

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The educational intervention based on a planned behavioral theory on promoting healthy behaviors associated with AIDS on labor children in Zahedan city in 2018

#### Protocol summary

##### Study aim

Determine the effect of The educational intervention based on a planned behavioral theory on promoting health behaviors associated with AIDS on labor children

##### Design

the clinical trial has control and intervention groups. Considering the fact that the total number for inclusion in the study is 200 persons, 100persons will be included in the intervention and 100persons in the control group .

##### Settings and conduct

Primary Information in the intervention and control group in child labor center through questionnaires and self-completion or interview with the help of the interviewers or self-researcher are completed and entered into the computer and analyzed using SPSS software. Then based on the findings, the curriculum includes the content of education, goals and educational media based on the needs of the participants in the research. Then, educational intervention was performed for the intervention group and after the waiting period, the information was recaptured and analyzed using descriptive statistics and descriptive statistics.

##### Participants/Inclusion and exclusion criteria

criteria for entering: satisfaction to participate in the study, the age of 5-15 years for girls and 6 to 18 years for boys, exit criteria: the reluctance to continue cooperation and participation in educational intervention or lack of ability to provide appropriate responses. Questions as well as those who change their place of residence during intervention.

##### Intervention groups

individual and group training, including Q & A sessions, discussions, classroom training, and presentation of a booklet are on the agenda.

##### Main outcome variables

Change consciousness, Chang attitude, Moral norms, Mental norms, Perceived behavioral

control, Perceived self-awareness, Perceived behavioral intent.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180904040951N1**

Registration date: **2018-11-14, 1397/08/23**

Registration timing: **prospective**

Last update: **2018-11-14, 1397/08/23**

Update count: **0**

##### Registration date

2018-11-14, 1397/08/23

##### Registrant information

##### Name

Raziyeh sadat Abolhasani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3252 2706

##### Email address

abolhasani73@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The educational intervention based on a planned behavioral theory on promoting healthy behaviors associated with AIDS on labor children in Zahedan city in 2018

**Public title**  
The planned educational intervention on promoting healthy behaviors associated with AIDS on labor children

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
consent to participating in the study age range of 5-15 years for girls and 6 to 18 years for boys.  
**Exclusion criteria:**  
Not having the ability to respond appropriately to questions Unwillingness to continue to cooperate and participate in educational intervention People who change their place of residence during an educational intervention.

**Age**  
From **5 years** old to **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **200**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Stratified Random Sampling The total number of eligible children in the study is 200, 100 of them are in the intervention group and 100 in the control group will be included in the study. First, according to the conditions of the subjects, they are divided into two groups according to sex. Then according to the age groups, the individuals are classified into three age groups and the individuals are randomly assigned to each group based on the percentage of the class relative to the total number of individuals.

**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 of zahedan University of Medical Sciences

##### Street address

Unvercity of Medical Sciences.Dr Hesabi Sq.Zahedan

##### City

zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2018-10-07, 1397/07/15

#### Ethics committee reference number

ir.zaums.rec.1397.286

## Health conditions studied

### 1

#### Description of health condition studied

AIDS

#### ICD-10 code

Z21

#### ICD-10 code description

Asymptomatic human immunodeficiency virus [HIV] infection status

## Primary outcomes

### 1

#### Description

Promoting healthy child labor behaviors

#### Timepoint

At the beginning of the study and two months later

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Child labor awareness rate

#### Timepoint

At the beginning of the study and two months after the intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

In the first stage, the preliminary information (before the intervention) was completed through a questionnaire and by self-completion or interview with the help of the interviewer or the researcher. Then based on the findings, the training program, including educational content, goals and educational media, is designed, based on the needs of the collaborators involved in the research. In addition, both intervention and control groups benefit from routine state welfare organization training classes. "Intervention group:" The educational intervention designed to promote healthy behaviors is implemented for the "intervention group" and After the waiting period (at least two months), the information is recaptured and analyzed using descriptive statistics and statistics test.

#### Category

Behavior

## 2

#### Description

Control group: "Control group:" There will not be any training intervention for this group, but this group will be done with the same time Post test and the information will be re-collected.

#### Category

Behavior

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

koosha Child Labor

##### Full name of responsible person

Makkeh Shahnavaizi

##### Street address

Keshavarz 6, Keshavarz Boulevard

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9813966345

##### Phone

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##### Email

a.makhdoomid73@gmail.com

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Ahmad Mehraban

##### Street address

Faculty of Medical Sciences, Zahedan Branch, Islamic azad university , zahedan , Iran

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

98138-987

#### Phone

+98 54 3113 5582

#### Email

ahmadmh2004@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### 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

Other

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Gholamreza Masoudy

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

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Unvercity of Medical Sciences, Dr. Hesabi. Sq, Zahedan

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Masoudy55@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

**Full name of responsible person**

Javid Dehghan Haghighi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

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**Phone**

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**Email**

abolhasani73@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

Islamic Azad University

**Full name of responsible person**

Raziyeh sadat Abolhasani

**Position**

Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner