FULL STUDY PROTOCOL,

STATISTICAL ANALYSIS PLAN (SAP)

Effectiveness of Three Typical Yoga Poses and Conventional Physiotherapy for Kinesio phobia Among Amateur Football Players with Chronic Ankle Instability

Ethical Approval: 30/32/2024/ISRB/SR/SCPT

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Table of Contents

1. Personnel

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2. Introduction

2.1 Background & Aims

Yoga is an Indian mind-body practice that has become well-known all over the world. During standing, sitting, and lying supine or prone, participants' bodily motions are gradual and have a wide range of motion. It has been demonstrated that yoga practice improves balance, coordination, emotional and mental well-being which assist in increasing joint flexibility, range of motion (ROM) and muscle strength.

Three yoga poses namely; the crescent lunge pose (Halasana), warrior II pose (Virabhadrasana II), and triangle pose (Trikonasana). These yoga manoeuvres reduce pain, which enhances people's quality of life. Reports indicate that yoga alters the perception of pain and influences brain waves. Since yoga promotes both pain treatment and psychosocial healing, it has been a popular alternative pain management technique in recent years for Kinesio phobia.

Injured athletes can benefit from deep breathing as a non-pharmacological pain management technique that increases localized tissue circulation and diverts attention from their discomfort. Inducing a shift in sympathetic nervous system activity by reducing stress hormone levels and activating the diaphragm by stimulating the vagal nerve, which regulates pain perception, guided or focused deep breathing functions as a mindful meditation technique.

The most successful strategy for collegiate athletes to handle stress and prepare for competition was deep breathing. Additionally, it has been demonstrated that deep breathing can assist individuals with chronic musculoskeletal pain manage their condition effectively, reducing movement fear and enhancing subjective wellbeing and quality of life.

Conventional physical therapy includes exercises for strengthening and flexibility as well as training for agility and balance. These therapies aim to improve muscular strength, speed,

agility, and neuromuscular control; restore a normal gait pattern without the use of assistive devices; improve balance; and increase range of motion and flexibility. Conventional physiotherapy uses a range of techniques centered on function restoration, strength enhancement, and injury prevention to address these problems.

By combining conventional physiotherapy with relaxation techniques like three typical yoga postures and deep breathing technique, our method not only helps people with Kinesio phobia but also improves their ankle range of motion, balance, and coordination so they can actively resume their daily lives.

2.2 Background Literature Review

YO Guvener et al (2023) pioneered the concept of 'psychological wellbeing through yoga poses': Regular meditation and yoga can enhance cognitive-emotional processes, which in turn can lead to greater psychological well-being. Yoga poses and breathing techniques have a significant impact on mental health. In a study by Deible et al., nurses who used stress reduction techniques like yoga and meditation reported feeling less stressed and having better coping skills.

Elizabeth Whissell et al (2021) proposed suggested that the motion patterns of the lunge and warrior II poses were comparable in terms of angular impulse, joint angles, and joint moments. Compared to the other two manoeuvres, the triangle position may be better since it increases hip joint range of motion, strength, and dynamic stability.

Bethany Forseth PhD et al (2021) suggests that practicing yoga has a connection to psychological well-being, as study participants who practiced yoga reported feeling less stressed and having fewer depressive symptoms than those who did not. Significant variations, however, were not found to substantiate the association between yoga practice and mitochondrial protein level and inflammatory indicators.

In a pilot study conducted by Ramalingam et al (2023) showed that young adults with Chronic Ankle Instability saw improvements in pain, balance, happiness, and attention after receiving Short-Duration Deep Breathing (SDDB) and Conventional Physiotherapy (CP) together for six weeks. In addition to the current Conventional physiotherapy, the gradual benefits of short duration deep breathing using smartphone applications among young adults as a pain management technique provide a further advantage to enhance the wellbeing of wounded sportsmen during their rehabilitation.

Bindu C.B et al. (2013) concluded that the immediate effects of deep breathing exercises on blood pressure, heart rate, and respiratory rate can be reversed very fast by just holding your breath until it breaks. This is likely due to central regulatory processes. On the other hand, peripheral variables that lower small airway resistance may provide a long-lasting, considerable 5% rise in peak respiratory flow rate. It implies that sympathetic dominance brought on by breath holding up to the breaking point swiftly counteracts the purported parasympathetic dominance brought on by deep breathing.

