DEM RESEARCH PROTOCOL

1. TITLE

Comparison of two exercise approaches for the management of low Back pain in the emergency department setting.

SHORT TITLE

Comparison of two exercise based physiotherapy approaches in treatment of low back pain.

2. STUDY INVESTIGATORS

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3. SETTING

Emergency department, Royal Brisbane and Women's Hospital (RBWH)

4. BACKGROUND INFORMATION

Acute low back pain (LBP) is a common presentation to the emergency department (ED). It is also a major health condition associated with high rates of absenteeism from work and more frequent use of health services [1]. As per the international back pain guidelines, primary contact practitioner aim is to classify back pain and rule out serious pathology [8]. The mechanical low back pain group (back pain from a musculoskeletal cause) makes up 90% of presentations to ED.[9] Currently in ED standard treatment comprises of [14-16]

1. **Standard Care in ED (RMO/ED registrar, or Physiotherapist):** Assessment of symptoms, physical and radiological investigations as appropriate for the individual and the provision of a diagnosis. Management will include patient education and assurance [11], symptom relief by analgesia (NSAIDS, paracetamol & opioids if necessary), as well as recommendation to stay as active as possible including return to work [12]. Depending on their response to the analgesia patients are discharged with Physiotherapy follow-up [8].

2. **Additional treatment when seen by the Physiotherapist in ED:**
The commencement of spinal stabilisation[10] and mobility exercises while in the ED because poor spinal stability and altered movement patterns have been shown to be a potential cause and/or effect of low back pain[28]. Alternatively a McKenzie exercise protocol may be provided but only if the Physiotherapist has appropriate training in this method.

Despite these forms of care twenty five percent (RBWH EDIS statistics) of low back pain patients are admitted to the short stay unit for overnight analgesia due to difficulties coping with the pain. They are then discharged after 1-2 days. Apart from adding to the cost [3], this also blocks a bed for other emergency patients. Patients who are admitted utilise health resources while those who are discharged are not followed up by physiotherapists for 1-3 weeks (due to the public hospital waiting list). This causes a delay in initiating formal assessment and treatment, sometimes leading to representation to ED. Effective treatment of acute LBP is important because it prevents patients from developing chronic LBP which needs more costly and complex investigations and treatment. The key point is that currently for patients presenting to ED with back pain treatment lacks an individualised approach with respect to alleviating mechanical low back pain. We propose this may be improved with the use of a McKenzie approach to management of back pain in the ED setting.

The McKenzie method of mechanical diagnosis & therapy is an active exercise approach involving repeated movements, sustained positions and therapeutic forces, it has an educational component with the purpose of minimising pain, disability, and improving spinal mobility [4.] This method involves the assessment of symptomatic and mechanical responses to repeated movements and sustained positions. The responses are used to classify them into subgroups or syndromes (Posture, Dysfunction and Derangement) which help in guiding the treatment principles [4-6]. Of the large number of classification schemes developed in the last 20 years, the McKenzie Method has the greatest empirical support (i.e. validity and reliability) among the systems based on clinical features[2]. This approach utilises exercises specifically to promote rapid symptom relief based on the patient's individual clinical presentation[17]. Therefore we propose this approach is of potentially great value in an ED where patients present primarily due to an episode of significant back pain.

The McKenzie approach unlike other therapeutic methods aims to make the patient as independent of the therapist as possible[7], thus preventing representations to ED. The McKenzie method of treatment has shown better results than other physical therapy procedures in some acute, sub-acute and chronic low back pain presentations[5,6]. In particular a high-quality randomised trial in which treatment was based on this approach showed larger reductions in pain[27] and disability[26] and promoted faster return to work in patients with acute LBP than other conservative therapy recommended by the clinical guidelines[13]. We propose that the 'McKenzie exercise' approach may be a more effective 'additional physiotherapy' intervention for patients seen by physiotherapists in the ED setting then the more standardly used muscular 'stability/mobility exercise' training.

Therefore the purpose of this study is to compare if more benefits are gained with a 'McKenzie exercise' approach compared to a 'stability/mobility' exercise approach for patients who are treated by a Physiotherapist for low back pain in ED. We anticipate the findings of the study will be informative to the best approach to

management of these patients in ED, and may be informative to guide appropriate professional development for physiotherapists who work in ED.

