

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

The efficacy of cognitive rehabilitation of executive function on quality of life and hope in adolescent survivors of Leukemia

Protocol summary

Summary

Current research intended to study The efficacy of cognitive rehabilitation of executive function on quality of life and hope in adolescent survivors of Leukemia .This is a quasi-experimental design with a pretest: post-test: follow up and control group. So: adolescent survivors of Leukemia who have medical records in Mofid Children Hospital will be identified and if there is an inclusion and exclusion criteria: they will be invited to participate in the research. After obtaining informed consent from participants. The assessment of executive functioning was tested to measuring impairment in executive functions: quality of life and hope was tested with the behavioral problem check list in order to recognize the effective issues on executive functions and determining inclusion and exclusion criteria with 4 subtest of Wechsler: to control the intelligence of participants are performing. Then individuals will be allocated in two groups of 15 survivor in experimental and 15 survivor in control randomly with table of random. And the experimental group will receive 12 sessions of progressive cognitive executive functioning rehabilitation with cognitive rehabilitation software. The group control will not receive any treatment in this period of time. Before and after intervention and one month after the intervention both group will be assessed with cognitive and quality of life and hope tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051122224N1**

Registration date: **2015-10-18, 1394/07/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-18, 1394/07/26

Registrant information

Name

Omid Amani

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 937 289 7485

Email address

o.amani@mail.sbu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences and Health Services

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of cognitive rehabilitation of executive function on quality of life and hope in adolescent survivors of Leukemia

Public title

The efficacy of cognitive rehabilitation of executive function on adolescent survivors of Leukemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children of age-range 12-16 year: being diagnosed with Acute Lymphoblastic Leukemia or Acute Myeloid Leukemia with at least 6 months after completion of therapy with no other chronic health conditions during the intervention: not having any psychiatric problems or disorders affecting on cognitive functioning: the ability to read and write: having at least one weakness in cognitive functioning with standard deviation: filling out the informed consent of research. Exclusion criteria: having any psychiatric problem or disorder: having a history of cancer in first degree relatives: lack of consent to participate in the research.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

individuals will be allocated in two groups of 15 survivor in experimental and 15 survivor in control randomly with table of random.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences and Health Services

Street address

Ayatollah Taleghani Hospital: Arabi avenue: Chamran Highway: Tehran

City

Tehran

Postal code

1985717443

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

SBMU.RAM.REC.1394.165.IR

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C91.0, C92

ICD-10 code description

This code should only be used for T-cell and B-cell precursor leukaemia

Primary outcomes

1

Description

Quality of life

Timepoint

pretest: post test: follow up

Method of measurement

self report Questionnaire

2

Description

hope

Timepoint

pretest: post test: follow up

Method of measurement

self report Questionnaire

Secondary outcomes

1

Description

executive function

Timepoint

pretest: post test: follow up

Method of measurement

Computer Software

Intervention groups

1

Description

Intervention group: Rehabilitation of executive functions will be performed with cognitive rehabilitation program Neurocognitive Joyfull Attentive Training Implement(NJATI). Nejati's program is designed in order to improving executive functioning in patients with brain injury: aphasia: and dyslexia by Nejati(2013) and it has a good effect on executive functions: this program is containing a group of hierarchical organized assignment which is improving all dimensions of attention(selective: sustained: alternating: dividing). In this program experimental group will receive 12 session of 45 minutes.

Category

Treatment - Other

2

Description

control group: will not receive any therapy.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Omid Amani

Street address

Mofid children's Hospital: Shariati Street: Tehran: Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Mostafa Rezaee Tavirani

Street address

Department of Pediatric Radiology: Mofid Children's
Hospital: Ershad masque: Shariaty street: Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Omid Amani

Position

Master Student

Other areas of specialty/work

Street address

Shahid Beheshti University: Evin: Iran

City

Tehran

Postal code

1983963113

Phone

+98 21 2990 5309

Fax

Email

o.amani@Mail.sbu.ac.ir

Web page address

sbu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Omid Amani

Position

Master student

Other areas of specialty/work

Street address

Shahid Beheshti University: Evin: Tehran: Iran

City

Tehran

Postal code

1983963113

Phone

00219829905309

Fax

Email

o.amani@Mail.sbu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Omid Amani

Position

Master Student

Other areas of specialty/work

Street address

Shahid Beheshti Univercity: Evin: Tehran

City

Tehran

Postal code

1983963113

Phone

+98 21 2990 5309

Fax
Email o.amani@Mail.sbu.ac.ir
Web page address sbu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty