**Spine Clinic Evaluation Protocol**

***Just what I wanted to hear. Evaluating reassurance delivered by either Physiotherapy or doctors following consultation in an orthopaedic spinal clinic: Pilot Study Protocol***

**Administrative information**

**Title:** Just what I wanted to hear. Patients effectively reassured by either Physiotherapy or doctors following consultation in an orthopaedic spinal clinic.

**Trial registration:** Not yet registered

**Protocol version:** Spine Clinic Evaluation Protocol.V3.3

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Abstract.

Spinal pain which is pain in the low back or neck is common with 1 in 8 people experiencing persistent spinal pain. Only a small number (5%) of patients benefit from surgical intervention yet there are long public waiting lists for assessment with a spinal surgeon. To address this demand and meet the needs of patients, Physiotherapists, in addition to medical officers, have been increasingly used to provide surgical triage assessments and non-surgical recommendations within Orthopaedic Spinal Clinics. Most patients are not offered spinal surgery following assessment in Orthopaedic Spinal Clinics. Instead patients are offered reassurance regarding their spinal condition and advice to promote non-surgical strategies such as a graded activity plan. There is evidence associating level of reassurance to patient satisfaction following consultation, confidence with condition management and acceptance of a person's spinal condition. There is limited evidence that Physiotherapists and medical officers can equally reassure patents following an assessment in Orthopaedic spinal clinics. The primary aim of this pilot study is to evaluate the level of reassurance reported by patients via the Consultation Based Reassurance questionnaire (CRQ) following exposure to either the Physiotherapist or medical officer model of care in an Orthopaedic Spinal Clinic. Secondary outcomes of interest include pain, functional limitations and confidence managing pain symptoms. Outcomes are assessed at baseline, 1 day following clinic and 3 months following clinic. Descriptive statistics will be used to examine all outcomes by treatment groups. Associations between treatment group and outcomes of interest will be tested using linear mixed models, with random effects of individuals and treatment group as a fixed effect. The results will add to the literature and certainty regarding the efficacy of a Physiotherapy or medical officer led model of care to reassure patients referred to and assessed in an Orthopaedic spinal clinic. The results will inform further research into these models of care and inform stakeholders considering scaling the use of a Physiotherapy model of care within Orthopaedic Spinal Clinics.

**Introduction**

**Background and rationale**

#### Back pain is the leading cause of disability worldwide and affects 7.8% of the population at any one time (Wu 2020, NPS MedicineWise, 2022.). Spinal conditions are commonly seen by General Practitioners (GP) and emergency departments, being the fourth and fifth most common presentation reason respectively. (NPS MedicineWise, 2022; Australian Institute of Health and Welfare, 2017–18). Most back pain is considered non-specific, meaning there is no identifiable cause and surgery is usually not indicated (Hartvigsen,2018). Non-specific back pain leads to reduced functional ability (Vachalathiti, 2020), an inability to carry out usual social/family activities and responsibilities, a sense of hopelessness regarding recovery, social withdrawal, and reduced wealth. (Hartvigsen,2018)

Acute Back pain continues for 59% of sufferers at 12months (Costa 2009) and is associated with symptom related factors (Previous episodes, Pain Intensity) , lifestyle (Body mass, smoking), cognitive (depression, anxiety, self efficacy) and social factors (Education level and work). (Hartvigsen,2018).

Demand for surgical consultation of back pain is high with one study reporting 18% of patients seen by GPs for back pain are referred for surgical consultation (Piccoliori 2013). Australian data indicates wait times for consultation with a spinal surgeon can be long as 4 years (SA Health, 2022) however the proportion of these patients proceeding to surgery (the surgical conversion rate) is 5% (Wood 2016 ). Long wait times have been associated with deterioration of patient's symptoms while they also carrying the physical and societal cost of their condition (Lynch, 2008). New models of care have been developed to address extended wait times and low surgical conversion rates whereby Physiotherapist perform surgical spinal triage with only patients likely to benefit progressing to surgical consultation (LaFrance 2023). Physiotherapists can accurately and safely perform spinal triage (Robarts 2017). Although patients expect to be seen by a spinal surgeon, an expert in spinal pain (Lewis,2000) who is more qualified than physiotherapists (Braeuninger-Weimer 2019A) there is a high level of patient satisfaction (Lafrance 2021) in these Physiotherapist led triage clinics. A variation of the physiotherapy led triage clinic model was introduced at John Hunter Hospital (JHH) in 2016. In the JHH model Physiotherapists will independently assess patients, discuss findings with the consultant in charge and agree on a recommendation. The Physiotherapist will discuss the rational for the decision and promote adherence to the recommendations provided. This is known as the Physiotherapy Model of Care. The alternative is the traditional Medical Officer model of care which operates similarly. In both models the consultant in charge occasionally meets patients face to face to confirm assessment findings/review imaging.

