absence of sufficient positive neck related physical assessment findings, or alternately a positive

vestibulo-ocular screen will be provided with standardised graduated return to activity information [14, 70] as well as appropriate referral where evidence of vestibulo-ocular or physiological impairment is identified by the SC.

Of note, the SC conducting the laboratory-based screening session will be a New Zealand registered physiotherapist, and hold a current annual practicing certificate, Physiotherapy New Zealand membership, and ACC registration. They will hold additional training in OMT with a minimum of 3 years clinical experience. They will also have received specialised training from the PI (OG) in assessments to be used during the screening session including performance of testing, data reduction, and analysis of quantifiable outcomes necessary to establish participant eligibility for enrolment in the treatment arm of the study.

Estimated duration of total testing time will be 1.25 hour (1 hour for the SPE and 0.25 hours for induction and consent). All participants who provide consent and complete the SPE will be provided with a $40 voucher to recognise the reasonable costs involved with participating in this study.

Treatment Sessions*:*

Treatment sessions procedure:

Participants identified as eligible for allocation to the treatment arm of the study will be booked for their initial treatment session a maximum of 2 weeks following the screening session. Participants will be assessed during the first treatment session using an extended standardised assessment of the cervical spine (1 hour). Additional tests of musculoskeletal [31, 71] and sensorimotor function [72] as well as neural mechanosensitivity [73], standard to physiotherapy clinical practice in management of disorders of the neck and concussion [74], in addition to baseline results (provided in report form via post from the SC and supplied to the treating physiotherapist) will inform individualised treatment plans [18, 75]. Following initial assessment by the therapist, participants will receive treatment twice weekly for 4 weeks. During this time participants will also be requested to avoid alternate treatments for their concussion (except for use of prescribed medication/s) to minimise potential for confounding.

Interventions:

Treatment for management of identified neck impairments provided will include OMT (For e.g., Maitland, and Mulligan intervertebral joint mobilisation techniques) neuromuscular and sensorimotor retraining techniques standard to musculoskeletal physiotherapy practice internationally and in New Zealand for management of neck disorders [18, 75]. Individual treatment plans will be pragmatically determined. All participants receiving treatment will be provided with advice and education relating to graduated return to activity and prescribed a sub-symptom threshold cardiovascular exercise program using previously published

guidelines for exercise intensity dose [76]. This adjunct treatment aligns with internationally accepted standards of best practice for concussion management [4].

Treating physiotherapists, up-skilling, and treatment monitoring:

Treating physiotherapists will be New Zealand registered, and hold current annual practicing certificates, Physiotherapy New Zealand membership, and ACC registration. They will hold additional training in OMT to at least diploma level with a minimum of 5 years clinical experience. Treating therapists will also participate in an initial 1 x 3 hour study induction session followed by 2 x 1 hour follow-up study review sessions (April to August). These sessions will be conducted by the PI (OG), a Masters (Musculoskeletal Physiotherapy) qualified physiotherapist, with 20+ years of clinical experience and expertise treating disorders of the neck including concussion, who is registered with the PNZ, and holds a current APC, and ACC registration. Sessions will provide physiotherapists treating patients in the study with an opportunity for continuing education related to concussion management. All sessions will be in person.

Follow up sessions:

Procedure:

Following completion of the treatment protocol all participants will be contacted by the SC and scheduled for follow-up review sessions (1 week and 3 months following completion of treatment sessions or if treatment sessions were not completed in full per-protocol follow up times). Follow-up sessions will be held at the same laboratories attended for the screening session. Participants will be requested to complete the same battery of questionnaires 1 day prior to attending each time and will also be examined using the SPE on both occasions. Participants will also be administered with activity monitors at each follow up and asked to wear these for a further 7 days and complete the daily activity and sleep logs. All participants completing these follow up sessions will be provided with a $40 voucher to recognise the reasonable costs involved with participating in this study.

