

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effectiveness of child-centered play therapy on resiliency and emotion regulation of children with cancer

Protocol summary

Study aim

Determining the effectiveness of child-centered play therapy on resiliency in children with cancer Determining the effectiveness of child-centered play therapy on Emotion regulation in children with cancer

Design

quasi-experimental research with pretest-posttest design with control group was conducted. 30 children with cancer between the age of 8-12, were selected and assigned randomly to two experimental (15) and control (15) groups

Settings and conduct

the study area of this study was the e Ali asgar hospital The intervention of this research consisted of 12 sessions on the test group and each session for 45 minutes of a child - oriented play therapy.

Participants/Inclusion and exclusion criteria

Inclusion : Children 8-12 years old with cancer The interest in collaboration and participation in research is based on the written consent of the legal guardian Having the power of speech Not receiving other psychological therapies part of the general body health to participate play therapy sessions Exclusion : Existence of severe behavioral disorders and uncontrolled aggression Missing more than 3 sessions of play therapy sessions Receive other psychology interventions

Intervention groups

play therapy as one of the treatment methods in child mental disorders is a concern for researchers.The experimental group was trained for 12 sessions for 45 minutes. The control group received no intervention during the training sessions of the experimental group and waited in the waiting list

Main outcome variables

emotion regulation in children with leukemia resilience in children with leukemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190512043576N1**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **retrospective**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

marziye talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4459 8186

Email address

marziyetalebi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2019-01-16, 1397/10/26

Actual recruitment start date

2019-01-16, 1397/10/26

Actual recruitment end date

2019-01-18, 1397/10/28

Trial completion date

2019-03-21, 1398/01/01

Scientific title

Effectiveness of child-centered play therapy on resiliency and emotion regulation of children with cancer		(including: name, surname, age, marital status, education, work and phone nummber), child information form and consent to participate in the study. The control and experiment groups were divided into two groups (n = 15).	
Public title	Effectiveness of child-centered play therapy on resiliency and emotion regulation of children with cancer	Secondary Ids	empty
Purpose	Supportive	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Inclusion criteria: Children 8-12 years old with leukemia cancer undergoing chemotherapy Inclusion criteria: The interest in collaboration and participation in research is based on the written consent of the legal guardian Inclusion criteria: Having the power of speech Inclusion criteria: Not receiving other psychological therapies (except drug therapy) Inclusion criteria: The relative ability to use hands and part of the general body health to participate play therapy sessions Exclusion criteria: Exclusion criteria: Existence of severe behavioral disorders and uncontrolled aggression Exclusion criteria: Missing more than 3 sessions of play therapy sessions Exclusion criteria: Receive other psychology interventions before or at the same time as conducting the research	1	
Age	From 8 years old to 12 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics committee of Islamic azad University - Science and Research Branch
Phase	N/A	Street address	Hesarek daneshgah Boulevard Islamic Azad University, Science and Research Branch
Groups that have been masked	No information	City	Tehran
Sample size	Target sample size: 37 Actual sample size reached: 30	Province	Tehran
Randomization (investigator's opinion)	Randomized	Postal code	۱۴۷۷۸۹۳۸۵۵
Randomization description	Simple randomization using drawing from the list of volunteers	Approval date	2019-01-13, 1397/10/23
Blinding (investigator's opinion)	Not blinded	Ethics committee reference number	IR.IAU.SRB.REC.1397.139
Blinding description		Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	Children Leukemia Cancer
Other design features	During a call to all parents of chidren with leukemia cancer in the blood clinic and the hospital's blood department, was invited to participate in the research project. by the approval of the head of the Department of Blood and the Supervisor, the registration of all volunteers was carried out for two weeks. Among the volunteers were 30 boys and girls aged between 9 to 12 years with an average age of 10 years, according to the criteria for entry and exit (previously mentioned) from Ali Asghar Children's Hospital (Blood Department), with a medical diagnosis of leukemia ,They were selected for chemotherapy and fill in demographic data form	ICD-10 code	C95.90
		ICD-10 code description	Leukemia, unspecified not having achieved remission
		Primary outcomes	
		1	
		Description	resiliency of children with cancer
		Timepoint	Resiliency of children with cancer was measured before intervention and a week after the intervention ended.
		Method of measurement	questionnaire Social Emotional Assets and Resilience Scales(SEARS)
		2	
		Description	emotion regulation of children with cancer
		Timepoint	emotion regulation of children with cancer was measured

before intervention and a week after the intervention ended.

Method of measurement

Emotion Regulation Questionnaire(ERQ), Emotion Regulation Checklist scoring(ERC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention of this research is based on a child-centered play therapy approach and is based on a client-centered treatment. Play materials(selected on the basis of Landreth principles) are provided by the therapist to create a safe and free environment for the child, then the child is helped to rebuild the traumatic event with toys so tha the child revisit and process thoughts and emotions in a secure environment with that traumatic event and get free.The skilled therapist also can best help through a healthy interpersonal relationship ,reflection on time and returning responsibility to the child itself.It is to be mentioned that the content of the child-centered play therapy sessions for each child varies according to internal problems and feelings, and actually it is a child who has the freedom to direct the play room according to their own internal desires.In order to better implement child-centered play therapy, the play room at the end of the blood section was prepared and equipped by a researcher.Then, according to the predicted schedule, the experimental group sessions were held in 12 sessions of 45 minutes and twice a week, conducted by the researcher

Category

Behavior

2

Description

Control group: During the intervention, the control group did not receive any intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Children's Hospital

Full name of responsible person

Khadijeh Arjmandi

Street address

Zafar Avenue, Ali Asghar Hospital

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Province

Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohamed Hussein Modaresi

Street address

Tehran - End of Shahid Sattari Highway - University Square - Shahdia Hesarak Blvd - Islamic Azad University, Science and Research Branch

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Marziye Talebi

Position

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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