Patient satisfaction with care in Orthopaedic spinal clinics has been related to receiving a plausible explanation regarding source of pain and the treatment options available (Braeuninger‐Weimer 2019A) including suitable and unsuitable physical activities, how to alleviate pain and prevent reoccurrence (Jain 2021, Jones 2021). Patients are concerned with the continuation/worsening of pain, loss of function, ability to work and permanent disability (Jones 2021). There is moderate to high quality evidence linking effective reassurance to patients' satisfaction, confidence with condition management, understanding of back pain and acceptance of their condition (Cheung 2021, Pincus 2013). There are limited trials set in orthopaedic spinal clinics (Braeuninger-Weimer 2021A) indicating that patients who are more reassured are more satisfied and more likely to improve in health-related measures including psychological distress (Bath 2015). Currently there is one trial (Braeuninger–Weimer 2019B) conducted in the United Kingdom suggesting reassurance provided by a physiotherapist is as effective as reassurance provided by a medical officer in spinal clinics. Certainty of these results is affected as reassurance was a secondary outcome and consultation time was not controlled. A recent systematic review (Lafrance 2021) evaluated Physiotherapy practice and outcomes in clinics similar to the Orthopaedic Spinal clinic at John Hunter Hospital. The authors found one trial conducted in Canada (Bath 2012) that investigates pain, function and general well-being outcomes following a single appointment in a Physiotherapist led spinal triage service. This pre-post Physiotherapy only trial did not assess for reassurance. The orthopaedic spinal clinic at JHH is in a unique position to compare reassurance reported by patients following exposure to either the Physiotherapy or Medical officer consultation to extend the literature in this area. We are also able to examine Pain Intensity, Physical function and mental health outcomes following a single Orthopaedic Spinal clinical consultation.

**Objectives**

This study is considered a pilot trial of usual practice evaluating clinic outcomes and informing further research in this area.

 Aim 1 (primary): The aim of this study is to describe and quantify the level of reassurance reported by patients with spinal (low back or neck) pain managed in an orthopaedic spinal clinic after an initial visit with either an orthopaedic medical officer or a physiotherapy model of care.

Aim 2: This study further aims to quantify patient-relevant outcomes including pain severity, function, pain self-efficacy, fear avoidance and global or overall health change in patients with spinal (low back or neck) pain following a clinical consultation by either a Physiotherapist or Medical officer within the setting of an orthopaedic spinal clinic.

**Study design**

This will be a prospective observational cohort study, utilising a quasi-experimental within and between group pretest–post-test observational design.

**Methods:**

**Study setting:** This study will be undertaken within the orthopaedic spinal clinic (OSC) led by consultants Dr Simon Abson and Dr Patrick Lim at the JHH, a tertiary referral hospital in New South Wales, Australia. The focus of the OSC is to evaluate and determine whether surgery may be helpful for a person’s spinal condition. The clinic also provides advice and information on non-surgical options for spinal conditions such as injection therapies and physical rehabilitation. Referrals are for acute or chronic conditions affecting paediatric, adolescent and adult populations and include scoliosis, fracture, neoplasms or spinal (Back/Neck) pain with or without peripheral limb referral or radiculopathy. Medical officers will manage all conditions referred to this clinic whereas Physiotherapists are restricted to seeing only adult back and/or neck pain (Including Radicular/Radiculopathy). Both Medical officers and Physiotherapists perform an assessment before discussing each case with the consultant in charge to establish clinic recommendations for ongoing care. The medical officer or Physiotherapist is then responsible for discussing the clinic outcome and recommendations to each patient and communicating the outcome to the patient's referrer.

All referrals to the OSC are triaged by JHH outpatient clinic staff through the Referral Information Management System (RIMS). At triage the clinician makes standardised comments to broadly categorise the presenting condition (eg. Back pain, Neck and arm pain, Scoliosis, Back Fracture etc.) and allocate the patient to a triage category with recommended wait times (Category A <30 days. Category B <90days or Category C <360days). Once triaged these referrals (with comments and triage category) are moved by JHH outpatients administrative staff to the Orthopaedic Spinal waitlist. All patients with triage comments of Back Pain, Back and Leg Pain, Neck Pain, Neck and Arm Pain triaged as Category B (up to 90 day wait) or Category C (up to 365 day wait) are eligible to be seen by either a Physiotherapist or Medical officer and are eligible for inclusion in this study. These patients are booked by JHH outpatient administrative staff, in waitlist order, into either the Medical officer or Physiotherapist clinic list.

Following assessment by the Physiotherapist or medical officer, each case is discussed with the clinic consultant who is ultimately responsible for determining the outcome or recommendations from the clinic. The outcomes/recommendations include the following . 1: Further investigations and clinic review 2: An offer of surgery 3: Reassurance, education and Non surgical options based on assessment findings, patient preference and current best practice guidelines. 4: Other – Such as referral to another specialty.

This evaluation will focus on any patient that is able to undertake recommendation 3, non-surgical care for at least 3 months following the clinic appointment. This may be in conjunction with any other outcome/recommendation.

Once the outcome has been determined to be non-surgical the primary clinician (Physiotherapist or Medical Officer) is responsible for delivering this recommendation of care and the rational for it.

**Eligibility criteria:**

Inclusion criteria (participants)

* Participants over 18 years of age presenting for care in orthopaedic spinal Clinics at JHH during the research period.
* Triaged as non-specific low back pain with or without leg pain (Cat B, 90day or Cat C, 365 days) or neck pain with or without arm pain (Cat B or C)and and appointment scheduled in either the physiotherapy-led or medical officer-led clinic.
* Able to provide consent
* Able to undertake non-surgical care for at least 3 months following the clinic appointment. Note: This criteria is considered after consent and Initial Survey are complete. We do not expect to withdraw many participants at this time as most patients are expected to be able to undertake non-surgical care for 3 months following the clinic appointment. Consent and initial survey must be administered prior to the clinic assessment to establish baseline measures.

Exclusion criteria (participants)

* Cognitive impairment limiting ability to understand or follow recommendations.
* Unable to read or speak English and does not have interpreter service support. It is expected there will be a very low number of patients who are non English speaking.
* Unable to undertake recommended conservative care. Reasons may include terminal disease, spinal tumor, fracture identified, active spinal infection
* Assessed as needing urgent (Less than 3 months) surgery.

Inclusion criteria (clinicians)

* Physiotherapist or medical officer working in JHH orthopaedic spinal clinic

Exclusion criteria (clinicians)

* N/A

**Recruitment and consent**

Prospective participants are identified on the Orthopaedic spinal Waitlist on the Health Service iPM system. Standard practice for these patients involves posting notification of an appointment time by JHH outpatient administration for the Orthopaedic spinal service and a patient questionnaire to be completed prior to the appointment. This contains 3 separate Questionnaires: Start Back Screening tool, Roland Morris Disability Questionnaire and Kessler Psychological Distress Scale (K6). It also contains questions regarding symptoms (Pain and location), previous and ongoing treatments. The current questionnaire is to be superseded by the questionnaire used in this study. As per the current questionnaire the study questionnaire will provide screening information such as pain and psychological risk factors for ongoing pain and disability. The study questionnaire will provide additional information for clinicians (duration of symptoms, educational level attained and current employment). The study questionnaire is of similar length (Time taken to complete) and has been reviewed by a previous patient of the clinic for validity and time burden. For this study Patients meeting the eligibility criteria are also posted the written Project information Sheet.. This information includes: A description of the Orthopaedic Spinal Clinic, What will happen/ Participants role in the project, project aims, data security, seeking additional care and freedom to consent or assent without penalty.

Participants will complete the clinic questionnaire as usual and attend their appointment as usual. At the conclusion of the appointment clinic staff will discuss the study and answer any questions patients have. Clinic staff will confirm eligibility and describe study and consent procedures. This will include: Expectations of the participant if they consent, voluntary participation and freedom to withdraw at any time without penalty. In no way will their decision (Consent/Assent) affect care during this clinic or any other. Patients are then provided with the consent form and on leaving the clinic may consent by placing a signed consent form in a red box marked ‘Spine Clinic’ located on the outpatient Administration desk. Placement of a confidential box on the administration desk has been trialled with success in this clinic setting to capture patient feedback questionnaires. The box is set down at the commencement of each clinic and removed by the research team at the conclusion. The box is monitored at all times by administrative staff and is located separately from the Spinal Clinic.

