The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients. A Mixed Method Study

Short title: The Psychosocial Impact of MRI Diagnosis in Chronic Non-Specific Low Back Pain

Acronym: Psychosocial-factors

FMHS REC reference:

Study Sponsor: **University of Nottingham**

Funding Source: **Prince Sattam Bin Abdulaziz University**

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SYNOPSIS

Title	The Relationship between MRI Diagnosis and Psychosocial Factors in Physiotherapy Treated Chronic Non-Specific Low Back Patients. A Mixed Method Study
Acronym	Psychosocial Factors
Short title	The Psychosocial Impact of MRI Diagnosis in Chronic Non-Specific Low Back Pain
Chief Investigator	Mr Ahmed Alhowimel
Objectives	• Identifying psychosocial factors associated with MRI diagnosis in people with NS-CLBP. • To study the relationship between identified psychosocial factors and MRI diagnosis in people with CLBP. • To explore knowledge among healthcare professionals in clinical guideline of imaging for NS-CLBP in Saudi Arabia. • The primary objective is to assess the feasibility of randomizing patients to two groups in terms of patients' acceptance, physicians' acceptance and healthcare reliance. • To estimate the recruitment rate and describe reasons for non-recruitment. • To assess the integrity of the study protocol • To appropriately estimate the sample size needed for the definitive RCT.

Study Configuration	Mixed methods study with part one encompassing three qualitative focus group (FG) or interviews followed by a quantitative feasibility randomized control trial (RCT) with concurrent process evaluation.
Setting	Multicentre, Primary and secondary care services in Riyadh, Saudi Arabia.
Sample size estimate and Study Participants	Focus groups or interviews using purposeful sampling will comprise of 6–8 people with chronic non-specific low back pain, 6–8 physiotherapists and 6–8 orthopaedic surgeons (part I); 30 patients with chronic low back pain for the feasibility RCT (part II). There will be 38 to 44 study participants overall for part I and II. Process evaluation will include interviews with 4-6 patients and 2-4 healthcare practitioners.
Eligibility criteria	Part I: Participants with history for three months chronic non-specific low back pain whom are diagnosed with MRI from King Fahad Medical City. For the healthcare professionals, physiotherapists and orthopaedic surgeons who have experience in managing people with chronic low back pain in addition to having a privilege to request MRI for doctors. Part II: Participants over the age of 18 and below 65, of any gender, who have been diagnosed with chronic low back pain for more than 3 months and didn't had physiotherapy treatment in the past 6 months.
Description of Procedure	Part I: using FG method or interview, three FGs will be conducted with patients with chronic non-specific low back pain, orthopaedic surgeons and physiotherapists from King Fahad Medical City, Saudi Arabia. If FGs is not applicable, one- to-one interview will be conducted This will take place for approximately four months, following this study; the main psychosocial factors associated with MRI diagnosis will be identified. Part II: the psychosocial factors will be assessed on two randomized groups of patients; those who receive physiotherapy alone and those who had an MRI scan proceeding physiotherapy treatment. Following the trial, further interviews will be conducted with staff (Surgeons and physiotherapists and recruiting staff) in each site in the form of 'end of site meetings' to explore factors affecting recruiting and trial procedures.
Duration of study	Approximately 28 to 36 weeks. For part I, FG or interviews will run for 12 to 16 weeks. Part II, will require 16-20 weeks.
Outcome measures	Primary outcome measures will be beliefs, perceptions of patients and healthcare professionals regarding the MRI diagnosis in respect to patient's improvement and the psychosocial impairments associated with MRI report. Secondary outcome measures will be the influence of these psychosocial impairments on patients' response to physiotherapy.
Analysis methods	Qualitative part of the study will utilize FG or one to one interview method of data collection, the audio recorded interview will be transcribed verbatim then thematically analysed. The quantitative part of the study will utilize questionnaires for data collection, which will be analysed by Statistical Package for the Social Sciences software program.

