

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effectiveness of respiratory care training on sleep quality of children with neuromuscular disease (NMD) and the stress of their parents

Protocol summary

Study aim

Determining the effectiveness of the educational-respiratory care program on the sleep quality of children suffering from neuromuscular diseases and the stress of their parents

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 50 patients and their parents. RAS software will be used for randomization.

Settings and conduct

The present clinical trial research will be conducted in armed forces hospitals. After collecting the information with the questionnaire, the eligible samples will be assigned to the control or intervention group to implement the intervention. The intervention group will receive a care training program to improve the respiratory condition of their children. The data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All children who do not have good sleep quality based on the score obtained in the questionnaire. Do not take specific medicine for insomnia. Parents do not have a mood disorder. Exclusion criteria: Incomplete participation of parents in filling out questionnaires or attending meetings. Dissatisfaction and unwillingness of the child's family to continue working with the researcher

Intervention groups

For the parents and children of the intervention group, in 4 sessions of 75 minutes, a care training program including effective breathing methods, exercises to increase the strength of the respiratory muscles, specialized care in removing airway secretions, effective cough, postural drainage and suction of secretions, oxygen therapy and cardiac resuscitation. Pulmonary will be done. The control group will receive the usual parental care related to respiratory care of their previously trained children.

Main outcome variables

Improving the sleep status of NMD children, reducing the stress of parents with NMD children

General information

Reason for update

The study's sample size has been corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221231056998N1**

Registration date: **2023-04-25, 1402/02/05**

Registration timing: **prospective**

Last update: **2025-11-05, 1404/08/14**

Update count: **1**

Registration date

2023-04-25, 1402/02/05

Registrant information

Name

Malihe Sadat Moayed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 5503

Email address

msmoayed@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-02, 1402/09/11

Expected recruitment end date

2024-06-02, 1403/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of respiratory care training on sleep quality of children with neuromuscular disease (NMD) and the stress of their parents

Public title
"Effectiveness of respiratory care training on sleep quality of children with neuromuscular disease (NMD)"

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children with neuromuscular diseases who do not have a good quality of sleep based on the score of the questionnaire. Do not take specific medicine for insomnia problems. The ability of parents to participate in webinars The child's family has the desire and consent to participate in the study. The parents do not have a mood disorder (not taking medication and not experiencing other stressful conditions outside of the child's hospitalization during the child's hospitalization)
Exclusion criteria:
 Incomplete participation of parents in filling out questionnaires or participating in meetings
 Dissatisfaction and unwillingness of the child's family to continue working with the researcher
 Death of a child
 Having more than one child with NMD disease
 Having more than one child with NMD disease

Age
To **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Children were selected by available sampling method and finally, each of the selected samples will be assigned to the control or intervention group with Random Allocation Software (RAS). In the main window of the program, the number of groups (2 groups), the sample size (44) and the name of each group (intervention group and control group) will be specified. Then, in the settings section, the randomization option will be set with the same blocks, and by clicking the generate option, the sequence will appear in the form of several columns, which indicate which group each sample should be assigned to.

Blinding (investigator's opinion)
Single blinded

Blinding description
I will do the analysis by coding the data and anonymizing

the questionnaire

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
 Ethics committee in biomedical research
Street address
 Research Management, Ground Floor, Research Institute of Baqiyatullah University of Medical Sciences,
City
 tehran
Province
 Tehran
Postal code
 8344117875
Approval date
 2023-03-01, 1401/12/10
Ethics committee reference number
 IR.BMSU.BAQ.REC.1401.129

Health conditions studied

1
Description of health condition studied
 Neuromuscular diseases
ICD-10 code
 G71.0
ICD-10 code description
 Muscular dystrophy

Primary outcomes

1
Description
 Children's sleep quality in Owens et al.'s questionnaire
Timepoint
 At the beginning of the study (before the start of the intervention) and 14 days after the start of the intervention
Method of measurement
 Owens et al.'s Children's Sleep Habits Questionnaire

2
Description
 Parental stress
Timepoint

At the beginning of the study (before the start of the intervention) and 14 days after the start of the intervention

Method of measurement

stress response inventory scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the parents and children of the intervention group, airway clearing training and breathing exercises will be carried out in the form of a care training program that includes effective breathing methods, exercises to increase the strength of the respiratory muscles, abdominal breathing training, specialized care in removing airway secretions, Effective cough, postural drainage and suction of secretions, proper position and ways of oxygen therapy, mouthwash and cardiopulmonary resuscitation will be effective. This training course will include 4 sessions of 75 minutes during a period of two weeks (two training sessions per week) of webinar training with the participation of parents on social networks. Also, educational content prepared for parents in the form of audio recording, as well as webinar video and pdf file will be shared on social networks for parents.

Category

Prevention

2

Description

Control group: The control group will receive the usual parental care that the parents have already been trained to take care of their children's breathing, and the questionnaires will be completed at the beginning and two weeks after the end of the intervention. The educational content will be provided to the control group after the completion of the research.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Malihe sadat moayed

Street address

Baqiyatullah Al-Azam Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 0436

Email

msmoayed@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe sadat moayed

Street address

Research and Technology Vice-Chancellor, 3rd Floor, , after Sheikh Bahai, Mulla Sadra Street, Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 81261

Email

pr@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe Sadat Moayed

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Sheikh bahaee

City

Tehran

Province

Tehran

Postal code

8344117875

Phone

+98 21 8755 5503

Fax**Email**

msmoayed@bmsu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe Sadat Moayed

Position

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Phone

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Fax**Email**

msmoayed@bmsu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Malihe Sadat Moayed

Position

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Fax**Email**

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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 confidentiality of the data of military families, it is not possible to publish it

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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