**Intervention/exposure**

The exposure of interest is treatment group according to the treating clinician (physiotherapist or orthopaedic medical officer) and associated model of care. As this is an observational study, there will be no random assignment to group. Participants will be aware of which group/clinician profession they are consulting with. Both groups (Group 1- physiotherapy, and Group 2- orthopaedic medical officer) undertake their normal assessments and provide education and recommendations for ongoing care. The education that is delivered by each group is tailored to each patient and will not be limited or adjusted during the study period. Education provided to patients in the clinic by both clinician types has been suggested to consist of:

* Spine pathology and possible sources of their symptoms
* Pain neurophysiology
* Mechanisms which affect pain that are separate from the specific pathological cause
* Suitability (risks/benefits/safety) for the patient to engage in physical activity including general activity and specific spinal exercises
* Indications to represent for medical care
* A letter dictated to the patient’s GP summarising the consultation findings and content of discussions with the patient
* Patient’s may be encouraged to seek follow-up care through suitably qualified community-based health professionals (eg., physiotherapist)

(Braeuninger-Weimer, 2021B)

Details of the Physiotherapy vs Medical officer model of care is measured using the therapist survey.

**Relevant concomitant care and interventions that are permitted or prohibited during the research project.**

Clinicians in group 1 and 2 will suggest follow-up care options for participants. Participants may elect to undertake additional health related care without restriction over the trial period.

**Data collection**

Data collection methods,

At time of consent participants are offered Data collection in their preferred format - written, electronic or verbal/phone call.

Participants are provided with their favoured data collection method at each timepoint of interest. That is day of clinic appointment (Baseline), 1 Day following baseline and 3 months(90days) following baseline.

Written instruments are provided in person or by post. All written surveys are entered into Redcap by a research assistant and marked ‘unverified.’ All unverified data entry points are checked by a second member of the research team to confirm accuracy. Once checked the data item is marked ‘complete.’ Written measures are stored in a locked cabinet in the Chief Investigators workplace.

Electronic instruments are provided by way of a link to the online survey generated in Redcap and sent via e-mail. The e-mail is headed with only the participants first name. For the 3 month follow up redcap will automatically send the e-mail 90days after baseline. If Participants do not return electronic surveys within 7 days a follow up e-mail is automatically sent from Redcap. If no response is received a maximum of 3 follow up phone calls are made to determine if the participant would like to continue in the research and if so confirm data collection methods and contact details.

Phone call/Verbal. Research assistant calls participants 1 day and 90 days (3 months) following the Orthopaedic Spinal Clinic appointment. The research assistant will confirm with the participant they are ready to provide responses to the survey now or if a later time is preferred and arranged. Responses are entered directly into Redcap. A maximum of 3 phone calls will be attempted to contact participants.

 The iPatient Manager system (iPM) is accessed to extract relevant data (Age; Gender; Referring practitioner; Postcode; Triage Category (A, B or C) Waitlist time (Days); Aboriginal and/or Torres Strait Islander). This is entered into Redcap under the participants account identified by name and MRN.

**Outcome measures.**

An overview of the primary and secondary outcomes of the study is provided in Table 1.

Table 1: Overview of study outcomes

|  |  |
| --- | --- |
| **Outcome** | **Instrument**  |
| **Primary outcome** |
| Reassurance  | Consultation-based re- assurance questionnaire (CRQ) (Holt & Pincus, 2016) |
| **Secondary outcomes** |
| Pain, Physical Function, Social Participation, Mental Health (anxiety and Depression) | Patient-Reported Outcomes Measurement Information System (PROMIS)-29 (Khutok 2021) |
| Confidence of a person with persistent pain to do a range of activities while in pain | Pain self-efficacy questionnaire (Dubé 2021) |
| Pain-related fear avoidance. | Tampa Scale of Kinesiophobia – 11 (TSK-11) |
| Global Health Change | Global Rating of Change Scale (GROC) |

Primary Outcome.