ABBREVIATIONS

AE	Adverse event
CI	Chief Investigator
CRF	Case report form
CLBP	Chronic low back pain
GCP	Good Clinical Practice
LBP	Low back pain
NS-CLBP	Non-specific chronic low back pain
REC	Research ethics committee
UoN	University of Nottingham
MRI	Magnetic resonance imaging
RCT	Randomised Control Trial

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STUDY BACKGROUND INFORMATION AND RATIONALE

Low back pain (LBP) is one of the most prevalent musculoskeletal disorders in industrialized societies (Kelsey et al., 1979, Haddad, 1987). Although the prevalence of LBP is high, with up to 80% of people reporting at least one episode during their lifetime (Leboeuf-Yde et al., 1997), most recover within one month (Jarvik and Deyo, 2002). However, between 10 and 40% of all LBP patients fail to recover, and go on to develop chronic symptoms and live with some form of disability. Of these patients, 85% are reported to have non-specific chronic LBP (NS-CLBP) in which a specific diagnosis using radiological imaging cannot be found (Leboeuf-Yde et al., 1997, Jarvik and Deyo, 2002).

Magnetic resonance imaging (MRI) is one of the most advanced imaging techniques available for investigating LBP. Since MRI is demonstrably superiority in detecting pathology to other techniques for imaging the lumbar spine anatomy, it is the preferred method for detecting pathological conditions such as neoplasm, metabolic disorders and degeneration (Borenstein et al., 2001).

Despite the accuracy of lumbar spine MRI and its preferred use in the identification of specific pathologies, false positive findings have been reported in the lumbar spines of asymptomatic individuals (Jarvik et al., 2005). In one study, 52% of an asymptomatic population was found to have disc bulges and 27% had disc protrusions (McCullough et al., 2012). These abnormalities did not predict LBP after a follow-up period of seven years (Modic et al., 2005). In another trial, 76 asymptomatic people underwent MRI scan and revealed no abnormalities in 50% of the subjects with LBP (Boden et al., 1990).

A recent systematic literature review of articles published about the prevalence of MRI finding in asymptomatic people (Brinjikji et al., 2015) indicated that the likelihood of detecting degeneration in asymptomatic individuals is proportional to age, meaning that it is part of the normal aging process. Since abnormalities can range from disk bulging or herniation, annular fissure and degenerative disk disease, many changes observed using MRI may be coincidental or unrelated to the patient's presenting symptoms. Based on the existing literature, the clinical application of MRI in CLBP is therefore unclear.

Although, in all LBP guidelines, a consensus exists MRI scan does not add a value in diagnosing NS-CLBP (Airaksinen et al., 2006) (NICE, 2009), the healthcare profession continues to request further investigations to explain symptoms radiologically. Various publications have addressed strategic plans to reduce the imaging rates for NS-CLBP patients (Jenkins et al., 2015).

A recent qualitative study suggested that patients were more relieved following MRI and that a radiological diagnosis of NS-LBP may result in increased feelings of guilt (Serbic and Pincus, 2014). On the other hand, the blinding of acutely diagnosed LBP patients to MRI results has been associated with a better sense of wellbeing (Ash et al., 2008). Nonetheless, the ordering of MRI for NS-LBP patients was not associated with an improvement in patient management; it merely increased the workload for primary care physicians (Kendrick et al., 2001).

The role of post-procedural information

A study by McCullough et al. (2012) indicated that the inclusion of an epidemiological information statement along with the MRI report resulted in a decrease in narcotic prescriptions. Moreover, re-wording the medical terminology of the MRI report with more understandable and less threatening terms resulted in less emotional distress and increased the comprehension of the report by the patients (Bossen et al., 2013).

Clinicians may ignore the clinical guidelines for CLBP imaging for multiple reasons that relate primarily to the specific patient and physician. As described by Serbic and Pincus (2014), patients may display urgency, requesting a more advanced diagnostic tool; those patients are relieved to finally receive a diagnosis, even when false positive results are obtained. Likewise, doctors may also hold certain beliefs regarding radiological diagnoses and their understanding of the usage of diagnostic tools for NS-LBP.

There is compelling evidence that MRI for NS-CLBP does not predict improvement in patient functional improvement, but instead is associated with increased prescription of pain medication and clinic visits.

The role of psychological factors and the chronicity

Psychological factors, such as depression and fear, are strong predictors for chronicity and non-recovery (George and Beneciuk, 2015). Painful experience can be likened to memory rather than patho-anatomical process, which are suggested by (Taylor et al., 2015) using functional MRI for the cortical representation of neuron firing in chronic pain patients how found that these patients display more neurons firing in the memory area when they asked to imagine doing daily activities whereas control group showed more firing in the motor areas. Chronic back pain patients tend to display a heightened fear of movement (kinesiophobia) and increased depression (George and Beneciuk, 2015).

The Saudi Arabian context

The healthcare system in Saudi Arabia is government-funded and publically available to all; 79% of all patients receive treatment in the public system while the remainder are treated privately (Almalki et al., 2011). Insurance companies cover the majority of private patients. The public healthcare system is structured into three levels: primary, secondary and tertiary. Advanced radiological investigations are not available at the primary level.

CLBP patients in Saudi Arabia have the option of directly seeking medical treatment in the private system, thus bypassing the primary triage level. A study performed in a 440-bed university hospital in the eastern region of Saudi Arabia showed that the average number of MRI assessments performed annually was 2725, with the highest proportion attributed to adult orthopaedic and spine referrals; these figures have increased yearly since 2007 (Jabali et al, 2015). This hospital is considered small in comparison to the referenced medical cities in the region, which serve 1200 beds. Nonetheless, university hospital practitioners could be expected to have a good awareness of the literature and guidelines.

McCullough et al. (2012) demonstrated that lower back pain patients who receive MRI reports without also receiving information of the likelihood of false positive results were more likely to be prescribed pain medication than those who had received information on asymptomatic prevalence. The increased prescription of medication was associated with increased symptoms. With the knowledge that psychological factors have a significant influence in NS-CLBP, and that MRI results can instigate a

change in symptoms as well, it will be interesting to determine whether pain is preceded by psychological changes.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

This study aims to identify the psychosocial factors associated with MRI diagnosis in patients with non-specific low back pain. It will explore the experience of this group of patients in Saudi Arabia and the healthcare providers who are in direct contact with their treatment.

PRIMARY OBJECTIVE

Qualitative study:

- To explore psychosocial factors associated with receiving MRI diagnosis in people with NS-CLBP in Saudi Arabia.
- To explore current practice in the use of MRI imaging amount healthcare professionals (physiotherapist and doctors) in NS-CLBP.

Quantitative Study:

- The primary objective is to assess the feasibility of randomizing patients to two groups in terms of patients' acceptance, physicians' acceptance and healthcare reliance.
- To estimate the recruitment rate and describe reasons for non-recruitment.
- To assess the integrity of the study protocol
- To appropriately estimate the sample size needed for the definitive RCT.

Process evaluation:

An embedded process evaluation will explore:

- The acceptability of randomization from the perspective of patients and healthcare professionals involved in trial delivery
- What aspects of the larger social, political, and economic environment might have influenced trial delivery and intervention implementation?

STUDY DESIGN

STUDY CONFIGURATION

A sequential exploratory mixed methods design in which both qualitative and quantitative research methods will be employed in this project. There will be two sequential parts: 1) focus group (FG) or interviews with people with LBP and service providers (Part I), a feasibility RCT (Part II) with an embedded process evaluation .

Part I: There will be three FG interviews of people with NS-CLBP, physiotherapists and doctors. The focus groups shall be held in the conference room of King Fahad Medical City, after obtaining approval from hospital management. The data from these focus groups will help in identifying the main psychosocial factors associated with receiving MRI diagnosis in people with NS-CLBP. Moreover, the data from the FG or interview of health professionals (physiotherapists and physicians) will help in understanding the current practice of using MRI as a diagnostic tool in people with NS-CLBP. Since we are considering the experience of multiple fields, conducting an FG will be appropriate for collecting data from a large sample in a relatively short time; in addition, the FG encourages interaction between the participants. If the formation of focus group is not applicable, then we shall conduct one to one interviews.

