Effects of Lumbar Stabilization Exercises with Real-Time Ultrasound Imaging Biofeedback on Lumbar Multifidus Muscle Cross-Sectional Area in Individuals with Chronic Nonspecific Low Back Pain: A Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background: Impairments in the lumbar multifidus muscle such as reduced muscle thickness and fat infiltrations are evident in individuals with low back pain. Lumbar stabilization exercises (LSE) with real-time ultrasound imaging (RUSI) biofeedback has been reported to improve preferential activation of as well as retention in the ability to activate of the lumbar multifidus muscle, thus enhancing recovery. However, the effects of using this treatment approach in individuals with nonspecific chronic low back pain (NCLBP) seemed not to have widely reported. The purpose of this study is, therefore, to investigate the effects of LSE with RUSI biofeedback on lumbar multifidus muscle cross-sectional area in individuals with NCLBP patients.

Method: This study is a prospective, single-center, assessor-blind three-arm, randomized controlled to be conducted at National Orthopedic Hospital, Kano State, Nigeria. Ninety-one individuals with NCLBP will be randomly assigned into one of the three treatment groups of equal sample size (n = 30); LSE group, LSE with RUSI biofeedback group, or control (minimal intervention). The participants in the LSE and LSE with RUSI biofeedback group will also receive the same intervention as the control group. All participants will receive treatment twice weekly for 8 weeks. The primary outcome will be lumbar multifidus muscles cross-sectional area while the secondary outcomes will be pain, functional disability and quality of life. All outcomes will be assessed at baseline, and at 8 weeks and 3 months post-intervention.

Discussion: The outcome of the study may support the evidence for the effectiveness of LSE with RUSI biofeedback in the rehabilitation of individuals with NCLBP. It may also provide a rationale for the physiotherapists to make use of diagnostic ultrasound as a feedback mechanism in enhancing the performance and retention of LSE program as well as monitoring the patient's recovery.

Trial registration: Pan African Clinical Trials Registry, (PACTR201801002980602), Registered on 16 January 2018.

Background

Low back pain (LBP) is a common musculoskeletal disorder and the leading cause of disability in both developed and developing countries [1]. Approximately, 80% of the population will experience an episode of LBP during their life [2]. It imposes a considerable economic burden on individuals, families, communities, industry and governments [3]. For example, the total costs of LBP exceed $100 billion per annum in the US, with two-thirds of these costs being indirect and due to lost wages and reduced productivity [4]. The impact of LBP, however, is expected to increase over the coming decades particularly in low-income and middle-income countries primarily due to the growing and aging population [5].

The one-year prevalence rate of LBP in Africa was reported to be 57% [6] which is significantly greater than the 38.5% reported globally [7]. In Nigeria, the one-year prevalence rate of LBP was reported to be between 33% and 74% [8] which affects mostly workers. These figures suggest that the occurrence of LBP is rising in Nigeria and strategies to curtail the burden of this disabling condition are crucial.

Low back pain is a major public health issue especially in its chronic state since it limits physical activity and subsequently affects the patient's quality of life (QOL) [9, 10]. Chronic LBP is a pain, muscle tension, or stiffness localized below the 12th costal margin and above the inferior gluteal folds, with or without leg pain, lasting 12 weeks or more [11]. Although many spinal structures could be claimed responsible for origin of pain in patients suffering from this disorder, 90% of the cases are nonspecific in nature which implies that the cause of the pain cannot be reliably identified [12]. However, previous researches attempted to identify possible underlying pain mechanisms that could be attributed to LBP. For example, it has been documented that structural as well as functional impairments of the deep trunk muscles, such as poor or delayed activation of the transversus abdominis (TrA) [13–15] and reduced muscle thickness (cross-sectional area [CSA]) as well as fat infiltrations in the lumbar multifidus muscles (LMM) [16–19] are evident in individuals with LBP.

