Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The investigation of efficacy of narrative-based language intervention (NBLI) on narrative production structures in Persian-speaking cochlear implanted children

Protocol summary

Summary

Objectives: The aim of this study is determination of efficacy of narrative-based language intervention (NBLI) on story-telling skills in cochlear implanted children. Design: The study will design in order to Randomized Clinical Trial. Major Inclusion criteria: Persian-speaking cochlear implanted children who have 5 to 7 years old, enable to produce sentences, and having psycho-physical health. Major Exclusion criteria: Demolishing the cochlear prosthesis during intervention in any type for more than 2 weeks, and no tendency to continue of study by child or his/her family. Sample size of study is 36 children. Intervention: The NBLI program, a non-invasive method, is based on verbal learning and repetition techniques for improving children's language skills and it will be accomplished in higher-levels of sentences production. Duration of intervention will be long 2 months and a two-monthly period will be considered for follow-up. The control group of study will be received conventional speech therapy similar to intervention group. Main outcomes measures: Frequency of story grammars, production of main information of story, observing the event sequencing, percent of narrative cohesion, and percent of accuracy performance in story-telling

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704247657N3**
Registration date: **2017-06-10, 1396/03/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-10, 1396/03/20

Registrant information

Name
Peyman Zamani

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 61 3322 1002

Email address
zamanip@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source
Thesis of PhD in Speech Therapy supported by Tehran University of Medical Sciences

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2017-12-22, 1396/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The investigation of efficacy of narrative-based language intervention (NBLI) on narrative production structures in Persian-speaking cochlear implanted children

Public title
Efficacy of narrative-based language intervention on narrative production structures in cochlear implanted children

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria consist of: Pre-lingual profound sensory-neural hearing loss; unilateral cochlear implantation (CI) before aged 5 years; having the 22 processors CI prosthesis; using the hearing aid on contra-lateral ear; able to sentence production; to roll at least 1 year from cochlear implantation; orally Persian as the preferred language in children's family; aged between 5 to 17 years; having the Intelligence Quotient (IQ) ability in normal range; no known eyesight disorders; learning disabilities or co-morbidity such as Attention Deficit Hyperactive Disorder (ADHD); motor disorders; Mental Retardation (MR); autism; and so on; nonexistence of the history of narrative interventions; lack of the story-telling ability whether due to speech therapy or self-learning. Exclusion criteria consist of: Family's or child's discontent to continue of the study; to be broken down the cochlear implant prosthesis for more than 2 weeks; to fall sick so that intervention process has to be disrupted for more than 3 weeks (except common colds).
Age
From **5 years** old to **7 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Random-number table

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

2

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran, Keshavarz Blv, Qods Ave, Markazi biulding, floor 6, Moavenat Pazuheshi
City
Tehran
Postal code
1417993337
Approval date
2017-03-12, 1395/12/22
Ethics committee reference number
1956-1395-REC.FNM.TUMS.IR

Health conditions studied

1

Description of health condition studied
Hearing Loss
ICD-10 code
H90.3
ICD-10 code description
Sensorineural hearing loss, bilateral

Primary outcomes

1

Description
Frequency of Story Grammar
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

2

Description
Frequency of Main Information in Story
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

3

Description
Event Sequencing
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up

Method of measurement
Questionnary of Language Sample Analaysis Test

4

Description
Frequency of Correct Clauses
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

5

Description
Frequency of Cohesive Markers
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

6

Description
Average of terminable-units Length
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

7

Description
Subordination Index
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

8

Description
Narrative Cohesion
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

9

Description
Accurracy Performance of Narrative
Timepoint
Before of Intervention, 2 months after Intervention, 2 months for follow up
Method of measurement
Questionnary of Language Sample Analaysis Test

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: Narrative Based Language Intervention is a kind of tell-story training program to children. It has four levels, consist of: warm up phase, story retelling stage, story generation stage, and repeated retelling tasks. Children will be received specific training, tasks, and practices in each levels of the intervention. Tasks of the intervention will be hierarchically easy to hard. Educational tasks will be presented in authentic and enjoyable context of book-reading and role-playing to children. Total duration of the educational intervention will be 2 months and educational 1-hourly lessons will be administered 3-times per week.
Category
Behavior

2

Description
Control group: The conventional tasks of speech therapy will be utilized for tell-story training in control group. These tasks are consisting of: imitation of compound sentences, phrasing, incomplete sentences completion, and questions scaffolding about story.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Cochlear Implantation Center of Amir-Alam Hospital in Tehran
Full name of responsible person
Peyman Zamani
Street address
Tehran, Enqelab Ave, Pich Shemiran, Rehabilitation School, Dep. of Speech Therapy
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Siences, Vice chancellor for research

Full name of responsible person

Dr. Masud Younesian

Street address

Tehran, Enqelab Ave, Vice chancellor of research

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Siences, Vice chancellor for research

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

Tehran University of Medical Sciences, Rehabilitation School, Dep. of Speech Therapy

Full name of responsible person

Peyman Zamani

Position

PhD Student of Speech Therapy

Other areas of specialty/work

Street address

Tehran, Enqelab Ave, Rehabilitation School, Dep. of Speech Therapy

City

Tehran

Postal code

Phone

+98 21 7750 0687

Fax

Email

zamanipdrst@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Rehabilitation School, Dep. of Speech Therapy

Full name of responsible person

Peyman Zamani

Position

PhD Student of Speech Therapy

Other areas of specialty/work

Street address

Tehran, Enqelab Ave, Rehabilitation School, Dep. of Speech Therapy

City

Tehran

Postal code

Phone

+98 21 7750 0687

Fax

Email

zamanipdrst@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences, Rehabilitation School, Dep. of Speech Therapy

Full name of responsible person

Peyman Zamani

Position

PhD Student of Speech Therapy

Other areas of specialty/work

Street address

Tehran, Enqelab Ave, Rehabilitation School, Dep. of Speech Therapy

City

Tehran

Postal code

Phone

+98 21 7750 0687

Fax

Email

zamanip@razi.tums.ac.irzamanipdrst@gmail.com

Web page address

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