Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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Shahid Beheshti University
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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
Ayatalaah 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 leukeamia

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
Camputer 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
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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
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
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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