One promising approach for addressing the impairments of the deep trunk musculature is lumbar stabilization exercise (LSE). This exercise program is commonly applied by physiotherapists to rehabilitate individuals with LBP disorders [20–25]. Importantly, there is evidence to supports the efficacy of this intervention in improving pain, functional disability and QOL among sufferers of chronic LBP even though it may not be superior to other types of exercise program or manual therapy [26–29].

The focus of LSE is to train the skilled activation of the deep trunk muscles, to train the integration of the deep and superficial trunk muscles targeting restoration of control and co-ordination of these muscles, and to progress toward more complex and functional tasks to ensure transfer to normal activity [26, 30]. However, to improve the precision of contraction of the deep trunk muscles while performing LSE, it is crucial to provide accurate feedback during training. This may involve any of the senses including tactile (palpation), auditory (electromyography) and visual ultrasound imaging information [31]. Though the use palpatory feedback is commonly practiced, visual feedback using real-time ultrasound imaging (RUSI) has been shown to be promising in providing preferential activation of the deep trunk musculature such as the LMM in healthy individuals [32, 33]. Moreover, Van et al [34] discovered that the use of RUSI biofeedback may not only improve muscle activation performance but also retention in the ability to activate muscle, which is extremely important for individuals with LBP as reoccurrences are common [22]. More specifically, earlier studies suggest that preferential activation of the LMM with LSE using RUSI biofeedback is associated with muscle recovery (i.e. increased LMM CSA) as well as reduced pain among individuals with LBP [35, 36]. While the use of this treatment approach may be highly relevant to enhance the performance of LSE and recovery from LBP, studies in the way of randomized controlled trial examining the effectiveness of such approach in individuals with nonspecific chronic LBP (NCLBP) are limited.

It is worth noting that, most observational and interventional studies have evaluated LMM CSA in non-weight-bearing positions [37]. However, non-weight-bearing positions are not relevant to most daily functional activities as weight-bearing positions. Thus, the question of whether measures of LMM thickness observed in non-weight-bearing positions in the spinal column, such as lying would differ or comparable with that measured in weight-bearing positions such as sitting and standing remains to be

clarified. The knowledge in the variation of LMM thickness in both weight-bearing and non-weight-bearing will be important for clinicians in the structural and functional evaluation of this muscle.

Our recent pilot study [38], even though was limited for being a single-group pretest-posttest quasi-experimental design, suggests the feasibility of conducting a large-scale randomized controlled trial (RCT) to investigate the efficacy of LSE with RUSI biofeedback in individuals with NCLBP. The treatment approach proved to be effective in reducing pain, functional disability and LMM CSA but physical and mental health which could be attributed to the shorter treatment sessions provided [38]. Thus, the purpose of this study is to investigate the effects of LSE with RUSI biofeedback on LMM CSA in individuals with NCLBP patients. The primary outcome will be LMM CSA in prone lying and standing positions whereas the secondary outcomes will be pain, functional disability and QOL.

Methods

Hypothesis

We hypothesized that that patients receiving LSE with RUSI as visual biofeedback will demonstrate significant improvements in LMM CSA, pain, functional disability and QOL compared to those receiving LSE without biofeedback or minimal intervention (control) after 8 weeks of treatment and at 3 months follow-up.

Primary objective

The primary aim of this study is to investigate the effects of LSE with RUSI biofeedback on LMM CSA in individuals with NCLBP patients.

Secondary objectives

This study will evaluate the effects of LSE with RUSI biofeedback on pain, functional disability and QOL. Additionally, LMM CSA measurement in lying position will be compared to that in standing position before and after 8 weeks of LSE with RUSI biofeedback.

Study design

This study will be a prospective single-center, assessor-blind, three-arm RCT and will be conducted at the physiotherapy department, National Orthopedic Hospital, Dala, Kano State, Nigeria. The outline of the study is presented in Fig. 1. The protocol for this study is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist (Additional file 1).