Nested Qualitative Focus Groups and Interviews:

Procedure:

Up to 10 health practitioners involved in the referring, assessing, and treating of study participants will be invited to participate in focus groups (n=2, 5 participants per group). They will be asked to complete a brief demographic questionnaire (including questions related to age, biological sex, number of years and scope of practice). Four of these individuals will be further invited to attend one-on-one semi-structured interviews. Focus groups will be used to determine health practitioner attitudes toward ease of use (including any challenges), and perceived effectiveness (acceptability and usefulness) of the SPE to identify individuals

appropriate for neck rehabilitation (Orthopedic Manual Treatment (OMT) and neuromuscular/sensorimotor retraining) following concussion, and utility of this method in the context of current practice. All focus group and interviews will be recorded using a digital voice recorder, which will be transcribed for analysis. All transcriptions will be checked and anonymised by the SC. Based on coding and thematic analysis of transcribed recordings of focus group proceedings the study team will iteratively determine main themes to be further explored in semi-structured interviews. Co-investigators of the study will conduct all focus groups and interviews. All academic members of the study team have experience in qualitative research.

Focus groups and interviews will be held at the University of Otago research rooms. Prior to participation in the focus groups, attending health practitioners will have the purposes of the focus group/ interviews explained and will provide written consent. All participants will be reimbursed at $120 per hour voucher to recognise the reasonable costs involved with participating in this study. Reimbursement for attendance at interviews will be provided in addition to reimbursement for attendance at focus groups.

Outcome Measures and Analysis:

Primary Outcomes: Feasibility

Qualitative data: focus groups and interviews

We will use Thematic Analysis, an evaluative deductive approach to analyse the qualitative focus group and interview data, as described by Clarke and Braun [77]. The SC will code each transcription and one of the researchers will code every third transcription, grouping the codes into themes and sub-themes. An iterative process will be used within the research team to define the main themes and emerging models related to the study aims. In this way thematic analysis will be reflexive to aid in identification of any instances where the PI's beliefs may unduly influence identification of these main themes.

Quantified feasibility outcomes: activity, compliance, and adverse event monitoring

Participants will record daily performance of home exercises prescribed by the treating therapist in an activity-log (yes/ no, minutes of exercise per day) to determine treatment compliance. Non-attendance at scheduled treatment sessions will be recorded by the treating therapist (yes/no per session) as well as any adverse reactions to treatment (number). Participants will complete an exiting questionnaire to assess patient satisfaction [78].

Experimental Outcomes:

Experimental outcome measures (experimental studies a. & b.) will include but are not limited to:

Category	*Exploratory OM*
Cervical Spine	

Kinematic Assessment - Virtual Reality	Total range of motion (deg)
	Peak Velocity – Rotation R (deg/s)
	Peak Velocity – Rotation L (deg/s)
	Peak Velocity – Rotation Ext. (deg/s)
	Global head motion accuracy (deg)
Muscle Function (CFET)	Total time (sec)
Manual Spinal Examination	Pos/ neg
Sensorimotor Function (JPE)	Degrees Error (deg)
	Neck Disability Index (tot/ 50)
	Headache Impact Test-6
Vestibulo-Ocular	
VNG OM Assessment	Full Assessment (≥ 2 pos/neg overall (pos/neg) ; pos/neg per assessment)
VOMS assessment	Increase in symptoms (11- point NRS) ; avg NPC > 5cm
	Dizziness Handicap Index
Participant Outcomes	
Physical Activity : Actigraphy	Minutes of Vigorous Physical Activity, min/day
	Physical Activity (TAC/d; steps/d; PAEE - kcal/kg/day)
	Activity log
	Consensus Sleep Diary
	PROMIS sleep questionnaires
	IPAQ (METs)
	Fatigue Severity Scale
Quality of Life	EuroQol-5D-5L (EQ VAS)

Data Management

Clinical data will be entered directly into the study's online data recording form which only the PI, SC and members of the research team will be able to access. Data in this form will be stored under a unique identifier generated during the initial screening session with the SC. Where raw data requires further analysis, it will be deidentified (VR and VNG outcomes) and routinely uploaded to the PIs (OG) password protected laptop or the password protected study laptop. Data collected using VR and VNG will be collected on the devices using the participants unique identifier.

Statistical Analysis

Descriptive analyses will be performed on sociodemographic data. Exploration of central tendency of all data will be evaluated using Kolmogorov-Smirnov and Shapiro-Wilk tests. Where data is significantly skewed, attempts will be made to transform using suggested methods [57]. Individual demographic variables (sex, age, BMI, IPAQ score) which could reasonably be expected to influence quantitative outcomes will be analysed for significance using univariate linear regression and included in models.

Objective 1:

Quantified feasibility outcomes: activity, compliance, and adverse event monitoring

a. Descriptive statistics will be used for recruitment frequency and the number of eligible participants, the drop-out rate, and degree of missing data for the patient rated and clinical outcomes measures. The programme will be considered feasible if 80% of patients complete the programme until formal discharge based on the physiotherapists' assessment and treatment documentation.

b. Adherence to the intervention by auditing and summarising patients' logbooks and the physiotherapists' assessment and treatment documentation. The SC will audit the documentation. Adherence will be considered acceptable if 80% of exercises had been recorded in the patient's logbooks.

c. Adverse events from the treatment will be determined by auditing the physiotherapists' assessment and treatment documentation as well as inclusion of formal reports submitted to the study or HEC in the event of serious adverse events. Number of events will be considered.

d. Patient satisfaction score (/12) from the patient satisfaction exiting questionnaire will be calculated and mean and 95% CI will be reported.

Triangulation of qualitative (analysis described above) and quantitative outcomes [79] will determine overall feasibility of using the SPE to inform treatment management.

Objective 2:

Linear mixed method analysis of repeated experimental outcomes will determine treatment effect. Effect modifiers including sex and age as well as statistically significant demographic confounders will be included in the final model. Further secondary analysis may be undertaken using data collected at all time points. Multivariable linear regression will identify items of the VOMS which best predict VNG OM.

Data storage:

All data (including patient and health practitioner data) will be stored on the personal password-protected laptops of the PI (Dr Olivia Galea) and or the password-protected study laptop. Any hard copies of the questionnaires and consent forms will be stored in the PI's office in a secure filing cabinet. Only the researchers mentioned in the application and the SC (tba) responsible for processing and analysis will have access to the de-identified data collected during the study. The principal researcher (Olivia Galea) and the SC will keep a list identification codes with participant names, so that participants can be identified by their coded data if needed.

A standardised hard copy of the summary report of the participants findings from the screening session completed by the SC will be provided to the treating physiotherapist (via postal mail). This will not be de-identified since it will be used by the treating physiotherapist to inform treatment. A copy of these reports will be kept on the PI's personal password-protected laptop.

The treating physiotherapist will record the clinical assessment and treatments, as required, on their usual practice management systems as well as information related to study feasibility.

All data will be stored for the duration of the study on the primary investigator's password-protected University laptop and will be accessible by members of the research team. It will also be stored for at least 10 years in the school's archive folder on the High-Capacity Storage System (HCSS). Any personal information held about the participants (such as contact details and hard copy questionnaires) may be destroyed at completion of the research. Coded study information may be kept by the University of Otago in secure, cloud-based storage indefinitely. All storage will comply with NZ l data security guidelines.

Potential problems: (medical/legal; issues with disclosure; conflict of interest, etc)

The study will be led by the PI, directly supported by the SC. Regular team meetings (face-to-face where possible) will be held to monitor study progress and address any issues arising including those related to potential problems (below), although risk of these is considered very low.

Screening and Follow up Sessions: Participants may feel uncomfortable with the laboratory environment; thus, care will be taken with familiarising them with the researchers, the set up and methods of the study. Participants may be uncomfortable with male or female researchers. To mitigate potential for participants to feel uncomfortable in the research environment they will be informed they are welcome to bring a support person to the laboratory. Other potential problems related to specific outcome measures have been described previously.

Participants will also be informed that in the unlikely event any symptoms resulting from attending the screening session, any of the treatment sessions or the follow up sessions does not subside, or they are concerned that the pain may re-appear, they will be welcome to contact the primary investigator (Olivia Galea). If any unresolved concern persist, referral to a GP or physiotherapist of their choice will be considered. If there is lingering pain or symptom reproduction as a result of the study, they will be informed that they may be able to seek an ACC claim to cover treatment of the pain.

