Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Comparative Effectiveness of Task-Oriented Training and Bimanual Therapy versus Conventional Occupational Therapy on Upper Limb Function in Children with Unilateral Cerebral Palsy: A Randomized Clinical Trial Using Functional Assessments and Wearable Sensor–Based Objective Metric

Protocol summary

Study aim

To compare the effectiveness of task-oriented training and bimanual therapy with routine occupational therapy on upper limb function in children with unilateral cerebral palsy and to evaluate the utility of wearable IMU sensors for assessing changes in upper limb motor performance.

Design

This is a randomized, assessor-blinded, three-arm parallel-group clinical trial. Participants will be allocated (1:1:1) using stratified randomization based on MACS level and affected side, with the allocation sequence generated in R. Allocation concealment will be ensured using sequentially numbered opaque sealed envelopes (SNOSE). The total sample size is 50 children.

Settings and conduct

This study is a parallel-group randomized clinical trial in children aged 7–12 years with unilateral cerebral palsy. Following screening, informed consent, and baseline assessment, participants will be stratified and randomly allocated in a 1:1:1 ratio to three groups. Interventions will be delivered over 4 weeks (12 sessions) by trained occupational therapists at the occupational therapy centers where the children routinely receive services in Tehran. Clinical assessments will be conducted at the child's school or usual rehabilitation center, and kinematic data will be recorded using wearable sensors at the Movafaghian Center.

Participants/Inclusion and exclusion criteria

Participants will be children aged 7–12 years with unilateral cerebral palsy, MACS levels II–III, and VFCS levels I–II. Children with significant comorbidities, recent upper limb surgery or botulinum toxin injection, or concurrent similar interventions will be excluded.

Intervention groups

Participants will be randomly allocated to task-oriented training, bimanual therapy, or routine occupational therapy.

Main outcome variables

Primary outcomes: Upper limb function (QUEST), school function (SFA), and IMU-based kinematic measures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260730070445N1**
Registration date: **2026-08-27, 1405/06/05**
Registration timing: **prospective**

Last update: **2026-08-27, 1405/06/05**
Update count: **0**

Registration date

2026-08-27, 1405/06/05

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-09-01, 1405/06/10
Expected recruitment end date
2026-12-31, 1405/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Effectiveness of Task-Oriented Training and Bimanual Therapy versus Conventional Occupational Therapy on Upper Limb Function in Children with Unilateral Cerebral Palsy: A Randomized Clinical Trial Using Functional Assessments and Wearable Sensor–Based Objective Metric

Public title
Comparing the Effectiveness of Task-Oriented Training and Bimanual Therapy with Routine Occupational Therapy on Upper Limb Function in Children with Unilateral Cerebral Palsy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Medical diagnosis of unilateral cerebral palsy Absence of associated conditions such as visual impairment, Rett syndrome, ADHD, or autism spectrum disorder Manual Ability Classification System (MACS) level II or III Visual Function Classification System (VFCS) level I or II Age between 7 and 12 years No history of upper limb surgery or botulinum toxin injection within the past 6 months Ability to understand simple instructions and participate in treatment sessions No cognitive impairment based on the SPARKLE test Not receiving concurrent interventions similar to the study treatments during the study period Written informed consent obtained from parents/legal guardians and assent from the child
Exclusion criteria:
Presence of a comorbid disease or condition that may affect motor function or participation in the study, such as uncontrolled seizures History of upper-limb surgery or botulinum toxin injection within the predefined period before study enrollment Concurrent participation in similar rehabilitation interventions Inability to understand simple instructions or participate safely and effectively in the treatment sessions Any medical condition that may prevent the child from participating safely in the study
Age
From **7 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized
Randomization description
After confirming eligibility and completing the baseline assessments, participants will be randomly assigned in a 1:1:1 allocation ratio to one of three intervention groups: Task-Oriented Training, Bimanual Therapy, or Conventional Occupational Therapy. Stratified randomization will be performed based on Manual Ability Classification System (MACS) level (II or III) and the affected upper limb side (right or left) to ensure a balanced distribution of these important prognostic factors across the study groups. Within each stratum, the random allocation sequence will be generated using R software with variable block sizes to maintain balanced group sizes while reducing the predictability of treatment assignment. The individual participant will be the unit of randomization. To ensure allocation concealment, Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) will be used. The envelopes will be prepared according to the randomization sequence by an individual who is independent of the recruitment, outcome assessment, and intervention processes. Following completion of the baseline assessments and confirmation of participant eligibility, the next consecutively numbered envelope will be opened to determine the participant's group assignment. This procedure will ensure that investigators and outcome assessors remain unaware of the allocation sequence until assignment, thereby minimizing the risk of prediction or manipulation of group allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
To minimize assessment bias, two independent outcome assessors will be employed. Each assessor will be responsible for administering and scoring only one of the outcome measures (SFA or QUEST) and will remain blinded to participants' group allocation, the type of intervention received, and the results of the other assessor. In addition, participants and their parents/legal guardians will be instructed not to disclose any information regarding the intervention received during the assessment sessions.
Placebo
Not used
Assignment
Parallel
Other design features
This study is a three-arm, parallel-group randomized controlled trial with a 1:1:1 allocation ratio. Following confirmation of eligibility, participants will be assigned to one of three intervention groups (Task-Oriented Training, Bimanual Therapy, or Conventional Occupational Therapy) using stratified randomization based on Manual Ability Classification System (MACS) level (II or III) and the affected upper limb side (right or left). Outcome assessments will be conducted at baseline and immediately after completion of the intervention by independent assessors blinded to group allocation. In addition to standardized functional outcome measures, wearable inertial measurement unit (IMU) sensors will be

