Title: Effects of Combined Graded Activity and Motor Control Exercises on selected Biopsychosocial Parameters among Nonspecific Chronic Low Back Pain Patients – A Pilot Study

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Abstract

Background

Low back pain is increasingly recognised as a major health problem in Africa. Individuals with this condition are burdened not only by pain and disability but by an array of psychosocial dysfunctions as unhealthy behaviours, beliefs and reduced quality of life. Non-specific chronic low back pain is multifactorial in nature, and no single intervention is optimal for these patients.

Objectives

To evaluate the logistics, feasibility and minimum sample size of conducting a randomised controlled trial (RCT) on effects of combined graded activity and motor control exercises on selected biopsychosocial parameters among nonspecific chronic low back pain patients. To determine minimal clinically important changes of the selected biopsychosocial parameters.

Methods

The study is a pre-test post-test single-group experimental design. Ten patients with non-specific chronic low back pain were managed twice a week for six-weeks using a combined graded activity with motor control exercise intervention. Primary outcome measured were pain intensity and functional disability measured using the numerical pain rating scale and Oswestry disability index questionnaire. Secondary outcome measured were pain catastrophizing, fear avoidance beliefs, quality of life, and kinesiophobia measured using the pain catastrophic scale, fear avoidance beliefs questionnaire, SF-36 and Tampa scale of kinesiophobia (TSK-11) respectively. All outcomes were assessed at baseline and immediately after six-week intervention. Descriptive statistics of frequencies, percentages, mean and standard deviation was used to describe the participants' sociodemographic variables and the questionnaires. Paired sample t-test was used to determine if significant changes in primary and secondary outcomes were observed.

Results

Feasibility findings show (77%) recruitment rate, (100%) patients' adherence, and retention respectively. Adverse events due to intervention were not reported. Pain intensity, functional disability, pain catastrophizing, quality of life, and kinesiophobia demonstrated statistically significant improvement ($p<0.01$) and clinically relevant changes among the patients. Pain intensity and functional disability show a minimal clinical important change (MCIC); $MCIC_{NPRS}=4.2\pm1.68$ and $MCIC_{ODI}=13.6\pm3.9$ respectively.

Conclusions

Feasibility findings show a high recruitment rate, patients' adherence, and retention respectively. Adverse events due to intervention were not found. Pain intensity, functional disability, pain catastrophizing, quality of life, and kinesiophobia demonstrated statistically significant improvement ($p<0.01$) and clinically relevant changes among the patients. Pain intensity and functional disability show a minimal clinical important change (MCIC); $MCIC_{NPRS}=4.2\pm1.68$ and $MCIC_{ODI}=13.6\pm3.9$ respectively.

Keywords: Graded activity exercises; Motor control exercises; Chronic low back pain; Non-specific; Biopsychosocial factors; Combined graded activity and motor control exercise (CGAMCE)

Introduction

Low back pain (LBP) is defined as pain, muscle tension, or stiffness localised below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica) and described as chronic if it persists more than 12 weeks (Doualla et al. 2019). It is one of the worrisome conditions treated in the world as it affects a wide range of people. According to the Global Burden of Disease (GBD) 2021 study, LBP is currently the fourth highest burden on a list of 371 conditions and is the leading cause of more years lived with disability globally than any other disease (GBD 2021 Low Back Pain Collaborators (2023).

In Africa, LBP is increasingly recognised as a major health problem (Doualla et al. 2019). In a recent update on the prevalence of LBP in Africa, a systematic review and meta-analyses (Morris et al. 2018), with the majority of the studies conducted in Nigeria (47%) and South Africa (25%), and reported a pooled lifetime prevalence of 47%, an annual prevalence of 57%, and a point prevalence of 39% in Africa. This is higher than the monthly prevalence 28.8% reported among American adults in 2013 (US National Centre for Health Statistics 2016). A systematic review on the prevalence of LBP in Nigeria estimated a prevalence ranging from 32.5% to 73.53% with a mean estimate of 55.39% (Bello & Adebayo 2017). The point prevalence of LBP in the review ranged from 14.7% to 59.7% and the lifetime prevalence ranged from 45.5% to 58% in Nigeria (Bello & Adebayo 2017).

For the management of chronic low back pain (cLBP), integrative care plans can achieve better outcomes than monodisciplinary care alone. However, what are the ideal components of integrated or multidisciplinary rehabilitation that can be assumed to be the most effective? The answer to this question is not straightforward, as various combinations have been suggested in the literature, with no single combination proven to be best (Mauck et al., 2022; Guzman et al. 2001). In spite of the growing number of studies evaluating the effectiveness of exercise interventions, most effective forms of exercise interventions for patients with cLBP is yet to be identified (Hayden et al. 2021). Among the wide variety of supervised exercise therapies available, motor control exercises and graded activity under the principles of cognitive behavioural therapy (CBT) are the most popular exercise for patients with cLBP (Magalhães et al. 2018). The primary reason for their popularity is that, unlike some other forms of exercise, each has a specific rationale for its mechanisms of action. The systematic review by May and Johnson (2008) reported that motor control exercises (specific stabilisation exercises) may be beneficial over no treatment, but went on to report that it was unlikely to produce an outcome better than any form of exercise. There has been considerable growth in the evidence base trials with a large number of new trials being published (Macedo et al., 2009; Wang et al., 2012; Byström, Rasmussen-Barr, Grooten 2013; Smith, Littlewood, May 2014; Saragiotto et al., 2016), with three of the systematic reviews performing a meta-analysis Wang et al.,2012; Byström et al., 2013; Smith et al., 2014). Macedo et al. (2009) included studies published up to 2008 and concluded that specific stabilisation exercises were no better than general exercises.

The CBT of the biopsychosocial model has proved effective in the management of cLBP (Vlaeyen et al. 2002). This cognitive behavioural model assumes that disability is determined by not only the underlying pathology, but also by social, cognitive, emotional, and behavioural factors (Vlaeyen et al. 2002). Therefore, to address patients with cLBP appropriately, there is a need for a holistic approach to management as with the use of graded activity exercises. This is to reduce pain and disability by addressing pain related fear, kinesiophobia, and unhelpful beliefs and behaviours about back pain (Macedo et al. 2012) while correcting physical impairments such as reduced endurance, muscle strength, or balance (Leeuw et al. 2008). It has been suggested that graded activity is effective in decreasing pain and functional disability in cLBP (Macedo et al. 2012). Van der Giessen, Speksnijder and Helders (2012), in a systematic review, concluded that there was insufficient evidence on the effects of graded activity on pain, disability and return to work in patients with non-specific cLBP.

