

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Effect of Clown Therapy on Fatigue, Anxiety and Depression of Children with Cancer Undergoing Chemotherapy

Protocol summary

Registration timing: **retrospective**

Study aim

Determining the effect of Clown Therapy on fatigue, anxiety and depression in children with cancer under chemotherapy

Last update: **2018-11-25, 1397/09/04**

Update count: **0**

Registration date

2018-11-25, 1397/09/04

Design

Semi-experimental intervention of two groups with pretest-post test design, parallel, non-blind and non-random groups

Registrant information

Name

Fereshteh Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 7540

Email address

fnajafi@zaums.ac.ir

Settings and conduct

The intervention was performed during 2 weeks(each week including two sessions during 2-3 hours) in the playing room. The researcher was dressed as a clown and welcomed the children. Magic, bubble games, word games, finger puppets, music and storytelling were used. There was no intervention in the control group

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Age between 7-15 years old, had received at least one cycle of chemotherapy, had not any history of impairments or chronic disease, had not taken any anti-anxiety or anti-depressant medications Exclusion criteria: Not willing to continue to participate in study, the absence of more than one of the class session

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

2018-02-03, 1396/11/14

Actual recruitment end date

2018-07-11, 1397/04/20

Trial completion date

2018-07-11, 1397/04/20

Intervention groups

The intervention was performed during 2 weeks(each week including two sessions during 2-3 hours) in the playing room. The researcher was dressed as a clown and welcomed the children. Magic, bubble games, word games, finger puppets, music and storytelling were used. There was no intervention in the control group

Main outcome variables

Fatigue, Anxiety, Depression

Scientific title

The Effect of Clown Therapy on Fatigue, Anxiety and Depression of Children with Cancer Undergoing Chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181118041698N1**

Registration date: **2018-11-25, 1397/09/04**

Public title

The Effect of Clown Therapy on Fatigue, Anxiety and Depression of Children with Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Had received at least one cycle of chemotherapy Had not any history of mental, hearing or visual impairments or chronic disease Had not taken any anti-anxiety or anti-depressant medications Not showing any fear of clown

Exclusion criteria:

The absence of more than one of the class sessions Death or feeling not well Not willing to continue to participate in research

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 committee of Zahedan University of Medical Sciences

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2018-04-08, 1397/01/19

Ethics committee reference number

IR.ZAUMS.REC.1397.011

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C80.0

ICD-10 code description

Disseminated malignant neoplasm, unspecified

Primary outcomes

1

Description

Fatigue

Timepoint

Before and immediately after the intervention

Method of measurement

Rhoten Fatigue Scale

2

Description

Anxiety

Timepoint

Before and immediately after the intervention

Method of measurement

Revised Children's Manifest Anxiety Scale

3

Description

Depression

Timepoint

Before and immediately after the intervention

Method of measurement

Child Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention was performed during 2 weeks(each week including two sessions during 2-3 hours) in the playing room. The researcher was dressed as a clown and welcomed the children. Magic, bubble games, word games, finger puppets, music and storytelling were used. There was no intervention in the control group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibne Abitaleb Hospital

Full name of responsible person

Fereshteh Najafi

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Email

fnajafi@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Najafi

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Email

fnajafi@zaums.ac.ir

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Najafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Email

fnajafi@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Najafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Email

fnajafi@zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Najafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Mashahir sq

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Email

fnajafi@zaums.ac.ir

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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data regards outcomes will be shared

When the data will become available and for how long

The access period will be start one month after the result is published

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

Data is sent through an official request and by email

From where data/document is obtainable

Dr. Fereshteh Najafi, Assistant professor, Community Health Nursing Department, Nursing and Midwifery School, Zahedan University of Medical Sciences, zahedan, Iran Address: Nursing and Midwifery School, Mashahir sq, Zahedan, Iran P.o. Box: 9816913396; Phone: 0098 54 33442482; E-mail: fnajafi@zaums.ac.ir

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

Data is sent through an official request and by email

Comments