Clinical Trial Protocol
Iranian Registry of Clinical Trials
17 May 2020

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

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/پ/د

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 Tavilani

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

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

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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

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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