used to obtain objective kinematic measures of upper limb function.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address
kodakyar Ave, daneshjo Blvd,Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2026-08-12, 1405/05/21

Ethics committee reference number
IR.USWR.REC.1405.071

Health conditions studied

1

Description of health condition studied
Cerebral Palsy

ICD-10 code
G80.2

ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Upper Extremity Skill Quality: Upper extremity movement quality and function will be assessed using the standardized Quality of Upper Extremity Skills Test (QUEST). The test evaluates four domains: dissociated movements, grasp, weight bearing, and protective extension. The total score ranges from 0 to 100%, with higher scores indicating better upper extremity skill quality and function. The assessment will be performed at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Timepoint
Following screening and informed consent, participants will undergo baseline assessment and will then be randomly allocated to one of three intervention groups. The interventions will be delivered for 4 weeks (3 sessions per week), with continuous monitoring throughout the intervention period. Outcome assessments will be conducted immediately after completion of the intervention (post-intervention) using the same assessment tools applied at baseline.

Method of measurement
Measurement will be performed using the Quality of Upper Extremity Skills Test (QUEST). The test assesses upper extremity movement quality across four domains: dissociated movements, grasp, weight bearing, and protective extension. The total score ranges from 0 to 100%, with higher scores indicating better upper extremity function.

Secondary outcomes

1

Description
School functioning will be assessed using the School Function Assessment (SFA), specifically the Activity Performance section. This section evaluates the child's ability to perform school-related tasks and activities associated with the student role. Higher scores indicate better school functioning. The assessment will be performed at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Timepoint
The assessment will be performed at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Method of measurement
Section III (Physical Tasks) of the SFA questionnaire, completed by parents and teachers.

2

Description
Elbow/Forearm Angular Velocity: Angular velocity is defined as the rate of change in joint angle per unit of time during functional task performance and represents the speed of joint movement. It will be calculated from angular data recorded by wearable inertial measurement units (IMUs) placed on the upper arm and forearm. Angular velocity will be derived from the first derivative of the angular signal with respect to time and reported in degrees per second (°/s). This outcome will be measured at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Timepoint
This outcome will be measured at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Method of measurement
Angular velocity will be measured using inertial measurement unit sensors placed on the upper arm and forearm. Angular velocity will be calculated as the first derivative of the angular signal with respect to time and reported in degrees per second (°/s).

3

Description

Movement Symmetry Between the Upper Limbs: Movement symmetry refers to the similarity in movement patterns and the level of participation of the affected and less-affected upper limbs during the performance of functional bimanual tasks. This outcome will be assessed using data recorded by wearable inertial measurement units (IMUs) placed on the affected and less-affected upper limbs. The Asymmetry Index will be calculated to quantify the difference in movement between the two upper limbs and reported as a percentage (%). Lower Asymmetry Index values indicate greater movement symmetry and more similar participation of the two upper limbs. This outcome will be measured at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Timepoint

This outcome will be measured at two time points: before the intervention (baseline) and immediately after completion of the intervention (post-intervention).

Method of measurement

Movement symmetry between the two upper limbs will be measured using inertial measurement unit sensors placed on the upper arm and forearm of both limbs. The Asymmetry Index will be calculated from the recorded movement data of the two limbs and reported as a percentage.

4

Description

Task Completion Time: The time required by the child to complete each functional task from task initiation to completion, calculated based on the onset and completion times extracted from IMU-recorded signals and reported in seconds. This outcome will be measured during selected tasks at baseline and immediately post-intervention.

Timepoint

This outcome will be measured during selected tasks at baseline and immediately post-intervention.

Method of measurement

Task completion time will be measured using inertial measurement unit sensors based on the timing of the recorded movement signals. The duration from the start to the completion of each task will be calculated and reported in seconds.

5

Description

Affected-Hand Use Ratio: The percentage contribution of the affected hand to the overall activity during a functional task, representing the extent to which the affected upper limb is used during task performance. This outcome will be calculated by extracting activity counts from the IMU signals recorded from both hands and determining the percentage ratio of activity in the affected hand to the total activity of both hands. The outcome will be measured at baseline and post-intervention and reported as a percentage (%).