Reassurance is measured via the Consultation-based re- assurance questionnaire (CRQ) (Holt & Pincus, 2016) assessed 1 day following orthopaedic spinal clinic appointment. The CRQ contains four subscales each with 3 items and scores ranging from 1 to 7 for each item. For this evaluation the total score will be used for the analysis. The CRQ was developed to capture clinician behaviours that will reduce concerns of patient's (Pincus 2013). Validity and reliability has been tested on spinal pain patients in primary care (Holt and Pincus 2016). Each subscale (Data Gathering, Relationship building, generic reassurance and cognitive reassurance) moderately to highly correlate with patient enablement, satisfaction with consultation and treatment outcomes (Cheung 2021). The CRQ has been administered in similar orthopaedic spinal clinics. (Braeuninger–Weimer 2021A). Correspondence with the CRQ’s developing author (Pincus July, 2023) included advice to delay the administering of the questionnaire for 24 hours following the clinic consultation to reduce the ceiling effect.

Secondary Outcomes.

Pain Intensity, Physical function, Social functioning, Anxiety and Depression are assessed using the Patient-Reported Outcomes Measurement Information System-29. (PROMIS-29). PROMIS-29 is administered prior to the participant receiving clinical care and 3 months following the clinical care episode. The PROMIS-29 is a validated, reliable and responsive measure (Deyo 2015) that assess multiple health domains important to patients and are related to recovery (Khutok 2021). Domains include pain intensity (0–10 numeric rating scale) and seven health domains (physical function, fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles and activities, and sleep disturbance) with four items per domain and five possible responses for each item. PROMIS-29 scores can be converted to functional outcomes measures of the cervical spine (Neck Disability Index) (Pennings 2020) and Lumbar Spine (Oswestry Disability Index) (Pennings 2019). Minimal Clinically Important Differences (MCID’s) have been established in the chronic low back pain population for each of the PROMIS-29 domains (Khutok2021)

Pain self-efficacy is assessed by the 10 item Pain self Efficacy Questionnaire (PSEQ). There are 7 possible responses for each item (0 to 6) giving a total score out of 60. The PSEQ is completed by participants prior to their clinic appointment and 3 months following. The PSEQ assess the confidence of people with persistent pain to be active at work, with social activities, household activities and to be able to manage pain without medication. Scores are correlated with quality-of-life measures, Disability, Pain anxiety, depression and catastrophizing. Excellent validity, reliability and responsiveness in similar populations with a MCID of 5.5 to 8.5 (Dubé 2021).

Pain related fear avoidance is assessed via theTampa Scale of Kinesiophobia – 11 (TSK-11) This 11 item questionnaire has 4 possible responses per question (Strongly agree to Strongly disagree) with scores ranging from 11 to 44. The TSK-11 is administered before and 3 months following consultation in the Orthopaedic spinal clinic. This 11 item version is valid, reliable and responsive to change in people with spinal pain (Woby 2005). In people with chronic pain kinesiophobia is strongly associated with disability and pain intensity (Luque-Suarez 2018) and may be a target of treatment. Alhowime 2018. A reduction of 4 points can be considered an important reduction in fear of movement for patients presenting with back pain (Woby 2005)

Global health change is assessed using the Global rating of change (GROC) scale. This is assessed using a single question on an 11 point scale with responses ranging from very much worse (-5), no change (0) to completely recovered (+5). The scale is quick to administer, assesses what the patient considers to be important and has strong correlations with established spinal disability measures and pain scales(Kamper 2009). The 11 point GROC scale has an established minimum detectable change (MDC) 0.45 points and minimally clinically important change (MCIC) of 2 points (Kamper 2009). This instrument has been used in similar populations to dichotomise patient outcomes between not improved/worse(-5 to +1) and improved(+2 to +5) (Raymer 2021).

**Covariates**

Demographic/ data - Reported through Hunter New England Health data sets (iPM): Age; Gender; Referring practitioner; Postcode; Triage Category (A, B or C) Waitlist time (Days); Aboriginal and/or Torres Strait Islander. The number of Aboriginal and/or Torres Strait Islander peoples will only be used to describe the population characteristics included in the study.

Patient Initial Survey: Education level attained, Current Employment status, Health care services use, Duration of symptoms, Pain intensity.

Therapist Survey: Profession, Length of consultation, Pain location (Back/Neck vs Leg/Arm), Clinician discussed outcome/recommendations such as Source of symptoms and suitability to engage in physical activity, Consultant recommendations/outcomes. Clinicians will complete this form with all eligible patients as they any not made aware if the patient in front of them has consented to participate in the study. Results will be presented to describe variation in the Physiotherapist and Medical officer model of care.

