Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of child-centered play therapy on internalization and extrapolation behavioral problems in children with cerebral palsy

Protocol summary

Study aim
The purpose of this study was to determine the effectiveness of child-centered play therapy on internalization and extrapolation behavioral problems of children with cerebral palsy

Design
The clinical trial of the study had a control group, community-based and pragmatic, with parallel groups, single blind, simple randomized, and individualized

Settings and conduct
Rofideh Rehabilitation and Maintenance Center in Tehran. First sessions were used to build a relationship between the child and the therapist. Sessions 4-12: the child discussed his problems through the game, and the therapist tried to give the child enough insight without trying to impose a subject on the child or directing their behavior to a particular direction, Sessions 12-16: Children were getting ready for finalzing treatment.

Participants/Inclusion and exclusion criteria
Children aged 6-8 years, the existence of emotional and behavioral problems based on Child Behavior Checklist، Interest in cooperation and participation in research، IQ above 55 ،No other treatments other than medication, ability to use language and speech, Uncontrollable aggression, absence more than twice a week, receiving other interventions at the time of study other than medication.

Intervention groups
Experimental group: sessions for 45 minutes, twice a week by researcher, control group: no intervention.

Main outcome variables
reducing anxiety; reducing depression; reducing breaking law; reducing aggressive.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181008041274N1**
Registration date: **2019-05-04, 1398/02/14**
Registration timing: **retrospective**

Last update: **2019-05-04, 1398/02/14**
Update count: **0**

Registration date
2019-05-04, 1398/02/14

Registrant information

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Name of organization / entity
The university of Science and branch

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-09, 1396/01/20

Expected recruitment end date
2017-07-16, 1396/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of child-centered play therapy on internalization and extrapolation behavioral problems in children with cerebral palsy

Public title

The effectiveness of child_centred play therapy on internalization and extrapolation behavioral problems in children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6-8 years, the existence of emotional and behavioral problems based on Child Behavior Checklist Interest in cooperation and participation in research based on the written consent of the legal guardian IQ is above 55 (based on the information recorded in the medical records available at the center) the lowest IQ is 55 and the highest is 70 and the average IQ is 62.5 No treatments other than medication The ability to use language and speech, Inserting the cerebral palsy injury in the medical file, The relative ability for using hands in the game according to the type of injury stated in the medical file and possibility of using evaluations like muscle tonicity, the growth of reflexes, status evaluation and movement of the daily activities recorded in the occupational therapy file

Exclusion criteria:

Uncontrollable aggression absence for more than twice a week receiving other interventions at the time of study other than medication

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization method was used in this study. In this method, there is the probability of inequality of the subjects assigned to each of the groups, especially in studies with small sample size. Due to the small sample size, instead of using random numbers table, randomization method was assigning the members of the population on a piece of paper and placing it inside a box, and then removing the papers one by one until the desired volume is filled out. In addition, to ensure the correctness of using simple randomization, besides the previous method, randomization production software was used. Random Allocation Software Producing the random sequence: besides the above methods run, online website - WWW.Randomization.com – was used as well. In order to hide the random assignment, one of its methods called the central randomization was used where the random sequence method was used. The researcher contacted the relevant center according to the order of entry of the participants to the study and asked questionsabout the random assignment of the participants. For selecting the sample, 30 children - boys and girls - aged 6-8 years old with a mean age of 7 years, were selected with cerebral palsy diagnosis of paraplegia type and mild to moderate monoplegia and then the sample group was randomly divided into two groups of 15 as control and experimental group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the main researcher who was involved in the intervention, among the other two researchers, knew which participant received which intervention. Thus, single-blind method was used and given the age and the IQ of the children and considering the ethical principles, a brief explanation of the game was given regard the game.However, the principal of the center, the maternity clinic and the center-based pediatrician were kept blind relative to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research Ethics Committee Islamic Azad University- Science and Research Branch

Street address

Tehran - End of Shahid Sattari Highway - University Square - Shahdia Hesarak Blvd - Islamic Azad University of Science and Research Branch

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Approval date

2018-10-31, 1397/08/09

Ethics committee reference number

IR.IAU.SRB.REC.1397.078

Health conditions studied

1

Description of health condition studied

Internalization and extrapolation behavioral problems

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Child Behavior Checklist
Timepoint
Before the intervention, 3 months later and 6 months later
Method of measurement
Children behavioral behavior questionnaire in pre-test and post-test

2

Description
Anxiety Score in Children's Behavioral Problems Questionnaire
Timepoint
Before the intervention, 3 months later and 6 months later
Method of measurement
Children behavioral behavior questionnaire in pre-test and post-test

3

Description
Aggression Score in Children's Behavioral Problems Questionnaire
Timepoint
Before the intervention, 3 months later and 6 months later
Method of measurement
Children behavioral behavior questionnaire in pre-test and post-test

4

Description
Breaking down Score in Children's Behavioral Problems Questionnaire
Timepoint
Before the intervention, 3 months later and 6 months later
Method of measurement
Children behavioral behavior questionnaire in pre-test and post-test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The sessions of the experimental, groups were held in 16 sessions (12 individual sessions and 4 group sessions), for 45 minutes and twice a week done by the researcher.Thechild-centered intervention approach where the child managed the therapy-session and the therapist was as the facilitatorusing different classificationsof toys given to the children.They help the child to gain an insight of themselves, self-control and appropriate emotional outburst.
Category
Treatment - Other

2

Description
Control group: they received no child-centered game therapy intervention and receivedroutine care along no additional work.The researcher also committed to the intervention for the control group at the end of the intervention period and, if it is effective, and if desired, the intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University, Science and Research Branch

Proportion provided by this source
1

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

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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
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

Not applicable

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

After the publication of the article, only a part of the data is related to the main consequence

When the data will become available and for how long

In 1398 and 3 months, he published a paper

To whom data/document is available

Only available to scholars working in academia and academia

Under which criteria data/document could be used

People who choose this approach and plan to test other issues

From where data/document is obtainable

By email with article authors samiravkl@yahoo.com S.ghasemzadeh@ut.ac.ir yasamanshahriari@yahoo.com

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

The method of intervention, the experimental group, the place of execution, and the dependent variables and the research outline for the authors, along with the signed letter of the authors of the proposed plan

Comments