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Efficacy of automated robotic Tuina and acupuncture for treating chronic lower back pain: a randomized controlled study

1. Background

Low back pain (LBP) is a common clinical symptom prompting patients to seek medical care. 80% of adults experience LBP during their lifetime [1]. It is the leading cause of disability worldwide, with a global prevalence of 7.3% in 2016 [2]. Usually most people recover with or without treatment, however a relapse of the pain is common and 10-15% LBP patients may develop chronic low back pain (CLBP), with symptoms lasting more than 12 weeks of pain[3]. CLBP can be categorized into sciatica/nerve root pain syndrome, specific low back pain, and non-specific low back pain [4]. The common causes of CLBP can include spinal injury, lumbar muscles strain, degenerative spinal intervertebral disc, and vertebra joints. 90% of CLBP patients do not have a clearly identifiable cause of pain, which is classified as chronic non-specific low back pain (CNLBP) [5]. CNLBP refers to pain and discomfort localized in the area between the costal margin and the inferior gluteal fold, not resulting from an identifiable or known specific pathology, with or without referred leg pain of more than 12 weeks' duration [6]. CNLBP originates from the waist and its symptoms onset, recovery, and clinical outcomes are influenced by biological, psychological and social factors, therefore its management is complicated and multimodal[7].

As the pathoanatomical cause of CNLBP remains an enigma, no specific evidence-based method in clinical practice has been recommended for medical providers to manage CNLBP[8]. Given the broad nature in diagnoses, localized lumbar pain is treated with a variety of interventions such as patient education, self-management, physiotherapy, psychological therapy, medication, injection, ablation techniques, surgery[9]. Although these treatments have shown some efficacy, there is no conclusive evidence for their continued use in mainstream treatment or sufficient knowledge of the extent of the side effects if any [7]. Nonetheless, multidisciplinary eclectic rehabilitation strategy is often recommended for patients with CNLBP [10]. Recent systematic reviews have reported that Tuina reduced the pain and improved functional status in 20 studies, however these studies used Tuina in combination with herbal medicine and acupuncture[11]. Tuina alone as modality of treatment was also investigated in the following systematic review[11]-[12], with positive findings of pain reduction, however results were not as favorable for functional improvement and not tested in long term studies beyond two months.

Tuina, also named "Tui Na", literally means "pushing (and) grasping" has been used in China for thousands of years[13]. It is a non-pharmaceutical manual therapy in traditional Chinese Medicine, which is mainly applied to the meridians or acupoints by manipulation of pushing, grasping, pressing, rubbing, etc. Over the years, Tuina has developed currently into one of the most popular TCM therapies with a wide range of techniques for various body locations[14]. It can treat diseases by removing obstruction in Meridian collaterals and relieving pain by reducing inflammation, separating adhesions in the tendon, improving circulation and re-aligning small joint disorders [11] The use of Tuina as a treatment intervention is also studied for other forms of pain management, pediatric cerebral palsy disorders, neurological and musculoskeletal conditions and rehabilitation [15]. In recent years, many studies have emerged to evaluate the effectiveness of Tuina to manage LBP [16]. A systematic review and meta-analysis evaluated the effectiveness of Tuina-focused integrative Chinese medical therapies on LBP inpatients, synthesizing 20 Randomized Control Trials (RCTs) and found that it might be effective for inpatients with LBP, while more high-quality RCTs with long follow-up were required [11].

As Tuina is labor intensive and its results are highly dependent on the individual practitioner, robotic solutions may aid medical workers in providing more consistent and physically sustainable treatments for patients. A study using a robotic device to apply compressive forces on injured skeletal muscle tissue in mice reported substantial improvements in their functional recovery. Currently, massage machines are available for purchase on the commercial market. However, these machines may not meet the precision and specifications required for clinical usage.

Robotics in surgery has significantly enhanced the safety and predictability of surgery. In the operating theatre, vital structures are protected due to the navigation aspect the robot and haptic feedback provides the correct amount of

force while ensuring precision in placing incisions and this translates to quicker recovery and improved success [17]. The use of the Tuina robot will similarly allow treating physicians to preplan the location and with haptic feedback allows the correct amount of force that will maximize the patient outcome. Improvements in learning curve and predictability have been noted in the use of robotics in knee surgery and this brings consistency to robotic Tuina removing physician fatigue [18].