Volker Busch et al. (2012) pioneered Deep and slow breathing along with relaxation is the key component in the regulation of sympathetic arousal and pain perception since breathing patterns have a significant impact on autonomic and pain processing.

Laurel Long et al. (2013) pioneered the concept of ‘6-week at-home foot and ankle exercise’ program was feasible and whether there would be any corresponding changes in older people' muscular function, flexibility, and balance. Participants showed statistically and clinically significant gains in the majority of the end measures after training. Further research is warranted since this study shows that a straightforward yet progressive home exercise program targeting the foot and ankle may improve several areas of balance and mobility in healthy older persons who live in the community.

3. Study Protocol

3.1 Research Design Outline

The study aims to perform a comparative study on chronic ankle instability with Kinesio phobia in Saveetha college of physiotherapy and Saveetha college of allied health sciences.

Formerly titled “Effectiveness of Three Typical Yoga poses and Conventional Physiotherapy for Kinesio phobia Among Football Players with Chronic Ankle Instability: A Comparative Study” involves amateur football players with Kinesio phobia by using the Tampa scale for Kinesio phobia and Cumberland ankle instability tool for Chronic ankle instability. The outcome is the total fear of movement, and fear of re-injury, severity of functional ankle instability. Total scores of 68 for Kinesio phobia, 30 for chronic ankle instability. Higher score means a better outcome.

3.2 Participants

Amateur football players from Saveetha Institute of Medical and Technical Sciences with Kinesio phobia along Chronic Ankle Instability will be eligible to participate in this study.

3.3 Recruitment

All amateur football players with Kinesio phobia along Chronic ankle instability attending Saveetha Institute of Medical and Technical sciences will be enrolled in the comparative study. The participation information and consent sheet will be distributed to amateur players which details including inclusion and exclusion criteria. Amateur players who agree to the investigation will be invited to undergo baseline assessments Tampa scale, Pain anxiety

symptom scale, Y-balance test, Cumberland ankle instability tool (CAIT). All amateur players will have to return a signed consent form to the site principal investigator.

3.4 Administration

The steps with yoga mat include:

For yoga:

1.Crescent lunge pose:

- Participants will be instructed to start in the Facing Downward as Dog Pose.
- All participants will be instructed to inhale and simultaneously raise the right leg behind them and exhale as they step the right foot forward between their hands.
- All of them will be asked to make sure that the right knee is aligned above the right ankle.

2.Warrior II pose:

- Participants will be instructed to start in mountain pose (Tadasana).
- All of them will be instructed to step their left foot back, extend their arms out, position their hips, and bend deeply into the right knee while gazing directly above their right middle finger.
- At that position, all will be instructed to breathe, hold, and strengthen.
- Then, all will be asked to step back into mountain pose.

3.Triangle pose:

- Participants will be instructed to stand straight with their legs apart. The distance between their legs will be a little more than the span of their shoulders.

- All will be instructed to inhale, to raise their right hand straight above their head, and will be asked to maintain the right arm parallel to the right ear.
- All of them will be instructed to exhale, to bend their torso at the waist, to their left side.
- Simultaneously, all will be asked to slide their left arm down along their left leg until their fingers reach their ankle.
- At that point, their right arm will be instructed to be horizontal as their head tilts left.
- All will be asked to hold the pose with their knees and elbows straight and to inhale. Everyone will be instructed to straighten themselves and stand erect. All will be asked to repeat the posture on the other side.

For Deep Breathing:

The participants will be seated on chairs and will be given a 3-minute, 6 deep breaths per minute session along with the CP protocol 5 times a week for 3 weeks.

Conventional physiotherapy:

In the first two exercises, which will include a heel raise and a toe raise, the focus will be on the strength and power of the plantar flexors and dorsiflexors. The exercise will be modified by 1) performing it on the ground or over the edge of a 10-cm step, 2) using both legs or one leg, and 3) adjusting the amount of upper extremity support to determine the progression of the exercise. The starting difficulty for the heel and toe raises will be adjusted to allow the participant to complete two sets of ten to fifteen repetitions.

