

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of board games on anxiety and fatigue of adolescents with leukemia

Protocol summary

Study aim

Due to the lack of suitable infrastructures for appropriate entertainments of adolescents in medical settings, and the high cost of infrastructure preparation in these centers, new methods are needed to control the symptoms of fatigue and anxiety as common side effects of treatment in adolescents. The results of this study may introduce an effective, innovative, and cost-effective method through the wider use of board games to control these symptoms.

Design

Controlled clinical trial - parallel groups - without blinding - randomized - on 66 patients

Settings and conduct

Due to the existence of two separate oncology wards in Mahak Center (Tehran city), one ward will be randomly assigned to the control group and the other to the intervention group. Routine medication and pamphlets in the Mahak will be considered as the routine intervention for both groups. Patients in the intervention group will be divided into groups of 4-6 people and a training session will be held to teach how to play games. In the intervention group, the researcher will play board games for 4 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria :having the experience of at least one course of chemotherapy, and clear evidence of cancer diagnosis based on the medical record and treatment hospitalization. exclusion criteria :mental illness based on the adolescent's medical record.

Intervention groups

Routine medication and pamphlets in the Mahak will be considered as the routine intervention groups. The people in the intervention group will be divided into groups of 6 people and a training session will be held to teach them how to play games. In the intervention group, the researcher will play board games 75 minutes per day for 4 days including mafia and chicken milk games in the game room. The researcher will have the

role of the facilitator in games.

Main outcome variables

Anxiety Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049901N1**

Registration date: **2021-04-07, 1400/01/18**

Registration timing: **retrospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name

fatemeh derakhshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 7520

Email address

kosar1171@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of board games on anxiety and fatigue of adolescents with leukemia

Public title
The effect of board games on cancer anxiety and fatigue

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Experience at least 1 course of chemotherapy Diagnosis of cancer based on medical records Adolescent hospitalization for treatment
Exclusion criteria:
Mental illness based on adolescent medical records

Age
From **11 years** old to **19 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the existence of two separate wards in Mahak Medical Center to prevent the dissemination of information between the two groups, one ward will be randomly assigned to the control group and the other to the intervention group. To do so, wards numbers will be written on two separate balls and will be placed inside a bag. The control group is assigned to the first piked ball and while the remaining ball represents the intervention group. The researcher will play in groups with 4-6 persons which are subbranches of the intervention group. It should be noted that these two wards are not distinguished in terms of hospitalizing physicians, physical space, and type of patients. patients will be randomly allocated to the control or intervention group with the help of 4 block randomization created with SPSS during the admission. To do so, the hospital admission will contact the researcher during patient reception to determine the patient ward based on the prepared SPSS list. To prepare the SPSS list, first in the "variable" section, a variable named ID is created, then the "compute variable" is chosen in the "transform" toolbar. In the "Compute variable" window, "ALL" is chosen for the "function group" and "Casenum" for the "function and special variables". Next, the "A" variable is created based on the $0.1 + (\text{casenum}/4) - 0.49$ formula. The "A" parameter is Rounded by choosing the "Rnd(1)" option in the "function and special variables" sub-window to create the "B" parameter. In the next step, a "random number" with a "uniform" distribution between 0-1 is created. After that, "the Rank case" is chosen in the "transform"

toolbar, and the "uniform" variable is ranked based on the "B" variable. As a result, in the created variable, numbers 1.0 and 2.0 represent the control group, and 3.0 and 4.0 represent the intervention.

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

Ethics Committee of Arak University of Medical Sciences

Street address

Shahid Zainuddin - Zulfikar 1, No. 18

City

Qom

Province

Ghoum

Postal code

3713197773

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.ARAKMU.REC.1399.269

Health conditions studied

1

Description of health condition studied

Fatigue and anxiety in adolescents with leukemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fatigue mark based on the "cancer related fatigue" questionnaire

Timepoint

Before and after intervention

Method of measurement

Iranian Version of Cancer-Related Fatigue questionnaire

2

Description

Anxiety marks based on Hospital Anxiety and Depression Scale (HADS)

Timepoint

Before and after intervention

Method of measurement

Anxiety section in the Hospital Anxiety and Depression Scale (HADS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: adolescents in the intervention group will be divided into groups of 4-6 people. A training session will be held to teach them how to play the games. In the intervention group, the researcher will play board games 75 minutes per day for 4 days (1 game every 2 days) including mafia and "chicken milk" in the game room. The researcher will play the role of facilitator in the playing games. In the "chicken milk" game, the players should define a product with the help of cards they receive. Then, they have to present their product to other players and persuade them to buy it. Mafia game is an interactive game based on the discussion between players. The players will be categorized into two groups of mafias and civilians by the cards they receive randomly. The civilians should identify mafia group members by cooperating with each other. At the beginning of the study, pre-tests will be taken from both groups based on questionnaires. After 4 days, post-tests will be taken from both groups with questionnaires.

Category

Treatment - Other

2

Description

Control group: medicine and existing pamphlets in the Mahak Hospital will be considered as routine care in both groups.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahak hospital

Full name of responsible person

Fatemeh Derakhshan

Street address

Mahak Hospital

City

Tehran

Province

Tehran

Postal code

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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3848176593

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Email

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Derakshan

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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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

Yes - There is 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

Title and more details about the data/document

There is no more information

When the data will become available and for how long

There is no more information

To whom data/document is available

There is no more information

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

There is no more information

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

There is no more information

Comments