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Improving comfort and mobility for children with special needs

Submission date 09/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/10/2025	**Overall study status** Ongoing	
Last Edited 13/10/2025	**Condition category** Other	

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

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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 Medcine, 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes