

# 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**

Mashhad

**Postal code****Phone**

+98 51 3882 8440

**Fax****Email**

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**

Mashhad, Daneshgah street, School of Nursing and  
Midwifery

**City**

Mashhad

**Postal code****Phone**

+98 51 3728 1015

**Fax****Email**

Ghayebie921@mums.ac.ir

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

Mashhad University of Medical Science

**Full name of responsible person**

Akram Rezaeian

**Position**

MS Nursing

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

Mashhad, Daneshgah street, School of Nursing and  
Midwifery

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Elahe Ghayebie

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

Mashhad, Daneshgah street, School of Nursing and  
Midwifery

**City**

Mashhad

**Postal code****Phone**

+98 51 3728 1015

**Fax**

+98 51 3728 1015

**Email**

Ghayebie921@mums.ac.ir

**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*