

Improving comfort and mobility for children with special needs

Submission date 09/10/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/10/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/10/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Different studies consider general rehabilitation for immobile individuals as a part of a 24-hour postural management programme. Little attention has been given to the importance of a sleep system in improving postural care. This study aims to highlight the importance of a sleep system in maximising functional ability and minimising the progression of any musculoskeletal deformity. It will include any neurological diagnosis from a variety of ages to guide therapists in best practice toward postural care.

Who can participate?

Children aged between 2 -17 who have a neurological condition and developed musculoskeletal deformities due to wrong positioning for long period of time.

What does the study involve?

Applying postural management care during bedtime to reduce body asymmetry, increase comfort, and improve the quality of the client's and caregiver's life. Education, guidance, and support will be given to families and caregivers throughout the research period to promote the success of the intervention. Assessments will be conducted in a Physical Medicine and Rehabilitation Hospital, and the intervention will be applied at home.

What are the possible benefits and risks of participating?

The study aims to prove that postural management care will help in reducing body asymmetry and improving the quality of clients' and caregivers' lives. No harm will reach the child from applying the intervention; it is a totally safe procedure.

Where is the study run from?

Physical Medicine and Rehabilitation Hospital, Kuwait.

When is the study starting and how long is it expected to run for?

September 2024 to May 2026. The study will start enrolling in October 2025 for 4 months and may extend to 6 months.

Who is funding the study?
Kuwait University, Kuwait.

Who is the main contact?
Bashayer Alkandery, bashayer.alkandery@ku.edu.kw

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Postural management care for children with neurological disorder

Study objectives

- Assess the Effectiveness of Sleep Positioning Systems: Evaluate whether sleep positioning systems can reduce body asymmetry for individuals with neurological disorders.
- Examine Impact on Quality of Life: Investigate how the use of sleep positioning systems affects the quality of life for both the client and their caregiver.
- Address Gaps in Existing Research: Highlight the limited evidence available on the benefits of sleep positioning systems across various neurological conditions, emphasizing the need for further research beyond cerebral palsy.
- Contribute to Healthcare Knowledge: Provide valuable insights for healthcare professionals regarding the importance of postural care in managing neurological disorders.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 04/05/2025, Health Sciences Center Ethical Committee for the Use of Humans in Research (College of Medicine, Kuwait University, P.O. box 24923 Safat, Kuwait city, 13110, Kuwait; +965 24636203; esther.samuel@ku.edu.kw), ref: VDR / EC - 2025, 92

2. approved 20/08/2025, Ministry of Health (Kuwait, Kuwait city, 13001, Kuwait; +9651810005; ccmhr@moh.gov.kw), ref: 428

Study design

Single centre experimental design (within-subjects repeated measure design) interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied

Implement postural care during sleep for children with neurological disorders who have developed musculoskeletal deformities

Interventions

Participants who meet the inclusion criteria will be randomly assigned using a random number generator to one of three groups:

1. Sleep System Group (Intervention Group) (N=5): Participants in this group will receive specialized sleep system equipment designed to improve posture and sleep quality during bedtime for 6 months.
2. Traditional Treatment Group (Comparison Group)(N=5): Participants in this group will receive traditional treatment, alternating clients' positions during bedtime for 6 months.
3. Control Group (No Treatment)(N=5): Participants in this group will not receive any form of sleep intervention or treatment during the study period. They will continue with their usual routines without additional support.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Sleep system equipment

Primary outcome(s)

The effectiveness of the sleep positioning system in reducing body asymmetry measured using Goldsmith Indices of Body Symmetry at the 4 to 6-month period

Key secondary outcome(s)

Client and caregiver quality of life (QoL) will be measured using a subjective measure at the 4 to 6-month period

Completion date

20/05/2026

Eligibility

Key inclusion criteria

1. 2 to 17 years old
2. Postural deformity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

17 years

Sex

All

Key exclusion criteria

1. Recent orthopedic corrective surgery with less than 6 months
2. Any condition that contraindicates postural adjustments

Date of first enrolment

08/10/2025

Date of final enrolment

01/02/2026

Locations

Countries of recruitment

Kuwait

Study participating centre

Physical Medicine and Rehabilitation Hospital, Kuwait
Sabah AL-Salem, Block 1, Mohammed Tahous Nasser Bin Tahous Street
Kuwait city
Kuwait
13001

Sponsor information

Organisation

Kuwait University

ROR

<https://ror.org/021e5j056>

Funder(s)

Funder type

University/education

Funder Name

Kuwait University

Alternative Name(s)

KU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Kuwait

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