Physiotherapists/research assistants

Two physiotherapists in addition to the principal investigator (RS) with more than 3 years of clinical experience in musculoskeletal physiotherapy will be responsible for patients' screening, appointments

and treatment. A consultant radiologist (AI) with over 10 years of experience in diagnostic ultrasound imaging will be responsible for operation of the RUSI for biofeedback imaging. All the physiotherapists will receive a training session and written instructions for the study protocols.

Participants and recruitment

Patients with NCLBP attending outpatient physiotherapy department will be recruited into the study. Eligibility for participation will be based on physician or consultant orthopedics referral and physiotherapists' diagnosis of NCLBP. The participants will be included in the study if they are male or female between the age of 18 and 65 years, have a primary complain of nonspecific LBP with or without leg pain for 12weeks or more, and are able to read and understand Hausa or English language or both. Participants will be excluded if they have history of spine surgery, obvious deformities affecting the trunk or upper and lower extremities, serious spinal pathology such as infection, fracture and metastases, unstable cardiovascular or pulmonary disorders, and history of serious psychiatric illness. Participants meeting the eligibility criteria and who accept willingly to participate will be given oral and written information about the study procedures. They will also be informed about their rights to withdraw from participation at any time without prejudice. Informed consent will be obtained via signature. Participants' baseline demographic variables such as age, gender, marital status, education and employment status, and clinical variables such as pain duration, height, weight and body mass index will be collected and recorded after group allocation. The participants will be identified only by their initials on the research notes.

Randomization and blinding

A record clerk who will not be involved in the assessment and treatment of participants will be responsible for random allocation of participants into different treatment groups. The participants will be randomly assigned into three treatment groups using the fishbowl technique. The randomization will be performed with the use of sealed and opaque envelopes. The envelops will be prepared in advance and marked inside with letters A or B or C, signifying group A or LSE group, group B or LSE with RUSI biofeedback (LSER) group, and group C or control (minimal intervention). The participants will be instructed to pick an envelope from the bowl without replacement. When an envelope is open, the letter written on the paper inside indicates the group of the participants. Patients will be consecutively recruited and randomly assigned to the treatment groups as described until the required sample size is met. All assessors will be blinded to participants' group allocation. However, because of the nature of the interventions, it is difficult to blind the treating physiotherapists to treatment allocation.

Outcome assessment

The primary outcome is LMM CSA assessed with RUSI whereas the secondary outcomes include pain, functional disability and QOL to be assessed with different self-report measures. All outcomes will be assessed at baseline, at 8 weeks post-intervention, and 3 months post-randomization (Table 1).

Table 1 SPIRIT figure: showing time points for enrollment, interventions, and assessment

	STUDY PERIOD				
	Before start of intervention	Allocation	Intervention over 8 weeks	Post-intervention	Post-allocation (3 months)
TIMEPOINT	$-t_x$	0		t_y	t_z
ENROLLMENT:					
Ethical approval	X				
Trial registration	X				
Eligibility screening	X				
Informed consent	X				
Baseline questionnaires	X				
Randomization		X			
INTERVENTIONS:					
Lumbar stabilization exercises (group 1)			⟷	X	
Lumbar stabilization exercises with RUSI biofeedback (group 2)			⟷	X	
Minimal intervention (group 3)			⟷	X	
ASSESSMENTS:					
Socio-demographic and clinical characteristics		X			
LMM CSA		X		X	X
NPRS (pain) *RMDQ (functional disability)* *SF-12 (quality of life)*		X		X	X

RUSI, real-time ultrasound imaging; LMM, lumbar multifidus muscle; CSA, cross-sectional area; NPRS, Numerical Pain Rating Scale, RMDQ, Roland-Morris Disability Questionnaire; SF-12, 12-item short-form health survey