A single-leg stand will be the third exercise, focusing on lower extremity stability and postural control. The identical hand position progression that will be used for the heel and toe rises

should be employed by the participants. The single-leg stand will be performed by the participants for two repetitions on each leg for 30 seconds to 1 minute.

A gastrocnemius stretch will be the final exercise. To feel a comfortable stretch in their gastrocnemius, participants will simultaneously lower their heel and lean forward while placing the ball of their foot onto the edge of the 10-cm step. Each leg should be stretched separately for 30 seconds to 1 minute, and the participants will be asked to execute the exercise twice during each training session.

3.5 Assessment & Outcomes Measures

3.5.1 Primary outcomes

Tampa scale:

The Tampa scale will initially be used to distinguish between non-excessive fear and phobia in patients with chronic musculoskeletal pain, i.e., the fear of movement. In its original form, the TSK will be a 17-item assessment checklist. It will use a 4-point Likert scale (Strongly Disagree-Disagree-Agree-Strongly Agree) with statements that will later be linked to the model of fear-avoidance, fear of work-related activities, fear of movement, and fear of re-injury.

Cumberland ankle instability tool (CAIT):

The Cumberland Ankle Instability Tool (CAIT) will be a 9-item, 30-point scale that will measure the severity of functional ankle instability. Using a numeric value, the

Cumberland Ankle Instability Tool (CAIT) will have the ability to discriminate between stable and unstable ankles.

3.5.2 Secondary outcomes

Y-balance test:

Absolute reach distance (cm) = (Reach 1 + Reach 2 + Reach 3) / 3. Relative (normalised) reach distance (%) = Absolute reach distance / limb length * 100 Composite reach distance (%) = Sum of the 3 reach directions / 3 times the limb length * 100.

Pain anxiety symptom scale:

Pain and anxiety symptom scale (PASS) is a 20-item self-report measure to assess pain-related anxiety. Each item is a 6-point scale anchored from 0 (never) to 5 (always). Total score is ranged from 0 (representing no pain anxiety) to 100 (representing severe pain anxiety.

4. Statistical Analysis Plan (SAP)

Descriptive and inferential statistics will be used. Normally distributed data will be presented by mean and standard deviation (SD), and non-normally distributed data will be presented by median and interquartile range. SPSS (version 24.0) will be used for all statistical analyses.

4.1 Primary Outcomes

The primary analyses will compare experimental vs control group guidelines on their mean and standard deviation: (i)Tampa scale, (ii) Cumberland ankle instability tool (CAIT).

Comparison will be tested by using the Paired t test to find the significant difference within the intervention effects and between the two groups (Experimental control group and Experimental Group) using independent t-test. P values <0.05 has been considered statistically significant.

4.2 Secondary Outcomes

The primary analyses will compare experimental vs control group guidelines on their mean and standard deviation: (i) Y-balance test (ii) Pain anxiety symptom scale.

Comparison will be tested by using the Paired t test to find the significant difference within the intervention effects and between the two groups (Experimental control group and Experimental Group) using independent t-test. P values <0.05 has been considered statistically significant.

4.3 Missing Data

For players who do not attend the assessment, the mean imputation of the assessment scores from their allocation group has been used.

5. Informed Consent Forms (ICF)

Written consent will be gained from the amateur football players with Kinesio phobia along with chronic ankle instability using the consent forms attached to the application.

5.1 Rights and Risks to participants

Rights

The Amateur players may decide to stop being a part of this research study at any time without explanation. The players have the right to omit or refuse to answer or respond to any question that is asked about their condition. In addition, they have the right to ask any questions about the procedures practiced (unless answering these questions would interfere with the study outcome). If they having any questions on this information sheet/test/training, they may ask the investigator or research in-charge person before the study begins or during the course of assessment and interventions. Participation in this study is voluntary and it does not carry any remuneration or reimbursement.

Risks

Researcher does not anticipate any risk from this research study.

5.2 Privacy and Confidentiality

All amateur players will be de-identified and assigned a unique ID number at the time of enrolment, which will be recorded by the administration officer at the study site. The videos of the Y balance will not be shared in any way due to the ethical policies of the study sites.

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