2. Methods

Trial Design

This is a parallel group, randomized controlled study in Singapore. This study will be submitted for approval by the Institutional Review Board at Nanyang Technological University (NTU). Informed consent will be obtained for all prospective participants. This study will adhere to the requirements of the World Medical Association Declaration of Helsinki. The reporting of this study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline and the ICH- Good Clinical Practice (GCP) guidelines.

Patients with CNLBP will be randomized into robotic Tuina group, Acupuncture group in a 1:1 ratio.

Blind Method

Due to the particularity of robotic Tuina and the acupuncture intervention, the operators or intervention providers and the patients are not blinded.

The research accessors performing the efficacy evaluations and follow-up observation, and statistical analysts will be blinded in this study.

Patients

The study site involved in this study is as follows:

1） **NTU Chinese Medicine Clinic**

60 Nanyang Drive, Nanyang Technological University, School of Biological Sciences, Singapore 637551

2）**Novahealth TCM Clinic**

51 Cuppage Road, #01-07, Singapore 229469

3) **Novahealth TCM Clinic**

160 Robinson Road, #03-16, SBF Medical Suites, Singapore 068914

We aim to recruit 56 patients from the three sites, and each treatment arm will consist of 28 patients. The control arm will undergo acupuncture while the treatment arm will undergo acupuncture and robotic Tuina treatment.

Inclusion Criteria	Exclusion Criteria
• Between 21 and 70 years of age (adults) • At least one primary care visit for back pain within the past 3–12 months at either CM or WM clinic • Non-specific, uncomplicated low back pain, i.e., ICD-9 codes: 724.2 Lumbago 724.5 Backache, unspecified 724.8 Other symptoms referable to back 846.0-9 Sprains and strains, sacroiliac 847.2 Sprains and strains, lumbar 847.3 Sprains and strains, sacral 847.9 Sprains and strains, unspecified site of the back • Able to communicate and write in English and/or Chinese	• Previous acupuncture for back pain within the past 3 months • Low back pain lasting less than 3 months. • Mild symptoms (less than 5 on a 0 to 10 Pain bothersomeness scale) • Specific diseases being diagnosed that could be the cause of back pain (sciatica , metastatic cancer, discitis, herniated disc, vertebral fracture, spinal infection, osteitis condensans ilii, severe or progressive scoliosis, spinal stenosis, spondylolisthesis, ankylosing spondylitis, protrusion or prolapse of 1 or more intervertebral discs with concurrent neurological symptoms); radicular pain; prior vertebral column surgery; infectious spondylopathy; low back pain caused by inflammatory, malignant, or autoimmune disease; congenital deformation of the spine (except for slight lordosis or scoliosis); compression fracture caused by osteoporosis; spinal stenosis; spondylolysis or spondylolisthesis) • Prior history of back surgery • Diagnosed with disabling chronic conditions that might confound treatment effects or interpretation of data (e.g., disabling heart or lung disease, diabetic neuropathy, active hepatitis, fibromyalgia, rheumatoid arthritis, paralysis, major psychoses, dementia, scheduling conflicts, severe vision or hearing problems) • Acupuncture contraindicated or safety not confirmed (Diagnosed with clotting disorders, on anticoagulant therapy, heart pacemaker, pregnancy, seizure disorder) • Deemed unfit by the Chinese medicine physician for acupuncture and/or robotic Tuina as a treatment due to the patient's current medical condition. • Currently consuming concomitant medication (long term medication, ie: patients needing to consume it daily or every few days for an extended time) for pain management and relief such as analgesics

Assessments and Outcomes

Primary Outcome:
The primary outcome will be change from baseline in back pain intensity, which will be measured by the visual analogue scale (VAS).