Lumbar multifidus muscle cross-sectional area in lying

The procedure for the LMM CSA in lying position will be identical to that described in our pilot study [38]. The imaging of the LMM CSA will be assessed using a D3 ultrasonic diagnostic imaging system with 5-MHz coplanar transducer (B-mode D3 version 1.6, Edan, China). Participants will be asked to assume prone lying position with proper pillow support and the neck turned to the participants' preferred side. The lumbar spine will be palpated cranially from the line joining the superior border of the iliac crest (L4/L5) to locate the position of L5 spinous process (a deep small blunted bony point lying at the center of the lumbosacral depression). The L5/S1 position will be checked and confirmed against the lumbosacral depression as visualized on the ultrasound imaging. The transducer head of the ultrasound with a coupling medium will be then placed at the L5/S1 level and moved laterally and angled in a cephalocaudal direction to obtain a clear visualization of the zygapophyseal joints, muscle bulk, thoracolumbar fascia, and echogenic lamina of L5 spinous process. The clearest image of the LMM will

be captured and the CSA will be determined as stipulated in the manual of the D3 ultrasonic diagnostic imaging system [38]. To ensure accuracy, average measures of three images of the LMM will be taken. This procedure will be repeated for each of the participants in the study.

Lumbar multifidus muscle cross-sectional area in standing

Herein the participants LMM CSA will be asked to stand up right while their LMM CSA is measured and recorded as described in the measurement procedure for the lying position. Also, to ensure accuracy, average measure of three images of the CSA will be recorded.

Pain

The level of pain intensity of the participants will be assessed by administering the Numerical Pain Rating Scale (NPRS). The NPRS consists of 11-point Likert scale, with 0 representing “no pain” and 10 representing “worst imaginable pain. The participants will be asked to indicate the best point that represents the greatest pain they experienced at the time of assessment. Both the Hausa and English versions of the NPRS will be used for the pain assessment. The NPRS has been reported to be a valid, reliable and responsive measure of pain intensity in patients with LBP [39–41].

Functional disability

The levels of functional disability of the participants will be assessed by administering Roland Morris Disability Questionnaire (RMDQ), It is a 24-item questionnaire, with scores ranging from 0 (no disability) to 24 (maximum disability). The participants will be asked to tick on any of the 24 items that describe their current disability level. To obtain the RMDQ total score, the items checked are summed up. The RMDQ is a valid and reliable measure of functional disability in patients with LBP [42, 43]. The Hausa version of this questionnaire will be also used following translation in accordance with established guidelines [44].

Quality of life

The QOL (physical and mental health) of the participants will be assessed by administering the 12-item short-form health survey (SF-12) questionnaire. The SF-12 is a shorter alternative to the SF-36 health survey. The questionnaire measures two health construct viz physical component scores (PCS-12) and mental component scores (MCS-12). A web-based scoring tool (www.orthotoolkit.com/sf-12/) will be used to calculate the PCS-12 and MCS-12 scores, with higher scores indicating better health status. Both the Hausa and English version of the SF-12 will be used for the pain assessment. The questionnaire has been reported to have adequate psychometric properties in measuring health-related quality of life [45–47].

Interventions

All interventions will be provided twice a week for 8 weeks and under the supervision of the physiotherapists. Participants in the LSE and LSER group will also carry out the same intervention as for the control group. All participants will be informed to perform exercise consistent with their group

allocation. Those allocated to LSER group will be advised to perform home exercise as prescribed for those in the LSE group. All participants will be advised not to partake in any related interventions during the study. Also, the importance of attending all treatment sessions will be emphasized to encourage treatment adherence.

Lumbar stabilization exercises

Participants allocated to this group will be taught LSE based on the approach of Richardson [30]. They will be asked to assume a prone lying position and with a small role in under each shoulder. A pillow will be placed under the lower legs and one under the hips to make the patient comfort and to ensure neutral positioning of the spine. Participants will be taught an active isometric contraction of the LMM in in synergy with other deep stabilizing muscles such as TrA using bracing methods. Contractions will be held for 10 seconds with a period of 2-minute rest between contractions and repeated 10 times. The exercise program will last for approximately 20 minutes.

