



Study Protocol

Effects of motor control exercise and patient education program in the management of chronic low back pain among community-dwelling adults in rural Nigeria: a study protocol for a randomized clinical trial

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ABSTRACT

Background: The impact of chronic low back pain (CLBP) is disproportionately higher in rural Nigeria than in urban areas but lack access to rehabilitation. While exercise and education are commonly advocated interventions for the rehabilitation of CLBP, there is a paucity of community-based randomized clinical trials assessing their benefits among adults with CLBP in rural Nigeria. The purpose of this study is to investigate the effects of motor control exercise (MCE) and patient education (PE) in the management of CLBP among community-dwelling adults in rural Nigeria.

Methods: This is an assessor-blind, three-arm parallel randomized clinical trial and will be conducted at Tsakuwa Primary Health Care Center in Kano, Northwestern Nigeria. One hundred and twenty adults with CLBP will be recruited and randomized to one of three intervention arms; MCE plus PE, MCE, or PE groups. The MCE will be administered twice a week for 8 weeks while the PE will be provided once a week for 8 weeks. Participants will be assessed pre-intervention, immediately post-intervention and at 3-month post-intervention. Primary outcomes will be pain intensity and functional disability. Secondary outcomes will be quality of life, fear-avoidance beliefs, pain catastrophizing, back beliefs, global perceived recovery, and physical performance.

Discussion: This will be the first community-based trial to assess the benefits of exercise and education in the management of CLBP among adults in rural Nigeria. The study may provide a relatively inexpensive, assessable, and effective alternative intervention for reducing CLBP disability in a low-resource rural Nigerian community.

Trial registration: This study is registered at ClinicalTrial.gov and the trial registration number is NCT03393104.

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1. Background

Low back pain (LBP) is one of the most prevalent musculoskeletal conditions that affects people of all ages, from children to the elderly.^{1,2} It is now recognized, among all health conditions, as the number one cause of years lived with disability globally.³ The burden is substantial and likely to increase exponentially in the coming decades due to the expanding and aging population.³ The impact, however, is of concern particularly in low-income and middle-income nations like those in the Sub-Saharan Africa, where most

people are living in rural areas with limited health care resources to address the problem besides other priorities such as infectious diseases.^{4–6}

The one-year prevalence of LBP (57%) among Africans⁷ is much higher than the global annual LBP prevalence (39%).² The prevalence rate of 33–74% reported for Nigerians⁸ is higher than the 14–51% reported for other African nations⁹ and also among the Western nations (20–56%).¹⁰ Moreover, the one-year prevalence rate ranging between 40% and 74%^{11,12} in rural Nigeria is considerably greater than the range 38–44% reported for urban areas.^{13,14} This suggest that rural Nigerians are likely to suffer the burden more than their urban counterparts. In addition to the foregoing, a number of biomechanical factors such as heavy physical work, heavy manual lifting, sustained posture, and prolonged trunk flexion (mainly due to peasant farming)^{11,12,15} as well as psychosocial

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factors such as fear-avoidance beliefs, catastrophizing, anxiety, and illness perception^{16,17} have been reported to be implicated in the etiology of LBP among rural Nigerians. Furthermore, it has been found in a qualitative study¹⁸ that cultural/spiritual beliefs facilitate maladaptive coping strategies resulting in adverse impact of chronic low back pain (CLBP) in rural Nigeria. This implies that biomedical and psychosocial factors are both important and should be considered when addressing CLBP-related disability in this context.

The higher burden of LBP in Nigeria may be partly explained for the less priority given to non-communicable diseases besides the fragile health care system to adequately deal with management. Even though rehabilitation outfits like physiotherapy appears to be available in most parts of the country, they are generally confined to tertiary and secondary health facilities in urban areas. Physiotherapy services thus are lacking in the rural primary health care facilities.¹⁹ The lack of access to this health care constitutes a major barrier to obtaining rehabilitation and contributes to rural–urban inequality. Additionally, factors such as unaffordability, poor knowledge of the roles and scope of physiotherapy, poor healthcare-seeking behavior and referral practices by community health workers adds to the challenges faced by rural Nigerians in obtaining rehabilitation.²⁰ Consequently, the management of back pain in this context is predominantly drug-based biomedical approach through patronizing unconventional practitioners such as herbalists or patent medicine sellers (chemists) as these are the only available and affordable services.^{18,21,22} The deprivation of effective health care in addition to the low socioeconomic status may thus deepen disability and increase the impact of living with LBP.^{18,19,22}

Though most episodes of acute LBP are self-limiting,²³ pain is typically ongoing and reoccurrences are common,²⁴ with about 40% of individuals developing CLBP,²⁵ which lasts for 12 weeks or more. CLBP is an important public health issue and has an estimated prevalence ranging from 3.9–23.3% in individuals aged 18 and above.²⁶ The prognosis of CLBP with persistent symptoms is uncertain and sufferers may continue to experience pain in addition to the functional limitation which can lead to long-term disability and reduce quality of life.^{27,28} In spite of the availability of many therapies for CLBP, its management remains challenging and the efficacy of most interventions are small to modest and generally of short-term.^{29,30} This is perhaps due to the fact that in majority of individuals it is not possible to identify a specific nociceptive cause, commonly referred to as non-specific LBP.^{31,32}