Secondary Outcome:
The secondary outcomes measured include the Roland-Morris Disability Questionnaire (RMDQ) for functionality, Brief Pain Inventory (BPI) for pain interference, World Health Organisation Quality of Life BREF (WHOQOL-BREF) for quality of lfie, patient's sleep report with smart ring to measure quality of sleep. We will also measure patient's acceptance to robotic Tuina with Technology Acceptance Model (TAM) questionnaire.

Trial Procedures

Each visit lasts from 1 to 1.5 hours, with a total of six sessions to be completed within 8 weeks. Each treatment session lasts between 30 to 60 minutes, over a total of twelve weeks. A breakdown of each treatment session and the treatment goals will be as follows.

Visit	Breakdown of activities
1	• Potential participants will be screened by an investigator, and a study clinician will confirm their eligibility for the trial. • Physical examinations • Filling out forms (informed consent, patient particulars and demographics) • Patients will then be randomized into either the "acupuncture only" or "acupuncture + robotic Tuina" group in a 1:1 ratio on a secure computer system that ensured full allocation concealment and used permuted blocks. • Explain the use of the smart ring to track the sleep quality • Fill up the VAS, RMDQ, BPI, QOL and TAM Scales
2	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment • Collect adverse event (AE) data • Record concomitant medication use
3	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment • Collect adverse event (AE) data • Record concomitant medication use
4	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment • Collect AE data • Record concomitant medication use
5	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment

	• Collect AE data • Record concomitant medication use
6	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment • Collect AE data • Record concomitant medication use
7	• Physical examinations • Deliver treatment according to randomization • Collection of VAS pre and post treatment • Collect AE data Record concomitant medication use
8	• Physical examinations • Fill up the VAS, RMDQ, BPI and QOL Scales • Return Smart Ring • Record concomitant medication use • Collect AE data

Leadtek Amor Ring

Leadtek Amor Ring is smart ring with health monitoring technology, allowing real-time tracking of key physiological indicators such as heart rate, autonomic nervous system activity, sleep quality and exercise data. Its design allows for wearing comfort, making it easy for users to integrate health management into their daily lives. This ring has been certified by the NCC (National Communications Commission) in Taiwan and FCC (Federal Communications Commission). It holds an IP67 dustproof and waterproof rating, as certified by SGS. The materials used in the ring are RoHS compliant, and the material of encapsulation is certified under ISO 10993-10 standards. The Amor Ring can be synced with the user's smartphone through an app, and it is used in this study to measure the sleep quality of the participants before and after treatment. Previous studies have shown that chronic low back pain is related to sleep disturbances, and some have shown that interventions can improve both the pain and sleep disturbances in patients. As such, we are using the wearable ring to track the sleep quality of participants before and after treatment to confirm the effect of the treatments on sleep quality as well. Subjects are required to wear the sleep tracker ring the night before treatment and the night after treatment before they sleep and sync the sleep data to the app the next morning. The sleep data will be collected for all of the 6 sessions. Below are pictures of the smart ring and how it is to be worn on the subject.





Interventions

Our interventions will be acupuncture for the control group, and acupuncture with robotic Tuina for the treatment group. For this study, we have chosen acupuncture as a control, as acupuncture has already been shown in past studies

to alleviate CNLBP. Hence, we now wish to evaluate the additional effectiveness of robotic Tuina as an additional treatment to acupuncture in alleviating CNLBP.

Treatment group

Robotic **Tuina**

Tuina aims to dredge the meridians and collaterals to provide pain relief by reducing the pain of muscle spasms, promote blood circulation, as well as soothe the muscles and regulate sinews and joints.

Regions and Points

Regions: Lumbosacral region, hip, and lower limbs.

Standardized Operating Procedures

The Robotic Tuina techniques that will be used for the treatment of CNLBP are as follows:

1. Robotic lower back Tuina:
2. Ask the patient to take a prone position.
3. Move the robot to one side of the patient.
4. Ask the patient to expose the lower back region.
5. Guide the robot to use Intel 3D realsense camera module to capture real-time three-dimensional point-of-cloud data of the patient's lower back region. The operator uses one finger to locate the positions of DU4, DU3 and BL23 and drag the markers shown on the monitor of the robot's controlling program to the corresponding locations of DU4, DU3 and BL23 on the monitor.
6. Set the initial tuina strength as 30N and the duration as 30mins. Start the robotic program to plan the robotic tuina motion.
7. Apply olive oil on the lower back and press "start" to initiate the robotic tuina.
8. After the robot starts tuina, ask the patient whether the force is comfortable and sufficient. Adjust the force to be stronger or weaker according to patient's feedback within the range of 10N and 90N.
9. Hand over the safety stop remote control to the patient and ask the patient to press the safety stop button if he/she experience any discomfort.
10. The robotic tuina will conduct finger rubbing tuina on the selected acupoints. (around 30 minutes)

The EMMA (Expert Manipulative Massage Automation) device, launched in 2017 in Singapore for Tuina treatments, has provided over 50,000 sessions across 12 TCM clinics. It underwent international studies in TCM clinics in Chengdu and hospitals in China. In the U.S., Mayo Clinic conducted human trials in 2023, affirming EMMA's safety, feasibility, and patient satisfaction. In the U.S., it's a Class I device under FDA regulations for relieving muscle aches, subject to general controls and exempt from premarket notification. EMMA holds a CE mark, signifying compliance with EU standards, including the Low Voltage Directive and Electromagnetic Compatibility Directive. The certification, issued on October 13, 2023, by UDEM International, validates EMMA's compliance with international standards until October 15, 2028, bolstering its credibility in therapeutic applications.

Acupuncture

The acupuncture treatment is derived from guidelines from MOH, and with consensus from acupuncture experts. will follow the guidelines of MOH shown in the table below. The acupuncture needles were inserted to appropriate depths based on the body type and acupoint location. The needles were then manipulated to achieve "de qi", a local

sensation of soreness or distension that accompanies effective needling. The needle retention time is 30 minutes. The needles used for the acupuncture will be from Kinhong brand, 0.25 x 25mm (1 Cun Needles).

Acupoints	Location	Symptoms and indications
Dachangshu (BL25)	On the lumbar region, at the same level as the inferior border of the spinous process of the fourth lumbar vertebra (L4), 1.5 cun lateral to the posterior median	Abdominal distension, borborygmus, diarrhea, constipation Lumbar pain
Shenshu (BL 23)	On the lumbar region, at the same level as the inferior border of the spinous process of the second lumbar vertebra (L2), 1.5 cun lateral to the posterior median line.	Lumbar pain, enuresis, frequent urination, tinnitus, deafness, cold feet Seminal emission, impotence, premature ejaculation Irregular menstruation, lecuorrhea, infertility Cough, asthma, weak breathing.
Pishu (BL 20)	In the spinous region, at the same level as the inferior border of the spinous process of the 11th thoracic vertebra (T11), 1.5 cun lateral to the posterior median line	Abdominal distension, vomiting, diarrhea Edema, jaundice Poor appetite, emaciation
Yaoyan (EX-B7)	In the lumbar region, in the depression at the same level as the inferior border of the spinous process of the fourth lumbar vertebra, 3.5 cun lateral to the posterior median line.	Lumbar pain Irregular menstruation, leucorrhea
Weizhong (BL40)	On the posterior aspect of the knee, at the midpoint of the popliteal crease	Lumbar pain, atrophy or paralysis of lower extremities Lower abdominal pain, difficult urination, enuresis Erysipelas, urticaria
Huantiao (GB 30)	In the buttock region, at the junction of the lateral one third and medial two thirds of the line connecting the prominence of the greater trochanter with the sacral hiatus.	Pain in the lumbar and hip, atrophy or paralysis of lower extremities, hemiplegia.

All treatments will be delivered by licensed TCM physicians recognized by the Traditional Chinese Medicine Practitioners Board (TCMPB). The physicians involved will be provided with a training manual with the treatment protocols for acupuncture and massage and they will be trained by the principal investigator and/or co-investigator. In addition, the physicians involved in performing the acupuncture and administration of robotic Tuina will be audited for at least 2 records per physician per week to ensure treatment fidelity. If the treatment procedure needs to be modified for medical reasons, the physicians will be instructed by the principal investigator to document the details of the modifications with an accompanying rationale for future reference.