Adverse event management: The risk of any adverse event is minimal. In case a participant presents with an adverse event, report to the internal Health & Safety Committee (Centre for Health, Activity and Rehabilitation Research—University of Otago) will be made immediately by the PI (OG) to assess whether reporting the adverse event to the study sponsor, and the Ethics Committee is necessary. If more than one serious adverse event of any kind occurs and if these are related or caused by the treatment interventions, we will suspend the study. If the cause of the events cannot be determined or remediated, and is plausibly related to the intervention, the study will be terminated.

Funding:

The School of Physiotherapy, University of Otago, is providing the laboratory and GST costs associated with running the project. Project expenses including cost of equipment for the SPE, physiotherapy treatment costs, participant/ health care practitioner reimbursement for time, focus group and interview costs including refreshment and transcription will be funded by the PI's Stanley Paris Fellowship Award ($99 986 NZD) and S fund.

Timeline

Project	PLANNED TASK	2023											2024					
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Ethics	Ethical Approval																	
Feasibility Study	Finalise Feasibility Study Protocol																	
	Recruit Study Coordinator																	
	Treating Physiotherapist Training																	
	Participant recruitment/ Data Collection																	
	Data extraction and analysis																	
	Data Extraction / Thematic Analysis																	
	Abstract and Manuscripts writeup and submission																	
Treatment Outcomes Pilot Study	Statistical Analysis																	
	Abstract writeup																	
	Abstract submission IFOMPT 2024/ AAOMPT 2024																	
	Manuscript Preparation - Treatment Outcomes Study																	
	Manuscript Submission - Treatment Outcomes Study																	
	Preliminary Analysis of treatment outcome data																	
Additional Study Objectives	Grant Preparation and Submission using pilot outcome data - Emerging																	

	Researcher First Grant																

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Appendices

1. Participant Questionnaires

(i) Rivermead Post-concussion Symptoms Questionnaire (RPQ)

The Rivermead Post-Concussion Symptoms Questionnaire*

After a head injury or accident some people experience symptoms which can cause worry or nuisance. We would like to know if you now suffer from any of the symptoms given below. As many of these symptoms occur normally, we would like you to compare yourself now with before the accident. For each one, please circle the number closest to your answer.

0 = Not experienced at all
1 = No more of a problem
2 = A mild problem
3 = A moderate problem
4 = A severe problem

Compared with before the accident, do you now (i.e., over the last 24 hours) suffer from:

Headaches.....	0	1	2	3	4
Feelings of Dizziness	0	1	2	3	4
Nausea and/or Vomiting	0	1	2	3	4
Noise Sensitivity, easily upset by loud noise	0	1	2	3	4
Sleep Disturbance.....	0	1	2	3	4
Fatigue, tiring more easily	0	1	2	3	4
Being Irritable, easily angered	0	1	2	3	4
Feeling Depressed or Tearful	0	1	2	3	4
Feeling Frustrated or Impatient	0	1	2	3	4
Forgetfulness, poor memory	0	1	2	3	4
Poor Concentration	0	1	2	3	4
Taking Longer to Think	0	1	2	3	4
Blurred Vision	0	1	2	3	4
Light Sensitivity, Easily upset by bright light.....	0	1	2	3	4
Double Vision	0	1	2	3	4
Restlessness	0	1	2	3	4

Are you experiencing any other difficulties?

		1	2	3	4
1. _____	0				
2. _____	0	1	2	3	4

*King, N., Crawford, S., Wenden, F., Moss, N., and Wade, D. (1995) J. Neurology 242: 587-592

(ii) Neck Disability Index (NDI)

Neck Disability Index

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life. Please answer every section and **mark in each section only the one box that applies to you**. We realise you may consider that two or more statements in any one section relate to you, but please just mark the box that most closely describes your problem.

Office Use Only
Name _____
Date _____

Section 1: Pain Intensity

☐ I have no pain at the moment
☐ The pain is very mild at the moment
☐ The pain is moderate at the moment
☐ The pain is fairly severe at the moment
☐ The pain is very severe at the moment
☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (Washing, Dressing, etc.)

