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Research Protocol

Physiotherapy Section

Evaluation of Effectiveness of Contrast Bath vs Knee Pad Device on Pain, Range of Motion and Functional Disability in Knee Osteoarthritis Patients: A Research Protocol

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ABSTRACT

Introduction: Osteoarthritis of knee is one of the most enfeebling conditions that causes pain and functional impairment that adversely affects life quality. Contrast bath therapy causes alternate vasodilatation and vasoconstriction when limb is dipped in warm and cold water, respectively. Knee pad device gives vibrations and heating therapy by infrared light and ice pack is used to give cryotherapy. Here otago exercise program is used to strengthen lower limbs and balance training along with walking protocol.

Need of Study: One of the most frequent joint ailments in the adult population is osteoarthritis because of which there is a notable limitation of mobility. In grade 1 and 2 osteoarthritis people experience pain and stiffness in knee joint. Many studies have been done using traditional immersion contrast bath technique for reducing pain. But it is difficult to find research on contrast therapy using a device.

Aim: To compare the effect of contrast bath therapy and knee pad device on pain, range of motion and functional disability in grade 1 and 2 knee osteoarthritis.

Materials and Methods: This study will be a randomised clinical trial and will be conducted in the Outpatient Department, AVBRH and Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha, Maharashtra, India. This study has been approved from Institutional Ethical Committee of Datta Meghe Institute of Medical Sciences, (DU). Duration of this study will be for a period of one year fromJanuary 2022 to January 2023. Sixty participants with grade 1 or 2 osteoarthritis of knee will be included in the study and randomly divided in two groups with 30 in each. Group A will be given contrast bath therapy and group B will be given treatment with knee pad device and otago exercise program given in both groups. Treatment will be given for two weeks with three sessions per week. Pre and post-treatment pain, range of motion and functional disability will be noted and statistical analysis will be done.

Conclusion: The present study results are expected to establish knee pad device as more effective and easy method than contrast bath therapy in knee osteoarthritis.

Keywords: Extension, Flexion, Goniometer, Otago exercise program

INTRODUCTION

Osteoarthritis, or degenerative joint disease of the knee, is one of the most enfeebling conditions which causes pain and functional impairment that negatively affects the quality of life [1]. It mainly affects the knee joint, which plays important role in stabilising the body in erect posture [2,3]. There is a worsening of the cartilage of the joint and sclerosis of bone beneath the cartilage's surface, leading to pain, stiffness and disability [4]. It indeterminately occurs in the elderly age group, above 45 years more predominant in females, while common in males before 45 years of age [5]. Osteoarthritis affects knee joints at a reported rate of 76% [6]. The condition characterised joint pain, tenderness, movement limitation, crepitus, periodic effusion and different degrees of inflammation characterised the condition [7].

On radiographic findings and using the Kallgren and Lawrence system, the severity of osteoarthritis is graded from 0-4 [8]. In grade 1 osteoarthritis, an X-ray may not reveal any damage, but osteophytes can be an early sign of it, and people experience discomfort or pain. In grade 2, X-rays will possibly show narrowing of the space in the joints, and osteophytes and people experience stiffness and joint pain, especially after resting for a while. In grade 3, there is a narrowing of joint space but not too severe, with osteophyte formation and some sclerosis with some bony end deformities. In grade 4, there is a severe reduction in joint space with osteophytes growth and deformities of bony ends. Intra-articular adhesions, as well as periarticular and intramuscular adhesions lead to stiffness [9].

Contrast bath therapy is a non pharmacological therapeutic option to reduce pain and stiffness in osteoarthritis. In this treatment extremity is dipped alternately in warm water and cold water. This cycle is repeated several times [10]. Immersion in warm water causes vasodilatation which increases blood flow and releases endorphins and encephalin hormones which helps to block pain stimulus. Immersion in cold water causes vasoconstriction, which reduces oedema, thus relieves pressure from pain receptors and provides relief [11]. But in this treatment large amount of water is used and along with that there is limitation in mobility and temperature control of water [12].

The knee pad device gives vibration and heating, along with this cooling is given by using an ice pack to treat pain. This device is built with heating pads inside, which provide a temperature of 40°-45°C. The heating and vibration mode can be adjusted according to the need. Infrared emits heat through vibrations of molecules which increases blood flow and intracellular fluid that removes metabolic waste and increase nutrient supply to the tissues. That leads to a decrease in pain and muscle spasms. Cryotherapy applied using an ice pack increases the pain threshold and dulls the sensations [12]. Vibrations work on the basis of pain gait theory to reduce pain perception [13].