Statistical Analysis

All randomized patients who have completed the trial will be included in the analysis. The sample size of our study was estimated using the Stata software program (version 15.1).

This is a randomized controlled trial with 2 parallel arms. The test group is AcuEMMA; the control group is the acupuncture group. The visual analogue scale (VAS) score is the primary outcome. We use ANOVA to calculate

the sample size. Following completion of a pilot study in patients with chronic nonspecific low back pain, the sample size was recalibrated using a hybrid approach: the established minimal clinically important difference (MCID) for VAS in chronic low back pain (Δ=2.0 points)[19]. A conservative standard deviation of 2.0, informed by the pilot data and typical variability reported in active-comparator CLBP trials, was applied. Using a two-sided significance level of α=0.05 and 90% power under a superiority design with 1:1 allocation, the required sample size is 22 participants per arm (44 total). Accounting for an anticipated 20% attrition rate, consistent with the original protocol assumptions, the revised target enrolment is 28 participants per arm (56 total).

Analysis parameters

All parameters and study elements will be analyzed. The statistical analysis will be performed using Statistical Analysis Software SAS 9.3.

Analysis sets

Full analysis set (FAS): The analysis will be conducted according to the intention-to-treat (ITT) principle which means to eliminate the participants with a minimum and reasonable method. ITT population refers to all participants who go through randomization and receive treatment at least one time. Missing values of efficacy will be imputed by the last-observation-carried forward (LOCF) method.

Per-protocol set (PP): PP population refers to all participants who complete relative observation according to protocol requirement and are confirmed to meet following conditions: ① compliance between 80% and 100%; ② not taking prohibited medications during the process of trial; ③ meeting inclusion criteria and not fitting any exclusion items; ④ completing all planned visits and necessary items of CRF. Missing values of this set will still be processed as missing data and not be inputted.

Safety analysis set: Population for safety analysis refers to all participants who enter the trial, receive treatment at least one time and have suitable follow-up data for safety analysis. All safety data including AEs and laboratory results from participants will be assessed.

Statistical analysis technique

Baseline data (gender, age, race, weight, height, vital signs, course of back pain, history of smoking and alcohol) will be descriptively summarized. Differences of measurement data between the groups will be assessed with the use of t-test for normally distributed continuous variables and Wilcoxon signed rank test for non-normally distributed. Differences of enumeration data between the groups will be assessed with the use of chi-square test or CMH test.

Measurement data of different groups in each visit will be reported as mean ± standard deviation (SD). Intra-group comparisons between baseline and each visit will be conducted by using paired t-test (or Wilcoxon signed rank test). Statistical analysis for the data which do not meet above conditions (e.g. non-normal) will be conducted with the use of non-parametric test.

Dropout analysis: Dropout analysis will be conducted with the use of chi-square test. If the data does not conform to chi-square test, Fisher's exact test will be used.

Compliance analysis: Compliance analysis will be conducted with the use of chi-square test. If the data does not conform to chi-square test, Fisher's exact test will be used.

Hypothesis testing: This trial will conduct superiority analysis first. Other difference test will be conduct by two-sided test. The statistical significance will be defined as two-sided P-value of ≤ 0.05 without any special explanation.

Safety analysis

Extent of exposure: Descriptive statistics will be conducted according to the number of treatments and time of treatment in different groups.

AEs analysis: Comparisons of incidence rate of AEs between groups will be conducted with the use of chi-square test. And investigators need to list and describe the AEs happened in this trial. If the data does not conform to chi-square test, Fisher's exact test will be used.

Laboratory parameters: Investigators need to list the change of normal and abnormal parameters before and after trial, and the relationship between the change and the treatment. Comparisons of incidence rate of abnormal parameters will be conducted with the use of chi-square test. If the data does not conform to chi-square test, Fisher's exact test will be used.

Physical examination and vital signs analysis: The vital signs as well as the change in every visit will be summarized in descriptive statistics. Abnormal vital signs during the treatment with clinical significance will be listed.

