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HACETTEPE UNIVERSITY
FACULTY OF PHYSICAL THERAPY AND REHABILITATION

COMPARISON OF THE EFFECTS OF BASIC BODY AWARENESS THERAPY TO CONVENTIONAL PHYSIOTHERAPY AND HOME EXERCISE PROGRAM IN INDIVIDUALS WITH KNEE OSTEOARTHRITIS

PRINCIPAL INVESTIGATOR

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INVESTIGATORS

Filiz CAN, PhD, PT, PhD, Prof

Study Type: Randomised Controlled Clinical Trial

Ankara, Turkey / 2026

Approved by Approved by Hacettepe University Faculty of Physical Therapy and Rehabilitation Ethics Committee (Approval Number: FTREK25/136)

STUDY PROTOCOL

1. Study Title

Comparison of the Effects of Basic Body Awareness Therapy to Conventional Physiotherapy and Home Exercise Program in Individuals with Knee Osteoarthritis

2. Background and Aim

Osteoarthritis (OA) is a common chronic musculoskeletal condition that predominantly affects weight-bearing joints such as the knee and hip, leading to pain, functional limitations, and reduced quality of life. Exercise therapy and physiotherapy-based interventions are recommended as first-line treatments in the conservative management of knee osteoarthritis due to their effectiveness in reducing pain and improving function. However, long-term adherence to conventional exercise programs remains challenging for many patients.

Basic Body Awareness Therapy (BBAT) is a body–mind–oriented therapeutic approach that focuses on movement quality, postural control, breathing, and body awareness. BBAT aims to enhance self-efficacy, promote efficient movement patterns, and support active patient involvement in rehabilitation. Owing to its holistic nature, minimal equipment requirements, and suitability for group-based application, BBAT may represent a sustainable and accessible alternative exercise method for individuals with knee osteoarthritis. Nevertheless, evidence regarding its effectiveness in this population is limited.

This randomized controlled clinical trial aims to compare the effects of BBAT combined with a home exercise program, conventional physiotherapy combined with a home exercise program, and a home exercise program alone on pain, physical function, proprioception, balance, muscle strength, range of motion, kinesiophobia, fatigue, and quality of life in individuals with knee osteoarthritis.

3. Methods: Study Design and Interventions

3.1. Study Setting

All study procedures, including participant assessment and treatment, will be conducted at the Orthopedic Rehabilitation Unit, Faculty of Physical Therapy and Rehabilitation, Hacettepe University.

3.2. Study Period

The study period has been defined as year of 2026 covering all phases of the research.

3.3. 3.3. Participants and Sample Size Calculation

Participants will be recruited from the Orthopedic Rehabilitation Unit of the Faculty of Physical Therapy, Hacettepe University. Sample size was calculated using G*Power 3.1 based on the minimal clinically important difference of the WOMAC scale. With an alpha level of 0.05 and a power of 0.90, the required sample size was determined as 21 participants per group. All eligible individuals were informed about the study procedures, and written informed consent was obtained prior to participation.

Inclusion Criteria

- Grade 2–3 knee osteoarthritis (Kellgren–Lawrence)
- Age 40–74 years
- Fulfillment of ACR diagnostic criteria

Exclusion Criteria

- Systemic inflammatory rheumatic disease
- Fixed lower extremity deformity or joint contracture
- Previous knee or hip surgery
- Neurological disorders affecting lower extremity function
- Inflammatory or infectious joint conditions
- Physical therapy, exercise program, or injection treatment within the last 6 months
- Regular exercise (≥3 days/week)
- Regular NSAID or corticosteroid use
- Severe cognitive or psychiatric disorders
- Cancer or pregnancy
- Non-adherence to the exercise program

Participants were assigned to the intervention groups using block randomization to ensure balanced group allocation. Randomization was performed after baseline assessment.

3.4. Study Type

- Randomised Controlled Clinical Trial

3.5. Study Design

This study was designed as a three-arm randomized controlled clinical trial. Participants were randomly allocated into one of three intervention groups:
(1) Basic Body Awareness Therapy (BBAT) plus home exercise,
(2) Conventional physiotherapy plus home exercise, or
(3) Home exercise only (control group).

The intervention period lasted six weeks, with supervised sessions conducted twice weekly. The total program duration was eight weeks. Outcomes were assessed at baseline and immediately after completion of the intervention.

