Feasibility Study and Process Evaluation of MRI Plus Physiotherapy vs. Physiotherapy alone in Non-Specific Chronic Low Back Pain Among Patients in Saudi Arabia

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Research

Keywords:

Posted Date: May 14th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-16388/v2

Version of Record: A version of this preprint was published at Pilot and Feasibility Studies on November 30th, 2020. See the published version at https://doi.org/10.1186/s40814-020-00731-w.

Abstract

Aim To determine the feasibility of conducting a definitive randomized control trial (RCT) to answer the question of whether an MRI diagnosis can negatively influence psychosocial and disability outcomes in patients with chronic low back pain (CLBP) treated by physiotherapy in Saudi Arabia.

Methods In a feasibility RCT in Riyadh City from 01/03/2018 until 29/07/2018, CLBP patients presenting to spine clinics were randomized to receive an MRI (intervention) plus physiotherapy rehabilitation or physiotherapy alone (control group). The acceptability of randomization to the control group (non-MRI) was tested during the recruitment by qualitatively interviewing study participants and referring physicians. Moreover, interviews with study participants exploring the broader social, political, economic, and environmental (context) aspects that may influence trial delivery and intervention implementation.

Results The recruitment target was not met: 16/24 (66%) participants were recruited in 4 months (12.4% of those screened); 33% declined. The process evaluation identified numerous factors that may affect the success of a definitive RCT in Saudi Arabia. These were research resources, the lack of research infrastructure to support recruitment to trials; limited research capacity in terms of knowledge and skills of the healthcare team; and limited funding.

Conclusion A definitive RCT to test the influence of MRI diagnosis on the psychosocial and disability outcomes in people with CLBP treated with physiotherapy in Saudi Arabia is feasible. However, the lack of research infrastructure, research capacity, the impact of MRI on patient outcomes, and a lack of clinical equipoise in the treatment and management of CLBP in Saudi Arabia pose major barriers to clinical trials.

Introduction

Although consensus in international guidelines is against the use of imaging to routinely diagnose low back pain (LBP) (1–3), several studies have identified an increase in the practice of imaging referral for diagnosis (4,5). This issue clearly indicates poor adherence amongst clinical practitioners to the established guidelines. Apart from the direct cost of imaging, the use of MRI for diagnosis of LBP in patients has received considerable criticism. Not only does it lack the ability to identify the primary pathology (6, 7) , but it is also prone to false-positive findings resulting in a larger number of patient referrals to specialist facilities (8).

Several studies have investigated strategies intended to reduce the use of diagnostic imaging in the LBP population. Jenkins et al. (5) reported that modifying the referral form for MRI resulted in a 36.8% decrease in the rate of referrals. This suggests that referral for imaging is permitted for only three conditions, i.e., presence of neurologic abnormalities (hypesthesia, hyperesthesia, or anesthesia of lumbar or sacral dermatomes), lower extremities weakness or hyporeflexia, and bladder or bowel incontinence, as indicated by the LBP management guidelines. The other strategy, which achieved a 22.5% reduction in MRI use, was a targeted reminder to primary care general practitioners (5).

Kindrachuk et al. (9) suggested a promising program to reduce the imaging rates in spine clinics, wherein a trained physiotherapist performed triaging for new patients and only referred those with clear indications (for example, chronic steroid use, presence of neurological deficits) for surgery to the spine surgeon. For the others who had no indication of the need for spinal surgery, adequate education and self-management advice was provided. Besides, patients were triaged based on the STarT Back tool as the most appropriate guideline for recommended treatment. The preliminary data suggested a reduction in referrals to imaging and waiting time to see a surgeon (9).

Providing an alternative treatment option for patients has been suggested as a strategy to overcome the idea of acceptability (10). Physiotherapy services are known to be a credible and acceptable option for many patients (11–13). When comparing LBP patients who underwent MRI at the first visit to a primary care clinic in the USA with those who received a physiotherapy intervention, Fritz et al. (11) showed that the cost of care was on average $4,793 higher over one year for the immediate MRI group than the physiotherapy group. Numerous studies have suggested that rapid physiotherapy intervention for LBP is linked to better patient outcomes and greater satisfaction (14,15). Moreover, the direct costs associated with LBP—including the number of MRI scans, GP visits, and prescription medications—were lower for people with chronic LBP (CLBP) who received early physiotherapy intervention than those that did not (14–17).

This evidence suggests that early access to physiotherapy treatments may prevent unnecessary medical expenditure while also improving the degree of patient satisfaction. On the other hand, delayed access to physiotherapy for CLBP patients is linked to poor outcomes, as seen by higher disability scores, delayed return to work, and less satisfaction and chronicity (18–20).