5. STUDY AIM AND HYPOTHESIS

AIM: To compare the additive clinical benefits (pain, disability, re-admission) of a McKenzie exercise approach (Mechanical Diagnosis and Therapy) versus a stability/mobility exercise approach, to that of usual care for patients who are managed by physiotherapists for their low back pain to ED, both in the immediate (immediately following intervention within ED), and short-term (2 weeks following ED consultation) time points.

Hypothesis: A McKenzie exercise approach (Mechanical Diagnosis and Therapy) will have greater additional benefits (pain, disability, re-admission) for patients who present with low back pain to ED than will a stability/mobility exercise approach, both in the immediate (immediately following intervention within ED), and short-term (2 weeks following ED consultation) time period.

Null Hypothesis: The McKenzie exercise approach will have no beneficial effects compared to the stability/mobility exercise approach for patients who present with low back pain to ED either in the immediate (immediately following intervention within ED), and short-term (2 weeks following ED consultation) time period.

6. STUDY DESIGN

This is a randomised clinical trial comparing the additive clinical benefits (pain, disability, re-admission) of a McKenzie exercise approach (Mechanical Diagnosis and Therapy) versus a stability/mobility exercise approach, to that of usual care, for patients who are managed by physiotherapists for their low back pain in ED. Outcomes will be evaluated both in the immediate (immediately following intervention within ED), and short-term (2 weeks following ED consultation) time points. Outcomes will conducted by an assessor blinded to the group allocation of the participant and as both forms are exercise based intervention participants will be blinded to their intervention group.

7. PARTICIPANTS

Fifty participants (25 in each exercise group) will participate in the study.

7.1 INCLUSION CRITERIA

Low back pain (LBP) – atraumatic onset.
Age – 20-50 years
Gender – Male and/or Female

7.2 EXCLUSION CRITERIA

History of substance abuse eg: IV drug user (IVDU), ETOH
Spinal fractures.
Pregnant women
Neurological compromise (as shown by loss of strength, sensations and reflexes).
Red flags eg: loss of weight, fever, history of cancer.
Multiple medical co-morbidities (chronic obstructive pulmonary disease, ischemic heart disease, chronic kidney disease, uncontrolled diabetes and hypertension).
Patients brought in by police who are under influence of illicit drugs and alcohol.
Patients bought in by police who will remain in custody.
Patients with known cognitive and intellectual disability (decided on the basis of information collected by the triage nurse).
Patients having an acute concurrent systemic illness.
Patients with congenital spinal structural deformity.
Patients unable to provide consent and comply with the home exercise program.

Sample size was calculated on the primary outcome measure Numeric pain score . To calculate a sample size between two independent means for a two tailed test at a significance of less than 0.05, a power of ≥ 0.8 for the outcome measure (pain score) a conservative minimum clinically important difference of 2 (±2.5) was used[19,20, 21]. This predicted that 25 patients in each group would be required.

8. OUTCOME MEASURES

Primary Measure

Low back Pain – This will be measured with a Numeric pain score form (0-10)[19,20,21].

Secondary Measures

Pain Related Disability - Roland Morris low back pain disability score (RDQ) [18,22].
The RDQ and ODI scores are highly correlated, with similar test–retest reliability and internal consistency[23]. Good internal consistency is reported for the RDQ, with Cronbach's alpha ranging from 0.84–0.96[22].

The primary and secondary measure will be handed and collected on the initial presentation by a non-participating clinician (nurse on duty), it will be handed over in a sealed coded envelope to the principal investigator. The associated investigators

(Venkat Acholi and Janelle Hiene) performing the initial intervention will be blinded towards these scores.

Re-presentation to the emergency department (ED)
Re-presentation to ED and any medical/allied health input sought by the patient during the next two weeks (asked over the telephone by the follow-up Physiotherapist) will also be recorded and analysed.

The clinician (Physiotherapist – Scott Russell) making the two week telephonic follow-up will be blinded towards the group status and the initial presentation details of the patient.
All scoring sheets will be handed to the principal researcher in a sealed coded envelope to be opened for data analysis.