Randomization

Participants will be randomly divided into two groups: control group (acupuncture), and treatment group (acupuncture and robotic Tuina). Eligible subjects will be randomly assigned to the two groups with 1:1 ratio.

In this study, we will use stratified blocked randomization method. The randomizing scheme will be produced by using statistical analysis software SAS 9.3 with "proc plan" program or excel randomization program to generate the randomization codes. After production, it will be signed and sealed by the staff that produces it and keep by other staff who takes no part in this trial. It will not be allowed to be checked by anyone except the principal investigator.

Concomitant medication

Eligible patients should stop taking medications stated in the exclusion criteria before entering the trial. Long term concomitant medications which may have a treatment effect on CNLBP such as analgesics should be avoided. If the patient is eligible for inclusion but needs to keep consuming their existing medication or drugs for comorbid diseases or for changes in illness state, it is necessary to record this information in the case report form (CRF) which will be provided to them by the physician.

Device management

Within the study center, an air-conditioned room will be provided to store the robotic Tuina device (EMMA). This room will be air conditioned to maintain a constant temperature and equipped with a hygrometer to measure the relative humidity, to ensure that EMMA is maintained in a good condition. Study center will be equipped with 1 main EMMA, and 1 backup EMMA in the event of technical malfunction on the main EMMA.

The room will be locked and only accessible to the physicians involved in the study to prevent unnecessary tampering with the device. Each EMMA will be labelled with a sign “only to be used by personnel involved in the RCT”.

For the acupuncture needles, we will be using acupuncture needles produced by Kinhong Pte Ltd. The needles used for this RCT will be separated from the rest of the needles used by the clinic, and each box of needles will be labelled with the corresponding date of expiry to ensure patient safety.

Standard of early termination and post randomization exclusion

For this study, patients are required to turn up for at least 80% of the total required number of treatment sessions to be included in the final analysis. During the study, patients can drop out of the study at any given point out of their own will. For patients with medical conditions or in special circumstances, the PI can make an exception to exclude the patient from the study with no consequences. In the unlikely event that a patient was misdiagnosed with CNLBP and mistakenly included in the study, these patients will be excluded.

For our study, patients will be allowed to return for treatment a maximum of 7 days after the stipulated next date of visit (with a maximum interval of 14 days). Patients must adhere to a treatment interval of no more than 14 days; exceeding this timeframe will result in exclusion from further treatments.

Additionally, eligible patients in the group who are confirmed to have one of the following will be excluded from the study:

1. Misdiagnosis of CNLBP, mistaken inclusion
2. Meeting the exclusion criteria
3. Who have not undergone a single treatment of acupuncture and/or robotic Tuina throughout the course of study.

Patients who are considered as dropouts will be patients who were eligible, but eventually lost to follow-up and cannot be found. Their results at the last follow up visit will be considered as the final result in statistical analysis and their CRF will also be kept for further reference.

Data collection and management

At the preliminary stage prior to the start of the study, baseline data will be collected and stored in individual patient files. Example of such general data collected will be patient particulars (full name, Date of birth, address, contact information, next of kin, nationality, ethnicity, and any other demographic data). To ensure patient privacy, these data will be stored in individual patient files on a secure encrypted drive with password protection which is only known to the PI. A backup drive will also be created with all these data if the original drive gets compromised during the study. In addition, each patient will be given a unique patient code throughout the study to mask their identity (eg: Patient TN0001). A subject identification log will also be created with the patient names and their corresponding patient code, and this information will not be available unless in the event of an emergency and it is necessary to break the code.

Breaking of the code will only be done in the event of an emergency, such as life-threatening situations where the family members or next-of-kin of the patient need to be informed. The breaking of code will only be authorized by the study PI and granted on a case-by-case basis at the PI’s discretion.