In a randomised controlled trial (RCT) comparing the effect of motor control exercises and graded activity, Macedo et al. (2012) suggested that motor control exercises and graded activity have similar effects for patients with cLBP. This suggests that a single intervention focusing on one area of fitness, either biological or psychological or even social for cLBP patients may not be appropriate in addressing the array of outcomes that comes with cLBP. Consequently, this highlights the importance of this study to look at the effect of combining graded activity and motor control exercises as a single treatment regimen among these patients, as past studies and literature support the use of each of these individually but conclude that neither of them is better than the other and not better than other forms of exercises (López-de-Uralde-Villanueva et al. 2016).

Motor control exercises were developed based on the results of laboratory studies which demonstrate that individuals with LBP have impaired control of the deep muscles (e.g. transversus, abdominis and multifidus) and superficial trunk muscles responsible for maintaining the stability of the spine (MacDonald, Moseley & Hodges 2004). These utilise the principles of motor learning to retrain control of the trunk muscles, posture and movement pattern (Tsao & Hodges 2007), ultimately leading to a reduction in the levels of pain and disability. The graded activity exercise, initially developed by Lindstrõm et al. (1992), recommends the use of an individualised and submaximal exercise programme with educational support in addition to ignoring illness behaviours (negative behaviours) and reinforcing wellness behaviours (positive behaviours) towards cLBP in order to increase patients' self-trust and tolerance to effort. It is tailored towards the development of the patients' functional and aerobic abilities with an operant conditioning behavioural approach that aims to reinforce healthy behaviours and reduce pain behaviours by using an exercise quota for increasing general activity levels, which are gradually built up towards a realistic predefined goal. Therefore, the aims of this study were to investigate a six-week combined effect of graded activity and motor control exercises (CGAMCE) on biopsychosocial parameters among patients with non-specific cLBP.

To the best of our knowledge, we did not find in Nigeria any previous study conducted on the combined effect of graded activity and motor control exercises in the literature. Thus, we hypothesise that a combined intervention more rooted in increased motor control, coordination and strength of the abdominal and trunk muscles together with an intervention rooted in aerobic exercises and CBT will result in significant changes in pain and functional disability as well as fear avoidance belief, kinesiophobia, pain catastrophizing and quality of life (QoL) of cLBP patients. This pilot study also aimed at determining the study logistics and feasibility as well as a guide for determining the sample size for a much larger RCT.

Materials and methods

Ethical considerations

Ethical approval was sought and obtained from the Health Research Ethics Committee Kano, Nigeria Ministry of Health (Ref: MOH/ Off/797/T.I/516) and the trial was registered at the Pan African Clinical Trial Registry (PACTR201711002675342) prior to the commencement of the study. The protocol of the study was explained to all the participants and their written informed consent was sought and obtained prior to their participation in the study.

Study design

The study is a single-group pre-test post-test experimental design conducted from February 2018 to April 2018. A total of 10 participants were enrolled. The study evaluated the efficacy of individualised treatment of two combined protocols. The intervention is discussed in detail below.

The primary null hypothesis was there would be no significant changes in pain intensity and functional disability before and after six weeks of combined graded activity and motor control exercises (CGAMCE) among participants with cLBP. The secondary null hypothesis was that there would be no significant changes in biopsychosocial factors (fear avoidance beliefs, kinesiophobia, pain catastrophizing, and QoL) before and after six weeks of CGAMCE among participants with cLBP.

Study population

Participants in this study were male and female patients with non-specific cLBP attending the outpatient physiotherapy clinic of Murtala Muhammad specialist hospital, Kano. The patients recruited were either referred by their treating physicians or presented themselves directly for expert physiotherapy management. The first 10 patients who fulfilled the study criteria and agreed to participate were included.

Screening of patients

At initial visit, patients were screened for inclusion and exclusion criteria before the commencement of the experimental procedure by one of the researchers.

Inclusion criteria

The study inclusion criteria were as follows: male and female participants aged 18–65 years with mechanical non-specific cLBP for at least three months and a medium to high risk level or score on the Start back screening tool (SBST); eligible participants must also have any three of the following features which constitute the clinical prediction rules (Hicks et al, 2005) for improvement with motor control and core stability exercises: Positive prone instability test – The patients lie on the examination table with the trunk, head and arms with the feet on the floor. Posterior-to-anterior pressure (P/A) to the spinous processes of the lumbar spine was applied by the researcher. Any painful provocation was recorded. They were then asked to raise one leg up off the floor and P/A pressure is again applied to the spine. A reduction in pain while the leg is raised is a positive test. Aberrant motion present with trunk forward bending – In standing, the patients bent forward while keeping the knees straight. Total spine flexion was encouraged without emphasis on touching the toes. The patients were encouraged to relax in the fully flexed position for 2–5 seconds. They were then asked to straighten up. A positive test is an instability catch, painful arc of motion, thigh climbing (Gowers' sign) or a reversal of the lumbo-pelvic motion. Positive prone spring test – In prone, P/A pressure was applied to the lumbar spinous processes with the therapist's thenar eminence. Segmental spinal mobility at each level was judged as hypomobile (stiff), normal or hypermobile (lax). Patients were also included if they had a high fear avoidance beliefs (FABQ) score, responded 'No' to all the questions in the physical activity readiness questionnaire (PAR-Q), had a minimum pain intensity score of three on the 11-point numerical pain rating scale (NPRS) and were able to read in either Hausa or English.

Exclusion criteria

The exclusion criteria for the study were as follows: Low risk level on (SBST). LBP of specific origin: spine surgery, neuromusculosketetal disease that could affect exercise performance, uncontrolled hypertension, pregnancy, recent lumbar cortisone injection. Yes to any question on the PAR-Q, under medications known to impair physical effort and limiting the capacity to undergo the evaluation and protocols of interventions that was used in this study.

Sample size estimation

A true sample size calculation was not conducted for this study. Thirteen cLBP patients were consecutively recruited from among non-specific cLBP patients attending the outpatient physiotherapy clinic with ten meeting the inclusion and exclusion criteria. Therefore, a sample size of ten participants was included in the study. A previous study by Sarafadeen et al., (2020) also uses a sample size of 10 chronic low back pain patients in their pilot study.

Study procedure

Sociodemographic characteristics of the participants

Patients' sociodemographic data, including age, gender, height, weight, body mass index (BMI), highest educational qualification, work status, occupation in the last 12 months, reason for not working where applicable, job satisfaction, any medical history (e.g. controlled hypertension, controlled diabetes mellitus), medications being used and three important functional limitations due to cLBP, were recorded on the sociodemographic form. Participants were also asked about whether they were currently receiving professional health services for their cLBP or other conditions (e.g. physiotherapy or medical treatment), location of pain (radiating below knee or localised) and troubling symptoms (LBP or leg pain) in the last past week on a scale of 0–10 (0 being unable to perform activity and 10 able to perform activity at the same level as before injury).