It is not known whether altering the practice of routine MRI use in Saudi Arabia (21) 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?

At the same time, the study will estimate the recruitment rate and estimate sample size parameters required for a definitive RCT. The process evaluation aims were to explore the acceptability of randomization and the broader social, political, economic aspects that may influence trial implementation.

Method

This study conformed to the Consort 2010 statement (22) of reporting feasibility and pilot studies. Ethical approval was obtained from the Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Ethics Reference Number: OVS 18082016) and King Fahad Medical City in Riyadh, Saudi Arabia (IRB: H-01-R-R-012).

Although studies involving human subjects are obligatory to be registered before the enrolment to ensure validity, this study is not concerned with the measurement of the effects of the intervention and adequately powered. The primary purpose is to assess the study delivery and to explore the barriers around RCT. Therefore, registration has not endeavored.

This study was designed as a single-center, two-arm, feasibility RCT in Riyadh City from 01/03/2018 until 29/07/2018 and used the opaque envelope technique. The sample size (n=36) was calculated from the number of patients matching the inclusion criteria who visited spine clinics in the three months before conducting the study. The estimated non-consent rate of 50%, suggested six new patients to be randomized per month. Following baseline the assessment, participants were randomly allocated to one of two arms. In the intervention arm (MRI+physiotherapy), the participant was referred for an MRI, the results discussed with the referring doctor, followed by referral to physiotherapy. In the control arm (physiotherapy alone), all participants were referred directly to physiotherapy without having an MRI scan.

Participants were eligible for inclusion if they satisfied the following criteria: participant of both sexes aged 18–65 years; complaint of CLBP with no apparent medical diagnosis and pain persisting for more than three months.

The following exclusion criteria were applied: pregnancy; new mother <6 months postpartum; those who had undergone pain-relieving procedures (injection or denervation) in the previous three months; and those who showed evidence of neurological impairment specific to LBP; established clear medical diagnosis (malignancy, fracture, infection, spinal stenosis, spondylolisthesis, or inflammatory disease) and received physiotherapy treatment for their LBP and/or MRI scan in the last six months before recruitment.

The initial plan was to begin recruitment from a governmental and private hospital. However, the ethics committee of the large private hospital declined participation because the research was contrary to their practice of routinely scanning CLPB patients. Therefore, the study was conducted only in one center—King Fahad Medical City, Riyadh. The center is a tertiary-care hospital in Saudi Arabia and receives referrals from secondary and primary care centers across the country. A member of the usual care team in the spine clinic screened all new patients for inclusion in the study. All patients who satisfied one or more of the exclusion criteria were excluded, and the reason for their exclusion was recorded.

Potential participants who fulfilled the inclusion criteria were recruited only after informed consent had been obtained by the principal investigator (AA) during their initial visit to the spine clinic. Several measures were implemented to achieve this: first, contact was established with prospective patients' healthcare providers (members of the usual care team) to provide information about the study and to request that they provide potential participants with an explanation of the study's aims and purpose, a description of what would be involved, and hand out participant information sheets to those fitting the inclusion criteria. Second, those fitting the inclusion criteria and expressing an interest to participate were approached by the principal investigator (AA) and given the opportunity to ask any questions. Once any

questions had been answered satisfactorily, written informed consent was obtained by AA from all patients, and baseline measurements were performed.

Concealing the approach to group allocation adopted in this research from either the participants or the health professionals was not possible. A successful approach to blinding would have required an overly creative and resource-intensive strategy; however, achieving this was not practical for this study. In view of these considerations, blinding was not applied in the present study.

Participants allocated to the intervention arm were sent for an MRI of the lumbar spine, and a follow-up visit was planned to discuss the results. The time interval to undergo the MRI ranged from 3 to 6 weeks. After discussing the results with their doctor, participants were referred to physiotherapy, which lasted for a period of 2–4 weeks. As a pragmatic trial, the physiotherapy was not predetermined, rather followed whatever interventions were routinely delivered in Saudi Arabian clinical practice. This could include passive treatment such as mobilization and electrotherapy or active treatment such as exercises and advice to stay active.

Following allocation, participants in the control arm were immediately asked to complete the booklet of questions and standard questionnaires. They 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 program, which lasted for 2–4 weeks, the second assessment was carried out.

Baseline data were collected by AA or the nurse in charge, and all endpoint data were collected in both arms by AA on completion of the physiotherapy treatment.

Demographic data (collected at baseline) included age, gender, marital status, number of children, employment status, monthly income, highest educational level, duration of back pain, number of sick days in the last three months, the severity of back pain in the last three months, and any history of surgery.

Four standardized outcome measures were completed at the bassline and after physiotherapy intervention:

Roland Morris Disability Questionnaire (RMDQ): This is a self-administered tool for assessing the level of physical disability caused by LBP. The reliability and validity of the RMDQ have been reported to be effective (23). Cross-cultural adaptation and translation of the RMDQ to the Arabic language is also reported to have good reliability and validity (24).

Fear-Avoidance Beliefs Questionnaire (FABQ): This questionnaire is based on the fear avoidance model (25). Its purpose is to measure the degree to which patients are fearful of physical activities and, thereby, avoid them, along with the impact of this avoidance on their work. The tool consists of 16 items scored from 0 (low fear) to 6 (high fear).

Orebro Musculoskeletal Pain Questionnaire (OMPQ): This questionnaire was developed to guide the primary care clinician in the identification of patients at high risk of persistent back pain (26). It is widely used and recognized in the clinical guidelines for back pain management (26). The questionnaire has been translated to Arabic in a previous study on the Saudi Arabian population (27), but the validity of the translated version is not reported in the literature.

Back Beliefs Questionnaire (BBQ): This questionnaire was developed to assess patients' beliefs relating to back pain and recovery. It is notable that the questionnaire has been translated and cross-culturally adapted to the Arabic population (28).

Given that this was a feasibility study, data analysis was primarily concerned with reporting feasibility outcomes using descriptive statistics. This included sociodemographic information pertaining to the participants, number of dropouts, number of participants who refused consent, and rate of loss associated with follow-up. Intergroup differences were reported using median scores along with means and standard deviations (SDs).

The process evaluation utilized both quantitative data from the recruitment process collected by the research team and qualitative data from participants' interviews.

In an ethnographical qualitative research approach, semi-structured interviews were used to explore the acceptability of the study protocol to both patient participants and healthcare practitioners involved in the trial delivery (Appendix 1). Since the process evaluation is set to explore the result of the feasibility outcomes, we invited seven participants (five patients and two doctors) representative for age and gender for one to one interviews. All interviews were audio-recorded and transcribed verbatim by (AA). Furthermore, a thematic analysis approach was used (29) using NVivo software. The validity of the obtained data was assured by data triangulation, whereby a summary of the finding was communicated with 20% of the qualitative interview participants.

The participating center was described in terms of the number of doctors, supporting staff, and the caseload. The number of participants was recorded to highlight the rate of participation, attrition, and drop out.

Results

In all, 129 patients were screened over the 4-month recruitment period. Of these, 24 (18.6%) satisfied the inclusion criteria Figure 1). Eight (33.3%) of these 24 did not wish to participate in the study. Some did not state the reason (n=5), others attributed their decision to the time-consuming nature of completing the outcome measure booklet (n=2), and the remaining patient (n=1) was dissatisfied with the concept of randomization. Of those consenting to take part in the study, five (41.6%) further consented to participate in the process evaluation interview.

The demographic characteristics of the included patients are shown in Table 1.

Out of the 105 excluded patients, 74 (57.3%) underwent MRI examination within the preceding 6 months, and 20 (15%) had a specific medical diagnosis (fracture, cancer, and lumbar stenosis) that excluded participation in the study. Of those screened, 11 (8.3%) were over the age of 65 years, which was one of the exclusion criteria.

Process evaluation

Telephone interviews were scheduled with 5 of the trial patient participants and 2 of 5 of the referring physicians involved in the feasibility study to collect qualitative data about the trial process.

The responses from trial participants enrolled in this study suggest that a diagnosis based on imaging and seeing a doctor was still important to patients with LBP.

"I do not think they will accept, according to my experience. I am a patient with lower back pain. Anyone who suffers from lower back pain wants first to be treated by a doctor, which means he needs imaging to see what is going on inside." PT5

However, some patients were not concerned about the group to which they were allocated on the grounds that they had already undergone several MRI scans.

"Being in either group was not a big issue for me as I have had many MRIs before."' PT3

At the same time, it is important to recognize that the implementation of a large-scale study may have an adverse impact on the degree to which patients are satisfied with the healthcare they receive. One doctor respondent in this study drew attention to this issue when the matter of feasibility was presented to him.

"Any patient wants to be in the group that is getting the most tests and diagnostics and treatment. I don't think patients will be satisfied." Dr. 1

Furthermore, it was suggested that LBP patients' referrals to the spine clinic might be reduced if they received physiotherapy as part of their primary care.

"Seventy percent of the cases that we see here could be treated by family doctors and physiotherapy." Dr. 2

The absence of additional help for recruitment and to support baseline data collection eliminated the option of conducting a multicenter study since additional human resources would have been required for the purpose of the screening and identification and recruitment of participants and completing the baseline measures and randomization.

'The only obstacle I foreseen is the lack of researchers or assistant researchers; hospitals are very supportive if you want to conduct research'. Dr.2

Time limitations are always problematic when attempting to collect clinical data, especially for doctors. This is because they rarely receive exemptions from normal working duties for research purposes, and they have to do this in their free time.

“If you are looking for a large study with follow-up then we cannot give our own time to research’. Dr.1

Treatment outcomes

With respect to the baseline measurements, both groups showed similar levels of disability based on scores on RMDQ. However, scores on other measures were higher in the intervention group than the control group.

Following physiotherapy, both groups indicated higher levels of disability on the RMDQ and a higher risk of persistent pain (OMPQ). Furthermore, the BPB scores showed a marginal increase in the control group compared to the 10% decrease in the intervention group (Table 2).

Discussion

This study aimed to evaluate the acceptability and feasibility of allocating non-specific CLBP patients randomly to an intervention (MRI) or control (non-MRI) group in addition to physiotherapy treatment. The main finding of this study is that randomization was possible; however, multiple factors emerged from the qualitative interview that might hinder proceeding to a definitive RCT. Although 16 patients were recruited to the study in 4 months, eight more patients were required to reach the required total of 24. Hence, the study fell short of achieving the recruitment target by 34%, which may be attributed to the study setting being limited to one governmental hospital. Moreover, the location of the study has been reported to be one of the barriers for participation (30).

It should be noted that the median recruitment rate of RCTs in the UK was found to be 0.92 participants per month per center (31). An insufficient recruitment rate has been reported in multiple RCTs on LBP (32–34). This finding is very valuable to highlight the fact that researchers should not be overly optimistic with respect to recruitment rate when designing definitive RCTs. Furthermore, we found no RCT conducted in Saudi Arabia, reporting the recruitment rate.

Despite the inability to recruit the proposed number of patients (n=24), this study was successful in randomly allocating people to undergo MRI in addition to physiotherapy treatment, suggesting that recruitment materials (patient information sheet) were effective in explaining the study and that the idea of random allocation was acceptable.

Moreover, it is notable that while the minimum permissible range of non-consent rate is not subject to standardization, 40% may be considered unacceptable (35). The present study’s non-consent rate of 33% was considered acceptable when compared to that reported in the available LBP literature (36).

The risk of bias is regarded as considerable when the loss to follow-up exceeds 20% (37). The loss to follow-up rate in the present study was 25% (n=4). However, this was dependent on the availability of participants attending their final session of physiotherapy. Therefore, it is not known whether this is truly reflective of retention at the follow-up point or adherence to the physiotherapy intervention. The limited duration of this study (4 months) owing to the chief investigator's (AA) visa restrictions meant that it was not possible to test the additional effectiveness of other follow-up methods such as online or telephonic data collection to boost follow-up or text message prompts. The lack of funding for the trial and lack of research infrastructure, including trained research nurses to assist with recruitment and data collection, meant that all follow-up depended on the efforts of (AA). Follow-up assessments would likely be better in a properly resourced trial.

The delay in the start of physiotherapy intervention in participants in the MRI group (compared to their counterparts in the non-MRI group) could introduce potential bias in the study findings. However, this is one consequence of routine scanning for people with LBP, which is delaying physiotherapy treatment.

Screening prior to recruitment involved examination of patient files in the recruitment center by one of the usual care team. It is possible that patients had had an MRI at another healthcare center, leading to contamination in the non-MRI group. This was highlighted by one of the control participants in the process evaluation interview, who stated that he was not concerned about being allocated to the non-MRI group having undergone numerous previous MRI exams. In a future trial, the mechanism for cross-referencing with electronic data records and confirmation with potential participants themselves should form part of the screening and consent procedures.

It might seem that doctors are supportive of recommending physiotherapy alone as a primary treatment for LBP; however, they are only concerned with patients' satisfaction. It should be noted that the inclusion of patient satisfaction measures is encouraged if full RCT to be implemented.

