Protocol Synopsis

Ⅰ.Protocol title: The whole body vibration training for total knee arthroplasty-the improvement of the lower limb

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Ⅱ.Objectives: Knee OA in elder cause pain and decrease their functional activity. After conservative rehabilitation failure, they might receive total knee arthroplasty. The post-operation rehabilitation could improve range of motion and might help them to back ADL earlier. However, the pain and swelling after the operation of total knee arthroplasty cause the limitation of early mobilization, cause ROM limitation, muscle strength decrease, functional activity decrease, and impaired ADL. In recent studies, the effect of whole body vibration included improving pain, swelling, muscle strength, balance, and functional activity, increasing metabolic rate and decreasing lactate accumulation. We expect the early intervention of whole body vibration and traditional physical therapy on the post-TKA patient could improve ROM, decrease swelling, increased muscle strength, functional activity, and balance as compared with traditional physical therapy.

Ⅲ.Test drug

1. **Name:** whole body vibration BW-750
2. **Dosage form:** frequency 4-10 Hz, 10-15minutes with rest for 3-5 minutes * 2 days in standing position
3. **Dose(s):** post-op day2, WBV 4-10 Hz, 10-15minutes with rest for 3-5 minutes, post-op day3 WBV 4-10 Hz, 10-15 minutes with 3-5 minutes in standing position
4. **Dosing schedule:** whole body vibration 4-10 Hz for 10-15 minutes with rest 3-5 minutes on post-op day 2 and day3
5. **Mechanism of action:** passive muscle contraction, improve swelling, increase blood flow, and improve muscle strength
6. **Pharmacological category:** N/A

Ⅳ.Study design

1. ■ **Control:** ■ **placebo**
   □ **active (please specify name and dosage)**
   □ **others**

   □ **Uncontrolled**

2. **Blinding: □ open-label □ single blind ■ double blind □ others**
3. **Randomized: ■ yes □ no**
4. **■ Parallel □ cross-over □ others**
5. **Duration of study：**

   From 2018 March first to 2019 December

   □ Multi-national □multi-center(Taiwan) ■ single center(Taiwan)
6. **Number of subjects:** 52 persons
7. **Is there any of the followings included DSMB, Data Safety Monitoring Board:**

   □ yes ■no

Ⅴ.Assessment criteria

1. **Efficacy:** pain (VAS)、swelling circumference、knee range of motion、knee extensor muscle strength、time up and go、and ADL
2. **Safety:** The duration and frequency of whole body vibration is relative low. The risk of damage is very low
3. **Pharmacokinetics:** Not apply
4. **Quality of life:** Through facilitate muscle contraction, improve blood flow, and decrease pain could improve muscle power, increase range of motion and ADL

Ⅵ. Selection criteria

1. **Main inclusion criteria:** knee osteoarthritis, post-operation of total knee arthroplasty, single leg
2. **Main exclusion criteria:** vital signs unstable, uncontrolled blood pressure, diabetes mellitus, neoplasm, neurological disorder, fibromyalgia, cardiac pacemaker, bilateral TKA, musculoskeletal involvement other than TKA

Ⅶ.Study procedures(summary)

1. **Written informed consent must be obtained before any study specific procedures are undertaken.**
2. **The process of the experiment (brief describe)**

   1. Randomized distribute participants into two groups, "whole body vibration(experimental group)+ traditional physical therapy" group and "placebo group with traditional physical therapy+ whole body vibration (placebo without turn-on vibration)".

2. Post-TKA day 1 (not op day)

Pre-test (baselin data) include pain(VAS), leg circumference, knee ROM, knee extensor strength (JAMMAR), sit to stand average duration, 6 meters ambulatory test.

Both groups receive traditional physical therapy and passive continuous passive motion (CPM).

3. Post-TKA day 2

Both groups keep trandition physical therapy and CPM.

(1) The experimental group perform pre-test before the treatment. After the pre-test, participants receive 10-15 minutes WBV exercise in standing position, amplitudem2mm, frequency 4-10Hz, with rest about 3-5minutes. After the treatment, perform post-treatment test 1.

(2) The control group standing on the WBV machine without turn-on for 10-15 minutes and then post-treatment test 1.

4. Post-TKA day 3

(1) The experimental group participants receive 10-15 minutes WBV exercise in standing position, amplitude 2mm, frequency 4-10 Hz, with rest about 3-5minutes. After the treatment, perform post-treatment test 2.

(2) The control group standing on the WBV machine without turn-on for 10-15 minutes and then post-treatment test 1.

Ⅷ. Concomitant treatment:

1. **Permitted:** pain-killer with acetaminophen, NSAIDs, and analgesic medication, traditional physical therapy and continuous passive motion of knee
2. **Prohibited:** nil

Ⅸ.Statistical analysis

1. **Statistical Method for Efficacy / Safety measurements:**

Demographic data were collected on age, pre-TKA OA X-ray Kellgren-Lawrence classification, sex, weight, height, side of involvement. We use t-test, or chi-square test to confirm homogeneity.

On the other side, measurement the circulation of the affected limb above knee 7cm, knee and below knee 7cm for swelling evaluation. Pain scale with Visual-Analogue scale; VAS) before intervention, post-test 1 and post-test 2. Muscle power of knee extensor by the duration with holding knee extension in

sitting position before intervention, post-test 1 and post-test 2
Knee range of motion with goniometer in sitting (prone position)
The duration of time up and go · 6 meter ambulation test with walker usage.
ADL evaluation with Barthel Index including transfer score, ambulation score, and up/down stairs score. Paired t-test is applied for statistical significance between these measurements.