Among the variety of techniques used by physiotherapists to manage CLBP, exercise therapy remains the cheapest and most commonly advocated approach.³³ Despite the existence of many forms of exercise and the lack of consensus on the most optimal technique, motor control exercise (MCE), also known as specific spinal stabilization exercise is the most popular form of exercise used to manage CLBP. The popularity of this exercise may be mainly due to the specific biological rationale for its mechanism of action³⁴ besides its promising evidence for beneficial effects on pain and disability as summarized by many systematic reviews.^{35–37} The exercise was developed based on the evidence that individuals with LBP tend to have impairments in the control of the deep (e.g. transversus abdominis and multifidus) and superficial trunk muscles responsible for maintaining the coordination and stability of the spine.^{38–40} MCE is thus applied to optimize control of the spine by rehabilitating the posture, movement and the coordination of the trunk muscles,⁴¹ which in turn may lead to a reduction in pain and symptoms associated with LBP.⁴²

Given that psychological factors have an influence on both the experience of pain and treatment outcomes,⁴³ it is important that such factors are addressed concomitantly with patho-anatomical

impairments. One important approach that can be used to modify the beliefs and behaviors of patients in order to improve their health outcomes is education or advice.⁴⁴ Patient education (PE) has been a traditional intervention given for patients with LBP.⁴⁵ Although biomedical-based education (back school) is widely used in the management of CLBP, such form of education has limited efficacy,⁴⁶ and may adversely affect outcomes for LBP.⁴⁷ On the other hand, psychosocial- or cognitive-based PE interventions with emphasis on self-management strategies have been recommended for patients with CLBP.^{48–51} However, it has been suggested that such educational programs should be combined with exercise programs for effective management of CLBP.⁵²

In view of the contemporary understanding that CLBP is a multifactorial disorder associated with both biophysical and psychosocial factors, it is essential to design a simple, inexpensive, and effective interventions acknowledging this understanding for individuals with CLBP particularly those in underprivileged communities where rehabilitation services might not exist.⁵³ Of note, there is a paucity of community-based research studies especially in the way of randomized clinical trials accessing the benefits of exercise and education for adults with CLBP in rural Nigeria even so they are often reported to have high levels of disability.^{16,18,19,54} Our pilot study⁵⁵ demonstrated the feasibility of recruiting adults with CLBP from a rural community in Nigeria for a trial of MCE and PE program. Patients were randomly allocated into MCE group, PE group or their combination. Even though all the groups exhibited significant improvement in pain and disability outcomes with better results being demonstrated in the combined group, the study is underpowered and evaluated the effects only in the short term. The results of the trial thus warrant further testing in a full scale, powered randomized clinical trial to confirm the effectiveness of such interventions.

The aim of this study is to investigate the effects of MCE and PE in the management of CLBP among community-dwelling adults in a rural Nigerian community. The primary outcomes will be pain and functional disability. The secondary outcomes will be quality of life, fear-avoidance beliefs, pain catastrophizing, back beliefs, global perceived recovery, and physical performance. We hypothesized that patients randomized to MCE plus PE will have better improvements in all outcomes compared to those receiving MCE or PE only.

2. Methods

2.1. Study design

This study will be a prospective study, single (assessor) blind, three arm parallel, randomized clinical trial. The protocol for this trial is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Checklist (Appendix 1).

2.2. Study setting

This study will take place at Tsakuwa Primary Health Care Centre, Tsakuwa village of Dawakin-Kudu Local Government Area, Kano State, Northwestern Nigeria. The center is the only health care facility for the people of Tsakuwa village as well as many neighboring small villages including Dosan, Fansallah, Kantsi, Tsinkakawa, Muras, Santolo, and Yan-dadi. People of this area are predominantly Hausa by tribe and majority are peasant farmers.

2.3. Ethical consideration

This study was approved by the Health Research Ethics Committee, Ministry of Health, Kano State, Nigeria (Ref:

MOH/Off/797/T.I./632). The trial was registered at ClinicalTrials.gov (NCT03393104) on 6 December 2017.

2.4. Eligibility criteria

Participants with CLBP will be recruited into the study via village-wide announcement, facilitated by village/ward heads (traditional rulers) and adverts via local posters with contact of the research coordinator pasted at the research site and at different locations in the community. Multiple village-wide announcement will be considered until the target sample size is achieved. They will be eligible if they meet the study criteria as shown in Table 1.

2.5. Recruitment procedure and consent

Potential participants willing to participate in the study will be invited to the health care center by the study coordinators. To ensure eligibility of the participants, screening to rule out red flags and specific causes of back pain will be conducted according to recommendations by evidence-based guidelines for the management of CLBP.^{26,56} Participants meeting the eligibility criteria and who accept to participate will be given oral and written information about the procedures and potential risks of the study. They will also be informed about their rights and the freedom to withdraw from the study at any time without prejudice. For treatment adherence, the importance of attending all treatment sessions will be stressed. Informed consent will be obtained via signature or thumbprint. Participants' baseline socio-demographic information (age, gender, marital status, education level, and employment status) and clinical characteristics (e.g. duration of pain, body mass index, smoking status, and analgesic consumption) will be collected prior to group allocation. The participants will be identified only by their initials and numbers on the research notes.

2.6. Physiotherapists/Research assistants

Three physiotherapists including the principal investigator with more than 3 years of clinical experience in musculoskeletal physiotherapy will be responsible for patient scheduling, screening as well as treatment. One licensed physiotherapist and two community health workers (CHWs) will be responsible for the outcome (baseline and follow-up) assessments. All physiotherapists and CHWs will receive a training session and written instructions for the study protocols.

2.7. Randomization and allocation concealment

After baseline assessment, eligible participants will be randomly allocated to one of three intervention arms; MCE plus PE, MCE, or PE groups in the ratio of 1:1:1. The randomization will be performed using a computer-generated randomization table with a block size of 6. Allocation of participants will be concealed by using consecutive numbered, sealed and opaque envelopes. An independent statistician will perform the randomization.

2.8. Blinding

In this trial, outcome assessors and data analyst will be blinded to treatment allocation of participants. However, due to the nature of the intervention, it is difficult to blind the treating therapists to treatment allocation. Unblinding conditions is only permissible in case of medical emergency.

2.9. Sample size estimations

Considering a minimum clinical important difference (MCID) of 2.0 and 10 points for the numerical pain rating scale (NPRS) and Oswestry Disability Index (ODI) respectively,⁵⁷ between the baseline assessment and the values at 8 weeks after the intervention, a priori sample size estimation was done to detect 1.0 and 1.5 points minimum difference between groups (i.e. between MCE plus PE and MCE or PE groups) on the NPRS and ODI respectively, assuming a standard deviation of 1.3 and 9.0, respectively (based on pilot data),⁵⁵ an alpha of 5%, a statistical power of 90%, a two-tailed *t*-test, and a possible attrition (drop-outs) of 40%. Based on these assumptions, a total of 120 participants (40 per group) will be required. Calculations were done with the G-power 3.1.9.2 software (University of Dusseldorf, Dusseldorf, Germany).⁵⁸

2.10. Interventions

The study interventions will be similar to that described in our pilot study.⁵⁵ The interventions will start immediately after previous assessments, and randomizations. Common interventions for the three groups will be stretching and aerobic exercises. Participants in the MCE plus PE group will receive a cognitive-based education followed by stretching exercise, MCE and aerobic exercise. Participants in the MCE group will only receive exercise program as described for the MCE plus PE group. For the PE group, participants will receive cognitive-based education program followed by stretching and aerobic exercises as described for other groups. The addition of stretching and aerobic exercise to this group is to enable the participants to learn and integrate simple exercises into the self-management program which will be taught to them. We felt that given education alone to this group might be inadequate to address the complexity of CLBP. All exercises except for the aerobics will be provided and taught under the supervision of the treating physiotherapists. The MCE will be administered twice per week for 8 weeks (16 sessions) while the PE will be administered once a week for 8 weeks (8 sessions). The MCE plus PE group will last for approximately 2.1 hours, the MCE for approximately 50 minutes while the PE group for approximately 1.2 hours. To avoid cross-contamination between groups, participants will be treated on alternate days. All participants will be instructed to perform their exercises consistent with their group treatment at least twice per day at home. They will also be encouraged to continue with the exercises at the end of the interventions so as to promote self-management. This will be facilitated through phone contact or village wide-announcement on a regular basis.

2.10.1. Patient education (PE)

The PE program described in this study will be similar to that described in our pilot study,⁵⁵ but with slight modification in terms of the sessions. It will be provided by the principal investigator (AAI). The program was designed to provide information and advice on LBP and self-management, based on the biopsychosocial model, which is also in line with the recommendation by most international clinical practice guidelines for LBP.³³ The main goals of the program are to provide non-threatening information to enable better understanding of pain; modify any unhelpful beliefs about LBP, encourage active coping and safe pacing, integrate self-management strategies, promote positive attitudes, and healthy behaviors.⁵⁵ The following main topics will be discussed during the sessions of the program: (1) meaning of LBP, (2) common facts about LBP, (3) beliefs about LBP, (4) robustness of the spine, (5) pain causation, (6) basics of pain physiology, (7) staying active and early return to normal activities, (8) coping and pacing

Table 1
Participant's Eligibility Criteria

	Inclusion criteria	Rationale
1	Both male and female	No gender bias
2	Age between 18 and 70 years	Chronic low back pain (CLBP) in children below 18 years results from different cause. To have wider inclusion of participants as many older adults are living in rural areas
3	Patients with current LBP experienced at least over the previous 3 month	Specifically CLBP condition
4	Mean LBP intensity for the previous week at least ≥ 3 on a 0–10 numeric pain rating scale (NPRS)	Pain severe enough to detect improvement and prevent against floor effects
	Exclusion criteria	Rationale
1	Disk herniation, lumbar stenosis, spondylolisthesis, and spinal fractures	LBP due to, or possibly the result of, specific disease/condition(s)
2.	Polyneuropathies, infections, tumors of the spine, systemic bone or joint disorders (e.g. rheumatoid, arthritis)	
3	Obvious spinal deformity as the primary indication for surgery or post-surgical patients	
4	Anatomically short leg or limb length discrepancy of >1 cm	These conditions causes postural instability
5	Any history of hip, knee, and ankle surgery within last 1 year or obvious lower limb injury in the last 6 month	and specific LBP other than CLBP
6	Inadequate visual and hearing ability	
7	Current pregnancy	
8	Unstable or severe disabling chronic cardiovascular and pulmonary diseases	Comorbid condition(s) pose inappropriate risk to safety or preclude compliance with interventions
9	History of serious psychological or psychiatric illness	
10	Significant participation in exercise, currently and or in the previous 6 months	Possible bias due to current or recent intervention users
11	Body mass index ≥ 35 kg/cm ²	May affect results
12	Lack of consent and not willing to be randomized	Research policy

Table 2
Patient Education Program

Week	Topic/focus	Goal	Activity/key message delivered
Week 1	Interactive session/discussions/questions	To establish a rapport with participants To set treatment goals. To explore participants beliefs about low back pain (LBP)	Treatment rationale and expected goals. Accept that you have persistent pain and begin to move on. Importance of realistic goals setting or action plans. Participants will be allowed to tell their story/experience about LBP. Unhelpful beliefs or information obtained in this step will be addressed in the subsequent steps.
Week 1	Meaning of LBP	To promote understanding of the meaning of LBP	Definition of LBP, non-specific LBP vs. specific LBP, acute vs. chronic LBP (CLBP), and persistent LBP. Brief epidemiology of LBP with a focus on Nigeria.
Week 2	Common facts about LBP	To promote understanding of the common facts/myth about LBP	LBP is common, not serious due to any disease, settle eventually, reoccurrence is common but still does not mean it is serious. Extended bed rest does not help and may actually prolong pain and leads to more disability.
Week 2	Common beliefs about LBP	To reshape false or unhelpful beliefs about LBP	Beliefs of having a serious injury, fear of movement due to pain or damage, beliefs about work or physical activity and pain are linked, excessive attention on pain, total bed rest or inactivity can reduce pain, LBP and infertility or impotence are linked, and medications are the only treatment for LBP will be addressed as unhelpful. Other beliefs learned from participants that are unrelated to LBP will be also addressed as false. False beliefs about pain can prolong pain experience. Avoiding movement and or activity due to fear of pain has negative consequences and can lead to pain persistence and loss of function. Total bed rest leads to stiff joints, weak muscles and bones, and decline physical fitness. Pain medications have doubtful effects and adverse effects on the long-term. Unresearched herbal preparations may pose some undesirable health effects.
Week 3	Basic anatomy	To promote understanding of the back (spine) as one of the strongest structure in the body	The spine is made of solid bony blocks joined by discs to give it strength and flexibility. It is reinforced by strong ligaments and surrounded by large and powerful muscles which protect it. Due to the inherent strength of the spine, it is surprisingly hard to damage it.
Week 3	Pain causation	To promote better understanding about the cause of pain	Feeling pain does not necessarily mean tissue injury or damage as pain and picture diagnostics (e.g. X-ray) correlates poorly. Scans are more useful for specific LBP such as fractures. In most people, it is difficult to pinpoint the exact source of the problem. Though it is frustrating, it is good news in another way you do not have any serious injury or damage in your spine. Simple back strain does not result in any permanent damage. Permanent serious back injuries are usually caused by high-energy trauma. Most people with LBP do not have any damage in their spine. Many people have disk bulge or degeneration but have no symptoms. Presence of such changes may not be a predictive of future pain. Even though some people with back pain have slipped disk, it usually gets better by its self and very few cases ever require surgery.
Week 4	Basics of pain	To promote basic knowledge about pain mechanism and common factors influencing it	Meaning of pain. Basic noiceptive pathways: noiceptors, spinal cord, and brain. Why do we get pain?: pain as an alarm (warning), meant to protect and motivate to create an action. Pain gate: gate that controls flow of signals (pain messages) between the body and the brain. The gate opens and closes, which defends on many factors related to our beliefs, behavior, experiences, and expectations. Examples of factors that open the gate include all the false beliefs mentioned previously. In addition, believing that hurt means harm, catastrophic thought, depression, anxiety, stress, tension, sadness, and anger. These factors also play a key role in pain chronification. Examples of factors that close the gate include happiness/laughter, distraction from pain with physical activity, exercises/stretching, relaxations/calm, massage and some medications. Since it is the brain that makes us feel pain, knowing the things that cause us feel can help us reduce pain. Since we know what influences our pain, we can understand that pain is not necessarily due to injury or damage in the spine. It can be therefore felt with no changes to the body structure.

