STUDY INFORMATION AND CONSENT FORM (EXPERIMENT GROUP)

INVITATION TO PARTICIPANTS TO PARTICIPATE IN THE RESEARCH STUDY

DATE:

Dear Sir/Madam,

My name is AHMED Usman Abba, a physiotherapist and a PhD candidate at the University of KwaZulu Natal; Westville campus, Durban South Africa.

My contact numbers: +2347034832760, +2765562856

My email address: uabba45@yahoo.com; 217077488@stu.ukzn.ac.za

You are being invited to consider participating in an experimental study that involves research described below:

My research is entitled: EFFECTIVENESS OF MUSCLE ENERGY TECHNIQUE (MET) ON QUALITY OF LIFE AND TRUNK MUSCLES FUNCTIONS IN PATIENTS WITH CHRONIC NON-SPECIFIC LOW BACK PAIN (NSLBP). The aim of this study is.

To determine the effectiveness of MET when combined with Dynamic Stabilization Exercises (DSE) in the management of chronic NSLBP patients and to analyze the additional effect the MET procedure will provide relative to DSE.

In this study, 129 participants will be randomly recruited for the study at both Rasheed Shekoni Teaching Hospital (RSTH) and Federal Medical Center Birnin-Kudu (FMC), and allocated into three groups with 43 participants in each group. The group will be tagged (A, B&C) group A will receive DSE plus MET, group B will receive DSE only and C Control will receive standard physiotherapy. The duration of your participation, if you choose to enrol and remain in the study, is expected to be 12 weeks (24 sessions of intervention) and there will be a follow-up evaluation on outcomes at 3 months post-study interventions. The procedure for the study will involve the followings:

1. All necessary permission and consent will be sought and obtained.
2. Physiotherapists and Medical Doctors will be recruited both from RSTH and FMC to participate as assistance for the study and would be oriented on the study procedure.
3. You will undergo comprehensive medical screening including medical history, physical examination before participation in this study. You will be required to undergo a physical examination (to be conducted by the study physician), which will involve checking the functions and integrity of the spine, range of motion, circulation, lungs, muscles and bones among others.
4. Additionally, the study Physician will screen you based on inclusion and exclusion criteria of the study to determine if you have NSLBP and then takes all the initial measurements for the study including anthropometric variables. The following are the process of measurements;
    - A health information form will be provided to record data. The form is designed by the researcher to assess the demographic and anthropometric data, also the health status of the study participants and clinical outcome measures will be recorded. The form consists

of three sections (A, B&C); first section of the form **A** will cover information on participants socio-demographic characteristics (age, gender, current medications, marital status, level of education, Occupation/employment status, place of residence (urban/rural), smoking status and anthropometric variables , height, weight, BMI, skinfold thickness and waist circumference), while the second section **B** is for recording information related to the participant LBP (pain duration, an illustration of the area of LBP, Pain Numeric Rating Scale (PNRS) score indicating current/worst pain in scale of 0-10). The third section is for the recording of variables of interest for the study which are clinical outcome measures that will be assessed at baseline, 6^{th}, 12^{th} week of interventions and 3 months post-intervention as a follow-up.

- The anthropometric parameters that included height, weight, body mass index (BMI) and skinfold thickness (SFT) will be measured as follows; Bodyweight in light clothes will be measured to the nearest 0.1kg using a weighing scale calibrated from 0-120kg with the participant in standing position and shoes off. A height meter calibrated from 70-190cm will be used to measure the height of each subject to the nearest 0.1cm. The subjects' heels, the back and the occiput will touch the stadiometer scale and the subjects looking straight ahead during measurement. Body Mass Index will be calculated from the formulae; Weight/Height2 (kg/m2). Participant Skin Fold Thickness will be measured using skinfold calliper, the participant will be asked to assume a standing position and exposed his/her supra iliac body part (which is located approximately one inch above hip bone), while standing, two of the researcher's fingers will be placed at approximately 2-3 inches apart (thumb and forefinger) to firmly grasp the supra iliac skin fold and gently pulled away from the body. The calliper jaw will be placed perpendicular to the skin fold; a slide on the curve will be moved to the right side and the jaws approximate. Reading will be taken in millimetre from the curve at a point where the slide stopped. Other variables of interest for the research will be measured as follows;
- Transversus Abdominis muscles activation using pressure biofeedback instrument (unit): the participant will be positioned in prone (lying face down) over a pressure biofeedback unit that is inflated to 70 mmHg. The participant will be instructed to draw in the abdominal wall for 10 seconds without inducing pelvic motion while breathing normally. Change in mmHg using a pressure biofeedback device is observed and the maximal decrease in pressure is recorded. A 4-mmHg decrease in pressure is established as normal, whereas the inability to decrease the pressure biofeedback device measure by 2 mmHg is associated with the incidence of low back pain.
- Measurement of trunk range of motion in flexion and extension: Inclinometers placed at the thoracolumbar junction (a point below your ribcage) and on the sacrum (tail end of the spine) are zeroed with the participant in a neutral position. The participant is asked to bend forward maximally and motion is recorded at the thoracolumbar junction (total flexion measure) and at the sacrum, which is presumed to be moving in the sacroiliac and hip joints. The difference in motion represents the lumbar flexion measure. The patient is then asked to bend backwards and the difference in motion is the lumbar extension measure. Measurements are recorded in degree and will be administered at baseline, 6-weeks and 12-weeks of the study period.