The data from these focus groups or interviews will be analysed thematically to assist in identifying the main psychosocial factors associated with diagnosing NS-CLBP patients using an MRI diagnosis.

Part II: Outcome measures will be selected according to the emerging themes from Part I. Patients who meet the inclusion criteria will be randomly allocated to have an MRI scan followed by physiotherapy or receive physiotherapy alone. A booklet of outcome measures will be completed following consent and prior to randomization before physiotherapy and repeated after physiotherapy treatment. Part II will be held in King Fahad Medical City.

Healthcare practitioners and patients with chronic low back pain and factors affecting trial delivery will conduct process evaluation alongside the feasibility study to explore the acceptance of randomisation.

STUDY MANAGEMENT

The chief investigator (CI), under the supervision of Professor Neil Coulson and Dr Kate Radford, will be responsible for the management and progression of the study.

The methods of data collection are focus groups or interviews and questionnaires. In Part, FG, the interviews or I will be audio recorded, after obtaining permission from each participant. The FG usually takes 90 minutes for each group and they will be held at King Fahad Medical City. The CI will contact candidate participants by telephone to arrange the time of the interview. After each FG or interview, the audio recording will be evaluated to ensure that a good quality recording was obtained. Then, the audio recording will be transcribed in verbatim and checked against the original audio recording. Finally, the transcripts and the audio recording will be stored in a computer hard drive with password protection.

In Part, II of the study, the themes that emerged from the interviews will be used to create a booklet of outcome measures. The handbook will contain outcome measures of psychosocial impairments with strong psychometric properties as well as modified questions, which are not

covered by the outcome measure questionnaires. The time needed to fill in the booklet should not exceed 20 minutes. This booklet of measures will be given to two groups of patients. The first group will be patients who have had an MRI diagnosis for their back pain in the last month and the second group will be those who have not had an MRI scan. The outcome measures booklet will be completed before starting and after finishing the physiotherapy treatment.

The CI is responsible for all of the study management and is the data custodian as well.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The duration of the study will be approximately 28 to 36 weeks. Part I will require 12 to 16 weeks to conduct the three focus group interviews, which will require additional time to arrange to accommodate the professionals' busy schedules. Part II of the study will run for 16 to 20 weeks. Additional process data collection will take place parallel to Part II and. Overall, the two parts of the data collection will require 32 to 40 weeks.

End of the Study

The study will end after completing the last participant interview during the process evaluation.

ETHICAL APPROVAL

Ethical approval for this study will be sought from the Faculty of Medicine & Health Sciences Research Ethics Committee (REC) and the local Ethics Committee at the hospital in Riyadh. Ethics approval will also be sought from each hospital participating in this study.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Part I: INTERVIEW STUDY

Recruitment of patient participants: Mr. Ahmed Alhowimel will obtain the ethical permission to conduct the study from King Fahad Medical City. The physiotherapy team leader will invite the patients who meet the inclusion criteria to a FG interview. Recruitment will take place in the physiotherapy department. A consent form and patient information sheet will be given to the patients. Mr. Ahmed Alhowimel will be responsible to answer any question participants may have before signing the consent. A signature is required from each patient to document his/her acceptance to enrol in the study. There will be six to eight patients, male and female without restriction in sex representation.

Recruitment of clinician participants: Mr. Ahmed Alhowimel will obtain the ethical permission to conduct the study from King Fahad Medical City. Physiotherapists and doctors who meet the inclusion criteria will be invited to participate in a focus group. Physiotherapists and doctors will be invited by the team lead. An ethical consent form and a participant information sheet will be given to the participants. A signature is required from each participant to document his/her acceptance to enrol in the study. Each group will contain six to eight clinicians, male and female. If FG is not possible, especially with physician, then one to one interview will be performed.

Part II:

In Part II of the study, Mr. Ahmed Alhowimel will approach the administrators at King Fahad Medical City for approval to conduct the second part of the study. The lead physician will invite all patients who met the inclusion criteria to take part in the study using the patients register program. An ethical consent form and an information sheet will be handed to the patients. Mr. Ahmed Alhowimel will be responsible to answer any question participants may have before signing the consent. A signature is required from each patient to document his/her acceptance to enrol in the study. To ensure equal

distribution between groups, block randomization schedule will be used to assign patient into groups; MRI group and control group. The MRI group will have MRI scan and discuss the result with their doctors before having the physiotherapy treatment. The control group will have physiotherapy treatment without MRI scan.

Process Evaluation:

Patient particepent of Part II, will be invited by email to participate in process evaluation interviews. Additional consent forms and information sheets related to this study will be emailed to participants. Reply from the participant with the approval is required t to document his/her acceptance to enrol in the study. Mr Ahmed Alhowimel will be responsible to answer any questions concerning these documents.

The research team in King Fahad Medical City, including doctors and physiotherapists, will be invited by email to participate in interview study to evaluate their experiences of the feasibility RCT. Mr Ahmed Alhowmel will be responsible for contacting the research team and explaining the study aims.

For the focus groups and interviews:

Inclusion criteria:

Patient participants:

Male and female aged 18 to 65 years, CLBP with no clear medical diagnosis who had an MRI scan and a report for LBP in the last month (e.g., malignancy, fracture, infection, spinal stenosis, sponylosthesis or inflammatory disease). Chronicity will be considered if the pain has persisted for more than three months.

Clinician participants:

Physicians in direct contact with people with NS-LBP and with the authority to refer patients for MRI will be recruited as clinician participants. Inclusion criteria for physiotherapists include outpatient physiotherapists with a primary interest in LBP management.

Exclusion criteria:

Women who are pregnant or less than six months postpartum, or have received pain-relieving procedures (injection or denervation) in the previous three months or have evidence of neurological impairment will be excluded from the study.

For the feasibility RCT:

Inclusion criteria:

Male or female aged 18 to 65 years; CLBP with no clear medical diagnosis who had an MRI scan and a report for LBP in the last month (e.g., malignancy, fracture, infection, spinal stenosis, sponylosthesis or inflammatory disease) will be included. Chronicity will be considered if the pain has persisted for more than three months. Patients must not have had physiotherapy treatment in the six months prior to the study.

Exclusion criteria:

Women who are pregnant or less than six months postpartum, or have received pain-relieving procedures (injection or denervation) in the previous three months or have evidence of neurological impairment will be excluded from the study.

Participant withdrawal

Participation in this study is voluntary. All participants are free to withdraw from the study at any time, without fear of penalty of impact on their healthcare and the researcher could remove participants from the study if needed as well. If there is a withdrawal from the study, the information collected prior to the withdrawal will not be removed and shall be used in the analysis. The treatment given to the patients will not be affected by their withdrawal from the study. Patients who drop out of the study will not be replaced.

Informed consent

The consent form must be signed and dated prior to participating in the study. The CI will explain the study by providing an information sheet and answering the questions of the patients and clinicians. Both healthcare practitioners and patients will be contacted during and after the feasibility trial asking if they would be willing to take part in an interview at the end of the trial, about their experiences of taking part in the trial, the process of the trial and factors affecting its delivery.

STUDY REGIMEN

Compliance

Participation in the FG and the returned handbook of outcome measures are the indictors for compliance.

Criteria for terminating the study

Dissolution of the study is unlikely, however if the ethical approval is withdrawn then the study will be terminated.

DATA ANALYSES

Methods

In Part I of the study, the qualitative part, the FG or interviews will be audio recorded and then transcribed verbatim to be analysed thematically using Framework analysis (Ward et al., 2013). The Nvivo software programme will be used later for coding and management.

In Part II of the study, the quantitative part, the Statistical Package for the Social Sciences (SPSS) will be used for analysis. The process evaluation will require interviews with both healthcare professionals and trial participants (patients) and analysis of recruitment process documentation completed by the research team.

All study data will be analysed using the University of Nottingham (UoN) computers and it will be stored in the UoN server.

Sample size and justification

Part I (FG or interviews): A purposive sampling method will be utilised. In this study, a subgroup of the populations, healthcare professionals with experience in the management of chronic LBP and people with chronic LBP, will be identified and then select cases from this subgroup will be recognised in a purposive manner. Both the patients with chronic LBP and the healthcare professionals will be intentionally and purposefully chosen according to the inclusion and exclusion criteria defined earlier.

Part II: since this is a feasibility study a sample size calculation is not required, however a realistic target of 30 participants estimated based on audit data from recruitment centre, which suggest 80 people with general spine problems are seen in each clinic per month. Assuming two third are not eligible and further 50% refused consent, we will recruit patients for 6 week from two clinics. The sample size for each arm of the feasibility RCT will be 15 participants.

Process evaluation interviews will involve 4-6 participants and 2-4 healthcare practitioners.

ADVERSE EVENTS

Since no adverse events (AE) are expected to occur because of participating in the study, no AE data will be collected. However, since the study will be exploring peoples' experiences, some individuals may become emotional and uncomfortable with sharing their experiences. If this occurs, the researcher will stop the discussion and ask that participant if he/she is willing to continue with the discussion. Again, they will have the option to withdraw from the study if they feel it is appropriate to do so. If participants are very distressed, they will be referred to their GPs.

PROCESS EVALUATION

We will conduct a process evaluation alongside the feasibility RCT to explore the acceptability of randomisation and the study design with both healthcare practitioners involved in trial delivery and

patient participants. Interviews will also explore the broader social, political, economic and environmental (context) aspects that may have influenced trial delivery and intervention implementation. The process evaluation will use quantitative data from the recruitment process collected by the research team and qualitative data from participants' interviews.

Quantitative data:

The participating centre will be described in term of number of doctors, supporting staff and caseload. The number of participants will be recorded to describe the rate of participation, attrition and drop out.

Qualitative data:

Interviews will explore the acceptability of the study design to both patient participants and healthcare practitioners involved in the trial delivery. Furthermore, it will explore the contextual aspects of implementing the study.

Telephone semi-structured interview will be conducted by (A.A) with purposive sample of 4-6 patients and 2-4 healthcare practitioners and research staff in each centre participating in the feasibility study.

All interviews will be audio- recorded and transcribed verbatim and analysed thematically using NVivo software. Validity of the obtained data will be assured by triangulating the findings with participants.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will commence after the study protocol, consent form and participant information sheet are approved from the (REC). Modification of the protocol after REC approval will require another full review of all of the documents. If the amendment involves eliminating an adverse event to the participants, the REC will be notified immediately and an updated approval will be sought. Amendments that do not have a major effect on the protocol might be implemented first and REC subsequently notified.

The study shall follow the Declaration of Helsinki (1996) in the Ethical Principles of Conducting Medical Research Involving Human Subjects and the Department of Health Research Governance Framework for Health and Social Care (2005).

INFORMED CONSENT AND PARTICIPANT INFORMATION

Obtaining informed consent from the participants will follow REC and Good Clinical Practice (GCP) regulations and guidance. The CI or team lead and the participant or authorised legal representative should both sign and date the consent form before the study commences.

Each participant will have a copy of the consent form. Another copy will be kept in the medical file of the patient participate and the original copy will be saved in the study records.

The investigator or the team lead shall explain to the participants that the study is voluntary and that withdrawal from the study will not affect the given treatment.

The investigator is responsible for updating the participants of any new information that emerges and explaining to them again that their treatment will not be affected if they would like to withdraw from the study.