History and physical examination of low back pain

The mode of onset of LBP (when pain started), frequency and duration of symptoms (how long pain lasts), daily pattern, aggravating and relieving factors as well as response to prior treatments where available were all elicited from the participants. Aberrant motions with flexion was also assessed (pain arc, painful arc on return, Gower's sign, instability catch, reverse lumbopelvic rhythm and prone instability test).

Outcome measures

Participants completed questionnaires at baseline and post 6 weeks of intervention. The primary outcomes were pain intensity and functional disability.

Pain intensity was measured using the 11-point NPRS ranging from 0 (no pain) to 10 (worst imaginable pain) (Childs, Piva & Fritz 2005). The NPRS is an acceptable tool with high test-retest reliability observed in both literate and illiterate patients with rheumatoid arthritis (r = 0.96 and r = 0.95) before and after medication (Ferraz et al. 1990).

Functional disability was measured using the Oswestry disability index (ODI; 0% – 100%) (Fairbank & Pynsent 2000). The ODI has been reported to be one of the most frequently used multidimensional, patient reported instruments in research studies examining LBP (Roland & Fairbank 2000). It contains 10 items that assess the extent of pain currently interfering with the patients' ability to perform various functions (e.g.travel, walk, sit) on a six-point Likert scale, increasing from no limitation (0) to complete inability to perform the activity (5). The ODI disability percentage is scored by dividing the total score (summing the highest numbers circled under each item), by the total possible score (50), and multiplying by 100 (Fairbank & Pysent 2000). Higher scores indicate higher percentage of disability. Multiple studies have shown that the ODI is more reliable and responsive than other low back instruments (Vela, Douglas & Denegar 2011). It has also demonstrated an acceptable internal consistency reliability (Cronbach's alpha = 0.76–0.87) and has shown convergent validity with other commonly used disability measures such as the pain disability index and the low back outcome score (Fairbank & Pysent 2000).

Secondary outcomes were QoL, fear-avoidance beliefs, kinesiophobia, pain catastrophizing, and the SBST

Fear-avoidance beliefs was measured with the fear avoidance belief questionnaire (FABQ) (Waddell et al. 1993). The FABQ measures patients' fear of pain and consequent avoidance of physical activity because of their fear (Fritz & George 2002; Waddell et al. 1993). It consists of 16 items, with each item scored from 0 to 6 for a maximum obtainable score of 96. Higher scores on the FABQ are indicative of greater fear and avoidance beliefs (Waddell et al. 1993).

Within the FABQ, two subscales exist: the Work subscale and the Physical Activity subscale. The Physical Activity subscale (FABQ-PA, range: 0 to 24) is the sum of items 2–5 with patients scoring more than 15 (Williamson 2005) considered to have greater fear and avoidance beliefs. The Work subscale (FABQ-W, range: 0 to 42) is the sum of items 6, 7, 9–12 and 15, with patients scoring more than 34 (Fritz & George 2002) considered to have greater fear and 213 avoidance beliefs. The FABQ has demonstrated a good test-retest reliability overall (ICC = 0.97), for the Physical Activity subscale (ICC = 0.72–0.90) and for the FABQ Work subscale (ICC = 0.80–0.91) (Williamson 2005).

Pain-related fear of movement was measured with the Tampa scale for kinesiophobia (TSK 11–44) (Woby et al. 2005). TSK- 11 was used to assess pain-related fear of movement in patients with chronic pain. It is an 11-item questionnaire scored or rated on a four-point Likert scale from 1 (strongly disagree) to 4 (strongly agree). The total possible TSK-11 scores range from 11 to 44 points, with higher scores indicating greater fear of pain, movement, and injury. The TSK-11 has demonstrated a high internal consistency (α = 0.79). It has also demonstrated a good test-retest reliability (ICC = 0.81, SEM = 2.54) (Wober et al. 2005).

Pain catastrophizing was measured with the pain catastrophizing scale (PCS 0–52) (Sullivan, Bishop & Pivik 1995). Pain catastrophizing is an exaggerated negative orientation toward noxious stimuli. The scale consists of 13 items in which each item is rated using a five-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. A score of more than 24 indicates a high level of catastrophizing. The PCS has demonstrated a high internal reliability (Cronbach's α for total PCS = 0.9) and has been reported in patients with chronic pain with adequate validity and test-retest reliability (Sullivan et al. 1995).

Quality of life (QoL): Participants' QoL was measured using the short-form health survey questionnaire (SF-36). The SF-36 has been studied in populations of patients with LBP and its reliability and validity have been well-established (Ware & Sherbourne 1992; McHomey et al. 1992). The SF-36 is subdivided into two separate health constructs: the physical component summary score (PCS) and the mental component summary score (MCS) (Ware et al. 1995). 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 (Ware et al. 1995; McHomey et al. 1993). The standard SF-36 score ranges from 0 to 100; 100 is the best score and 0 is the worst. The Cronbach's α coefficients for each of the eight scales were over 0.70, except the scale for social function with a coefficient of 0.63 (Zhang et al. 2012). For the purpose of this study, only the summary of the physical health (PSC) and mental health component (MCS) was assessed.

The SBST is a screening measure consisting of questions related to physical and psychosocial factors used to categorise patients with LBP in primary care settings, based on risk for poor disability outcomes (low, medium and high risk) (Hill et al. 2008). The tool produces two scores: the overall score and the distress subscale score. The distress subscale score ranges from 0 to 5 with patients scoring 4 or 5 being classified into the high risk subgroup. Scores that range from 0 to 9 are produced by adding all positive items; patients who achieve a score of 0–3 are classified into the low risk subgroup and those with scores of 4–9 into the medium risk subgroup (Hill et al. 2008). Test-retest reliability values have been reported of 0.79 for the SBST overall and 0.76 for the psychosocial scale. Physical activity readiness was measured with the PAR-Q (Shepard 1988). It also offers a safe preliminary screening of candidates for exercise testing and prescription. It consists of seven items used to assess level of physical fitness and ability to engage in physical activity (Shepard 1988). Answering 'yes' to any of the questions excludes patients from the study.

Recruitment rate: The recruitment rate expressed as the percentage of all eligible study participants that consented to participate in the study (Ibrahim et al., 2018).

Retention/dropout rate: This was expressed as the percentage of participants who completed the intervention without loss to follow-up. An acceptable retention rate was set at 50% of the participants completing the interventions (Ibrahim et al., 2018). Dropout rate (loss to follow-up) was expressed as the percentage of participants who were lost during follow-up and it was not possible to collect outcome data.

Adverse events: Adherence was assessed through treatment logs by the researchers. Any adverse events/effects observed during the study were advised at the point of enrolment to be reported to the researcher immediately.

