

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effectiveness of hypnotherapy, relaxation and music therapy on control of pain in children with cancer

Protocol summary

Study aim

The effectiveness of hypnotherapy, relaxation and music therapy on control of pain in children with cancer

Design

In this study, our 56 patients with acute leukemia lymphoblastic, and abdominal mass between the age of 6 to 16 years that diagnosed by specialist oncologist at oncology ward in Besaat hospital were chosen. The sample will be allocated as an accessible method until the sample is finished and then we will use the four blocks of design. in this study, we have three intervention groups

Settings and conduct

At Onchlogy ward in Besaat hospital in Sanandaj, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Patient diagnosed with cancer who take routine medication (such as Acetaminophen for decreasing pain) 2. Age below 16 3. Normal IQ Exclusion criteria: 1. Having cognitive and sensitive deficits 2. Co-morbid psychological disorders based on clinical interview by clinical psychologist 3. Age below 6.

Intervention groups

Hypnotherapy, Relaxation, Music therapy and Control group. In this study , we have three intervention groups including hypnotherapy, relaxation and music therapy for decreasing pain based on the protocols described in method section.

Main outcome variables

Decreasing pain stemmed from cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120905010744N2**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

Registration date

2019-07-14, 1398/04/23

Registrant information

Name

FAYEGH فایق YOUSEFI یوسفی

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3317 3590

Email address

fykmsu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2019-08-13, 1398/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of hypnotherapy, relaxation and music therapy on control of pain in children with cancer

Public title

The effectiveness of hypnotherapy, relaxation and music therapy on control of pain in children with cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patient diagnosed with cancer who take routine medication(such as Acetaminophen for decreasing pain) age below 16 normal IQ

Exclusion criteria:

having cognitive and sensitive deficits Co-morbid psychological disorders based on clinical interview by clinical psychologist age below 6

Age

From **6 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate samples to each test and control group, blocked randomization method is used; firstly, the size of blocks was considered as 4, according to the number of samples, 15 blocks based on the random number table Selected people were assigned to groups based on their positioning in the blocks. Blocks are selected from the oncology section of Besat Hospital in Sanandaj

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

Ethical Committe of Kurdistan University of Medical Sciences

Street address

Keshavarz Ave, Besaat Hospital

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2017-04-26, 1396/02/06

Ethics committee reference number

IR.MUK.REC.1396.15

Health conditions studied

1

Description of health condition studied

Cancer disease

ICD-10 code

C80.9

ICD-10 code description

Malignant neoplasm, primary site unspecified

Primary outcomes

1

Description

Severe pain due to cancer

Timepoint

Before and after in per session intervention

Method of measurement

Visual Analogue Scale. For assessing pain we will use of a ruler that depicted on the paper. Then we will tel; the patient zero means the lack of pain and 10 means intolerable pain and then we tell patient put his or her finger on the ruler point that she or he feels. So, we will record the score separately.Also,period of time is every every session in a week.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groups: the first intervention group is hypnotherapy in which we will use the protocol that referred in the method section. The second intervention group is relaxation training that was referred in the method section. The last one is music therapy which is described also in the method section.

Category

Behavior

2

Description

Control group:The next group is control group which any intervention does not it.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Besaat Hospital

Full name of responsible person

Fayegh Yousefi
Street address
Keshavarz Ave
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Phone
+98 87 3317 3590
Fax
+98 87 3366 4643
Email
fykmsu@gmail.com
Web page address
<http://research.muk.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Farzin Rezaea
Street address
Besaat Hospital, Keshavarz Ave
City
Sanandaj
Province
Kurdistan
Postal code
6617713446
Phone
+98 87 3317 3590
Email
fyousefi@gmail.com
Web page address
<http://research.muk.ac.ir/>

Grant name

IR.MUK.REC.1396/15

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan University of Medical Sciences

Proportion provided by this source

70

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
Kurdistan University of Medical Sciences
Full name of responsible person
Fayegh Yousefi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Keshavarz Ave Besaat Hospital
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Phone
+98 87 3317 3590
Email
Fykmsu@gmail.com
Web page address
<http://www.muk.ac.ir/Muk.aspx>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Fayegh Yousefi
Position
Associate proffesor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Keshavarz Ave , Besat Hospital ,
City
Sanandaj
Province
Kurdistan
Postal code
6619943838
Phone
+98 87 3328 5914
Fax
+98 87 3366 4661
Email
fykmsu@gmail.com
Web page address
<http://www.muk.ac.ir/Muk.aspx>

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fayegh Yousefi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Keshavarz AVE, Besat Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3328 5914

Fax

+98 87 3366 4661

Email

Fykmsu@gmail.com

Web page address

<http://www.muk.ac.ir/Muk.aspx>

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

The data gathered in this study such as name and surname and the type of the disease are completely confidential.

When the data will become available and for how long

From 2017 to 2019

To whom data/document is available

The Corresponding author Fayegh Yousefi

Under which criteria data/document could be used

Yes, for data analysing

From where data/document is obtainable

fykmsu@gmail.com

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

By email

Comments

none