The secondary aim of this research was to estimate appropriate values for a power calculation for a definitive trial. The present study's small sample size, along with the high dropout rate, did not warrant a power calculation (38). However, it is plausible to draw on comparable studies that had a larger sample size (35). The RMDQ is one of the primary outcome measures used in this study and has been used in previous research to calculate the mean baseline and minimal clinically important change required for calculating the sample size (39–41). Using this measure, a sample size of 136 in each arm would have 90% power to detect a difference in means of 2.5 points in the RMDQ scores between the intervention and control groups. Assuming a mean of 9.7 and SD of 5.6 points in the control group, with a two-sided significance level of 0.05, and a sample size inflated by 25% to account for loss of follow-up would require 340 participants with CLBP. Based on this feasibility study and allowing 12 months for recruitment, we would require at least 7 centers with spine clinics to screen approximately 2,709 people with CLBP for eligibility.

The findings of this feasibility and process evaluation study provide valuable insights for researchers planning to conduct a clinical trial for CLBP treatment in Saudi Arabia.

Various barriers limit the feasibility of conducting a definitive RCT to test the influence of MRI diagnosis on psychosocial and disability outcomes in people with CLBP treated with physiotherapy in Saudi Arabia. A large trial would require multiple recruitment centers, a lengthy recruitment period and research staff trained in good clinical practice. Moreover, physician and participant concerns surrounding the acceptability of randomizing patients not to receive an-MRI may limit success and suggest that progressing to large scale RCT would be impractical at the present time.

Conclusion

A definitive trial for the present study would invariably be faced with the following obstacles: time limitations, the need to find a greater number of recruitment centers, the need to employ a research assistant, and, in view of the previous point, the need for substantial funding. Additionally, randomization might be less acceptable as an MRI scan is imperative for the diagnosis of CLBP in Saudi Arabia.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Medicine and Health Science at the University of Nottingham (Ethics Reference Number: OVS 18082016) and from King Fahad Medical City in Riyadh, Saudi Arabia (IRB: H-01-R-R-012). Additionally, all participants have signed participation consent before recruitment.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This project is partially funded by the Saudi Spine Society Grants Program (project number 10/2017 RC 01).

Authors' contributions

All authors have contributed equally in writing the study protocol and obtaining ethical approval. A.A and MA were involved in the data collection. All authors have contributed equally in the data analysis and interpretation. All authors read and approved the final manuscript

Acknowledgements

We are also immensely grateful to King Fahad Medical City for their contribution in facilitating the data collection process.

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Tables

Table 1 Participants' characteristics

	Control group n=7 (43.75%)			Intervention group n=9 (56.25%)		
Age	Mean	S.D.	Range	Mean	S.D.	Range
	40.57	10.77	22–52	37.78	11.25	24–55
History of back pain (months)	54.86	27.59	24–96	32.67	17.78	6–72
Initial pain level (out of 10)	6.00	1.15	1–7	5.88	1.83	3–9
Gender	N	%		N	%	
Female	6	85.7		5	55.6	
Level of education						
Primary school	1	14.3		2	22.2	
Secondary school	1	14.3		1	11.1	
College/Diploma	2	28.6		1	11.1	
University Degree	2	28.6		4	44.4	
Postgraduate	1	14.3		1	11.1	
Occupational status						
Employed full-time	1	14.3		6	66.7	
Employed part-time	1	14.3		1	11.1	
Retired	1	14.3		0	0.00	
Unemployed	2	28.6		0	0.00	
Housewife	2	28.6		2	22.2	

Table 2 outcome measure scores for both groups

Intervention or Control group		RMDQ	FABQ-W	FABQ-P	OMPQ	BPB	RMDQ	FABQ-W	FABQ-P	OMPQ	BPB
		Baseline					After physiotherapy				
MRI	Mean	8.88	19.24	16.22	57.66	29.66	9.16	15.55	10	59.66	26.33
	SD.	5.41	9.14	4.81	11.63	4.61	3.86	13.65	8.71	12.50	5.50
Non-MRI	Mean	8.57	14.71	18.42	62.00	26.57	9.00	9.28	12.42	69.50	27.16
	SD	4.43	4.64	12.32	10.59	5.62	4.29	4.71	9.37	10.44	6.73

RMDQ: Roland Morris Disability Questionnaire, FABQ-P: Fear-Avoidance Beliefs Questionnaire Personal, , FABQ-W: : Fear-Avoidance Beliefs Questionnaire Work, BPB: Back Beliefs Questionnaire, OMPQ: Orebro Musculoskeletal Pain Questionnaire

Note Regarding Figures

Figure 1, mentioned on page 8, was omitted by the authors in this version of the manuscript.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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