

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 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**

۱۹۵۶۹۹۳۴۶۱

##### **Phone**

+98 21 2350 1000

##### **Email**

pr@mahak-charity.org

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Mahboobeh Sajadi

##### **Street address**

Arak University of Medical Science

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3848176593

##### **Phone**

+98 86 3417 3501

##### **Email**

amozesh@arakmu.ac.ir

#### **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

##### **Street address**

Qom - Zeindodin - Zolfaghar 1` N 18

**City**

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**Email**

kosar1171@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Fatemeh Derakshan

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

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Arak University of Medical Sciences

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Fatemeh Derakhshan

**Position**

Master Student of Pediatric Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Phone**

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**Fax**

**Email**

kosar1171@gmail.com

**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**