The most often utilised treatment for osteoarthritis of the knee is exercise therapy. Physical activity is one type of non pharmacological pain management approach [14]. It can help you maintain your

strength and mobility [15]. In people with knee osteoarthritis, proprioceptive exercises in both weight-bearing and non weight-bearing positions can improve proprioceptive acuity and reduce pain and functional dysfunction [16]. Otago exercise help osteoarthritis patients improve their static and dynamic balance through focused limb strength and balance function training. Walking is the second portion of the programme [17].

A smart knee pad device used to treat knee joint pain which gives vibration, heating and cooling alternately, shows improvement in pre and post values of the pain [18]. When contrast bath therapy was compared with contrast therapy using infrared and cryotherapy on forearm pain, which showed better improvement in contrast therapy group. These devices are easy to move and temperature is controlled easily. As they overcome the disadvantage of contrast bath therapy i.e. difficulty in maintaining mobility and constant treatment temperature [12].

Studies have been done giving contrast bath therapy using traditional water dipped in method, towel compression, alternate heat packs and cold packs [19], method for knee osteoarthritis [10,11,19]. But authors did not find the study comparing the contrast bath therapy with knee pad devices in knee osteoarthritis patients.

The present study will be conducted with a research question, will there be any significant effect of knee pad device when compared to traditional contrast bath therapy method in reducing pain, increasing range and reducing functional disability? There are two possible hypotheses derived: Null hypothesis (H0): There will be no significant effect of knee pad device and contrast bath therapy on pain, range of motion and functional disability in patients with osteoarthritis of knee (or) Alternate hypothesis (H1): There will be significant effect of knee pad device and contrast bath therapy on pain, range of motion and functional disability in patients with osteoarthritis of knee with either of them superseding each other.

MATERIALS AND METHODS

Study will be a randomised clinical trial conducted in the Outpatient Department (OPD), AVBRH and Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha, Maharashtra, India, as this study has been approved from Institutional Ethical Committee (IEC/2022/797) of Datta Meghe Institute of Medical Sciences, (DU) and the CTRI number for the study is 2022/05/042506 which was prospectively registered. The prevalence of osteoarthritis of knee is 3.63 per hundred [20]. So, this population has been selected for the study. Patients who came to the OPD with knee osteoarthritis and who fulfilled the inclusion criteria will be included in the study. Randomisation will be done by computer generated sequential random numbers and the allocation will be done using sealed envelope method.

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Sample size calculation: Sample size was calculated by taking prevalence of osteoarthritis of knee as 3.8% from previous study [21]. With the level of significance at 5% i.e., 95% confidence interval and desired error of margin of 7%, Dnaiel formula

$$n=\frac{\frac{Z_{\alpha}^{2}}{2}P(1-P)}{d^{2}}$$

was used and 28.65 was the sample size which was rounded off to 30. So, 30 participants will be recruited in group A and 30 participants in group B (n=60).

Inclusion criteria: Both male and female participants aged between 40-60 years, with unilateral knee osteoarthritis grade 1 or 2 diagnosed in X-ray according to Kallgren and Lawrence classification [8] and with stiffness occurring in the knee should not lasting for more than 30 minutes will be included in the study [22].

Exclusion criteria: Patients with grade 3 or 4 of osteoarthritis according to Kallgren and Lawrence classification, having superficial and deep sensory impairments, suffering from systemic illness like cardiac diseases, physical disabilities that are severe (i.e., not able to walk even with a walking aid), participating in another OA intervention study, and patients not willing to participate in the study will be excluded from the study.

Study Procedure

Participant timeline: Duration of the study will be one year i.e., from January 2022 to January 2023 and duration of intervention will be two weeks. Assessment will be done on 1st day before treatment and then at the end of treatment (2nd week).

Implementation: Randomisation will be supervised by the research coordinator and principal investigator. Subjects will be asked to select the sealed envelope and were randomly allocated in either group.

Blinding: Assessor will be blinded for group allocations i.e which treatment group patient belong is not known to them.

Before starting, the intervention, research, and data confidentiality will be explained to all participants and who meet the inclusion criteria (n=60) will be required to sign an informed consent form before being enrolled in the study, which will last for two weeks.

Intervention and intervention design: Group A will get contrast bath therapy. Patient will be in sitting position, with lower limb exposed till mid-thigh and will be dipped in the warm water with set temperature between 38-40°C for four minutes and then in cold water with temperature between 12-14°C for one minute. This alternate dipping in warm and cold water is continued for 20 minutes.

Group B will get knee pad device: The device will be applied over the knee joint. The heating and vibration mode will be adjusted according to patients need. This is applied for four minutes and then cryotherapy is given using ice pack for one minute. This alternate heat and cold treatment are applied for 20 minutes.