Adherence to the prescribed exercise program will be recorded on a two week checklist (copy attached), exercise diagrams will be provided to both groups (copy attached). Patients will be advised on the number of repetitions and daily frequency which will be recorded by the patient on the two week checklist provided. The checklist will be returned to the principal investigator by a reply paid envelope (funded by the principal researcher)

9. INTERVENTIONS

All patients will receive the standard usual care provided in ED as detailed in section 4 that also includes a letter to their regular general practitioner (GP) outlining the assessment, management, and follow-up physiotherapy plan.

In addition to this standard care patients will also receive one of two additional physiotherapy exercise approaches provided to them during the ED consultation.

9.1 McKenzie Exercise Approach Group

Patients in this group will be assessed and treated using mechanical diagnosis and treatment (McKenzie) concepts. This method involves the assessment of symptomatic and mechanical responses to repeated movements and sustained positions. These responses are used to classify them into subgroups or syndromes (Postural, Dysfunction and Derangement), which help in guiding the treatment principles[4-6].

9.2 Standard Exercise Approach Group

Patients in this group will receive standard ED physiotherapy assessment and treatment which includes the commencement of spinal stabilisation exercises[10] and mobility exercises.

10. STUDY PROCEDURE

Participant recruitment and consent process: The patients presenting to the emergency department are triaged by nursing staff, assessed by medical staff/Physiotherapist and accordingly given analgesia. After 30 minutes of receiving analgesia, the patient will be approached by the Physiotherapist and given information regarding the study and if the patient is agreeable, written consent will be obtained.

Baseline outcome measures: The initial pain score (0-10), Roland Morris score will be recorded by the patient themselves without any guidance from the investigator. They will be handed over by a non-participating clinician (nurse on duty).

Group allocation process: Patients will then be randomised to one of the two groups via sealed envelopes (concealed allocation picked by non-participating medical/nursing staff).

Intervention: The participant will then be assessed for lumbar range of motion, neurological status, lumbar stability and mobility. Depending on the group the patient belongs, exercise will be performed under supervision. The participant will be provided with exercise sheets and checklist for home. Participants will be offered follow-up Physiotherapy two weeks after discharge in a public or private setup depending on his/her preference and availability of private cover.

Follow-up outcome measures: The two week telephonic follow-up to record the pain score, Roland Morris disability score will be obtained by a non-participating Physiotherapist. The exercise check-list provided to the patient on discharge, will be returned to the principal investigator by a reply paid envelope funded by the principal investigator. Patients are unaware of the follow-up process and thus will not feel as if they are being offered special treatment to participate in the study.

Resource impact on service: There will be negligible impact of services in ED as both treatment types are presently being used by Physiotherapists in treatment of LBP patients in ED at RBWH. Some of the outcome measures are not routinely done in ED will only take an additional 20-30minutes to complete without any clinician time being utilised. The referral process will not add to the workload to peripheral hospitals as the patient would normally be referred anyway.

11 DATA ANALYSIS

All analysis will be on the basis of an intention to treat analysis. The two groups will have their demographics compared at baseline by a combination of parametric (t-tests) and non-parametric (chi-square tests). The data for pain and disability score will

be tested and if found to have a normal distribution will consist of a between/within repeated measures ANOVA to test if there is a difference between groups over time. If a non-normal distribution is found a Kruskal Wallis test will be used. The need for admission to a Short stay unit will be compared between groups by a chi-square crosstabs.

12 WITHDRAWAL FROM STUDY PARTICIPATION

In accordance with the Declaration of Helsinki, each subject has the right to withdraw from the study at any time. An investigator also has the right to withdraw subjects from the study in case of any adverse effect, lack of compliance or reasons concerning the subject's wellbeing.

In case of withdrawal, the subject will continue to receive standard care in ED and follow-up as appropriate. Clinical notes will be documented for the same

13 PROJECT TIMELINE

ITEM	EXPECTED DATE OF COMMENCEMENT	EXPECTED DATE OF CONCLUSION
Ethics application	January 2016	May 2016
Recruitment and data collection	15th June 2016	30th September 2016
Data analysis	1st October 2016	30th November 2016
Writing and publication	1st December 2016	31st January 2017

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