☐ I can look after myself normally without causing extra pain
☐ I can look after myself normally but it causes extra pain
☐ It is painful to look after myself and I am slow and careful
☐ I need some help but can manage most of my personal care
☐ I need help every day in most aspects of self care
☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3: Lifting

☐ I can lift heavy weights without extra pain
☐ I can lift heavy weights but it gives extra pain
☐ Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently placed, for example on a table
☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
☐ I can only lift very light weights
☐ I cannot lift or carry anything

Section 4: Reading

☐ I can read as much as I want to with no pain in my neck
☐ I can read as much as I want to with slight pain in my neck
☐ I can read as much as I want with moderate pain in my neck
☐ I can't read as much as I want because of moderate pain in my neck
☐ I can hardly read at all because of severe pain in my neck
☐ I cannot read at all

Section 5: Headaches

☐ I have no headaches at all
☐ I have slight headaches, which come infrequently
☐ I have moderate headaches, which come infrequently
☐ I have moderate headaches, which come frequently
☐ I have severe headaches, which come frequently
☐ I have headaches almost all the time

Section 6: Concentration

☐ I can concentrate fully when I want to with no difficulty
☐ I can concentrate fully when I want to with slight difficulty
☐ I have a fair degree of difficulty in concentrating when I want to
☐ I have a lot of difficulty in concentrating when I want to
☐ I have a great deal of difficulty in concentrating when I want to
☐ I cannot concentrate at all

Section 7: Work

☐ I can do as much work as I want to
☐ I can only do my usual work, but no more
☐ I can do most of my usual work, but no more
☐ I cannot do my usual work
☐ I can hardly do any work at all
☐ I can't do any work at all

Section 8: Driving

☐ I can drive my car without any neck pain
☐ I can drive my car as long as I want with slight pain in my neck
☐ I can drive my car as long as I want with moderate pain in my neck
☐ I can't drive my car as long as I want because of moderate pain in my neck
☐ I can hardly drive at all because of severe pain in my neck
☐ I can't drive my car at all

Section 9: Sleeping

☐ I have no trouble sleeping
☐ My sleep is slightly disturbed (less than 1 hr sleepless)
☐ My sleep is mildly disturbed (1-2 hrs sleepless)
☐ My sleep is moderately disturbed (2-3 hrs sleepless)
☐ My sleep is greatly disturbed (3-5 hrs sleepless)
☐ My sleep is completely disturbed (5-7 hrs sleepless)

Section 10: Recreation

☐ I am able to engage in all my recreation activities with no neck pain at all
☐ I am able to engage in all my recreation activities, with some pain in my neck
☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck
☐ I am able to engage in a few of my usual recreation activities because of pain in my neck
☐ I can hardly do any recreation activities because of pain in my neck
☐ I can't do any recreation activities at all

Score: ___/50 **Transform to percentage score x 100 = %points**

Scoring: For each section the total possible score is 5: if the first statement is marked the section score = 0, if the last statement is marked it = 5. If all ten sections are completed the score is calculated as follows:
Example: 16 (total scored)
50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:
16 (total scored)
45 (total possible score) x 100 = 35.5%

Minimum Detectable Change (90% confidence): 5 points or 10 %points

NDI developed by: Vernon, H. & Mior, S. (1991). The Neck Disability Index: A study of reliability and validity. Journal of Manipulative and Physiological Therapeutics. 14, 409-415

(iii) Dizziness Handicap Inventory (DHI)

The Dizziness Handicap Inventory (DHI)