Lumbar stabilization exercises with real-time ultrasound imaging biofeedback

Herein the intervention will be similar to that described in our pilot study [38]. Participants will be instructed on how to perform isometric contraction of the LMM in synergy with other deep stabilizing muscles such as TrA as described above. However, the exercise will be enhanced with RUSI biofeedback. While maintaining neutral spine position in prone lying, the transducer head of the ultrasound will be placed at the L5/S1 level and then the participants will be instructed to perform isometric contraction of the deep stability muscles. Specifically, they will be instructed to focus on the monitor to see the changes in the thickness of LMM CSA as they contract the muscles and put in their best effort to increase the thickness with successive contractions. Contractions will be held for 10 seconds with a period of 2-minute rest between contractions and repeated 10 times. The entire exercise is expected to last approximately for 30 minutes.

Minimal intervention

Participants allocated to this group will receive two stretching exercises to increase flexibility of the lower back and one strengthening exercise to increase strength of the lower back. These exercises are commonly prescribed for patients with LBP. The exercises are knee to chest, lumbar rotation and bridging. The entire exercise will last for approximately 15 minutes. The description and dosage of the exercise is provided in Table 2.

Table 2
Minimal intervention

	Exercise type	Description	Dosage
1.	Knee to chest	In crook lying position, pull both knees to the chest with interlocked fingers until a comfortable stretch is felt in the hip and lower back. Maintain the highest position	5–10 sec hold, 10 reps
2.	Lumbar rotation	In crook lying position, slowly rock knees from side to side as far away as possible and maintain each position	5–10 sec hold, 10 reps
3.	Bridging	In crook lying position, lift the pelvis in a straight line as far up as possible and maintain the highest position	5–10 sec hold, 10 reps

Adverse events

Serious adverse events (AEs) are generally rare with therapeutic exercise interventions. All participants will be informed before enrollment about the possibility of experiencing some common AEs associated with exercises such as mild muscle or joint pain and muscle pull, which are often self-limiting. However, in the event of any serious adverse experiences such as exacerbating joint pain, marked joint swelling, light-headedness, angina and shortness of breath or dizziness, the participants are expected to report such experiences immediately to the treating physiotherapists or primary investigator. All serious AEs will be then promptly reported to the physician for evaluation and prompt action. Additionally, reports will be sent to the Research and Ethical Committee of National Orthopedic Hospital, Dala, Kano State. The participants will be allowed or be asked to withdraw from the study if they make such a request or develops serious AEs as mentioned previously

Sample size calculations

The sample size was estimated a priori, to detect a significant difference in the primary outcome (LMM CSA) between the experimental groups (LSE and LSER) and control (minimal intervention) group, assuming a standard deviation (SD) of 2.5 points based on our pilot study [38], a medium effect size of 0.30; a statistical power of 85%; an alpha of 0.05 (two-tailed test). The calculations revealed that a sample size of 81 is required. However, while anticipating a 15% drop out rate (n = 12), a total sample size of 93 (31 per group) will be finally required.

Statistical methods

All statistical analyses will be conducted on IBM SPSS Statistics ver. 23.0 (IBM Co., Armonk, NY, USA) with a significant level of 0.05. Intention to treat (ITT) analysis will be applied with all randomized participants, who have any outcome data available for analysis, included in the trial regardless of the presence or absence of follow-up. A normality test for the dependent variables will be examined using the

Kolmogorov–Smirnov and Shapiro–Wilk test. Descriptive analysis will be used to summarize the data with the use of mean, standard deviation, frequencies and percentages. One-way analysis of variance (ANOVA) (for normally distributed data) or Kruskal–Wallis (for skewed data) test will be used to compare baseline continuous variables whereas Chi-square test will be used to compare baseline categorical variables among the three groups. Mixed between-within subject ANOVA will be applied to evaluate main effect of time, interaction effect and between-subjects effect in all outcomes if the data is normally distributed. Otherwise, Friedman's ANOVA and Kruskal–Wallis test will be applied to evaluate within-group changes and between-group differences, respectively in all the outcomes when the data is skewed. Post-hoc analysis will be also applied for any significant within- or between-group differences detected. Effect size will be computed to evaluate the magnitude of change in all the outcomes. To analyze the difference between LMM CSA measured in lying position and that measured in standing position before and after 8 weeks of LSE with RUSI biofeedback, independent *t*-test will be used.

