Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

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

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

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

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181118041698N1**
Registration date: **2018-11-25, 1397/09/04**
Registration timing: **retrospective**

Last update: **2018-11-25, 1397/09/04**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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

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Zahedan

Province
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+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

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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
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

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Nursing and Midwifery School, Mashahir sq

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
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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
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