

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating The Effect Of Using Smartphone-Based Home Physical Activity On the level of Anxiety and Depression Of Adolescents With Juvenile Idiopathic Arthritis

Protocol summary

Study aim

Investigating the effect of using smartphone-based physical activity on the level of anxiety and depression of adolescents with juvenile idiopathic arthritis

Design

The intended clinical trial includes two intervention and control groups in parallel through simple randomization using the website (<https://www.Randomization.com>). This study is done in the form of a blind strain on the evaluators of the results.

Settings and conduct

The study will be conducted at the Akbar Children's Hospital located in Mashhad, on adolescents aged 12-18 years old with JIA. The patients will be randomly divided into two intervention and control groups. In addition to routine care, the intervention group will receive exercise Menzel use a sports software with the permission of a rheumatologist. Finally, the amount of changes in the levels of depression and anxiety of both groups will be analyzed through questionnaires. This study is a blind and the evaluators are in this group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range of 12-18 years, consent of the adolescent and their parents, not being in the acute phase of the disease, involvement of less than 5 joints, obtaining a score of less than 20 from the CDI questionnaire and obtaining a score of less than 78 from the MASC questionnaire in the initial screening. Exclusion criteria: severe pain when moving

Intervention groups

In addition to routine care, the intervention group will do their exercise regimen at home based on a sports application. The control group will receive routine JIA care as usual.

Main outcome variables

Anxiety score and depression score using MASC and CDI questionnaires respectively

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230511058152N1**

Registration date: **2023-05-19, 1402/02/29**

Registration timing: **prospective**

Last update: **2023-05-19, 1402/02/29**

Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

Mitra Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3366 8266

Email address

gholamimt3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect Of Using Smartphone-Based Home Physical Activity On the level of Anxiety and Depression Of Adolescents With Juvenile Idiopathic Arthritis

Public title

Investigating The Effect Of Physical Activity On Adolescents With Juvenile Idiopathic Arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients Should be in the Age Range of 12-18 Years. Declare the Consent of Adolescents and their Parents. Patients should not be in the Acute Phase of the Disease. Patients have less than 5 Joints Involved. A Smart Mobile Phone with at least Android 4.0 and the Ability to Use It. Do not have other Underlying Diseases, Including Cardiovascular, Neurological, and Musculoskeletal diseases. Have Permission to Exercise and Physical Activity from a Rheumatologist. Having Access to the Internet Obtaining a Score less than 20 from the CDI Questionnaire and less than 78 from the MASC Questionnaire in the Initial Screening

Exclusion criteria:

Parents or adolescents do not agree to participate in the study. Intolerance of exercises do to severe pain

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a Simple Way. Randomization Tool: <https://www.Randomization.com> The Randomization Website Will be Used to Perform Simple Randomization. The System Completely Impartially Assigns the Samples to Two Control and Intervention Groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding has been done for the data analyst. They are unaware of which group each sample belongs to. After randomization, the participants will be informed which group they are in and what intervention they will receive. The main researcher of the project is also fully aware of which group the patients belong to. The sports doctor and the rheumatologist of the patients are also aware of the grouping of the patients

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice President of Research and Technology, Qurashi building, Next to Hoveizeh cinema, Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2023-04-11, 1402/01/22

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.015

Health conditions studied

1

Description of health condition studied

Juvenile idiopathic arthritis

ICD-10 code

M08

ICD-10 code description

Juvenile arthritis

Primary outcomes

1

Description

The anxiety score is checked using the Multidimensional Anxiety Scale for Children questionnaire, which includes a total of 39 questions in 4 dimensions of anxiety. The scoring range in this questionnaire is 0 to 117. With the increase in the score, the degree of anxiety disorder will be more likely.

Timepoint

Baseline phase and also with the purpose of screening and then after 8 weeks of intervention

Method of measurement

Multidimensional Anxiety Scale for Children questionnaire

2

Description

The depression score is evaluated using the Children's

Depression Inventory questionnaire, which includes 27 items. By answering them, the subject gets a score between 0 and 54. The higher this number, the higher the level of depression

Timepoint

Baseline phase and also with the purpose of screening and then after 8 weeks of intervention

Method of measurement

Children's Depression Inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine care, people in the intervention group will receive a home exercise program based on a smartphone in the context of a sports application. This program uses a pre-designed application called "Sworkit Kids". Teenagers who have received permission to enter the program from their rheumatologist will be visited individually by a sports doctor in the presence of the researcher. For every teenager, a suitable exercise regime will be prepared and adjusted, including the type of movements, the number and time required for each movement. The application suitable for each patient's exercise regimen is adjusted by the researcher and installed on the patient's smartphone, and how to work with it is taught. Finally, after 8 weeks of intervention, depression and anxiety questionnaires will be completed again by both the intervention and control groups.

Category

Rehabilitation

2

Description

Control group: People in this group will receive routine care including drug care, physical therapy and diet.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital

Full name of responsible person

Mitra Gholami

Street address

Akbar Children's Hospital, In front of 14 Shahid Kaveh St, Shahid Kaveh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Web page address

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mitra Gholami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Ibn Sina St, Doctor's
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Email

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After publishing the results of the research and completing the evaluations, the data of the research, including the level of anxiety and depression in adolescents with idiopathic arthritis of the youth before the intervention and also its changes after the intervention, the difference in the levels of depression and anxiety in male and female patients, the level of adherence to physical activities in Patients with chronic diseases will be published without mentioning the patient's profile.

When the data will become available and for how long

After the end of the study, all the medical data of the patients can be shared.

To whom data/document is available

Researchers working in academic, scientific and industrial institutions

Under which criteria data/document could be used

Other than the main researcher, no one is allowed to use the documents.

From where data/document is obtainable

The desired request should be sent to Ms. Mitra
Gholami's email: gholamimt3@mums.ac.ir

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

The desired request should be sent to Ms. Mitra
Gholami's email: gholamimt3@mums.ac.ir

Comments