Both groups will get Otago Exercise Program (OEP): This program is a collection of muscle-strengthening and balance-retraining exercises developed by the University of Otago. It begins warm-up that includes flexibility exercises, followed by lower-limb strengthening and balancing exercises [23]. Strengthening exercises will be given to knee extensors and flexors, hip abductor, ankle plantar flexors and dorsiflexors. Resistance is provided by ankle weight cuffs with 10 repetitions in each set. Balance retraining exercise will be given as knee bending, walking and turning around on figure of eight-mark, Sideways walking, Backward walking, Tandem stance, Tandem walk and one leg stance according to this program.

Primary Outcome Measures

Visual analogue scale: It is a measurement tool for pain. It's a 10 cm bidirectional straight line with "no pain" and "worst possible pain" written on it, at either end of the line. Patients are asked to draw vertical line as a mark on it which will indicate their level of perception of pain. The distance from the left end point to the marked point is calculated and recorded [24].

Universal goniometer: It is an instrument used to measure range of motion of joint. Knee flexion and extension will be measured using goniometer and this range of knee flexion between 0-150° and extension 150-0° will be recorded in degree.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): It is a 24-item questionnaire. It measures three variables (pain, stiffness and function) that are thought to be important in determining patient-reported outcomes (PROs) in Osteoarthritis (OA). Each item offers 5 responses that is 0 means 'none', 1 means 'mild', 2 means 'moderate', 3 means 'severe' and 4 means 'extreme'. The total score for each subscale is the sum of scores for each response to each item is calculated. Higher

scores mean worse pain, stiffness, or physical function, 96 would be the maximum score obtained by the subjects. Based on the WOMAC score obtained, patients were categorised as low risk (score ≤60), moderate risk (score 60-80) and high risk (score ≥81). Patients are instructed to fill out the scale after it has been explained to them [25].

Secondary Outcome Measure

2-minute Walk Test (2-MWT): The 2MWT is regarded to be a tool for determining exercise tolerance. It will be performed in a quiet passageway 30 m in length approximately. Subjects will be given two minutes to go as far as they could using their usual walking aid [26].

Data collection and management: All baseline tests and assessments, as well as the information about the study given at the time of recruitment (explaining the purpose, nature, process, advantages, and after effects of the intervention), will be repeated one more time.

STATISTICAL ANALYSIS

The difference between two means will be tested using descriptive and interferential statistics, including Chi-square and students t-test. Statistical Package for the Social Sciences (SPSS) software version 27.0 and Graphed Prism version 7.0 will be utilised in the analysis, with a threshold of significance of p-value <0.05 being used.

EXPECTED OUTCOME

Osteoarthritis being a prevalent disease, affects the routine activities and increases liability. The present study findings are expected to bring out knee pad device as an effective method to decrease pain, improve range of motion and reduce the functional disability in knee OA patients. This is an expected outcome.

DISCUSSION

This study will be done to the effect of contrast bath therapy with otago exercise program and knee pad device along with otago exercise program in knee osteoarthritis patients on pain, range of motion and functional disability. The alternate vasodilatation and vasoconstriction help to reduce pain and thus helps to increase range.

A study conducted by Priya L et al., in which they used smart knee pain relief pad based on vibration, alternate heating and cooling for the treatment of knee pain. Pain score on NPRS before and after the treatment was taken. Results showed that mean value of pain before treatment was 5.666666667 and after the use of device was reduced to 2.466666667. This concluded that treatment provided by the gadget is highly significant [18].

Rusminingsih E et al., conducted a study, participants selected with knee pain and contrast bath was warm and cold compresses using a towel. Results showed significant change in pain score before and after the treatment. And they concluded that contrast bath is effective in reducing knee joint pain in elderly [11].

elFatah MIA et al., conducted a study, participants were selected with osteoarthritis of knee. Group 1 was given cold application by using wrapping cold pads, and group 2 was given contrast hydrotherapy using heated pads and alternately cold pads. The results showed that there was greater pain relief and functional improvement in contrast hydrotherapy group than cold therapy group [19].

CONCLUSION(S)

The knee pad device is compared with the traditional contrast bath method. If knee pad device is proved to be more effective, it can be an easy method for pain relief than the long procedure of contrast bath therapy. Temperature regulation will be easy with this device which is important for the effect of treatment.

Ethical approval and dissemination: The study's participants and the DMIMSU that will sponsor it will be able to access the study's findings. After the study is completed and the results are published, the data will be archived in the DMIMSU data repository.

Patient consent: A written informed consent in local language will be taken from the patients by the principal investigators as a proof of confidentiality.

Confidentiality: The participant will be briefed about the study protocol, and the primary investigator will collect subjective data. The confidentiality declaration, as well as the signatures of the principal investigator, the patient, and a witness, will be included on the permission form. If the patient's consent is required to share some information for the study, he will be given total assurance of his privacy.

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