Interventions

Basic Body Awareness Therapy (BBAT) Group

Participants in the BBAT group received group-based BBAT sessions twice weekly for six weeks, administered by a physiotherapist certified by the Institute of Basic Body Awareness Therapy (IBK). The program included progressively introduced exercises focusing on body alignment, breathing, postural control, and movement awareness in supine, standing, and functional positions. Participants also followed the standardized home exercise program.

Conventional Physiotherapy Group

Participants in the conventional physiotherapy group received standard physiotherapy interventions, including hot pack application, therapeutic ultrasound, and supervised exercise therapy, twice weekly for six weeks. The same home exercise program was prescribed.

Home Exercise Program Group

Participants in the home exercise group performed an exercise program based on international guidelines (ACSM, OARSI, AAOS, ESCEO, and EULAR). The program included strengthening,

flexibility, aerobic, neuromotor exercises, and patient education. Exercise adherence was monitored using exercise diaries.

Outcome Measures

All outcome measures were assessed before and after the intervention period. Primary outcomes included pain severity, pressure pain threshold, pain catastrophization, active joint position sense, knee function, physical mobility, balance and muscle strength. Secondary outcomes included range of motion, kinesiophobia, fatigue, edema, aerobic and physical performance and quality of life.

Data Management and Confidentiality

All collected data were stored securely in password-protected electronic files accessible only to the research team. Participant confidentiality was strictly maintained, and personal identifiers were removed prior to data analysis.

Study Completion Criteria

The study was considered complete after post-intervention assessments were obtained from all participants. Withdrawal from the study, failure to adhere to the intervention protocol, or absence from three consecutive sessions were recorded as secondary outcomes

3.6. Statistical Analysis

Statistical analysis will be performed using the Statistical Package for the Social Sciences (SPSS) software (version XX.0; IBM Corp., Armonk, NY, USA). Descriptive statistics will be calculated for all variables. Continuous variables will be presented as mean ± standard deviation or median (interquartile range), depending on data distribution, while categorical variables will be expressed as frequencies and percentages. Normality of data distribution will be assessed using the Shapiro–Wilk test and visual inspection of histograms. Between-group differences at baseline will be analyzed using one-way analysis of variance (ANOVA) for normally distributed variables or the Kruskal–Wallis test for non-normally distributed variables. Categorical variables will be compared using the chi-square test. Within-group comparisons before and after the intervention will be analyzed using paired t-tests or Wilcoxon signed-rank tests, as appropriate. Between-group differences in outcome measures over time will be evaluated using repeated-measures ANOVA or mixed-model analysis. In the presence of significant main or interaction effects, post hoc analyses with appropriate correction methods will be applied. The level of statistical significance will be set at $p < 0.05$. All analyses will be conducted according to the intention-to-treat principle.

❖ **INFORMED CONSENT FORM**

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Informed Voluntary Consent Form for Participants

You are invited to participate in a research study titled "Comparison of the Effects of Basic Body Awareness Therapy to Conventional Physiotherapy and Home Exercise Program in Individuals with Knee Osteoarthritis''. This study has been approved by the Ethics Committee of the Faculty of Physical Therapy and Rehabilitation, Hacettepe University (approval date: 04.12.2025 / approval number: FTREK25/136) and is conducted by Filiz CAN PT, PhD, Prof and Emine Esra DİKMEN PT, MSc.

Your participation in this study is entirely voluntary. You may choose not to participate or may withdraw from the study at any time without providing a reason and without any effect on your current or future medical care or patient rights.

Before signing this form, please read the information carefully. There will be no cost to you for participating in this study, and no financial compensation will be provided. All data collected during the study will be used solely for research purposes and will be kept confidential. Study records may be reviewed by authorized monitors, ethics committees, or regulatory authorities when required.

If you have any questions during the study or regarding your participation, you may contact the research team at any time using the contact information provided below.