Study protocol

Interventions

Patients in the pilot study carryout both graded activity and motor control exercises (combined) individually for 6 weeks. The duration of treatment intervention was 6 weeks, 2 times per week respectively with treatment session lasting 1 hour 25 minutes. An expert physiotherapist with an extensive experience of more than 10 years assisted the researcher.

Motor Control Exercises

The motor control exercises comprise of warm-up, the main exercises and cool-down. Participants were instructed to wear ordinary clothes or whatever they feel comfortable in during exercises. Participants carried out motor control exercises protocol as described by Sokunbi *et al.,* (2014). It was carried out as described below:

Patient Preparation: Participants were shown how to maintain a neutral spine in prone kneeling and made to combine both the neutral spine and activation of the core back muscles i.e. Participants were informed that maintenance of neutral spine posture is essential for core activation. If spinal posture is slumped, the core abdominal muscles will not work as well. They were then instructed on how to maintain a neutral spine posture by adopting a comfortable chest lifting and spine tall posture while maintaining the normal inward curve of their lower back. They were made to repeat this manoeuvres several times until they are able to repeat it in three consecutive attempts. Participants were then shown the locations of the core-stability muscles in the body and how to activate or contract those muscles. This technique was as described by Sokunbi *et al.,* (2014). Participants were asked to place their hands on the iliac crest on both sides, such that the thumb is pointing posteriorly and the remaining four fingers are pointing anteriorly. They were then instructed to slide the hands downward and inwards by 2 inches after which they were asked to cough and feel a muscle bulging under their fingers. They were informed that this muscle is the Transversus abdominis. They were then instructed to take a deep breath out and feel the point muscles under their fingers will change tension. At this point, they were asked to hold on to the tension for few seconds and then relax. They were encouraged to practice this several times to get use to activating the core muscles of spinal stabilization. Participants were then instructed on how to locate and activate the core lumbar spine stabilization muscles by placing their fingers on the iliac crest on both sides and slide the hands inward and downward by 2 inches. To find the core muscles they were asked to cough and feel the muscles bulging out under their fingers. While maintaining their hands and fingers in this position, they were asked to gently draw in the lower abdominal wall towards the spine until they feel a gentle tension

under their fingers and then hold to a count of ten. The tension should not be too strong or forceful and participants were instructed to breathe normally during all exercises for the core.

Warm-up: The motor control exercises start with warm-up exercises based on McGill *et al.,* (2003) cat-camel exercises for 5 minutes as described: Participants were asked to kneel prone on all four (hands and knees) that is quadruped position. With the back flattened and level, appropriately to maintain the neutral posture of the spine, Participants perform flexion and extension of the spine. This helps to reduce spine viscosity (internal resistance and friction) and floss the nerve roots as they exit at each lumbar level. Participants were instructed to perform the procedure in a motion like exercise and not a stretch or pushing at the end ranges of flexion and extension. Participants were instructed to move all three sections of the spine together. This procedure was performed 5-8 cycles as it can majorly reduce most viscous-frictional stresses

Main Protocol (motor control exercise): The main exercise was carried out in an order of progression from supine lying, side lying positions and then to Quadruped position. Patients must be able to demonstrate the ability to identify, isolate, and activates the contraction of the spinal core muscles (Transversus Abdominis and Multifidus) in supine or side-lying positions before they were allowed to progress into the next phase, starting from stage one before progressing to stages 2, 3 and 4 respectively.

Stage one: Crook lying position: In the first phase, participants were instructed in the activation of the spinal stabilization muscles in a crook lying position, before moving into a pelvic bridging position with two feet support and later progressed with one-foot support this was alternated after 3 sets to the other foot for 3 sets. They were instructed to perform at least 3 sets each of 10 contractions with each contraction lasting 10 seconds.

i. Bridging position: participants were instructed to carry out 3 sets of 10 repetitions of pelvic bridging along with 10 second deep abdominal muscle holds as described above.

ii. Bridging position with limb loading: Same as above with the right lower limb elevated keeping the right hip in neutral position, knee in extension and ankle in neutral position while the left lower extremity will maintain contact with the floor same as during bridging position.

Same procedure was repeated with the left lower extremity, 3 sets of 10 repetitions were carried out with each of the lower extremity.

Stage two: Quadruped position (Bird-Dog): In this phase, the participants were instructed to kneel prone on all fours. In this position, participants were required to maintain a neutral spine and activate the core lumbar spine stabilisation muscles as described above and at the same time, they were required to carry out alternate arm and leg extension while maintaining neutral spine and core muscles activation. This position was maintained for 10 seconds before the participants were asked to reverse the movements, repeat with the opposite leg, and arm. Three sets of 10 contractions were carried out.

Stage three: Sitting, standing, and walking positions: In the third phase patients were then instructed in the activation of the spinal stabilising muscles in sitting and standing positions.

i. Sitting position: participants were instructed to sit on a chair with feet firmly on the floor and both arms resting on the thighs. While maintaining a neutral spine in this position and activating the core lumbar muscles as described above, they were instructed to perform at least three sets of 10 contractions in this position with each contraction lasting for at least 10 seconds.

ii. Standing position: participants were instructed to maintain a neutral spine posture by adopting a comfortable chest lifting and spine tall posture while maintaining the normal inward curve of their lower back in standing. While in this position, they were instructed to activate the core lumbar muscles of stabilization 3 sets of 10 contractions with each contraction lasting for at least 10 seconds.

iii. Sitting to standing and walking position**:** In this phase, patients were instructed to perform the activation of spinal stabilising muscles while rising from siting to standing and taking some few steps of walking. They will be instructed to perform at least 3 sets of 10 contractions in this position with each contraction lasting for at least 10 seconds while performing this activity of sitting to standing and walking at the same time contracting the spinal stabilising muscles.

iv. Walking position: participants were progressed from activation of the core muscles in standing position to activation of the core muscles in walking position. Participants were instructed to perform the described technique while walking and were encouraged to maintain the neutral spine. They were instructed to perform at least 3 sets of 10 contractions in this position with each contraction lasting for at least 10 seconds within a self-chosen distance.

Stage four: Throwing and catching ball in standing position: In this phase, patients were instructed in the activation of spinal stabilising muscles while standing and throwing and catching a football. Three sets of 10 contractions were carried out with each contraction maintained for 10 seconds. Throwing and catching ball in sitting position: In this phase, patients were instructed in the activation of spinal stabilising muscles while sitting on a gymnasium ball and throwing and catching a football. Three sets of 10 contractions were carried out with each contraction maintained for 10 seconds.

Cool-down: Participants performed the cat-camel exercises as described in the warm-up above for the cool down exercises.

Frequency and Duration of Exercise

The researcher and assistants individually supervised the exercise sessions and it lasted for about 25 minutes two times per week for six weeks.

