

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of oral health education through role playing on observing health behaviors of educable mentally disabled boy students in high school in Hamadan

Protocol summary

Summary

Objective: Investigating the effect of oral health education through role playing on observing health behaviors of educable mentally disabled boy students in high school 1. Design: Semi-experimental study in a form of pre and post study. Sample size: 42 students through census sampling. Methods: Educable mentally disabled boy students who are studying in special-aided high school 1 in Hamadan in the school year of 2013-2014. Inclusion criteria: (a) Educable mentally disabled boy students educating in special-aided high school 1; (b) Students without obvious neurological and psychological problems; (c) Ages between 12 to 19 years. Exclusion criteria: (a) Non-cooperative student; (b) Absence more than one session during the course. Interventions: Data collection through checklist and OHI-s measurement before and after the intervention. Scenarios will be performed in 4, 20 minutes sessions that will be held for 1 month. One person as a dentist and three persons as patients will be chosen to play roles and each person will describe a group of problems. The students performance will be measured again by means of checklist and OHI-s measurement, 15 days after the end of intervention. Primary outcome: Students observation of health behaviors that will be evaluated by checklist. Secondary outcome: OHI-s index measurement that consists of two parts of the Accumulated Debris Index and Calculus Index that each one is scored from 0 to 3

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061612439N2**

Registration date: **2013-07-26, 1392/05/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-26, 1392/05/04

Registrant information

Name

Fatemeh Pakrad

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3131 4041

Email address

f_pakrad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice_chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral health education through role playing on observing health behaviors of educable mentally disabled boy students in high school in Hamadan

Public title

Effects of oral health education on observing health behaviors of mentally disabled boy students

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (a) Educable mentally disabled boy students educating in special-aided guidance school; (b) Students without obvious neurological and psychological problems; (c) Ages between 12 to 19 years. Exclusion criteria: (a) Non-cooperative student; (b) Absence more than one session during the course.

Age

From **12 years** old to **19 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

N/A

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

Ethical Human Subject Review Board of Hamadan
University of Medical Sciences

Street address

Hamadan, Hamadan University of Medical Sciences

City

Hamadan

Postal code

Approval date

2013-06-12, 1392/03/22

Ethics committee reference number

16/35/9/753/د/پ

Health conditions studied

1

Description of health condition studied

Mental Retardation

ICD-10 code

F70

ICD-10 code description

Approximate IQ range of 50 to 69 (in adults, mental age from 9 to 12 years). Likely to result in some learning difficulties in school. Many adults will be able to work and maintain good social relationships and contribute to society

Primary outcomes

1

Description

Observe health behavior of students

Timepoint

Before and 15 days after the end of intervention

Method of measurement

checklist

Secondary outcomes

1

Description

Oral Hygiene Index-Simplified

Timepoint

Before and 15 days after the end of intervention

Method of measurement

Using explorer and measuring the debris and calculus on the specific teeth

Intervention groups

1

Description

Intervention group: scenarios will be performed in 4, 20 minutes sessions that will be held for 1 month. One person as a dentist and three persons as patients will be chosen to play roles and each person will describe a group of problems. The students performance will be measured again by means of checklist and OHI-s measurement, 15 days after the end of intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pooyandegan special-aided high school

Full name of responsible person

Street address

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr. Heidar Tavalani

Street address

Shaheed Fahmideh Ave, Hamadan University of
Medical Sciences

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor of Research and Technology, Hamadan
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**

Hamadan University of Medical Sciences

Full name of responsible person

Fatemeh Ashtarani

Position

Postgraduate nursing student

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

Shaheed Fahmideh Ave, Hamadan University of
Medical Sciences, School of Nursing and Midwifery

City

Hamadan

Postal code**Phone**

+98 81 1838 0150

Fax**Email**

f.ashtarani@umsha.ac.ir; f_ashtarani@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan University of Medical Sciences, Nursing and
Midwifery School

Full name of responsible person

Dr. Farshid Shamsaei

Position

Phd of Nursing

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

Shahid Fahmideh Ave, Nursing and Midwifery School,
Department of Psychological Nursing, Hamadan
University of Medical Sciences

City

Hamadan

Postal code**Phone**

+98 81 1838 0150

Fax**Email**

shamsaei68@yahoo.com; shamsaei@umsha.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Hamadan University of Medical Sciences, Nursing and
Midwifery School

Full name of responsible person

Fatemeh Ashtarani

Position

Postgraduate Nursing student

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

Shahid Fahmideh Ave, Hamadan University of Medical
Sciences

City

Hamadan

Postal code**Phone**

00

Fax**Email****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