Table 2 (Continued)

Week	Topic/focus	Goal	Activity/key message delivered
Week 5	Return to normal activities and stay active	To encourage the importance of early return to normal activities and staying active despite in pain	<p>Make an early return to normal or vocational activities as tolerated without thinking that activities such as bending are harmful.</p> <p>Since the muscles, ligaments or joints of the spine helps you get moving and most pain are felt from these structures, when you stop moving, these structures stops working properly. To get your back working properly, you must move.</p> <p>It is safe to stay active and the sooner you get active, the sooner your back will feel better.</p> <p>Avoid unaccustomed or extended bed rest when there seems to be serious pain or overdo activities when there seems to be less pain. This is crucial in dealing with an acute attack, getting better faster, and preventing more back trouble.</p> <p>Physical activity even with pain is unlikely to further damage back.</p>
Week 5	Pain coping and pacing	To promote better active coping through adopting safe and effective pacing during flare-ups	<p>Identify the likely contributing factors to your pain exacerbations or amelioration.</p> <p>Safe pacing involves basing your activity level on pre-set, reasonable goals. Alternating activity with rest, slowing down when performing tasks especially during flare-ups, is essential. Plan your activity and engage in a variety of meaningful physical activities despite being in pain. Do not let your back take over your life.</p> <p>Performance of more natural spinal movements in less pain is essential to good pacing.</p> <p>Pacing for common activities like peasant farming will be discussed.</p>
Week 6	Self-management	To promote active self-management strategies at home	<p>Effective self-care strategies are important in coping with pain and enhancing recovery. Self-care options including the use of common pain relievers (only prescribed by the physician), heat and cold packs, massage (with topical pain creams), stretching exercises, and relaxation techniques (e.g. listening to music, dancing, watching comedy, attending social events, relaxation) will be advised/taught.</p> <p>Do not rely on single treatment; a combination of approaches will likely have the greatest benefit.</p>
Week 6	Postural hygiene	To promote healthy postural habit at home or at work as means of reducing the risk of temporary pain episodes	<p>Postural modification is important to reduce muscle tension and risk of temporary pain episodes from physical overload or prolonged static activities.</p> <p>Postural modifications for common daily tasks/activities involving standing, sitting, bending, and lifting postures will be taught as a means of reducing back muscle tension to ease pain.</p> <p>Special considerations will be given to some common practices such as peasant farming, water fetching, manual lifting. For example, the use of modifiable farming tools and other means of carrying goods will be advised.</p>
Week 7	Increasing activity level	To promote the importance of increasing activity levels	<p>Increase physical activity levels gradually without flaring up your pain symptoms. Choosing the right physical activity is essential.</p> <p>Moderate physical activities (based on the [ACSM's] position statement) may include brisk walks, bicycling, vacuuming, washing clothe and swimming.</p> <p>Schedule your day and exercise regularly. You can try walking or bicycling instead of going by bus or motor cycle.</p> <p>Regular activity develops muscles, gives stronger bones, release natural chemicals that reduce pain, promote fitness and sense of well-being.</p>
Week 7	Lifestyle modification	To promote a healthy lifestyle	<p>Monitor your own functional progress and do more each day.</p> <p>Physical inactivity, sedentary lifestyle, overweight, smoking, sleeping less, physical and mental stress can all have a negative direct and indirect impact on your back and overall health.</p> <p>Adopt a healthy lifestyle and always check your health. Have adequate sleep (at least 7 h), remain physically active, quit smoking, avoids physical and mental stress, and eats healthy food (balanced diet). Also, maintain good social participation.</p>
Week 8	Warning signs of LBP and what to do	Promote understanding of the warning signs (red flags) of LBP and the importance of hospital visit	<p>In case of signs such as weight loss, night sweating like legs weakness, sensory disturbances (pins and needles) around the buttocks, anus, genital area or inner surfaces of the thighs and difficulty in passing or controlling urine/bowel, consult a physician immediately.</p> <p>These symptoms, however, are rare and do not let them worry you.</p>
Week 8	Review of discussions and applications	To reinforce understanding and application of information	<p>Previous concepts learned will be reviewed. Areas of doubt or requiring additional explanations will be further discussed.</p>