P1. Does looking up increase your problem?	o Yes o Sometimes o No
E2. Because of your problem, do you feel frustrated?	o Yes o Sometimes o No
F3. Because of your problem, do you restrict your travel for business or recreation?	o Yes o Sometimes o No
P4. Does walking down the aisle of a supermarket increase your problems?	o Yes o Sometimes o No
F5. Because of your problem, do you have difficulty getting into or out of bed?	o Yes o Sometimes o No
F6. Does your problem significantly restrict your participation in social activities, such as going out to dinner, going to the movies, dancing, or going to parties?	o Yes o Sometimes o No
F7. Because of your problem, do you have difficulty reading?	o Yes o Sometimes o No
P8. Does performing more ambitious activities such as sports, dancing, household chores (sweeping or putting dishes away) increase your problems?	o Yes o Sometimes o No
E9. Because of your problem, are you afraid to leave your home without having someone accompany you?	o Yes o Sometimes o No
E10. Because of your problem have you been embarrassed in front of others?	o Yes o Sometimes o No
P11. Do quick movements of your head increase your problem?	o Yes o Sometimes o No
F12. Because of your problem, do you avoid heights?	o Yes o Sometimes o No
P13. Does turning over in bed increase your problem?	o Yes o Sometimes o No
F14. Because of your problem, is it difficult for you to do strenuous homework or yard work?	o Yes o Sometimes o No
E15. Because of your problem, are you afraid people may think you are intoxicated?	o Yes o Sometimes o No
F16. Because of your problem, is it difficult for you to go for a walk by yourself?	o Yes o Sometimes o No
P17. Does walking down a sidewalk increase your problem?	o Yes o Sometimes o No
E18.Because of your problem, is it difficult for you to concentrate	o Yes o Sometimes o No
F19. Because of your problem, is it difficult for you to walk around your house in the dark?	o Yes o Sometimes o No

E20. Because of your problem, are you afraid to stay home alone?	o Yes o Sometimes o No
E21. Because of your problem, do you feel handicapped?	o Yes o Sometimes o No
E22. Has the problem placed stress on your relationships with members of your family or friends?	o Yes o Sometimes o No
E23. Because of your problem, are you depressed?	o Yes o Sometimes o No
F24. Does your problem interfere with your job or household responsibilities?	o Yes o Sometimes o No
P25. Does bending over increase your problem?	o Yes o Sometimes o No

Used with permission from GP Jacobson.
Jacobson GP, Newman CW: The development of the Dizziness Handicap Inventory. *Arch Otolaryngol Head Neck Surg* 1990;116: 424-427

DHI Scoring Instructions

The patient is asked to answer each question as it pertains to dizziness or unsteadiness problems, specifically considering their condition during the last month. Questions are designed to incorporate functional (F), physical (P), and emotional (E) impacts on disability.

To each item, the following scores can be assigned:
No=0 Sometimes=2 Yes=4

Scores:
Scores greater than 10 points should be referred to balance specialists for further evaluation.

16-34 Points (mild handicap)
36-52 Points (moderate handicap)
54+ Points (severe handicap)

(iv) Headache Impact Test – 6 (HIT-6)

HIT-6™ Headache Impact Test

HIT is a tool used to measure the impact headaches have on your ability to function on the job, at school, at home and in social situations. Your score shows you the effect that headaches have on normal daily life and your ability to function. HIT was developed by an international team of headache experts from neurology and primary care medicine in collaboration with the psychometricians who developed the SF-36® health assessment tool. This questionnaire was designed to help you describe and communicate the way you feel and what you cannot do because of headaches.

To complete, please circle one answer for each question.

When you have headaches, how often is the pain severe?

never rarely sometimes very often always

How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

never rarely sometimes very often always

When you have a headache, how often do you wish you could lie down?

never rarely sometimes very often always

In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

never rarely sometimes very often always

In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

never rarely sometimes very often always

In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

never rarely sometimes very often always

COLUMN 1 6 points each	+	COLUMN 2 8 points each	+	COLUMN 3 10 points each	+	COLUMN 4 11 points each	+	COLUMN 5 13 points each

To score, add points for answers in each column.

If your HIT-6 is 50 or higher:

You should share your results with your doctor. Headaches that stop you from enjoying the important things in life, like family, work, school or social activities could be migraine.

TOTAL SCORE

(v) Fatigue severity scale (FSS)

FATIGUE SEVERITY SCALE (FSS)

Date _____ Name _____

Please circle the number between 1 and 7 which you feel best fits the following statements. This refers to your usual way of life within the last week. 1 indicates "strongly disagree" and 7 indicates "strongly agree."

