# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

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**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**

Tehran

**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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**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**