

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect developmental stimulation on development criteria in child 3-1 years old with celiac disease

Protocol summary

Summary

In this randomized clinical trial, conducted at Ghaem and Doctor Sheikh hospitals of Mashhad, a developmental stimulation package was utilized. Fifty toddler with the age of 12-36 months eligible according to inclusion criterion were randomly divided into the intervention (25) and control (25) groups. Then, the developmental stimulation program was administered for children in the intervention group, three times a week for 8 consecutive weeks (24 sessions, each two hours). psychosocial, Language, Fine and Gross motor developmental age of the children was assessed by the Bayley Scales of Infant and Toddler Development, before the intervention, 2 and 4 months after the intervention. Control group received routine care in hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021521090N1**

Registration date: **2015-07-13, 1394/04/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-13, 1394/04/22

Registrant information

Name

Elahe Ghayebie

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3728 1015

Email address

ghayebie921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Mashhad University of Medical Sciences

Expected recruitment start date

2015-01-03, 1393/10/13

Expected recruitment end date

2015-05-05, 1394/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect developmental stimulation on development criteria in child 3-1 years old with celiac disease

Public title

Developmental stimulation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children between 3-1 years old, celiac diseases by physicians with pediatric gastroenterologist confirmed, Along with celiac disease and not other physical and mental, Exclusion criteria: unwillingness to cooperate in the study of parents and children for any reason, the child's death or hospitalization during the study

Age

From **1 year** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

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 Mashhad University of Medical Sciences

Street address

Building Qureshi, Daneshgah street, Taghi Abad, Mashhad--

City

Mashhad

Postal code

Approval date

2015-01-03, 1393/10/13

Ethics committee reference number

930524

Health conditions studied

1

Description of health condition studied

celiac disease

ICD-10 code

k90.0

ICD-10 code description

Coeliac disease

Primary outcomes

1

Description

developmental criteria

Timepoint

post intervention, after and 4 month after intervention

Method of measurement

bayley scale infant and toddler developmental 3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group:The intervention group at 3 sessions per week for 24 sessions held over a 5 hour stimulation according to the guidelines"west Virginia"

Category

Other

2

Description

Control Group: in the control group there was no intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr Seyed Ali Jafari

Street address

Ahmad Abad street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Mashhad University of Medical Sciences

Full name of responsible person

Saed Eslami

Street address

Taghi Abad, Daneshgah street, Building Qureshi

City

Mashad

Grant name

Grant code / Reference number

930524

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

Yes

Title of funding source

Vice Chancellor for Research of Mashhad 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

City

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RezaeianA@mums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Science

Full name of responsible person

Elahe Ghayebie

Position

MS in Pediatric Nursing, School of Nursing and
Midwifery

Other areas of specialty/work**Street address**

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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