Reason for the Study	The purpose of this study is to compare the effects of Basic Body Awareness Therapy, a novel therapeutic approach, with conventional physiotherapy in individuals with knee osteoarthritis. Specifically, the study aims to evaluate and compare the effects of these interventions on pain, knee function, fear of movement, balance, quality of life, muscle strength, deep sensation, joint range of motion, edema, functional mobility, and aerobic and physical performance. This study will be conducted within the Department of Musculoskeletal Physiotherapy and Rehabilitation, Faculty of Physical Therapy and Rehabilitation, Hacettepe University. Your participation is important for the successful completion of this research.
Study Procedures	If you agree to participate in this study, you will be examined by Filiz CAN PT, PhD, Prof or Emine Esra DİKMEN PT, MSc and your clinical findings will be recorded. Based on the initial assessment, eligibility for participation will be determined. If you meet the inclusion criteria, you will be enrolled in the study and randomly assigned to one of three study groups. Regardless of group allocation, all participants will follow a standardized home exercise program prescribed by a physiotherapist for a total duration of eight weeks. In addition, participants assigned to one of the two treatment groups will receive one of two physiotherapy and rehabilitation programs administered by a physiotherapist twice weekly for six weeks. At the beginning of the study, the content of the assigned treatment and exercise program will be explained and demonstrated in detail by the physiotherapist. All interventions and exercise programs used in this study are considered safe and are not expected to pose any risk to your health. On the contrary, the exercises and treatment approaches used in all three groups may have beneficial effects on knee pain and knee function.

	With your consent, data will be collected before and after the intervention period. First, demographic information (such as age, height, weight, body mass index, medical and family history) will be recorded using a standardized data collection form. Subsequently, you will be asked to complete ten questionnaires assessing pain, knee function, fear of movement, balance, fatique and quality of life. Your pressure pain threshold will be measured using an algometer, a device that assesses sensitivity to pressure applied to the skin. Deep sensation related to knee movements will be evaluated using a photographic recording method during specific knee movement tasks. These photographs will not be shared with any third parties, will be stored on a password-protected computer, and will be analyzed using computer software. Joint range of motion will be measured using a goniometer, and lower extremity muscle strength will be assessed using a hand-held dynamometer applied externally over the skin. Functional mobility will be evaluated using the Timed Up and Go Test, while physical performance will be assessed using the Stair Climbing Test and the Six-Minute Walk Test. All assessments are non-invasive and will not cause pain, harm, or adverse effects. The total assessment duration will be approximately 70 minutes, including rest periods. If you experience fatigue, pain, balance problems, or discomfort during the assessments or exercises, the procedures will be stopped and resumed on another day if necessary. The exercises included in this study are designed to be low intensity and non-strenuous, focusing on improving body awareness and movement control through simple movements. Mild discomfort or muscle soreness may occur during the initial adaptation period; this is considered normal and is expected to resolve over time. If pain or other symptoms become persistent or severe, the exercises will be discontinued, rest periods will be provided, or you may be withdrawn from the study if necessary. You may also withdraw from the study at any time at your own request. No significant risks are anticipated in this study. All procedures used are routinely and safely applied in clinical practice. Detailed information regarding the content and safety of the intervention corresponding to your assigned group will be provided. You will be encouraged to ask questions at any time, and all concerns will be addressed. Although no risks are expected, information regarding safety measures and the exercise environment will be provided to you and, if necessary, to your family. Basic Body Awareness Therapy will be administered by a physiotherapist who has successfully completed an internationally certified training program and holds official certification in this therapeutic approach.
Study Location	Orthopedic Rehabilitation Unit, Faculty of Physical Therapy and Rehabilitation, Hacettepe University
Will any images and/or audio recordings be obtained?	Yes ☒ No ☐

PARTICIPANT STATEMENT

I confirm that I have been informed about the purpose and content of the research study described above. Following this information, I have been invited to participate in the study as a participant. I have been assured that my identity will be kept confidential both during the conduct of the study and in any resulting publications.

I voluntarily consent to the use of my data for research purposes. I have been informed that my personal information will be carefully protected during the use of study results for educational and scientific purposes. I understand that I may withdraw from the study at any time without providing a reason and that my legal patient rights will be fully preserved in the event of withdrawal.

I understand that I will not incur any financial responsibility related to participation in this study and that no financial compensation will be provided. I confirm that I have fully understood all explanations provided to me regarding the study. I am participating in this study voluntarily, without any pressure or coercion.

I understand that I may contact the researchers at any time using the contact information provided below if I have any questions during the study or regarding any aspect of the research. I acknowledge that a signed copy of this consent form will be provided to me.

Investigators

Name-Surname-Title	Filiz CAN PT, PhD, Prof	Date and Signature
Contact Information	Hacettepe University Faculty of Physical Therapy and Rehabilitation Sıhhiye Campus 06100 Samanpazarı/ANKARA +905324575652	
Name-Surname-Title	Emine Esra DİKMEN PT, MSc	Date and Signature
Contact Information	Hacettepe University Faculty of Physical Therapy and Rehabilitation Sıhhiye Campus 06100 Samanpazarı/ANKARA +905394063945	

Participant

Name-Surname		Date and Signature
Contact Information		