

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Developing play therapy based on resilience and Comparison of its effectiveness with cognitive behavioral play therapy on pain severity , sleep disturbance, resilience, improving parent- child interaction and parenting stress in children with functional abdominal pain

Protocol summary

Study aim

Determining the effectiveness of play therapy based on resilience and its comparison with cognitive behavioral play therapy on pain severity , sleep disorder, resilience, improving parent- child interaction, parenting stress , in children with functional abdominal pain

Design

Clinical trial with control group, , with 24 subjects, in a parallel groups, and random assignment by lottery to three groups

Settings and conduct

Play therapy sessions will be conducted in the Amin Hospital Specialist Clinic by a person with a valid educational credential in the field of play therapy.

Participants/Inclusion and exclusion criteria

1. Patients diagnosed with gastrointestinal functional abdominal pain by Pediatrician(baby). 2. Patients are satisfied with the research (parent - child). 3. Age range from 5 to 9 years (child).

Intervention groups

1. play therapy based on resilience 2- cognitive behavioral play therapy 3-Control (without intervention, intervention after completion of research)

Main outcome variables

pain severity , sleep disorder, resilience, improving parent- child interaction, parenting stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200131046320N1**

Registration date: **2020-03-23, 1399/01/04**

Registration timing: **retrospective**

Last update: **2020-03-23, 1399/01/04**

Update count: **0**

Registration date

2020-03-23, 1399/01/04

Registrant information

Name

shekoufeh nikneshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 5729

Email address

shnikneshan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Developing play therapy based on resilience and Comparison of its effectiveness with cognitive behavioral play therapy on pain severity , sleep disturbance, resilience, improving parent- child interaction and parenting stress in children with functional abdominal pain

Public title

Developing play therapy on severity pain, sleep disturbance, resilience, improving parent- child interaction and parenting stress in children with abdominal pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have been diagnosed with gastrointestinal functional abdominal pain (child). 2. Patients are satisfied with the research (parent - child). Age range from 5 to 9 years (child).

Exclusion criteria:

Patients who are in the acute phase of psychiatric disorders (eg, bipolar disorder, severe depression) (parent - child). Patients who have acute physical symptoms that prevent them from attending treatment (parent - child).

Age

From **5 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Study participants will be selected by lottery and assigned randomly to the experimental and control groups by assigning a numeric identification code to each of their names.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Biomedical Research, Islamic Azad University, Isfahan Branch (Khorasgan)

Street address

Arghavanieh, Jey St., Esfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81595-158

Approval date

2018-06-03, 1397/03/13

Ethics committee reference number

IR.IAU..KHUISF.REC.1397.012

Health conditions studied

1

Description of health condition studied

Functional abdominal pain

ICD-10 code

R10.9

ICD-10 code description

Unspecified abdominal pain

Primary outcomes

1

Description

Severity of Pain

Timepoint

Before and after intervention

Method of measurement

Abdominal Pain Questionnaire (APQ-1977),

2

Description

Sleep Disorders

Timepoint

Before and after intervention

Method of measurement

sleep disturbance scale (SDS-1996)

3

Description

Resiliency

Timepoint

Before and after intervention

Method of measurement

children's resiliency scale

4

Description

Parent-Child Relationships

Timepoint

Before and after intervention

Method of measurement

Parent-Child Relationships scale (CPRS-1992)

5

Description

Parenting Stress

Timepoint

Before and after intervention

Method of measurement

Parental Stress Scale (SPS-1995)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: play therapy based on Resilience Including Emotion recognition training, Problem solving, self-esteem, optimism and connecting with friends through play- 8 weekly sessions of 2 hours(one session a week)

Category

Behavior

2**Description**

Intervention group: play therapy based on cognitive-behavioral therapy Including Psycho-education, Self-monitoring, Coping skills training for children, (Deep breathing exercises, Progressive muscle relaxation, Guided imagery, Positive self-talk, Distraction and alternate activities, Self-reinforcement), Parent training, - 6 weekly sessions of 2 hours(one session a week)

Category

Behavior

3**Description**

Control group: No intervention, Training after the end of the research

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin Hospital Special Clinic Isfshan

Full name of responsible person

shekoufeh nikneshan, paiman nasri, fatemeh famouri

Street address

Amin Hospital, Sonbolestan Alley, Ebnsina, Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۴۸۶۵۳۱۴۱

Phone

+98 31 3445 5051

Email

amin@mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

shekoufeh nikneshan

Street address

No37, Hafez Deadend, Amirkhani Alley, Majmar Street

City

Isfahan

Province

Isfahan

Postal code

8143734611

Phone

+98 31 3222 5729

Email

shnikneshan@ gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

شخصی

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

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

Islamic Azad University

Full name of responsible person

Shekoufeh Nikneshan

Position

Psychologist

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

No37, Hafez Deadend, Amirkhani Alley, Majmar street

City

Isfahan

Province

Isfahan

Postal code
8143734611
Phone
+98 31 3222 5729
Email
shnikneshan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
DR Ahmad Abedi
Position
Associate Professor in Psychology of Children with Special Needs, Department of Children with Special Needs
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Isfahan University, Azadi Square
City
Isfahan
Province
Isfahan
Postal code
8143734611
Phone
+98 31 3793 2128
Email
Info@ui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
shekoufeh nikneshan
Position
Psychology
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No37, Hafez Deadend, Amirkhany Alley, Majmar street
City
Isfahan
Province
Isfahan
Postal code
8143734611
Phone
+98 31 3222 5729
Email
shnikneshan@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable