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# Early physiotherapy for chronic low back pain patients

**Submission date**
02/08/2020

**Recruitment status**
No longer recruiting

**Registration date**
04/08/2020

**Overall study status**
Completed

**Last Edited**
06/09/2023

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Low Back Pain (LBP) is a very common symptom experienced by a high number of the population. Mostly, LBP symptoms resolve with time or conservative treatment. It has been proposed that imaging, MRI mainly, can negatively impact patient's recovery in terms of high consumption of pain killers, frequent visits to the doctors and elevating the anxiety and fear of the patients. This study is set to examine whether providing physiotherapy in secondary care level hospitals instead of MRI imaging is feasible and acceptable.

Who can participate?
Patients with non-specific LBP, no underlying serious pathology, who are referred to spine clinics in a secondary care center in Riyadh, Saudi Arabia aged from 18-65. There should be no recorded of MRI or physiotherapy in the past 6 months.

What does the study involve?
The patients will be randomized into two groups. the first group will be referred to have physiotherapy immediately. the second group (routine practice) will have MRI for their spine then discuss the result with the doctor before being referred to physiotherapy.

What are the possible benefits and risks of participating?
There are no expected benefits or associated risks from participating in this study.

Where is the study run from?
King Fahad Medical City (Saudi Arabia)

When is the study starting and how long is it expected to run for?
October 2015 to July 2018

Who is funding the study?
Saudi Spine Society (Saudi Arabia)

Who is the main contact?
Dr Ahmed Alhowimel, a.alhowimel@psau.edu.sa

# Contact information

### Type(s)
Scientific


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# Additional identifiers

# Study information

### Scientific Title
Feasibility study and process evaluation of MRI plus physiotherapy vs. physiotherapy alone in non-specific chronic low back pain among patients in Saudi Arabia

### Study objectives
It is not known whether altering the practice of routine MRI use in Saudi Arabia would be acceptable to healthcare practitioners and patients and lead to improved psychosocial and disability outcomes. Therefore, this study will seek to examine the feasibility and acceptability of conducting an RCT to answer the following question: Does MRI diagnosis negatively influence psychosocial and disability outcomes in patients with CLBP who are undergoing physiotherapy?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Approved 21/12/2016, Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Medical School, Queen's Medical Centre Campus, Nottingham, NG7 2UH; louise.sabir@nottingham.ac.uk; +44(0)115 8232561), ref: OVS 18082016
2. Approved 21/11/2016, King Fahad Medical City (Riyadh, Saudi Arabia; +966 12889999; okasule@kfmc.med.sa), ref: H-01-R-R-012

### Primary study design
Interventional

### Study design

Single-center two-arm non-inferiority feasibility randomized controlled trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Chronic low back pain

### Interventions
MRI+ Physiotherapy
Participants allocated to the MRI group were sent for an MRI scan of the lumbar spine, and a follow-up visit was planned to discuss the results. The time interval to undergo MRI ranged from 3 to 6 weeks. After discussing the results with their doctor, the patients were referred to physiotherapy. Next, another copy of the questionnaire booklet was completed by the participants after finishing the physiotherapy treatment, which lasted for a period of 2 weeks to 4 weeks.

Early Physiotherapy
Following allocation participants in the control arm (namely, the non-MRI group) were immediately asked to complete the booklet of questions and standard questionnaires. Participants were then referred to a physiotherapist for treatment, and the time required to initiate physiotherapy ranged from 1 week to 2 weeks. After completing the physiotherapy treatment programme, which lasted for 2 weeks to 4 weeks, the second assessment was taken

### Intervention Type
Behavioural

### Primary outcome(s)
The feasibility and acceptability of a large scale RCT:
1. Recruitment: Recruit at least 24 participants
2. Follow-up: If there is no more than 20% of loss to follow-up
3. Acceptability: If most participants interviewed stated that randomisation is acceptable and if at least 65% of eligible patients consent to participate in the trial

### Key secondary outcome(s)
There are no secondary outcome measures

### Completion date
29/07/2018

## Eligibility

### Key inclusion criteria
1. Aged 18 – 65 years
2. Complaint of CLBP with no clear medical diagnosis (malignancy, fracture, infection, spinal stenosis, spondylolisthesis, or inflammatory disease)
3. Pain persisting for more than 3 months

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
All

### Total final enrolment
16

### Key exclusion criteria
1. Pregnancy
2. New mother <6 months postpartum
3. Those who had undergone pain-relieving procedures (injection or denervation) in the previous 3 months
4. Those who showed evidence of neurological impairment specific to LBP and received physiotherapy treatment for their LBP and/or MRI scan in the last 6 months prior to recruitment

### Date of first enrolment
01/03/2018

### Date of final enrolment
24/07/2018

## Locations

### Countries of recruitment
Saudi Arabia

### Study participating centre
**King Fahad Medical City**
Kurais Street
Riyadh
Saudi Arabia
12231

## Sponsor information

**Organisation**
Saudi Spine Society

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Saudi Spine Society

# Results and Publications

**Individual participant data (IPD) sharing plan**
All data generated or analysed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 30/11/2020 | 06/09/2023 | Yes | No |
| Preprint results | | 09/03/2020 | | No | No |
| Protocol file | | | 07/08/2020 | No | No |