- Measurement of Health-related Quality of Life: You will be required to answer some questions related to your health status at baseline, 6th and 12th week period of intervention and 3 months post interventions. Prior to providing answers to these questions, you will be given a careful explanation about the questions and adequate instruction on how they should be answered. However, Hausa translated version is also available for better understanding.
- Pain measurement: Clinical assessment of your low back pain will be conducted at baseline, 6th and 12th week of the study period and 3 months post-intervention. Primarily pain perception will be assessed with Pain Numeric Rating Scale (PNRS). The PNRS is a straight horizontal line drawn on a sheet of paper with a fixed length, usually 10-cm (i.e. 100mm). The ends are defined as the extreme limits of the parameter to be measured with anchor points 0 (no pain) and 10 (maximum pain). You will be asked to indicate the level of your pain perception on the drawn horizontal line. The indicated number will be recorded as your level of pain perceptions.
- Level of Functional Disability: Your level of functional ability will be measured using the Oswestry Disability Index. This index contains 10 items: 8 related to activities of daily living and 2 related to pain. Each item is scored from 0 to 5 and the total score is expressed as a percentage, with higher scores corresponding to greater disability. The level of functional disability will be assessed at baseline, 6-weeks and 12-weeks of the study period.
- Measurement of limitation in activities and participation restriction: The Örebro Musculoskeletal Pain Screening Questionnaire (OMPSQ) which is used to identifying patients at risk for future work disability due to LBP will be used to measure this variable. The OMPSQ is a 25-item screening questionnaire (of which 21 are scored) that consists of items involving pain location (item 4), work absence due to pain (item 5), pain duration (item 6), pain intensity (items 8 and 9), control over pain (item 11), frequency of pain episodes (item 10), functional ability (items 20 through 24), mood (items 12 and 13), perceptions of work (items 7 and 16), patients' estimate of prognosis (items 14 and 15), and fear-avoidance (items 17 through 19). The scored items are summed to provide a total score potentially ranging from 0 to 210, with higher scores indicating a higher risk of poor outcome. This questionnaire will be administered at baseline, 3-month and 6-month of the study period.
- Trunk endurance test: For this study, the assessment of trunk muscles endurance will be limited to the assessment of the performance of trunk flexors and extensors, and lateral flexors. Biering-Sorensen test will be used to test trunks extensor endurance while McGill's torso muscular endurance test battery will be used for the assessment of trunk flexors and lateral endurance. This will be conducted as follows;
    1. **Trunk Extensor:** The participant will be positioned prone on a treatment couch with the lower half of the body below the level of the anterior superior iliac spines strapped to the couch at three positions: at the ankles as close to the malleoli as possible, at the knee creases, and at the level of the greater trochanter of the femur. The seat belts are tightened as firmly as possible while considering the participant's level of comfort. Before beginning the test the participant will be allowed to rest the top half of the body on a chair. The participant will then be

told that at the beginning of the test he or she would be required to lift the upper trunk clear of the chair, place the arms across the chest and maintain the trunk in neutral alignment for as long as possible. A stopwatch will be used by the assessor to measure the time taken by the participant to maintain the position. The criteria for termination of the test include the inability to maintain the upper trunk in a neutral position, excessive fatigue, pain or discomfort are too much to bear. To ensure the trunk position is maintained an inclinometer will be placed on the interscapular region.

2. **Trunk Flexors:** The participant is positioned on plinth with their back resting against a wedge that maintains flexion at 60° from the horizontal. Knees are flexed to 90°, the feet secured with a seat belt and the head at a neutral position. Additionally, the participant is instructed to fold arms across the chest, touching each hand to the opposite shoulder. The therapist can stabilize the feet under a strap if necessary and the board is removed while the participant is asked to maintain the trunk flexion at 60°. The goal is of the test is held the position for as long as possible without the back support. The test is terminated when there is noticeable change in the trunk position such as a) a deviation from the neutral spine or increase in the low-back arch, b) part of the back is touching the backrest. A stopwatch will be used by the assessor to measure the time taken by the participant to maintain the position.
3. **Trunk Lateral Endurance:** For the lateral flexors endurance test, participant lay on their side with their legs extended, resting on their forearm with the elbow at 90°. Participants will be instructed to raise the hip up and maintain a full side-bridge position throughout the test°. The body should be in straight alignment and the torso supported only by the client's feet and the forearm. Also, the goal is to hold this position for as long as possible and once the position breaks the test terminated.

5. Participants in their respective groups will receive physiotherapeutic intervention aimed at management of participant NSLBP. However, for this study participants are not supposed to know the details of the intervention due to blinding which is an accepted research protocol. The blinding will helps prevent the influence of subjective opinions (expectations) of the participants, however, in case of a report of serious adverse events (e.g. comorbidities, injuries, persistent excruciating pain, decrease spine ROM, poor balance, etc.) after intervention or at any point during the trial, then we would consider unblinding the participant to the intervention for his/her safety. In addition, to guarantee a treatment allocation balance within the groups (A, B, C), a stratified permuted blocks will be used to randomly allocate different treatments within the groups. In any group, the participants will be instructed to pick a block at random and the order of treatments given in the block will determine the sequence of the treatments allocation in that session and this will be maintained throughout the 24 sessions of the study intervention.

This study is funded by the College of Health Sciences of the University of KwaZulu-Natal, Durban South Africa.

The research does not potentially involve any serious risk or harm, MET procedure is generally described safe. However, those participants who form part of the DSE program groups may suffer minor injuries; although every precaution will be taken to prevent these. In case of any eventualities resulting from comorbidity or injuries, proper and prompt medical attention will be given to the participants. A proper arrangement would be made with Accident and Emergency units of the hospitals where the research will be conducted. Also, psychosocial interventions will be put in place where necessary to give the participants reassurance on their safety.

The study will provide no direct benefits to participants. However, scientifically it's hoped that the findings of this study will provide information which will be used to develop a treatment protocol that is most effective in the rehabilitation of patients with chronic NLBP and that would help reduce the rate of recurrence, prevent deformities and improve functional disabilities. Additionally, the result of this study will help provide a wealth of information that will add value to the existing literature in the management of chronic NSLBP.

This study was ethically reviewed and approved by the UKZN Biomedical Research Ethics Committee. Prior to that, approval of the ethical committee of both Rasheed Shekoni Teaching Hospital and Federal Medical Center was obtained for the conduct of the research. In the event of any problems or concerns/questions; you may contact the researcher (see details provided in 1st paragraph); or the UKZN BREC. Contacts as follows:

BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X54001
Durban
4000
KZN, South Africa
Tel: 27 31 2604769
Fax: 27 31 260 4609
Email: brec@ukzn.ac.za.
Participation in this research is voluntary and the participant may withdraw participation at any time. In the event of withdrawal/refusal of participation; participants will not incur any penalty or loss of benefit to which they are normally entitled.

Consequences of withdrawal from the study; will be a worsening of the symptoms of pain and/or functional disability. In order to withdraw from the study; the participants should notify the PI via his email address above.

The cost incurred by the participants will only be the cost of the charges for the treatment of their condition, this cost is borne by the participants, whether research-related or not for the treatment of their condition. However, there will be incentives to participants given for participation in this research study.

Confidentiality of personal/clinical information will be strictly protected by using a number to identify the participant, as opposed to the participant's name. The raw data will be kept on the PI's personal laptop and hard copies at the PI's home and this will then be shredded on completion of the study.

While I anticipate your favourable consideration, please do accept my optimum assurance, thanks.

Yours Sincerely

Usman Abba Ahmed PT, MSc (Physiotherapy)

CONSENT FORM

I _____ have been informed about the study entitled "EFFECTIVENESS OF MUSCLE ENERGY TECHNIQUE (MET) ON QUALITY OF LIFE AND TRUNK MUSCLES FUNCTIONS IN PATIENTS WITH CHRONIC NON-SPECIFIC LOW BACK PAIN (NSLBP)" by Usman Abba Ahmed; the Principal Investigator (PI).

I understand the purpose and procedures of the study.

I have been given an opportunity to ask questions about the study and have received answers to my satisfaction.

I declare that participation in this study will be entirely voluntary and that participants may withdraw at any time; without affecting any treatment or care that they would normally be entitled to.

Participants have been informed about any available compensation or medical treatment if an injury occurs to them as a result of study-related procedures.

If I have any further questions/concerns related to the study; I understand that I may contact the PI at: uabba45@yahoo.com

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS COMMOTTEE (BREC)

Research Office, Westville Campus
Govan Mbeki Building
Private Bag X54001
Durban
4000
KZN, South Africa
Tel: 27 31 2604769
Fax: 27 31 260 4609
Email: brec@ukzn.ac.za.

_____ _____

Signature of Participant **Date**

_____ _____

Signature of Witness **Date**

_____ _____

Signature of Translator **Date**