Table 3
Motor Control Exercise Protocol

Stage/progression	Exercise	Intensity
Stage one (1 st to 4 th sessions, week 1–2)	1. ADIM in supine	7 s hold, 10 reps
	2. ADIM in quadruped	✓
	3. ADIM in sitting	✓
	4. ADIM in standing	✓
Stage two (5 th to 12 th sessions, week 3–6)	5. ADIM in supine with leg lift (each leg)	✓
	6. ADIM in supine with bridging (two legs)	7 s hold, 10 reps
	7. ADIM in supine with single-leg bridge	✓
	8. Supine ADIM with curl-up (elbows on the table)	✓
	9. Supine ADIM with curl-up (hands over the forehead)	✓
	10. ADIM in horizontal side support with knees bent	✓
	11. ADIM in horizontal side support with knees straight	✓
	12. Side-lying horizontal side support with ADIM	✓
	13. ADIM in quadruped with arm raise	✓
	14. ADIM in quadruped with leg raise	✓
	15. ADIM in quadruped with alternate arm and leg raise	✓
Stage three (13 th to 16 th sessions, week 6–8)	16. Rolling from side to side with ADIM	✓
	17. Sit-stand transfer with ADIM	10 reps
	18. Wall squatting with ADIM	5 s hold, 10 reps
	19. Walking with ADIM (10 min)	7 s hold, 10 reps

ADIM, abdominal drawing-in maneuver.

strategies, (7) self-management strategies, (8) postural modifications, (9) lifestyle modifications, and (10) warning signs/red flags of LBP. The educational sessions will be provided in groups of 5–7 patients, and will begin with 15–20 minutes of interactive discussions and questions and followed by a 1-hour lecture. Visual aids such as slides or prepared diagrams will be used where necessary to aid descriptions. Also, simple cultural metaphors will be used to reinforce some information. Descriptions will be provided as simple and clear as possible using simple language considering the low literacy level as well as the culture of the participants. The English version of the program was translated into Hausa (the native language of the patients) using a forward–backward translation procedure.⁵⁹ A detailed description of the PE program is provided in Table 2.

2.10.2. Motor control exercise (MCE)

The treatment approach will be similar to that described in our pilot study⁵⁵ but here it will be delivered in groups of 5–7 participants as the number of participants will be larger in this study compared to the pilot study. The MCE was designed to improve the function of specific muscles of the lumbopelvic region and the control of posture and movement,⁶⁰ using principles of motor learning such as segmentation and simplification.⁴¹ At the beginning of the program, the participants will be educated briefly on the anatomical location and function of the targeted trunk muscles. The exercise will be performed at three stages. The first stage (1st to 4th sessions) will focus on low load, isometric contraction of the deep stability muscles (e.g., lumbar multifidus, transversus abdominis) through performing an abdominal drawing-in maneuver (ADIM) in minimally loading positions (supine lying, quadruped, sitting, and standing). The second stage (5th to 12th sessions) will involve additional loads on the spine through various upper and lower extremities and trunk movement patterns with the aim of recruiting a variety of trunk (deep and superficial) muscles. In the third stage (13th to 16th sessions), functional movement patterns will be incorporated while performing an ADIM and maintaining a neutral lumbar spine. In each stage, the recruitment of the trunk muscles, posture, movement pattern, and breathing will be assessed and corrected. The MCE program will last for 30 minutes/session. Summary description of the exercise protocol is presented in Table 3.

2.10.3. Stretching exercise

The stretching protocol is aimed at targeting muscles and connective tissue around the lumbo-pelvic-hip region and leg to decrease stiffness and increase flexibility, which are essential in CLBP.⁵⁵ It will include double knee to chest stretch, piriformis stretch, erector spinae stretch, hamstring stretch, hip adductor stretch, triceps surae stretch, prone on elbow, trunk rotation, and trunk extension stretch. The exercises will last for 20 minutes/session. See Ibrahim et al⁵⁵ for detail description of the stretching protocol.

2.10.4. Aerobic exercise

Similar to that described in our pilot trial,⁵⁵ aerobic exercise in the form of continuous overground walking at desirable speed for a minimum of 30-minutes, 5 times/week will be advised to the participants to perform at home.

2.11. Outcomes assessment

The primary outcomes will be pain and functional disability. These outcomes will be assessed pre-intervention, immediately post-intervention and at 3-month post-intervention. The secondary outcomes will be quality of life, psychological outcomes, global perceived recovery, and physical performance. These outcomes will be assessed pre-intervention and immediately post-intervention except for the quality of life and global perceived recovery which will be also assessed at 3-month post-intervention. Prior to the commencement of the study, all self-reported measures that are not available in Hausa (the native language of the target population) were cross-culturally adapted into Hausa using established guidelines,⁵⁸ and psychometrically tested in terms of reliability and validity to ensure they retained equivalence with the original English measures. Because of the expected low literacy rates among the participants, measures will be interviewer-administered except for physical performance tests, which will be objectively evaluated. However, participants who are literate in Hausa (ability to read and write) will be allowed to respond to the measures using self-administration method.

