

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

“The effect of nursing intervention based on the use of humor on pain and depression of adolescents with leukemia”

Protocol summary

Summary

The main purpose: to determine the impact of nursing interventions based on the use of humor on pain and depression in adolescents with leukemia. Design: This study example of empirical research among 12 to 18-year-old with leukemia. These are referred to in the first half of 1394 will see Kashani hospital. The sample size was calculated according to the formula for each group of 31 people. Inclusion criteria: Patients with leukemia undergoing chemotherapy are referred to Kashani hospital, a minimum of 12 and maximum of 18 years old. Exclusion criteria: repeated absences from meetings or give up the child to participate in implementing programs joke; an unwillingness to provide peer after starting the research process. Methods: Demographic data through questionnaires, McGill pain questionnaire and scale of depression in children is collected. Pain and depression were measured by questionnaire will be their first. The same is done and patients are randomly assigned to two experimental and control groups. Then CD and DVD (which contains a collection of short funny videos, jokes) and programs accredited by the Ministry of Culture and Ethics Committee of Social Welfare and Rehabilitation Sciences University, for 30 minutes, three times a week, to for example, the study will run for 8 weeks. At the end of 8 weeks, all patients of pain and Children Depression Scale questionnaire to be completed. Aftermath: After the intervention, depression and pain is measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022526762N1**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Elahe Raesi Vastegani

Name of organization / entity

University of Rehabilitation Sciences and Social Welfare

Country

Iran (Islamic Republic of)

Phone

+98 38 3426 5760

Email address

el.raesi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-20, 1394/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

“The effect of nursing intervention based on the use of humor on pain and depression of adolescents with leukemia”

Public title

“The effect of nursing intervention based on the use of humor on pain and depression of adolescents with

leukemia"

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: allow parents to attend their children's use of humor in meetings; the ability to communicate effectively with the researcher during the initial interview have, are able to handle meetings and physical fitness (stable hemodynamic conditions) have to answer questions at least literacy Exclusion criteria: Frequent absences from meetings or give up the child to participate in implementing programs joke; an unwillingness to provide peer after starting the research process

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomized control group and the control group using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the University of Welfare and Rehabilitation Sciences

Street address
Tehran

City
Tehran

Postal code

Approval date
2015-05-15, 1394/02/25

Ethics committee reference number
IR.USWR.REC.1394.168

Health conditions studied

1

Description of health condition studied

Leukemia, pain, depression

ICD-10 code

C94.7,R52.

ICD-10 code description

Depressive episode,Other specified leukaemias,Pain, unspecified

Primary outcomes

1

Description

Depression

Timepoint

Before intervention,2 months after the intervention.

Method of measurement

CDS-A

2

Description

Pain

Timepoint

Before the intervention, two months after the intervention.

Method of measurement

McGill pain questionnaire

Secondary outcomes

1

Description

nothing

Timepoint

nothing

Method of measurement

nothing

Intervention groups

1

Description

control group did not receive any training.

Category

Behavior

2

Description

In the Intervention group we use of gags were based nursing intervention. This means that the first explanation about the use of humor was given to the participants. In each session, with three happy and fun competitions with prizes running joke (ten minutes), witticism (ten minutes), CD player funny collection of

short films, video clips humor (ten minutes) approved by the Ministry of Culture , Islamic Guidance and ethics Committee of the University of Welfare and rehabilitation Sciences and 5 of the child and adolescent psychiatry and psychotherapy nurses for a period of 30 minutes, 3 times a week for 8 weeks for samples performed by the researcher.

Category

Behavior

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

Kashani Hospital

Full name of responsible person

dr.malekpour

Street address

Chaharmahal va Bakhtiari

City

Shahrecord

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

Investigator

Full name of responsible person

Investigator

Street address

Boroujen

City

Boroujen

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

Yes

Title of funding source

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

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

empty

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

Welfare and Rehabilitation Sciences

Full name of responsible person

Raesi vastegani Elahe

Position

Nursing Graduate Student

Other areas of specialty/work**Street address**

Boroujen

City

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elahe.raesi@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of Rehabilitation Sciences and Social Welfare

Full name of responsible person

Mohammad Ali Hosseini

Position

PhD

Other areas of specialty/work**Street address**

Tehran, University of Rehabilitation Sciences and Social Welfare

City

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Position

Nursing Graduate Student

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City

Boroujen

Postal code**Phone**

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Fax**Email**

Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>