Graded Activity Exercise

The graded activity programme was based on the treatment programme reported by Magalhaes *et al.,* (2013). For the present study, the graded activity program was achieved through the following three protocols: Increased functional activity with behavioural reinforcement, Graded exercises with behavioural reinforcement and Nigerian back school educational handbook.

Functional activity with behavioural reinforcement

i. Participants were asked about two to three functional limitations/ activities they could not perform fully or can partially perform. Examples of such functional limitations include forward flexion (bending), side flexion, back extension, trunk rotation, lifting, walking some distances, squatting etc. activities like sweeping, washing, household chores were also stated as limitations.

ii. Participants were individually encouraged to perform the respective functional activities they found difficult to partake. So as to identify their functional ability or deficits.

iii. Patient's maximum baseline capacity to perform each of the mentioned activities was then established at this stage by the therapist and participant. This was mutually agreed on as the goal of care. E.g., the maximum distance a patient is able to walk before fatigue and back pain aggravation might be 30 meters or the maximum distance a patient is able to sweep is 20 meters, maximum time a patient is able to squat to standing is 5 minutes.

iv. Participants were then instructed to start with 70 to 80% of the already established maximum baseline capacity, with gradual increased activity levels towards the final treatment goals of 100% that is the maximum capacity.

v. Participants were verbally encouraged with appropriate cues and guided to perform those (functional limitations) properly without much abnormal motor/movement control throughout the treatment.

vi. Participants were individually encouraged to perform these respective functional activities following quotas for each visit to increase their activity tolerance towards normal or near normal function.

vii. Each of the mentioned activities were re-assessed and progressed at subsequent visits, by the therapist and participant

viii. Participants were allowed to carry out these activities at their own pace.

xi. They were also instructed only to perform the agreed amount of activity and not to perform less or more, even when they felt capable of doing so.

x. Patients were encouraged by reinforcing them through positive cues to perform these activities whenever they came for treatments and at home.

Frequency and Duration of Exercise

They performed 3 sets of 10 repetitions for each activity they reportedly find difficult to perform with 2 minutes rest in-between sets.

Graded exercises with behavioural reinforcement

The graded exercise with behavioural reinforcement was through aerobic treadmill exercise and lower limbs strengthening/Stretching exercises**.** This was tailored towards the development of the patients' functional and aerobic abilities with an operant-conditioning behavioural reinforcement. The graded exercise was based on the protocol reported by Magalhaes *et al.,* (2013).

Aerobic treadmill training

Participants carried out treadmill exercise according to the following phases: Warm-up, Aerobic exercise and Cool down.

Warm-up

Participants were instructed to perform treadmill exercise for 5 minutes at 2-5km/h.

Aerobic Exercise

i. Warm-up was then followed at initial visit by a continuous treadmill exercise at 50% of maximum heart rate for 10 minutes. This was maintained for the first treatment session.

ii. Subsequently treadmill exercise was carried out by the participants as follows:

In weeks, two and three participants exercised at 55-60% of maximum heart rate for 10 minutes. In weeks 4 and 5, participants exercised at an increased maximum heart rate of 65-70% for 15 minutes. In weeks 6-8, participants exercised at 70%-80% maximum heart rate for 20 minutes.

Cool-down

Cool down: 5 minutes slow-down with gradual speed reduction to stoppage.

Criteria for exercise stopping before the specified time; was breathlessness, dizziness or pain aggravation. Heart rate was calculated using the Karvonen formula (maximum HR=200-AGE) for sedentary individuals: exercise HR=Resting HR+70% to 80% maximum HR (McArdle, 1997).

Frequency and Duration of Treadmill Exercise

Aerobic exercises was carried out two times per week for 6 weeks of the pilot study

Lower limbs strengthening/Stretching exercises

It' has shown that there is relationship especially in muscle coordination, between the muscles that stabilise the lumbar spine and the muscles in the lower extremity (Sakamoto *et al.,* 2009).

Quadriceps isometric exercises in lying: Participants were asked to assume a full supine-lying position on a plinth with the two feet pointing upwards. They were instructed to perform 5 seconds quadriceps contractions by pressing down on a towel roll placed under the knee and squeezing the thigh muscles. 3sets of 10 repetitions for each limb with 30 seconds rest intervals between each set was performed.

Hamstrings stretching in lying: Participants assumed a full supine- lying position on a plinth with the two feet pointing upwards. One of the lower limbs was stabilize manually by the researcher across the thigh and over the anterior superior iliac spine to stabilize the pelvis. The other lower limb was stretched passively into hip flexion up to the limit where participants will feel a gentle stretch at the posterior aspect of the thigh. This places the hamstring muscles at their greatest possible length. This stretch was sustained for 15 seconds (Roberto *et al.,* 2010). Participants were instructed to perform 3sets of 10 repetitions for each limb with 30 seconds rest intervals between set.

Reinforcement during exercises

Positive reinforcement were provided through out these sessions, positive reinforcement such as (‘‘you are doing great’’, ‘‘congratulations’’, ‘‘keep up with the good work’’, you can make it’’, ‘‘well done’’ etc.), were given with the aim of maintaining the motivation and reinforcing behaviour.

Education of patient using the Nigerian back school (NBS)

The educational session lasted for about 15 minutes before the commencement of the physical exercises. Questions were also entertained and answers were given appropriately. The patients' education contains educating and discussion on the following: Simple anatomy of the backbone structure (spine), factors predisposing to back pain and good and bad back postures assumed during activities, stages involved in executing a lift, tips on good (correct) back posture and simple back exercises for the alleviation and/or prevention of back pain.

This was meant to provide the participants with sufficient knowledge about the mechanism of the human spine. These educated participants on the proper handling of their backs and thereby avoiding further pain and damage

Process: Patients in the combined graded activity with motor control exercises were each given a copy of the NBS handbook to go through at home on their first visits of intervention. For those that cannot understand English, they go through the book with their therapist (researcher). On their second visits, participants were educated on the epidemiology of low back pain and a simple description of the spine and its functions were explained to the patients by the researcher. On their third visits, patients were further educated on the causes and types of low back and on bad and good back postures assumed during activities as illustrated in the NBS handbook. On patients, fourth visits they were further educated on the stages of executing a lift and on tips on correct back posture. On their fifth visits, they were educated on some selected back exercises for the alleviation and prevention of low back pain as illustrated on the handbook.

In addition to patient education, patients were also encouraged to adopt a positive pain coping strategy either at home or at work. They should also not desist from functional activity whenever they experience pain or overdo functional activity whenever they have less pain. All experimental procedures were carried out in the gymnasium of Murtala Muhammad specialist hospital.

