

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Effectiveness of Brief Exposure-Based Intervention on Reducing Nighttime Fears in 4-8 Years Children

Protocol summary

Study aim

Determining the effectiveness of a brief exposure-based intervention on the intensity and frequency of nighttime fears in children aged 4 to 8 years. Determining the effectiveness of a brief exposure-based intervention on the self-efficacy of 4 to 8-year-old children in dealing with nighttime fears.

Design

A clinical trial with a single-case experimental design with asynchronous multiple baselines

Settings and conduct

This intervention is implemented by parents at home.

Participants/Inclusion and exclusion criteria

The child's age at the beginning of the treatment should be 4 to 8 years. Fear, anxiety, and avoidance should be constant and repeated and at least 6 months have passed since the child's fears started. According to the parents, fear and anxiety harm the performance of the child and the family. The child should avoid sleeping alone due to nighttime fears. The child and parents should have a complete command of the Persian language.; The child is currently receiving medication or psychotherapy for nighttime fears or other internalizing problems. The child has major health, neuro-developmental, and psychological problems that need treatment. Parents are illiterate or unable to read.

Intervention groups

The intervention is implemented by parents during 8 weeks. So parents should read a part of the story of the book to the child every night or play the book games with the child. During this period, once a week, parents share their problems with the researcher in a phone call. The intervention is provided by the book "Uncle Lightfoot: Flip that Switch". In 21 chapters, this book teaches 4 to 8-year-old children bedtime skills and reduces nighttime fears by presenting stories and teaching games.

Main outcome variables

The score of nighttime fears in the interview form with

the child and the score of the child's Sleep Habits questionnaire; Self-efficacy in dealing with nighttime fears

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240129060841N1**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Zahra Nourian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 4300

Email address

zah.nourian@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-18, 1403/01/30

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of Brief Exposure-Based Intervention on Reducing Nighttime Fears in 4-8 Years Children

Public title
The Effectiveness of Brief Exposure-Based Intervention on Reducing Nighttime Fears in 4-8 Years Children

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The child's at the beginning of the treatment should be 4 to 8 years Fear, anxiety, and avoidance should be constant and repeated and at least 6 months have passed since the child's fears started According to the parents, fear and anxiety harm the performance of the child and the family The child should avoid sleeping alone due to nighttime fears The child and parents should have a complete command of the Persian language
Exclusion criteria:
The child is currently receiving medication or psychotherapy for nighttime fears or other internalizing problems The child has major health, neuro-developmental, and psychological problems that need treatment Parents are illiterate or unable to read

Age
From **4 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **6**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee in Research of University of Social Welfare and Rehabilitation sciences

Street address

No. 14, Motammedi Alley, Dollat Ave., Pasdaran Crossroad

City

Tehran

Province

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Postal code

1945874154

Approval date

2024-01-24, 1402/11/04

Ethics committee reference number

IR.USWR.REC.1402.223

Health conditions studied

1

Description of health condition studied

nighttime fears

ICD-10 code

F93.1

ICD-10 code description

Phobic anxiety disorder of childhood

Primary outcomes

1

Description

The score of nighttime fears in the interview form with the child and the score of the child's Sleep Habits questionnaire.

Timepoint

Before starting the intervention, measurement of nighttime fears will be done every 3 days. During the intervention, the interview form with the child will be administered every three days and the Sleep Habits questionnaire will be administered every seven days.

Method of measurement

Child interview form and Child Sleep Habits Questionnaire

2

Description

Self-efficacy in dealing with nighttime fears

Timepoint

It will be evaluated every 3 days before starting the intervention and every 7 days during the implementation of the intervention.

Method of measurement

What My Child Can Do at Night in the Dark (Coffman, 1987)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the initial assessment, a training session will be held for parents. During this meeting, explanations about the intervention process are presented and the required forms and materials are provided to the parents. Also, in this session, the translated version of the book, which includes stories and instructions for playing each of the games, will be presented to the parents. These guidelines help ensure that all subjects play the games in similar ways. The intervention is implemented by parents during 8 weeks. So parents (father or mother) should read a part of the story of the book to the child every night or play one or more of the book games with the child. It is also recommended that parents spend at least 1.5 hours reading books or playing games every week. After the end of 8 weeks, parents must have finished the book at least 2 times. During this period, once a week, parents share their problems with the researcher in a phone call for 10-20 minutes. The intervention is provided by the book "Uncle Lightfoot: Flip that Switch". In 21 chapters, this book teaches 4 to 8-year-old children bedtime skills and reduces nighttime fears by presenting stories and teaching various games. At the end, explanations are provided for parents about how to play the book and its games. 5 psychological techniques are used in this book: 1) Modeling: in this method, learning skills occur through observing the activities of the child whose story is narrated. 2) Gradual exposure: the child is first exposed to scary stimuli in the book and then Gradually, this encounter occurs in reality. 3) Desensitization: Using this technique, the child learns to associate positive and pleasant activities and images with darkness. 4) cognitive behavioral techniques: these techniques lead to changing the child's way of thinking when faced with scary situations and stimuli. Also, the child learns more about darkness. 5) Reinforcement: By using a reward (for example, a courage necklace), the child's appropriate behaviors are strengthened. The story of the book is about a boy with nighttime fears. Each chapter of the book is a step towards reducing these fears, and the child in the story plays games with his family members. In each chapter, the client who uses this book, after facing their fear in the story, plays the game related to that chapter with the family. Stories should be read to the child before bedtime. It is also recommended that games that require more movement be played 30 minutes to 1 hour before children's bedtime so as not to interfere with their sleep process. But other games can be played when the child is ready to sleep. Before playing each chapter of the book, parents should read the practical guide on how to play the game related to that chapter.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Jarfandish preschool and elementary school

Full name of responsible person

Mohammad Nourian

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<http://jarfandish-school.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr Hamidreza Khankeh

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kodakyar Ave., daneshjo Blvd.,Evin

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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

Zahra Nourian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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Person responsible for updating data

Contact

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University of social welfare and rehabilitation sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

All data can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

People working in scientific and academic institutions and industry

Under which criteria data/document could be used

-

From where data/document is obtainable

Contact the researcher via email. (Zahra Nourian, email address: znourian2000@gmail.com)

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

After checking the industrial or academic affiliation of the applicant, the request will be answered.

Comments