Data management

All data will be carefully recorded in a logbook and electronically using Microsoft Excel sheets by the assessors. All data values will be double-checked by assessors for missing values and errors before analysis

Trial status

This study is currently recruiting participants and we anticipate continuing recruitment till March 2021. However, due to the ongoing Covid-19 pandemic, the recruitment may be extended for an additional 4 months beyond the originally expected date of completion of April 2021. The protocol version number and date are as follows: Second Edition, 20 July, 2020.

Dissemination

The results of this study will be disseminated through publications in peer-reviewed journals and also presented at national or international conferences, regardless of whether the results are positive, negative, or inconclusive.

Trial amendments

Any amendment to the study protocol will be reported to the Health Research Ethics Committee of National Orthopedic Hospital, Dala, Kano State as well as updated in the Pan African Clinical Trials Registry.

Discussion

Lumbar stabilization exercise program has been widely reported to be effective in ameliorating pain, functional disability and QOL in patients with NCLBP [26–29]. Moreover, the use of RUSI as visual biofeedback has been shown to enhance the performance of this exercise intervention [32, 34] and recovery from LBP [35, 36]. However, there is limited evidence regarding the effects of such treatment

approach in individuals with NCLBP. This study will be aiming at exploring the effects of LSE with RUSI biofeedback on LMM CSA as primary outcome and pain, functional disability and QOL as secondary outcomes. The study will also seek to determine whether there will be significant difference between LMM CSA measured in weight-bearing (up right standing) and LMM CSA measured in non-weight-bearing (lying) before and after LSE training with RUSI biofeedback.

The outcome of the study may support the evidence for the effectiveness of LSE with RUSI biofeedback in the rehabilitation individuals with NCLBP. It may also provide a rational for the physiotherapists to make use of diagnostic ultrasound as a feedback mechanism in enhancing the performance and retention of LSE program as well as monitoring the patient progress.

Abbreviations

AEs
Adverse events
ANOVA
Analysis of variance
CSA
Cross-sectional area
ITT
Intention to treat
LBP
Low back pain
LMM
Lumbar multifidus muscles
LSE
Lumbar stabilization exercises
LSER
Lumbar stabilization exercises with real-time ultrasound imaging
NCLBP
Nonspecific chronic low back pain
NPRS
Numerical Pain Rating Scale
MCS-12
Mental component scores
PCS-12
Physical component scores
QOL
Quality of life
RCT
Randomized controlled trial

RMDQ
Roland:Morris Disability Questionnaire
RUSI
Real-time ultrasound imaging
SD
Standard deviation
SPIRIT
Standard Protocol Items:Recommendations for Interventional Trials
TrA
Transversus abdominis

Declarations

Trial registration

The study trial was registered prospectively at the Pan African Clinical Trials Registry (https://pactr.samrc.ac.za/) on January 16, 2018 (Registration number: PACTR201801002980602).

Ethics approval and consent to participate

This study was approved by the Research and Ethical Committee of National Orthopedic Hospital, Dala, Kano (Ref: NOHD/RET/ETHIC/60). Written, informed consent will be obtained from all participants before participating in the study

Consent for publication

Not applicable.

Conflict of interest

The authors declare no conflict of interest.

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Availability of data and materials

After the study is completed, the data will be made available on request from the corresponding author.

Authors' contributions

RS, SOG and AS conceived the study. RS and AIA developed the first draft of the protocol. MKO and AIA reviewed and edited the protocol. SOG supervised the protocol. AWA proposed the statistical analyses. All

authors contributed to the trial design. All authors have read, contributed to, and approved the final manuscript.