The outcomes assessors (one physiotherapist and two CHWs) will receive training on the interviewer-administration method prior to the commencement of the study so as to minimize bias to patient responses. This is similar to what was done in previous

Table 4
Summary of the Outcome Assessment in the Study

Measures	Baseline	8 weeks	3 months
Baseline information			
Age	✓		
Gender	✓		
Height	✓		
Weight	✓		
BMI	✓		
Marital status	✓		
Educational level	✓		
Occupational status	✓		
Duration of symptoms	✓		
Primary outcomes			
Perceived pain (NPRS)	✓		✓
Perceived disability (ODI)	✓		✓
Secondary outcomes			
Quality of life (SF-12)	✓	✓	✓
Fear-avoidance beliefs (FABQ)	✓	✓	
Pain catastrophizing (PCS)	✓	✓	
Back beliefs (BBQ)	✓	✓	
Global perceived recovery (GPES)	✓	✓	✓
Finger–floor–distance test (FFD)	✓	✓	
Repeated sit–stand test (STS)	✓	✓	
50-foot walk test (50 FWT)	✓	✓	

BMI, body mass index; NPRS, Numeric Pain Rating Scale; ODI, Oswestry Disability Index; FABQ, Fear Avoidance Beliefs Questionnaire; PCS, Pain Catastrophizing Scale; GPES, Global Perceived Effect Scale.

researches in another rural Nigerian setting.^{16,61} During the follow-up period, the principal investigator will keep in touch from time to time with the participants through phone calls so that they are reminded of their follow-ups. Participants will also be advised to record their frequency of pain medication use. Table 4 provides a summary of all the outcome measures to be assessed.

2.11.1. Pain

Pain intensity will be rated by the participants using the numeric pain rating scale (NPRS; 0–10 cm), with 0 representing no pain and 10 worst imaginable pain.⁶² This scale is chosen because it is easy to use and has minimal language translation difficulties when used across cultures and language.⁶³

2.11.2. Disability

Self-reported disability will be evaluated by the Oswestry Disability Index (ODI; 0–100%), with higher scores indicating higher levels of disability.⁶⁴ The index assess LBP and the difficulty it has caused in nine different areas of everyday life (personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling).⁶⁴

2.11.3. Quality of life

Participants' quality of life, using the short-form health survey (SF-12)⁶⁵ will be evaluated. The questionnaire evaluates two global health constructs: the physical and mental component summary scales (PCS and MCS). The PCS assesses four subdomains of physical functioning, role-physical, bodily pain, and general health while the MCS assess the four subdomains of vitality, social functioning, role-emotional, and mental health. The scale scores are calculated by summing responses across scale items and then transforming these raw scores to a 0–100 scale, with 100 indicating the highest level of health.⁶⁵

2.11.4. Fear-avoidance beliefs

Fear-avoidance beliefs will be evaluated with the Hausa version of the Fear-Avoidance Beliefs Questionnaire FABQ.⁶⁶ The questionnaire assesses fear-avoidance beliefs about how work (FABQ-W; score range 0–42) and physical activity (FABQ-PA; score range

0–24) affect LBP. The work and physical activity subscale consist of 4-, and 7-item, respectively. Each item is scored with a Likert scale ranging from 0 (completely disagree) to 6 (completely agree). The two subscales can be summed to give a total score (0–66) with higher scores indicating greater fear-avoidance beliefs.

2.11.5. Pain catastrophizing

Pain catastrophizing will be evaluated by the Pain Catastrophizing Scale (PCS).⁶⁷ This consists of 13 items in which each item is rated using a 5-point rating scale ranging from 0 (not at all) to 4 (all the time). Each item is rated according to the respondent's perceived thoughts and feelings while experiencing pain. The total score ranges from 0 to 52 with a higher score indicating more catastrophic thoughts.⁶⁷

2.11.6. Back beliefs

Beliefs about back pain will be evaluated by the Back Beliefs Questionnaire (BBQ).⁶⁸ This tool consists of 14 statements ranking from complete disagreement to complete agreement on a Likert 5-level scale. Nine items (1, 2, 3, 6, 8, 10, 12, 13, and 14) will be used for scoring as the remaining five items are distractors. The score obtained for each item is reversed and summed to give a total score with higher scores reflecting less fear and false beliefs about back pain.⁶⁸

2.11.7. Global perceived recovery

Participants' level of perceived of recovery will be assessed using the Global Perceived Effect Scale (GPES).⁶⁹ This scale compares the onset of symptoms within the last few days. It is an 11-point numerical scale ranging from –5 (vastly worse) to 0 (unchanged) to +5 (completely recovered), with higher scores indicating better recovery. The participants will be asked, "Compared to when this episode first started, how would you describe your back these days?".⁷⁰

2.11.8. Physical performance

Physical performance as additional secondary outcomes will be evaluated using finger–floor distance, repeated sit-to-stand, and 50-foot walk test.

