

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The impact of health literacy training based on bandura's social learning theory on self-care in child labor

Protocol summary

Study aim

Determining the effect of health literacy education based on Bandura's social learning theory on self-care in working children

Design

Clinical trial with one intervention group, unblinded, randomized and with concealment, 75 samples, block randomization codes generated by Random Allocation Software.

Settings and conduct

The current research is a clinical trial type, the research population of which will include child labor aged 13-18 who refer to the Association for the Support of child labor in Molavi neighborhood located in Tehran. Available samples will be randomly collected and assigned to an intervention group. The health literacy training program will be conducted by the researcher during 60-90 minutes sessions in a total of 6 sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Willingness and satisfaction of the child and parents to participate in the research, 2. Having an age range of 13-18 years, 3. Not having physical and mental problems and disabilities based on the existing records of working children in the association, which can prevent self-care, 4. Not having any history of health literacy training Exclusion criteria: Absence (even one session of training sessions)

Intervention groups

In the health literacy training package, health literacy constructs (understanding, communication, reading, evaluation, access, use, self-efficacy and calculation) using Bandura's social-learning theory (attention, memorization, re-creation and motivation stage) in the intervention group We will upgrade.

Main outcome variables

Self-care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230104057041N1**

Registration date: **2023-02-02, 1401/11/13**

Registration timing: **prospective**

Last update: **2023-02-02, 1401/11/13**

Update count: **0**

Registration date

2023-02-02, 1401/11/13

Registrant information

Name

Fatemeh Soleimantabar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of health literacy training based on bandura's social learning theory on self-care in child labor

2022-11-28, 1401/09/07

Ethics committee reference number
IR.TUMS.FNM.REC.1401.114

Public title

The impact of health literacy training on self-care

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness and consent of the child and parents to participate in the research Having an age range of 13-18 years Not having physical and mental problems and disabilities according to the existing records of child labor in the association, which can prevent self-care. Not having any history of health literacy training

Exclusion criteria:

Absence (even one session of training sessions)

Age

From **13 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St. (East Nusrat), Tawheed Square

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

Health conditions studied

1

Description of health condition studied

Health literacy training & self-care

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health literacy score in adolescent health literacy questionnaire

Timepoint

One month after the health literacy training intervention

Method of measurement

Adolescent health literacy questionnaire: Adolescent health literacy questionnaire has 8 subscales and 44 items, including access (5 items), reading (5 items), understanding (10 items), evaluation (5 items), use (4 items), communication (8 items), self-efficacy (4 items) and calculation (3 items) and on a 5-point Likert scale from never (score 1), rarely (score 2), sometimes (score 3), most of the time (score 4) and It is always graded (5 points).

2

Description

Self-care score in adolescent self-care questionnaire

Timepoint

One month after the health literacy training intervention

Method of measurement

Adolescent self-care questionnaire: Adolescent self-care questionnaire has 3 subscales and 48 items including physical self-care (17 items), psycho-social self-care (18 items) and emotional self-care (13 items). The options are scored on a Likert scale from always (score 4) to never (score 0) and the score ranges from 0 to 192.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training will be done in the form of lectures, group discussions, questions and answers, role playing, intellectual games, using pictures and educational clips. We will promote the constructs of health literacy (comprehension, communication, reading, assessment, access, use, self-efficacy and calculation)

using Bandura's social-learning theory (through a validated program). Bandura's observational learning model consists of the following four stages: 1) attention stage, 2) memorization stage, 3) recreation stage and 4) motivation stage. During each session, in the first stage, the attention of the audience will be attracted by the high knowledge of the presenter, stating the goals of the session, encouraging questions and answers in order to receive points; In the second stage, live, symbolic or symbolic models will be used to present the content (according to the content, videos, images, PowerPoint, speech, problem solving, and scenario implementation will be used to present the content); In the third stage, we will repeat and practice the learned material to consolidate what we have learned, as well as question and answer; In the fourth stage, according to the pre-determined rules, they will receive points.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Association for protection of child labor (Molavi Center)

Full name of responsible person

Fatemeh Abra Dari

Street address

No. 7, Shahid Mehdi Hosseini Alley, Shahid Mehdi Hosseini Alley, Shahr-dari St., Borbor St., Mustafa Khomeini End

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotohi

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6th floor of Research and Technology Vice-Chancellor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.

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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 Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Soleimantabar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to
make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to
make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to
make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to
make this available