Safety data

Baseline data will be collected from the patients prior to start of the trial. To ensure that the patients are all in good health prior to the start of the trial, patients will undergo a full body screening. These diagnostics will be confirmed by a Western Medicine doctor. During the study, the patients will be assessed by the attending physicians at the start of each session. Patients will be asked to voice out any physical discomforts if any. The patients will be referred for follow-up medical action if deemed necessary by the attending physician. At the end of the study, the patients will also be asked to undergo a full body screening identical to the one conducted at the start of the trial, to compare any changes in their baseline characteristics.

Safety profile

A possible treatment related AE that could result from this trial would be bruising. Some AEs that might result from acupuncture and/or robotic Tuina are:

AE Associated with Acupuncture:

1. Bruising and Bleeding:
    - Some people may experience bruising or minor bleeding at the acupuncture needle insertion sites. This is generally mild and temporary.
2. Fainting or Dizziness:
    - Sensations of lightheadedness, dizziness, or fainting can occur, especially if a person is sensitive to needle stimulation.
3. Infection:
    - While rare, there is a potential risk of infection at the needle insertion sites. This risk can be minimized by ensuring proper hygiene and sterile needle use.
4. Pain or Discomfort:
    - Acupuncture involves the insertion of thin needles into specific points on the body. While most people find it painless, some may experience discomfort during or after the procedure.
5. Fatigue or Drowsiness:
    - Some individuals may feel tired or drowsy after an acupuncture session. This is usually temporary and can be related to the relaxation response induced by the treatment.

AE Associated with robotic Tuina:

1. Muscle Soreness:
    - Deep tissue massage or intense manipulation of muscles can sometimes lead to temporary muscle soreness. This is a common and expected side effect.
2. Bruising:
    - Aggressive or deep tissue massage can occasionally cause bruising, particularly in individuals with sensitive skin or those taking blood-thinning medications.
3. Allergic Reactions:

- Some individuals may be allergic to massage oils, lotions, or other products used during the massage. Allergic reactions can manifest as skin irritation.

4. Aggravation of Existing Conditions:

    - In some cases, massage may exacerbate existing conditions, especially if the therapist is not aware of the person's medical history or specific sensitivities.

5. Temporary Discomfort:

    - The pressure applied during a massage may cause temporary discomfort. It's essential for individuals to communicate with their massage therapist to ensure the pressure is appropriate for their comfort level.

6. Emotional Release:

    - Deep tissue massage or certain techniques may trigger emotional responses in some individuals. This can include feelings of sadness or elation and is generally considered a natural part of the therapeutic process.

The reported AE will be judged by the PI and determined if it is an AE or serious adverse event (SAE). The PI will also advise on the next steps to take to manage the AE, such as further medical attention.

Collection of AE data (if any) will be gathered at the end of every visit. The attending physician will be tasked to ask the patients “Do you have any adverse or side effects to report after the last visit?”. If an AE was reported, the AE will be recorded by the physician and reported to the PI. All AE will be recorded on a separate password protected document and assessed. A serious or SAE will be immediately dealt with, and a safety pause will be called for if necessary. We also intend to track the use of analgesic and pain relief medications used using weekly pain medication diaries.

For this trial, we will inform the patients prior to the trial to the possible AEs. We will also teach them techniques on how to alleviate bruising after the treatment session, such as applying heat using small heat packs to boost circulation and increase blood flow. If the bruising does not improve after 2 days, we will request for the patient to return for a follow-up visit to assess the extent of injury.

If a SAE occurs, such as injury or death, here are the steps that we will take to ensure patient safety and well-being:

Immediate Medical Care:

- Ensure that the affected participant receives prompt and appropriate medical care.

Unblinding:

- In the event of a SAE, all data will be unblinded to the study with permission of the PI to determine the nature of the treatment received.

Reporting to Ethics Committee/IRB:

- The investigator is required to report the SAE to the Institutional Review Board (IRB) or Ethics Committee overseeing the trial. This report includes details about the event, the actions taken, and an assessment of the event's relatedness to the study intervention.

Sponsor Notification:

- The sponsor of the clinical trial must be informed of the SAE promptly. The sponsor will work closely with the investigator to assess the situation and determine the appropriate course of action.

Regulatory Reporting:

- Depending on the severity and regulatory requirements, sponsors may need to report the SAE to relevant health authorities.