The *Finger–floor distance test (FFD)* measures mobility of both the whole spine and the pelvis in the overall motion of bending forward. The measurement will be carried out with the participants standing erect on a platform 20-cm high bare footed and feet together. The participants will be instructed to bend forward as far as possible while maintaining the knees, arms, and fingers fully extended. The vertical distance between the tip of the middle finger and the platform is measured with a supple tape measure expressed in centimeters.⁷¹

The *repeated sit-to-stand test (STS)* will be assessed using a standard upright chair with no armrests, participants will be required to rise to stand and return to sitting as quickly as possible 5 times. The time taken for the participants to complete the test will be measured using a stopwatch.⁷²

The *50-Foot walk test (50 FWT)* will be assessed by instructing the participants to walk a distance of 25 feet, turned around, and walked back to the starting point, once as fast as they could and once at their preferred speed. The shorter the time taken to complete the sit-to-stand and 50-foot walk tests, the better the performance.⁷²

2.12. Adverse events

The adverse events (AE) of exercise interventions are well known considering their wide application in health care. Participants in all the groups will be informed at enrollment the possibility of experiencing common AE with exercise such as muscle soreness and cramp. They will be informed that these AE are temporary and only last for a couple of days. However, in case of any serious

adverse events (SAE) such as worsening back pain, excessive fatigue, shortness of breath, light-headedness, dizziness, and so on, they will be advised to report to the research coordinators at the primary health care center as soon as possible. All potential serious adverse events (SAE) or outcomes reported will be recorded and discussed by the research team for appropriate action.

2.13. Data management/Integrity

The integrity of the study data will be monitored by regularly scrutinizing data anonymously for errors and omissions. All data will be carefully recorded on paper sheets and electronically at the same time to have a backup copy. All data values will double-checked by assessors prior to analysis.

2.14. Statistical analysis

Data analysis will be performed by a statistician who will be blinded to the intervention and study protocols. All statistical analyses will be performed on IBM SPSS Statistics ver. 23.0 (IBM Co., Armonk, NY, USA) at an alpha level of 0.05. Intention to treat (ITT) analysis will be considered with randomized participants included in the groups in which they were allocated regardless of their adherence with the treatment or subsequent withdrawal from treatment. Descriptive analysis will be used to describe data using mean, standard deviation, median, inter-quartile range and percentage. A normality test for the dependent variables will be checked using the Shapiro-Wilk test. Paired t-test for normally distributed data or Wilcoxon signed-test for non-normally distributed data will be used to detect the effects of intervention within each group for outcomes assessed at two time points. Repeated measures of analysis of variance (ANOVA) followed by Turkey post-hoc test in case of normally distributed data or Friedman's Anova followed by Dunn's test with a Bonferonni correction in case of non-normally distributed data will be used to analyze within group changes in outcomes assessed at the three time points. One-way ANOVA followed by Turkey post-hoc test for normally distributed data or Kruskal Wallis test followed by Dunn's test with Bonferonni correction for non-normally distributed data will be applied for comparison of outcomes between the groups at the 8 weeks and 3 months follow-up.

2.15. Trial status

Recruitment is ongoing and anticipated to be completed by May 2019.

2.16. Dissemination

The study is expected to last approximately 15 months, depending on the recruitment rate. The results of this study will be submitted for publication to an international peer-reviewed journal and will be presented at national or international conferences, irrespective of whether the results are positive, negative or inconclusive with respect to the study hypotheses.

2.17. Potential trial amendments

Any amendment that is necessary will be reported with justifiable reasons to the Health Research Ethics Committee of the Kano State Ministry of Health, updated in the ClinicalTrials.gov, and communicated in the main trial report.

3. Discussion

Adults with CLBP from rural community backgrounds in Nigeria may be disproportionately affected due to lack of access to rehabilitation. To the best of our knowledge, this is the first community randomized clinical trial to evaluate the impact of exercise and education in the management of CLBP in rural Nigeria. The study is aimed at testing a rehabilitation program consisting of MCE and PE on pain and functional disability as primary outcomes, and on quality of life, fear-avoidance beliefs, pain catastrophizing, back beliefs and physical performance as secondary outcomes. A 10-month follow-up will be conducted if the 3-month follow-up results suggest this would be useful.

3.1. Significance of the study

The outcome of this study may (1) provide a better appraisal of the effectiveness of MCE and PE as non-pharmacological treatment options for CLBP which may guide clinical decision, (2) guide rehabilitation professionals especially physiotherapists to provide a relatively inexpensive, assessable and effective alternative intervention for reducing CLBP disability in low-resource settings such as rural Nigeria, (3) have the potential to encourage and promote awareness of non-pharmacological therapies including self-management strategies for CLBP among rural dwellers in Nigeria especially those involved in the study, which may minimize dependency on patronizing unconventional treatments, and (4) to provide a strong foundation and direction for larger multisite studies and implementation of community-based programs for similar population in Nigeria.

Conflict of interest

The authors declare no conflict of interest.

Data availability

Data will be made available on request.

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Supplementary.

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.imr.2019.02.001](https://doi.org/10.1016/j.imr.2019.02.001).

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