Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effectiveness of art therapy on self-efficacy and self-concept of children and Adolescents Suffering of cancer: A clinical trial

Protocol summary

Study aim

Determining the effectiveness of art therapy on self-efficacy and self-concept of children and adolescents with cancer

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, 34 people, using Sealed EnveloPe Ltd. software. 2017 for randomization

Settings and conduct

Participants will fill two self-efficacy and self-concept questionnaires once, before the intervention and once, a month and a half after the intervention. Location: 17 Shahrivar Hospital, Rasht

Participants/Inclusion and exclusion criteria

Entry criteria: age 5-18 years, children diagnosed with various malignancies, having the ability to read and write, the ability to participate in the program, the absence of severe stressful events (death of first-degree relatives, illness, accident, parental divorce) during the past year.Inclusion criteria: absence of pain based on VAS criteria, presence of specific problems such as autism and ADHD, as well as physical problems, lack of family satisfaction in children and adolescents under 18 years of age

Intervention groups

In the intervention group, at the beginning of each session, the trainer will do a warm-up exercise to prepare and create relaxation to enter the main exercise . Then the practice of each session will be done according to the content of that session. After each exercise, people are asked to express their feelings. At the end of each session, there is a relaxation exercise with soft music and mental imagery to put yourself in a pleasant atmosphere along with breathing. Two self-efficacy and self-concept questionnaires will be filled once, before the intervention and once, a month and a half after the intervention.exercises. Control group: will receive routine care.

Main outcome variables

Improving self-efficacy and self-concept, before the intervention and one and a half months after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221119056541N2**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name

parichehr shahroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of art therapy on self-efficacy and self-concept of children and Adolescents Suffering of cancer: A clinical trial

Public title

Investigating the effectiveness of art therapy on self-efficacy and self-concept of children and Adolescents Suffering of cancer: A clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 5 to 18 years Children diagnosed with various malignancies Having the ability to read and write Ability to participate in the program Absence of severe stressful events (death of a first-degree relative, illness, accident, divorce of parents) during the past year

Exclusion criteria:

Absence of pain based on VAS criteria The presence of special problems such as autism and ADHD and... Physical problems (verbal, mental, vision and hearing) Lack of family satisfaction in children and adolescents under 18 years of age

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using permutation block method. The method used to generate a random allocation sequence by mentioning the name of the software or site used: Using Sealed EnveloPe Ltd software. 2017 available through www.sealedenvelope.com five blocks of six and one block of four, a total of six blocks will be defined, which will be assigned to groups according to the order of the random list specified by the mentioned software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the person analyzing the data and assessing the outcome will not be aware of which group each person is in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق در پژوهش دانشگاه علوم پزشکی گیلان

Street address

خیابان نامجو، خیابان شهید سیادتی، روبروی بیمارستان 17 شهریور

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Province

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Postal code

4193893345

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.GUMS.REC.1402.387

Health conditions studied

1

Description of health condition studied

Self-efficacy and self-concept

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-concept

Timepoint

Once, before the intervention and once, a month and a half after the intervention

Method of measurement

Using the Rogers self-concept scale: Rogers made this scale and it includes two forms. Form "A" measures the person's attitude towards the real self and form "B" measures the person's attitude towards the ideal self. Each form contains 25 personality traits, the opposite of which is stated on the other side. The distance between two opposite adjectives is graded with a seven-point scale. After scoring and calculating the total score of each subject, the type of self-concept is determined according to the obtained score. A total score of 0 to 7 indicates a positive self-concept, a score of 7 to 10 indicates a negative self-concept, and a score greater than 10 indicates a neurotic self-concept.

2

Description

self-efficacy

Timepoint

Once, before the intervention and once, a month and a half after the intervention

Method of measurement

Using the child and adolescent self-efficacy questionnaire: Morris created this form in 2001 to measure the self-efficacy of children and adolescents (7-18 years old). The three subscales of this questionnaire are: social self-efficacy, academic self-efficacy and emotional self-efficacy. This questionnaire has 23 items and the answer to each item is according to a 5-point Likert scale from the option "not at all" = 1) to the option "very much" = 5 (47). The range of scores related to overall self-efficacy is 23-115. Social and academic self-efficacy is 8-10 and emotional self-efficacy is 7-35(48). A higher score means a higher level of self-efficacy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this intervention, although people are placed in groups, in each session, the focus is on the implementation of the method for each person, and the supervision of this issue is the responsibility of the implementing coach, who is one of the researchers and has mastery of the work method. . The explanation of the coach's working method will be presented to the group in each session, and in the stage of implementation by children and teenagers, the coach will be fully supervised by the coach. The use of different arts are included in the content of the sessions and are performed in a way that encourages relaxation and introspection and creates a bond of feelings in people. At the beginning of each session, the trainer will give a welcome, warm-up exercise to prepare and create relaxation to enter the main exercise (the goal of each session). This initial exercise is planned by creating visualization for people for the main exercise that describes their situation or its solutions. Then, the practice of each session is done according to the content of that session by using accessible and low-cost artistic tools in a way that can put the person in the current mental state. After each exercise, people will be asked to express their feelings and then the instructor will help each person understand their artistic product. At the end of each session, there is a relaxation exercise with soft music and mental imagery to put yourself in a pleasant atmosphere along with breathing exercises, and the participants take their artwork home. On average, at the end of each session, the warm-up, relaxation and guided imagery phase will last 7-10 minutes; The stage of artistic output will last 60 minutes and the stage of verbal development will take 15 to 20 minutes.

Category

Prevention

2

Description

Control group: They will not receive any additional intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

به بیمارستان 17 شهریور رشت

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Rasht 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
Rasht University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of data
Study Protocol
No - There is not 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
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
Title and more details about the data/document
The research report will be sent to deputy of research and technology of Guilan University of Medical Sciences
When the data will become available and for how long
Around Azar 1403
To whom data/document is available
Relevant policy makers
Under which criteria data/document could be used
Descriptive analysis
From where data/document is obtainable
Deputy of research and technology of Guilan University

of Medical Sciences

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

To deputy of research and technology of Guilan University of Medical Sciences

Comments