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Figures

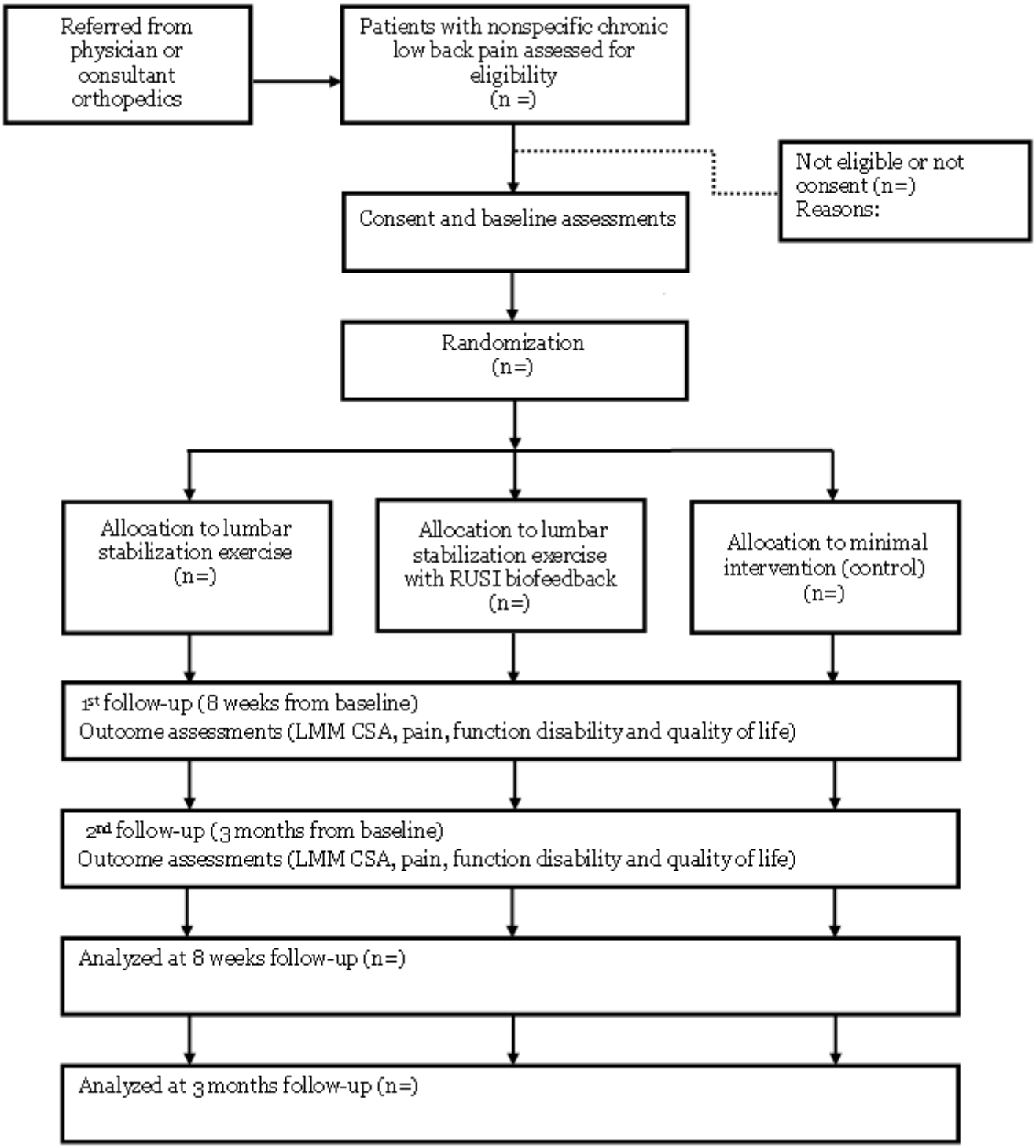

Figure 1

Flow of participants through the study

Supplementary Files

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- SPIRITChecklistAppendix1.docx