Post Spinal Clinic Participant Survey (1 day following Clinic Intervention). Did you receive an explanation for your symptoms. Yes/No. Did you receive information on what you can do to help your symptoms. Yes/No. We will present responses to this survey.

Week 12 Spinal Pain Survey

Did you receive an explanation for your symptoms. Yes/No

Did you receive information on what you can do to help your symptoms. Yes/No

What advice from the clinic have you followed?

Results will be presented next to Post Spinal Clinic Survey measured 1 day following clinic.

**Routine service feedback.**

Post Spinal Clinic Participant Survey (1 day following Clinic Intervention)

Participants will be asked 1. What aspects of the Spinal Clinic did you find helpful? And 2. What could have been improved? Comments will be grouped in themes and presented as consumer feedback regarding the clinic.

A description of timing of assessments is summarised in Table 2.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TIMEPOINT** | **Clinic Appointment made** | ***T1. Arrival to clinic.******(Baseline)*** | ***During Clinic Appointment*** | ***T2. 1 Day Post Clinic Appointment*** | ***T3. 3 Mths (90 days) Post clinic*** |
| Eligibility screen | **X** |  |  |  |  |
|  *Trial Information posted* | **X** |  |  |  |  |
|  Allocation | **X** |  |  |  |  |
| Signed Informed consent |  | **X** |  |  |  |
| **INTERVENTIONS:** |  |  |  |  |  |
|  Therapist Survey |  |  | **X** |  |  |
| **ASSESSMENTS:** |  |  |  |  |  |
| *Patient Initial Survey* |  | **X** |  |  |  |
| *PROMIS 29* |  | **X** |  |  | **X** |
| *TSK-11* |  | **X** |  |  | **X** |
| *PSEQ-10* |  | **X** |  |  | **X** |
| Post Spinal Clinic Participant Survey  |  |  |  | **X** |  |
| *CRQ*  |  |  |  | **X** | **X** |
| Health Care usage |  | **X** |  |  | **X** |
| GROC |  |  |  | **X** | **X** |

PROMIS 29 - Patient-Reported Outcomes Measurement Information System; TSK-11 : Tampa Scale of Kinesiophobia; PSEQ-10 : Pain self Efficacy Questionnaire; CRQ : Consultation based Reassurance Questionnaire; GROC: Global rating of change.

**Consumer input into project design and measures:**

A consumer with spinal pain who has previously attended the Orthopaedic spinal clinic was consulted regarding the project aims/design and the primary and secondary outcome measures. The consumer felt the included measures asked questions they and likely others with spinal pain could relate to regarding their spinal condition. An additional measure (Back pain attitudes questionnaire (Krageloh 2020) was rejected by the consumer due to ambiguous questions – The consumer was not sure how to answer the questions correctly. The consumer felt time taken to answer all the questions was reasonable at 10 to 15minutes.

**Sample size.**

An equal proportion of patients consulting either a physiotherapist or a medical officer will be recruited. Once recruitment has commenced it is anticipated an average of 3 participants per group per fortnight will consent to participate. Data collection is planned to occur over 9 months, and therefore approximately 54 patients per group are anticipated. We will assess the size and precision of the difference in the estimates between groups.

**Blinding (masking)**

All outcome assessments are conducted by a blinded research assistant.

Treating clinicians in the Orthopaedic spinal clinic are unaware if the patient they are seeing will consent to participate.

Patients are not blinded to treating clinician group.

**Statistical analysis**

Descriptive statistics will be examined for all outcomes by treatment groups (means with SD, medians with interquartile range, or proportions).

Prior to conducting additional analyses, observations will be dropped if greater than 50% (6) items of the CRQ (primary outcome) are not completed. We will use multiple imputation to impute other missing items. Histograms will be used to assess the distribution of scores on the CRQ. Associations between treatment group and CRQ score at the time of consultation and 3-month follow-up will be tested using linear mixed models, with random effects of individuals and treatment group as a fixed effect. Associations between treatment group and secondary outcomes (PSEQ; PROMIS-29) at 3-month follow-up will be tested using linear mixed models, with random effects of individuals and treatment group as a fixed effect. Statistical significance will be assessed at an alpha level of 0.05. P-values, along with 95% confidence intervals will be presented alongside the treatment effect estimates, and the width of the confidence intervals will be used to interpret findings.