Timepoint

It will be measured at two times: before the intervention (Baseline) and immediately after the intervention (Post-intervention).

Method of measurement

The affected hand use ratio will be measured using inertial measurement unit sensors placed on the upper arm and forearm of both upper limbs. The activity of each hand will be quantified based on the activity count extracted from the recorded movement signals, and the ratio of activity of the affected hand to the total activity of both hands will be calculated and reported as a percentage.

6

Description

Elbow/Forearm Movement Smoothness: The degree of smoothness and consistency of elbow and forearm movement during functional task performance, assessed using jerk-based metrics such as the Jerk Index or Spectral Arc Length. This outcome will be derived from angular movement data recorded by IMU sensors placed on the upper arm and forearm, and a movement smoothness index will be calculated for each selected task. Measurements will be performed at baseline and immediately post-intervention and reported as a normalized, unitless value.

Timepoint

Measurements will be performed at two time points: before the intervention (Baseline) and immediately after the intervention (Post-intervention).

Method of measurement

Elbow and forearm movement smoothness will be measured using inertial measurement unit sensors placed on the upper arm and forearm. Movement smoothness will be determined by analyzing the angular data and calculating the Jerk Index, reported as a normalized, dimensionless numerical value.

Intervention groups

1

Description

Intervention group: Task-Oriented Training Group: The task-oriented training intervention is based on principles of motor learning, activity-based practice, purposeful repetition, and problem-solving during meaningful activities. Children will practice a series of functional tasks related to daily living, school activities, and self-care, tailored to their abilities and functional goals. Task selection and progression will be individualized, with task difficulty gradually increased according to the child's performance. During the sessions, the therapist will provide appropriate feedback and adjust the level of verbal guidance or physical assistance according to the child's progress.

Category

Rehabilitation

2

Description
Intervention group: Bimanual Therapy Group: The intervention focuses on promoting coordinated and functional use of both hands during daily activities. Activities will be designed so that active participation of the affected upper limb is necessary for successful task completion. Tasks will include functional, play-based, educational, self-care, and object-manipulation activities, with the aim of improving bimanual coordination, increasing use of the affected upper limb, and reducing compensatory movement patterns. As in the task-oriented training group, task complexity will be progressively increased according to the child's performance and progress.

Category
Rehabilitation

3

Description
Control group: Routine Occupational Therapy Group: Participants in this group will receive routine occupational therapy services according to the usual practices of the treatment centers. Interventions will be guided by the therapist's clinical judgment and may include general range-of-motion exercises, strengthening exercises, fine motor activities, commonly used neuromuscular facilitation techniques, and motor coordination exercises. A structured task-oriented training or bimanual therapy protocol will not be used in this group; the type and sequence of activities will be determined according to the usual clinical practice of the treatment center.The intervention will be discontinued if requested by the parents, in the event of an adverse event, a change in the child's medical condition, or excessive absenteeism. All groups will receive at least a standard level of occupational therapy care, and no participant will be deprived of effective treatment.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Occupational therapy and rehabilitation centers in Tehran and at the Movafaghian Center

Full name of responsible person
Omid Rustamzadeh

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kodakyar Ave, daneshjo Blvd, Evin, University of Social Welfare and Rehabilitation Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
University of social welfare and rehabilitation sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Omid Rustamzadeh

Position
Ph.D. of student in occupational therapy

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Nazila Akbarfahimi
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the nature of the individual-level study data and confidentiality and data-protection considerations, particularly because the participants are children, there are no plans to publicly share or disseminate individual participant data. Study findings will be reported in aggregated form without identifying individual participants.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The informed consent form used in the study, including the version provided to parents/legal guardians of participants, will be considered for sharing. The final version of the consent form, with any identifying information removed, may be shared where permitted by applicable ethical requirements and regulations for participant data protection.
When the data will become available and for how long
Access to the shareable version of the informed consent form will be considered after completion of the study and the final study report, and will remain available as long as permitted by applicable ethical and participant data protection requirements.
To whom data/document is available
Researchers, rehabilitation professionals, and other scientifically qualified individuals may request access to the shareable version of the informed consent form for legitimate research or academic purposes.
Under which criteria data/document could be used
The informed consent form may be used only for legitimate research, educational, and academic purposes. Its use must not result in the identification of participants or disclosure of confidential information. Any use must comply with applicable ethical requirements and regulations for participant confidentiality and data protection.
From where data/document is obtainable
Applicants seeking access to data and documents related to this study may submit their requests to the study investigator. The primary contact method is email at

kardarmangar.or@gmail.com. The contact person is Omid Rostamzadeh, Department of Occupational Therapy, University of Rehabilitation Sciences and Social Health.

What processes are involved for a request to access data/document

Each access request will be reviewed by the principal investigator. The purpose of the request and compliance with applicable ethical and confidentiality requirements will be assessed. If approved, the shareable version of the informed consent form will be provided to the requester. The time required to respond and provide the document will depend on the nature of the request and any necessary review.

Comments