Read and circle a number.	Strongly Disagree → Strongly Agree						
1. My motivation is lower when I am fatigued.	1	2	3	4	5	6	7
2. Exercise brings on my fatigue.	1	2	3	4	5	6	7
3. I am easily fatigued.	1	2	3	4	5	6	7
4. Fatigue interferes with my physical functioning.	1	2	3	4	5	6	7
5. Fatigue causes frequent problems for me.	1	2	3	4	5	6	7
6. My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7
7. Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3	4	5	6	7
8. Fatigue is among my most disabling symptoms.	1	2	3	4	5	6	7
9. Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7

VISUAL ANALOGUE FATIGUE SCALE (VAFS)

Please mark an "X" on the number line which describes your global fatigue with 0 being worst and 10 being normal.

0	1	2	3	4	5	6	7	8	9	10

(vi-vii) PROMIS Sleep Questionnaires

Sleep Related Impairment – Short Form 8a

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep10	I had a hard time getting things done because I was sleepy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep119	I felt alert when I woke up	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep18	I felt tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep25	I had problems during the day because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep27	I had a hard time concentrating because of poor sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep30	I felt irritable because of poor sleep.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep6	I was sleepy during the daytime.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep7	I had trouble staying awake during the day.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance –
Short Form 8b

Please respond to each item by marking one box per row.

In the past 7 days...

		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep108	My sleep was restless.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep115	I was satisfied with my sleep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep116	My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep44	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Sleep87	I had trouble staying asleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep90	I had trouble sleeping.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep110	I got enough sleep	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

(viii) International physical activity questionnaire

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   No vigorous physical activities ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   ☐ →

   _____ **hours per day**

   _____ **minutes per day**

   Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   ☐

_____ **days per week**

No moderate physical activities ***Skip to question 5***

☐ →

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

☐

_____ **days per week**

No walking ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

☐ →

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during

leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

☐

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

☐

SHORT LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

(ix) EuroQol 5 Dimension (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

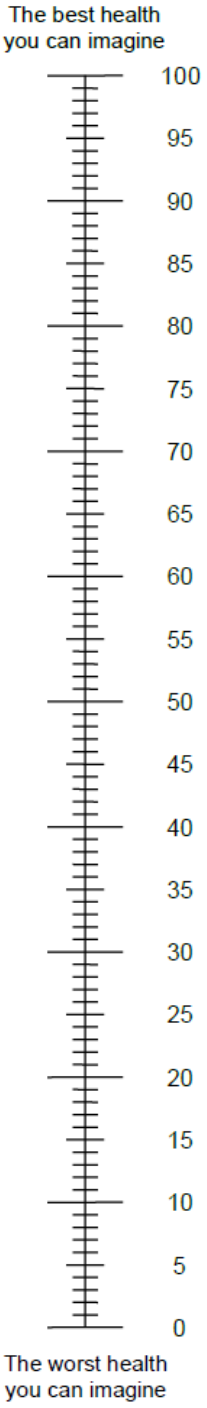
ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

2

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



(x) Sleep Log

Sample **Consensus Sleep Diary-Core** ID/Name:______________________________

Today's date	4/5/11							
1. What time did you get into bed?	10:15 p.m							
2. What time did you try to go to sleep?	11:30 p.m							
3. How long did it take you to fall asleep?	55 min.							
4. How many times did you wake up, not counting your final awakening?	3 times							
5. In total, how long did these awakenings last?	1 hour 10 min.							
6. What time was your final awakening?	6:35 a.m.							
7. What time did you get out of bed for the day?	7:20 a.m							
8. How would you rate the quality of your sleep?	☐ Very poor ☑ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good
9. Comments (if applicable)	I have a cold							

(xi) Participant Satisfaction Questionnaire

1. Please rate how satisfied you were with the physiotherapy treatment you received.

1	2	3
Not satisfied	Satisfied	Very much satisfied

2. Please rate how satisfied with the frequency of the physiotherapy treatments.

1	2	3
Not enough	Just right	Too much

3. Please rate how satisfied you were with the duration of the treatments.

1	2	3
Too short	Long enough	Too long

4. Please rate how satisfied you were with the time spent with the physiotherapist during the treatments.

1	2	3
Not enough	Just right	Too much