

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### **Efficacy of Acceptance and Commitment Therapy (ACT) on severity of Internet Gaming Disorder in 13-18 years old adolescents comorbid with ADHD**

#### **Protocol summary**

##### **Study aim**

Evaluation of the effectiveness of ACT psychological therapy on the severity of symptoms of IGD comorbid with ADHD

##### **Design**

In this randomized clinical trial with parallel groups, 40 patients were randomly divided into two groups of 20 (case and control). After obtaining informed consent, a demographic questionnaire will be completed for each patient. After reaching the patients to number of 16 (equivalent to 2 groups of 8 individuals), each individual is assigned a specific code by permuted block randomization method and thus individuals are assigned to the intervention and control groups.

##### **Settings and conduct**

Adolescents between 13-18 years old with ADHD (under treatment of Ritalin from at least 3 months ago) and IGD are included in the study. For each person, the IGD questionnaire is filled by a psychiatrist before and after the treatment. The score of this questionnaire is considered as an indicator of severity of IGD and is compared for each individual before and after treatment. ACT psychotherapy sessions are held at Kargarnejad Hospital in Kashan.

##### **Participants/Inclusion and exclusion criteria**

Entry requirements: Adolescents with IGD aged 13-18 years who are comorbid with ADHD. Exclusion criteria: Receive other psychological treatment in the last year and time of research. Other psychiatric disorders other than ADHD. Psychosis. Mental disability. Thoughts and attempted suicide and homicide.

##### **Intervention groups**

Patients in the intervention group will receive ACT psychotherapy as part of their weekly group sessions (8 person per group) for 8 weeks as they receive ADHD medication. Patients in the control group are treated with ADHD medication and for IGD, psychoeducation is

performed on the patient and his family.

##### **Main outcome variables**

Severity of Internet Games Disorder Using IGDS-SF9 Questionnaire

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200118046168N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### **Registration date**

2020-02-01, 1398/11/12

##### **Registrant information**

##### **Name**

Fahimeh Moghaddas

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

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 5558 2655

##### **Email address**

moghaddas-f@kaums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2020-01-08, 1398/10/18

##### **Expected recruitment end date**

2020-05-20, 1399/02/31

##### **Actual recruitment start date**

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Efficacy of Acceptance and Commitment Therapy (ACT) on severity of Internet Gaming Disorder in 13-18 years old adolescents comorbid with ADHD

**Public title**  
efficacy of ACT treatment on severity of internet gaming disorder

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Adolescents between 13-18 years old Internet gaming disorder ADHD  
**Exclusion criteria:**  
Receive other psychological treatment interventions in the last year and time of research Psychiatric comorbidities other than ADHD Psychosis Mental disability Thoughts and attempted suicide and homicide

**Age**  
From **13 years** old to **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After diagnosis of psychiatric disorders and evaluation of inclusion and exclusion criteria, and after reaching 16 persons, each individual is assigned a unique code by permuted block randomization method and thus individuals are assigned to intervention and control groups

**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 Kashan University of Medical Sciences

## Street address

kargarnejad hospital, end of Parastar Blvd, Ghotb ravandi Blvd, Kashan

## City

Kashan

## Province

Isfahan

## Postal code

8715981151

## Approval date

2020-01-07, 1398/10/17

## Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.121

## Health conditions studied

1

### Description of health condition studied

Internet Gaming Disorder

### ICD-10 code

6C51.0

### ICD-10 code description

Gaming Disorder, predominantly online

## Primary outcomes

1

### Description

IGDS-SF9 questionnaire severity score for internet gaming disorder

### Timepoint

Measurement of severity of internet gaming disorder before intervention, at the end of intervention and one month after intervention

### Method of measurement

Internet Gaming Disorder Scale-Short-Form 9 questionnaire (IGDS-SF9)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: These patients will receive ACT psychotherapy as part of weekly group sessions for 8 weeks while receiving ritalin medication (at a dose that has been stable for at least three months) and psychoeducation for IGD. These ACT sessions are run by a child and adolescent clinical psychologist trained in the field.

### Category

Treatment - Other

**2**

**Description**

Control group: these patients undergo psychoeducation for IGD while receiving Ritalin (at a dose that has been stable for at least three months).

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kargarnejad Hospital

**Full name of responsible person**

Fahimeh Moghaddas

**Street address**

Kargarnejad Hospital, end of Parastar Blvd, Ghotb ravandi Blvd

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5554 9111

**Email**

fah\_mds@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Hamid Reza Banafsheh

**Street address**

Kashan University of Medical Sciences, Pezeshk Blvd, Ghotb ravandi Blvd

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5554 0021

**Email**

research@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Fahimeh Moghaddas

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnejad hospital, end of parastar Blvd, kilometer 5 qotb ravandi Blvd, kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5558 2655

**Fax**

**Email**

moghaddas-f@kaums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Fahimeh Moghaddas

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnejad hospital, end of parastar Blvd, kilometer 5 qotb ravandi Blvd, kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

+98 31 5558 2655

**Fax****Email**

moghaddas-f@kaums.ac.ir

**Phone**

+98 31 5558 2655

**Fax****Email**

moghaddas-f@kaums.ac.ir

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

Kashan University of Medical Sciences

**Full name of responsible person**

Fahimeh Moghaddas

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Kargarnejad hospital, end of parastar Blvd, kilometer  
5 qotb ravandi Blvd, kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**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**

Not applicable

**Data Dictionary**

Not applicable