Continuation or Termination of the Trial:

- Depending on the nature and frequency of SAEs, the Data Safety Monitoring Board (DSMB) may recommend continuation, modification, or termination of the trial.

Rights and interest protection in clinical trial

To protect the rights and interests of participants in our study, here are key measures in place to ensure the ethical treatment of participants and safeguard their well-being. These measures include:

Informed Consent:

- Before participating in a clinical trial, individuals must provide informed consent. This involves a detailed explanation of the study, its purpose, procedures, potential risks, benefits, and alternatives.

Ethics Review by IRB:

- Our study will undergo ethical review by NTU IRB to ensure it meets ethical standards and that the rights and well-being of participants are protected.

Voluntary Participation:

- Participation in clinical trials is voluntary, and participants have the right to withdraw from the study at any time without facing negative consequences. This will be mentioned during the informed consent process.

Confidentiality:

- Personal information about participants is kept confidential to the greatest extent possible. Data is anonymized or coded to protect privacy, and access is restricted to authorized personnel.

AE Reporting:

- Procedures are in place to promptly report AEs to regulatory authorities, the sponsor, and the ethics committee. This ensures that appropriate action can be taken to protect participants.

Right to Information:

- Participants have the right to be informed of any new information that may affect their willingness to continue participating in the trial. This includes updates on the research, changes to the protocol, and new findings that may impact their decision to remain in the study.

Medical Care and Compensation:

- Participants are entitled to medical care for any treatment-related injuries.

Compliance with Regulations:

- This study will adhere to the requirements of the World Medical Association Declaration of Helsinki. The reporting of this study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline and the ICH-GCP guidelines.

Education and Training:

- Investigators, research staff, and those involved in the conduct of clinical trials are required to undergo training in research ethics. This helps ensure a thorough understanding of the principles and responsibilities involved in protecting participant rights.

Quality control and assurance in clinical trial

Quality control and quality assurance are critical components of the management of clinical trials. Here is an overview of quality control and quality assurance in our study:

Quality Control:

1. Site Monitoring:
    - Regular on-site monitoring visits are conducted to verify that the trial is being conducted in accordance with the approved protocol, GCP guidelines, and applicable regulatory requirements.

2. Data Validation:
    - Verification of the accuracy and completeness of data collected during the trial is a crucial aspect of QC. This may involve source data verification and comparison of data against source documents.

3. Adherence to Protocol:
    - QC measures include confirming that the study is being conducted as per the approved protocol, and any deviations are documented and justified.

4. Investigator Training and Compliance:
    - To ensure that investigators and site staff are adequately trained and comply with the study protocol and regulatory requirements.

5. Equipment Accountability:
    - Verifying the proper handling, storage, dispensing, and accountability of the acupuncture needles and EMMA.

6. Monitoring of AEs:
    - Monitoring and assessing the documentation of AEs to ensure they are reported accurately and in a timely manner.

Methods for ensuring compliance

To improve patient compliance during the study, our study team will send out SMS messages to the participants 3 days prior and 1 day prior to their supposed visit. We will also request a read receipt to confirm their attendance at the next visit.

During the study, patients will be provided with a leaflet containing information on the trial and some key pointers to adhere to during study. The information sheet will contain a list of items which they should not do during the study, and any other matters to take note of. This information sheet will be passed to each individual patient after registration at the initial visit, and the research assistant will personally go through the leaflet with them and to brief them on the study procedure.

Responsibilities

PI:

- Supervision of the study
- Management of study site(s)
- Adjudicate AE and/or SAE reports
- Designate appropriately qualified investigators to manage, monitor and conduct clinical trials

Co-I:

- Screening of appropriate subjects
- Collation and assessment of AE and/or SAE events
- To provide interventions
- Explain to patients the information related to this clinical trial
- Obtain informed consent from the patients
- Provide necessary advice to the patients
- Statistical analyses

Research assistants:

- Assist with patient recruitment
- Arrange follow-up visits for the participants
- Logistical management
- Coordinate and communicate with the investigators and research unit

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