**Additional analyses.**

Covariates including demographic data, educational level attained, Triage category, Duration of Symptoms, pain intensity and employment status will be presented in a table showing all participant data, data for each group and comparison between groups using T-Tests.

We will use T-Tests to compare health care usage (Number of visits and costs) in relation the patient's spinal complaint in the 3 months before clinic appointment and compare to the 3 months following clinic appointment.

**Data monitoring**

During the study period there are no plans to perform an interim analysis of the results. The results of this pilot trial inform further investigations. The CPI will calculate number of participants in each group (Physiotherapist verse Medical Officer) every 2 Months following commencement of recruitment. If a difference of 20% or more is found the CPI will seek to increase the number of appointments offered in the lower group. For instance, If the Physiotherapist group has lower numbers of participants, the Physiotherapy Manager and Clinicians will be consulted and opportunities to increase clinic capacity considered. If this is not possible the study will continue as per the protocol.

 **Harms.**

Being a trial of usual care no serious harms are anticipated. Any Identified or potential harms are to be brought to Principal Investigators attention for assessment and action. Complaints may be made directly via the research team, through HNEHealth complaints process or through HNE Research office. The HNE complaints brochure is displayed in the outpatient department. Contact details for the HNE research office are noted on the project information sheet.

**Auditing.**

The research assistant will be educated on trial processes and audited by the Principle Investigator initially and every 3 months following trial commencement. Research assistant will monitor survey data for completeness. For example, Completion of Spinal Clinic Therapist Survey, and flag concerns to the Principle Investigator.

**Ethics and dissemination**

**Research ethics approval**

This protocol along with the patient information and consent forms and data collection forms are to be reviewed by the HNE Human Research Ethics Committee.

**Protocol amendments**

Any protocol amendments affecting the study such as design, conduct, patient safety, administrative procedures will require a formal review by the HNE Human Research Ethics Committee.

**Confidentiality**

All participant information will be stored in a locked cabinet in the PI’s workplace on site at JHH. All research staff have training in and abide by confidentiality requirements of NSW health.

**Declaration of interests**

 The principal investigator has no financial or other interests declared for this trial.

**Ancillary and post-trial care**

 Patient complaints are brought to the attention of the Principal Investigator(PI). The PI will manage the complaint as per HNELHD complaints management processes. This may include the facilitation of written complaints, or a resolution pathway based on negotiation. Issues with the research process are directed to the HNELHD research office. Complaints are brought to the attention of relevant department managers (Outpatient, Physiotherapy, Surgical services, Clinic Consultants) to consider further response and action.

**Dissemination policy**

Results will be presented to the investigating team and interested Hunter New England staff through clinical meetings and Symposia.

The aim is to have results published both in print and electronically, shared through electronic platforms.

The investigating team will discuss findings at invited conferences.

Patients may elect on the consent form to have summary results of the project sent to them.

**Data Management:**

Data will remain the property of Hunter New England Health.

The co-ordinating principle investigator (CPI) will act as the custodian of data generated through this study.

Data Storage

Physical data includes Patient consent and Forms completed by participants and therapists. Physical data will be stored in a locked cabinet for a period of 5 years following reporting of study results. After this time data will be destroyed through JHH confidential shredding.

Electronic data is generated through IPM reports, RIMS reports and Redcap. All data is transcribed across to or directly entered into Redcap. Some data may need to be stored by the HNE internal server before being uploaded to Redcap. (eg iPM reports). Redcap data will be maintained for 5 years following the reporting of study results.

**Access to data**

The full dataset is only accessible by the Principal Investigator and study supervisors listed in this protocol.

The research assistant will have access to redcap to input data. They will not have export rights. They will have access to the storage cabinet during the study period to secure written information.

The statistical team will have access to de-identified data for analysis purposes.

Members of the broader research team will have access to de-identified data. This will occur prior to analysis. The research team will consider results of the data analysis in the context of the Spinal CLinic and what impact it may have.

Participants can opt in to have access to a summary of study results and to comment on these results.

**Sharing and Re-use of Data**

Data and research methodology will be shared by the CPI to those with an interest in this reseach. For example to confirm analysis, as part of a Systematic review. Data offered will be de-identified.

**References**

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