Post-intervention assessments

After six weeks of treatment, patients were re-assessed for pain intensity, functional disability, fear avoidance beliefs, pain catastrophizing, kinesiophobia and QoL as previously discussed.

Data analysis

Descriptive statistics of frequencies, means, and standard deviations were used to describe the participants' sociodemographic and physical characteristics (body mass index, height, and weight) and summarise the tools for data collection (NPRS, ODI, short-form health survey, SBST, TSK-11, pain catastrophizing, and FABQs). Data collected from the study outcomes were tested for normality, using Shapiro Wilki's test ($p>0.05$) and Kolmogorov-Smirnov's test ($p>0.05$) and from the normality test results, all data were approximately normally distributed, therefore were analysed using parametric statistics. Paired sample t-test was used to determine within group effects of the intervention, that is, if the intervention showed any significant change in pain intensity, functional disability, QoL, kinesiophobia, pain catastrophizing and fear avoidance beliefs from pre-test to post-test.

Level of significance was defined as $p < 0.05$. All statistical analyses were performed on IBM SPSS version 23.0 (IBM Co., Armonk, NY, USA).

Results

Thirteen participants were assessed for the study eligibility criteria of which 10 fulfilled the inclusion criteria demonstrating (77%) feasibility recruitment rate. Patients' adherence and retention was 100%, as all patients were able to complete the prescribed sessions of treatments. No adverse events were reported during the study. Therefore, no potential risks observed due to interventions**.**

Sample size was estimated to detect a 10-point difference in the functional disability outcome measured by the ODI, based on the minimum clinically important difference (MCID) and the pilot study results. We assumed a standard deviation of 2.3 as reported by a previous study (Ibrahim et al. 2019), with a power of 0.9, an alpha level of 0.05, and a 15% dropout. Based on these assumptions, a total sample size of 85 participants will be considered for the RCT. Calculations were done with the G-power 3.1.92 software (Faul et al. 2007).

Sociodemographic characteristics of the participants

The participants in this study (N = 10) had a mean age (years) of 40.4 ± 8.6, with a higher proportion of women (f = 6, 60%) than men (f = 4, 40%). They reported a mean BMI (kg/m2) of 19.2 ± 2.98. Bending (f=6, 20.7%) was the highest activity limitation reported by the participants followed by prolong sitting (f=5, 17.2%) and getting out of bed (f=5, 17.2%). (See Table 1)

TABLE 1: Sociodemographic Characteristics of the Participants

Variables	f	Mean(SD)	Percentage(%)
Age(years)	10	40.4±8.6	
Gender	6		60.0
Female	4		40.0
Male	10		100
Total			
Weight(kg)	10	63.0±9.60	
Height(cm)	10	1.64± 0.08	
BMI(kg/m2)	10	19.2± 2.98	
Marital status			
Married	8		80.0
Divorced	1		10.0
Widowed	1		10.0
Single	0		0.00
Total	10		100
Highest Educational Qualification			
No formal education	1		10.0
Less than primary	1		10.0
Primary school completed	0		0.0
Intermediate school completed	0		0.0
High School (or equivalent) completed	4		40.0
Tertiary degree or diploma completed	4		40.0
Postgraduate degree completed	0		0.0
Total	10		100
Work status			
Part-time	1		10.0
Full-time	3		30.0
Not working	6		60.0
Total	10		100
Job satisfaction			
Extremely dissatisfied (0)	0		0.0
Very dissatisfied (1)	1		16.7
Dissatisfied (2)	2		33.3
Undecided (3)	0		0.0
Satisfied (4)	2		33.3
Very satisfied (5)	1		16.7
Extremely satisfied (6)	0		0.0
Total	6		100
Activities unable/difficult to perform			
Walking	4		13.8
Prolong sitting,	5		17.2
Gardening/washing plates	2		6.9
Bending	6		20.7
Getting out of bed	5		17.2
Vacuuming/sweeping	4		13.8
Running	1		3.4
Lifting	2		6.9
Total	29		100

Key: f-frequency; SD- standard deviation.

Table 2 presents a list of activities participants found difficult to do because of LBP. The majority of the participants (*n* = 5, 50%) were able to perform 40% – 60% of prolonged sitting of 1 h while only one (10%) participant was able to perform 70% – 100% function (prolonged sitting). Also, three (30%) of them reported having no difficulty in performing this activity.

Table 3 presents the physical profile of the study participants. The majority of them reported a positive painful arc on flexion and a positive Gower's sign. Six (60%) of the participants reported having a positive instability catch with seven (70%) having a negative reverse lumbopelvic rhythm.

TABLE 2: Activities difficult to perform due to low back pain among the participants

Activities difficult to perform	f	percentages (%)
Prolong sitting		
0-30% ability	1	10.0
40%-60% ability	5	50.0
70%-100% ability	1	10.0
NA	3	30.0
Total	10	100
Walking		
0%-30% ability	0	0.0
40%-60% ability	3	30.0
70%-100% ability	1	10.0
NA	6	60.0
Total	10	100
Picking up objects/bending		
0%-30% ability	2	20.0
40%-60% ability	3	30.0
70%-100% ability	1	10.0
NA	4	40.0
Total	10	100
Getting out of bed		
0%-30% ability	2	20.0
40%-60% ability	1	10.0
70%-100% ability	0	0.0
NA	7	70.0
Total	10	100
Lifting heavy weight		
0%-30% ability	2	20.0
40%-60% ability	0	0.0
70%-100% ability	0	0.0
NA	8	80.0
Total	10	100
Home activities		
Vacuuming/sweeping		
0%-30% ability	3	30.0
40%-60% ability	1	10.0
70%-100% ability	0	0.0
NA	6	60.0
Total	10	100
Gardening/washing plates		
0%-30% ability	3	30.0
40%-60% ability	0	0.0
70%-100% ability	0	0.0
NA	7	70.0
Total	10	100

Key; f-frequency; NA, not applicable

TABLE 3: Physical profile of the study participants

Variables	*f* (%)
Aberrant motions with flex painful arc	
Positive	9(90.0)
Negative	1(10.0)
Total	**10(100)**
Painful arc on return	
Positive	9(90.0)
Negative	1(10.0)
Total	**10(100.0)**
Gower's sign	
Positive	7(70.0)
Negative	3(30.0)
Total	**10(100.0)**
Instability catch	
Positive	6(60.0)
Negative	4(40.0)
Total	**10(100.0)**
Reverse Lumbopelvic rhythm	
Positive	3(30.0)
Negative	7(70.0)
Total	**10(100.0)**
Hands flat on floor	
Positive	7(70.0)
Negative	3(30.0)
Total	**10(100.0)**

Key: f- frequency; %- percentage

Changes in treatment outcomes from baseline and post treatment

Table 4 shows the within differences of outcome measures among the study participants before and after the six-week intervention. Both primary and secondary outcome measures observed, reported statistically significant changes ($p < 0.01$) immediately after the six weeks of CGAMCE. The result shows a mean pain intensity of 6.8 ± 1.8 at baseline, with a clinically relevant mean difference of 4.2 ± 1.7 post treatment (95% CI = 2.99–5.40), which was statistically significant. Functional disability was moderate at baseline (35.3%). Functional disability was also observed to improve significantly on the ODI (0–100) from baseline 35.3 ± 10.1 to post treatment 21.7 ± 7.3. The ODI among the study participants demonstrated a significant minimum clinical important change of 13.6 ± 3.9 (95% CI = 10.77–16.42).

Kinesiophobia among the cLBP patients was high at baseline. The result shows a statistically significant (*p*< 0.001) reduction in mean kinesiophobia at baseline from 32.9 ± 5.45 to 19.2 ± 3.2. We observed significant improvement in the scores of the fear avoidance belief questionnaire: Physical Activity subscale (9.0 ± 4.1, 95% CI = 6.09–11.9) and Work subscale (29.2 ± 1.7, 95% CI = 5.78–18.82). The fear avoidance belief questionnaire Work subscale score was reported to be high after the six-week intervention, a score of greater than 29 points post-test was found which is the established cut-off score that is predictive of long-term outcomes. Quality of life significantly improved from pre-test to post-test in all eight subscales among participants. The highest mean difference score was observed in the mental component scale which was -33.6 ± 15.9 (95% CI = -45.00 – -22.26). The physical component scale of the SF-340 36 observed a MCIC of 14.5 ± 10.0.

Table 4: **Changes in Treatment Outcomes from Baseline and Post-Treatment**

Outcome measures	Mean± SD	Mean difference ± SD	95%CI	*t*	p-value
NPRS(0-10)					
Pre-test	6.8±1.8				
Post-test	2.6±0.97	4.2±1.7	2.99-5.40	7.875	.000*
ODI					
Pre-test	35.3±10.1	13.6±3.9	10.77-16.42	10.889	.000*
Post-test	21.7±7.3				
FABQ-PA (0-24)					
Pre-test	19.0±7.9				
Post-test	10.0±4.4	9.0±4.1	6.09-11.9	7.018	.000*
FABQ-WS (0-42)					
Pre-test	41.5±8.2				
Post-test	29.2±1.7	12.3±9.1	5.78-18.82	4.266	.002*
TSK-11(11-44)	32.9±5.5				
Pre-test	19.2±3.2	13.7±3.6	11.15-16.24	12.167	.000*
Post-test					
PCS[1] overall (0-52)					
Pre-test	38.80±12.95				
Post-test	20.4±7.7	18.4±6.4	13.85-22.96	9.119	.000*
Rumination	12.4±3.3				
Pre-test	6.50±1.8	5.9±2.3	4.23-7.57	8.004	.000*
Post-test					
Magnification	8.6±3.30				
Pre-test	4.1±2.33	4.5±1.96	3.09-5.90	7.268	.000*
Post-test					
	17.8±6.7				
Helplessness	9.80±4.4	8.0±3.2			
Pre-test			5.73-10.26	8.000	.000*
Post-test					
SF-36					
PCS	30.2±8.7				
Pre-test	44.8±5.7	-14.5±10.0	-21.71- -7.35	-4.579	.001*
Post-test					
MCS	14.8±12.7				
Pre-test	48.3±6.0	-33.6±15.9	-45.00- -22.26	-6.691	.000*
Post-test					
Keele STarT back tool (0-9)					
Distress subscale					
Pre-test	4.9±0.3				
Post-test	1.2±1.6	3.70±1.6	2.578-4.821	7.467	.000*
Overall STarT score					
Pre-test	8.6±0.5				
Post-test	2.6±1.96	6.0±2.3	4.348-7.652	8.216	.000*

Key: *=significant at p<0.05; SD- Standard Deviation; CI- Confidence interval; t-independent t-test; p-Probability; NPRS- Numerical Pain Rating Scale; ODI- Oswestry Disability Index; PCS-Physical component subscale; MCS-Mental component subscale; PA-Physical Activity(subscale of FAB); TSK-Tampha scale of kinesiophobia; PCS1-pain catastrophizing.

Discussion

The objectives of this study were to determine the effects of a six-week CGAMCE on some biopsychosocial variables among a subgroup of patients with cLBP. At the end of the six weeks of CGAMCE, pain intensity was found to reduce among these participants with non-specific cLBP. The mean improvement in NPRS scores within participants was significantly higher than the reported consensus cut-off minimum clinically important change (MCIC) value of 2 points (MCICNPRS = 4.2 ± 1.7) (i.e. the smallest effective change within a group) reported by Childs et al. (2005). The study by Ostello et al. (2005) documented similar MCIDs for the NPRS, to range from 1.0 to 4.5 among patients with LBP, which is in line with the present study. The present study observed similar pain values and comparable improvement as the established MCIC reported in the previous studies. Chronic pain is the most central symptom among patients with cLBP. It is therefore of the outmost importance to determine how to improve it, especially in Nigeria where there is little or no reference data on pain intensity and its management. As researchers, it is up to us to find the most effective evidence-based means of relieving chronic pain. It seems that the CGAMCE intervention in the present study has proved to be effective in reducing pain from a moderate level to a minimal level among patients with non-specific cLBP.

Disability is any restriction in or lack of (from impairment) ability to perform an activity in the manner or within the range considered normal for a human being (WHO, available at https://www.cdc.gov/nchs/icd/index.htm). It has been reported that disability that often accompanies LBP varies in extent as seen in chronic back pain where it is persistently on going and difficult to manage (Pengel et al. 2013). Disability has been reported to be accompanied with batteries of psychosocial factors among patients with non-specific cLBP (Slons & Hicks 2011).

The present study reported a moderate mean functional disability at baseline on the ODI. A mean significant change after the six weeks of combined intervention was also reported for disability in this study. This is in line with previous studies that established the MCIC for the ODI as 6-10 points (6% - 10%) in patients with LBP (Fairbank & Pynsent 2000; Vela et al. 2011).

This indicates that the reported mean improvement or change of 13.5 points is higher than the cut-off values, which were enough to show a MCIC of 95% probability in our study. This suggests that combined graded activity with motor control exercise has a meaningful clinical efficacy in reducing functional disability among the cLBP patients after six weeks.

Overall, the reductions in functional disability and pain were both statistically significant in this subgroup of patients. The improvement observed was, however, not in line with the study of O'Keeffe et al. (2019) in which greater functional disability than for pain intensity was observed.

Secondary outcomes of fear avoidance beliefs, kinesiophobia, pain catastrophizing, and QoL reported statistically significant improvement immediately after intervention in this study. This demonstrates the effectiveness of CGAMCE intervention for these patients with non-specific chronic low back. The observed results are consistent with previous studies (Macedo et al. 2012; Magalhaes et al. 2013) where psychosocial measures were significantly changed after rehabilitation. Thus, CBT has been documented to be useful in modifying health behaviours and providing positive coping strategies (Vlaeyen et al. 2002) in patients with cLBP.

The fear avoidance questionnaire was constructed to measure fear levels and activity avoidance in patients with LBP (Waddell et al. 1993). Fear avoidance belief in this sample of patients was high at baseline with the Work subscale score being higher than the Physical Activity subscale score. It has been reported that elevated fear avoidance belief in cLBP patients remain unchanged overtime (Newcomer et al. 2010). Nevertheless, both the Physical Activity and Work subscales in this study show significant improvement from baseline to post intervention. The persistence of fear avoidance beliefs was previously reported even after physical therapy that was followed by improvement in pain and other parameters (Sorensen et al. 2010). The present study also reported similar findings of persistent fear avoidance (both subscales) after six weeks of intervention among the participants even with the statistically significant improvement in pain and disability as well as other psychosocial outcomes. Conversely, preliminary research has established cut-off scores for these subscales that are predictive of long-term outcomes. These are greater than 14 for physical activity subscale and greater than 29 points for the work subscale (Cleland, Fritz & Brennan 2008; Klaber, Carr & Howarth 2004). Therefore, participants in this group would have benefited more from a much longer session of CGAMCE intervention. As there were no established values for the MCIC of the overall fear avoidance beliefs questionnaire, it was not compared to the fear avoidance beliefs improvements in this study.

Based on the fear-avoidance model (Vlaeyen & Linton 2000), when pain is perceived as threatening, pain catastrophizing occurs which may develop into pain-related fear and anxiety, in turn leading to avoidance behaviour. The mean pain catastrophizing score among participants in this study was high at baseline, indicating an inference to the high fear avoidance beliefs reported at baseline, as pain in the long term could lead to disuse, disability, and depression as well as increased fear of pain (Larsson et al. 2016).

Kinesiophobia had been widely assessed in various conditions including Parkinson's disease, fibromyalgia, spinal stenosis, and LBP (Monticone et al. 2015). Larsson et al. (2016) classified TSK scores greater than 35 as high levels of kinesiophobia. However, participants in this study demonstrated medium kinesiophobia at baseline. This finding could be due to the high level of pain experienced by the participants at intake level. It is noteworthy that six weeks of CGAMCE shows a statistical reduction in levels of kinesiophobia among these participants with cLBP.

Similar levels of kinesiophobia were reported by Ishak, Zahari and Justine (2017). Participants in this pilot study were mainly female; it is not known whether gender difference may affect levels of kinesiophobia in cLBP patients. We suggest that future research should take this into consideration. Participants in this study reported high impairment of psychological status with a low QoL due to their cLBP as observed at baseline on the SF-36 survey. At the end of the intervention, participants had demonstrated significant changes in both physical health and mental health domains.

The significant improvement in the two subscales of the QoL among these participants may be unrelated to the reduction or improvements in the other observed outcomes (i.e. pain intensity, disability and other psychosocial measures) at the end of the intervention. The extent of improvement on the scale due to the intervention is in line with findings from previous studies (Lauridsen et al. 2006; Macedo et al. 2012).

As well as the significant changes observed in the PCS, an important minimal significant clinical change was observed among these participants (14.5 points) which falls within the 0–25 points equalling a MCID of 1 point as reported by Lauridsen et al. (2006).

Previous studies have indicated improvement in psychosocial measures to be positively associated with beneficial clinical outcomes (Hill & Fritz 2011; Turner, Holtzman & Mancl 2007). The magnitude of changes as observed in the primary outcomes of this study (pain and disability) and the secondary psychosocial measures suggests the positive clinical efficacy of CGAMCE intervention among this cohort of non-specific cLBP patients. Macedo et al. (2012) and O'Keeffe et al. (2016) compared the efficacy of physical and psychological informed interventions among cLBP patients and found that none of the interventions was more effective than the other. In the present study, the effects of CGAMCE (i.e. biopsychosocial intervention in the form of CBT and a more biomedically-inclined intervention) on biopsychosocial measures was carried out to determine whether clinically significant effects will be observed on the outcomes measured. This study reported high improvement in both primary outcomes and secondary outcomes, in line with the hypothesis that a combination of graded activity with motor control exercises will provide significant meaningful improvements in both physical and psychosocial measures of pain, functional disability, fear avoidance beliefs, pain catastrophizing, kinesiophobia, and QoL as seen with cLBP patients.

The researchers did not find any documented study in Nigeria that compared the combined effect of graded activity and motor control exercises from baseline to post treatment on non-specific cLBP patients. Therefore, to the best of our knowledge this is the first study that attempted to explore the effectiveness of CGAMCE among patients with non-specific cLBP. Many limitations were observed in the study; among them was the lack of a control group in the form of a waiting list or a comparison group to conclude the superiority or non-superiority in efficacy of any one of the interventions. Failure to use a random sampling method in the recruitment of patients together with the small sample size in the pilot study makes this sample unlikely to be representative of the wider population. However, the study results presented statistically significant and clinically relevant changes in all observed outcomes among the subgroup of patients with non-specific cLBP. The magnitude of these changes in the range of measured outcomes suggests that the CGAMCE intervention affects several relevant psychosocial factors effectively, even though the magnitude of changes could have been more specifically ascertained by comparison with another type of intervention. Another limitation is the use of self-reported questionnaires where there is a possibility of the severity of cLBP and disability conditions being overestimated. Therefore, the use of a more objective measurement is recommended in future studies. The study also recommends conducting further studies with a much larger group of cLBP patients from different regions, which would be useful for confirming the results of this study. In the same light, an RCT where CGAMCE is compared with motor control exercises and a control group is currently underway. This ongoing RCT addresses several limitations of the present study including the use of a control group, randomisation, and assessor blinding.

Participants and the researchers could not be blinded to the treatment in this study due to the nature of physical rehabilitation. Due to the small number of participants in the pilot study, not many challenges were encountered during the study. Participants were contacted by phone a day prior to their appointment to remind them. Generally, the participants were compliant with the study procedures as they are manageable. Although referral of new patients was not forthcoming initially, on contacting the orthopaedic unit of the hospital, new patients were referred appropriately.

Conclusions

The results showed that six weeks of CGAMCE has a significant meaningful improvement in both primary and secondary outcomes measured among non-specific cLBP patients. The results show the feasibility of a much larger RCT of CGAMCE among non-specific cLBP patients. The results of the present study should be interpreted with caution because of the aforementioned limitations.

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