With any changes in the informed consent form, the investigator shall follow the regulatory process of the protocol pertaining to REC and update what needs to be updated.

RECORDS

Case Report Forms

The study identity code will be allocated to each participant. The code will be utilised in the case report forms (CRFs) and other study documents (electronic and paper). The documents will use the initial name of the participant and the date of birth (day/month/year).

The investigator will treat the CRFs as confidential documents and follow the regulations in keeping them secure. The patient's name, date of birth and the name of the hospital will be kept in a separate confidential record.

Permission should be obtained from the CI to access the CRFs. This access should be recorded.

Paper documents are filled in only with a black ballpoint pen. Any error shall be lined out and corrected. All error corrections must be initialled and dated.

Source documents

Source documents, including consent forms, study records, field notes, interview transcriptions and a handbook of outcome measures, shall be filed at the investigator's site. The CRFs could serve as a source of data. These documents will only be accessed by study staff. Adherence to the regulations below is required for access.

Direct access to source data/documents

The source data and the CRF documents will be available for review from the sponsor or the regulatory authorities.

DATA PROTECTION

The study staff shall adhere to the Data Protection Act (1998). Participant privacy and informed consent shall be guarded throughout the study. The CRF will only be used to collect the required information from the participants for the study. Access to the CRFs is limited to study staff and regulatory authority. All of the information shall be held is a secure cabinet in a locked room. For the computer data, all data will be stored in a web-based server with access restricted by user identification.

Medical information in the patient files will follow the hospital regulations in terms of confidentiality and how long the information is kept.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

As a research sponsor, The University of Nottingham insures the study staff, participants and the protocol with public obligations and clinical trial research.

STUDY CONDUCT

The study will conduct a systematic audit of the major documents, which include adherence to protocol procedures, consent procedures, ethical approval of the study, CVs of the study staff, and responsibility for the study material and equipment.

A nominated designee from the sponsor or study coordinator shall perform a systematic audit at least annually.

STUDY DATA

A nominated designee from the sponsor or the study coordinator shall constantly monitor the following: confirmation of consent forms, data storage, scours data confirmation, and a back-up plan for recovering the information.

The CRF data will be checked regularly against the source data.

A portion of the CRF entries (10% or as per the risk assessment) will be verified by inspection against the source data. If there is evidence of matching error, a whole or a full audit will be performed.

Study monitoring processes and system audits will be accessible to REC if required.

RECORD RETENTION AND ARCHIVING

The CI will retain all study data for at least seven years and in accordance with GCP guidelines and the University of Nottingham Code of Research Conduct and Ethics. If for any reason the CI is not able to maintain these data, a second person will be nominated to be responsible for it.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The sponsor has the right to discontinue the study in the instance of failure to meet the study goals, safety issues or any administrative reason.

STATEMENT OF CONFIDENTIALITY

The study results and any information pertaining to the individual participants are considered confidential and disclosure to a third party is forbidden. The use of an identification coding system will ensure the privacy of the participants.

PUBLICATION AND DISSEMINATION POLICY

The study findings shall be presented in professional conferences and published both nationally and internationally in peer reviewed journals. Utilizing social media channels will be considered for educating patients and professionals.

STUDY FINANCES

Funding source

This research is funded through a PhD scholarship from Prince Sattam bin Abdulaziz University, Saudi Arabia, at the University of Nottingham, UK.

Participant stipends and payments

Participants will be fully reimbursed for any expenses incurred in travelling to an FG or interview (if necessary), reasonable travel allowance and car parking.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: Mr. Ahmed Alhowimel

Signature: _____ahmed alhowimel

Date: 28-09-2017

Co-investigator: **Professor. Neil Coulson**

Signature: _____ Neil Coulson

Date: 28-09-2017

Co-investigator: **Dr. Kathryn Radford**

Signature: _____ 

Date: 28-09-2017

Study Statistician: **Mr.** Ahmed Alhowimel

Signature: _____ahmed alhowimel

Date: 28-09-2017

Reference

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