

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The Effect of Parent-child Storytelling based on Quranic story on Ethical Intelligence and Spiritual lives of Children with Cystic Fibrosis

#### Protocol summary

##### Study aim

Determining The Effect of Parent-child Storytelling based on Quranic story on Ethical Intelligence and Spiritual lives of Children with Cystic Fibrosis

##### Design

A clinical trial has a control group, with parallel groups, randomized of 64 Cystic fibrosis patient. Randomization is going to compute with block by sealedenvelope.com.

##### Settings and conduct

Available samples will be chosen from Children's Medical Center and divide in two groups by random 4 and 6 blocks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: children with Cystic fibrosis 6-9 years old, parent should have the ability of reading and access to online messengers. Exclusion criteria: child with Endstage CF, parent with no ability of storytelling 8 weeks in a row

##### Intervention groups

Intervention group: The group which parent tells Quranic story. Control group: The group which parent tells non-quranic story chosen by themselves.

##### Main outcome variables

Ethical intelligence, Spiritual life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220630055328N1**

Registration date: **2022-08-21, 1401/05/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-08-21, 1401/05/30**

Update count: **0**

##### Registration date

2022-08-21, 1401/05/30

#### Registrant information

##### Name

Romina Naimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4429 6978

##### Email address

rnaimi@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2022-07-11, 1401/04/20

##### Expected recruitment end date

2022-09-20, 1401/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The Effect of Parent-child Storytelling based on Quranic story on Ethical Intelligence and Spiritual lives of Children with Cystic Fibrosis

#### Public title

Effect of quranic storytelling on Ethical Intelligence and Spritual lives of children

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

6-9 child with Cystic fibrosis Parent should be able to read stories Parent should have accessibility to phone or online messenger applications

##### Exclusion criteria:

Child with endstage CF Parent with no ability of storytelling 8 weeks in a row

**Age**  
From **6 years** old to **9 years** old

**Gender**  
Both

**Phase**  
N/A

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

**Sample size**  
Target sample size: **64**

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

**Randomization description**  
In order to have same number of participants in both groups, We use Sealedenvelope.com for randomization with block. We define 64 participants, two groups and block size 4 and 6 . It is going to give us a list that shows which group participants belong.

**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 Nursing and Midwifery and Rehabilitation school- Medical University of Tehran

**Street address**  
Keshavarz Ave.

**City**  
Amol

**Province**  
Mazandaran

**Postal code**  
1417653761

**Approval date**  
2022-06-18, 1401/03/28

**Ethics committee reference number**  
IR.TUMS.FNM.REC.1401.034

## Health conditions studied

### 1

**Description of health condition studied**  
Cystic fibrosis

**ICD-10 code**

E84

**ICD-10 code description**  
Cystic fibrosis

### 2

**Description of health condition studied**  
Ethical intelligence

**ICD-10 code**

**ICD-10 code description**

### 3

**Description of health condition studied**  
Spiritual life

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**  
Ethical intelligence

**Timepoint**  
Before, one week and one month after intervention

**Method of measurement**  
Children's Ethical Intelligence questionnaire

### 2

**Description**  
Spiritual life

**Timepoint**  
Before, one week and one month after intervention

**Method of measurement**  
Children's spiritual Lives questionnaire

## Secondary outcomes

### 1

**Description**  
No secondary variable

**Timepoint**  
No secondary variable

**Method of measurement**  
No secondary variable

## Intervention groups

### 1

**Description**  
Intervention group: parent tells 8 Quranic stories chosen by research team during 8 weeks.

**Category**  
Behavior

### 2

**Description**

Control group: parent tells 8 Non-Quranic stories chosen by themselves during 8 weeks

**Category**  
Behavior

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Children's Medical Center

**Full name of responsible person**  
Dr. Shervin Badv

**Street address**  
Keshavarz Ave.

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1419733151

**Phone**  
+98 21 6147 9000

**Email**  
cmcpr@tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Dr. akbar fotuhi

**Street address**  
Keshavarz st.

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Tehran

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+98 21 8163 3698

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vcr@tums.ac.ir

**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**  
Romina Naimi

**Position**  
Master student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

**Street address**  
Noor st.

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rominanaiemi@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**  
Dr. Akram Sadat Hoseini

**Position**  
Associate professor

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Ph.D.

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ashoseini@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Romina Naimi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**City**

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**Province**

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**Postal code**

4617736556

**Phone**

+98 11 4429 6978

**Email**

rominanaiei@gmail.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 is needed.

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Parts of data related to consequence will be shared.

**When the data will become available and for how long**

Data will be available after publish.

**To whom data/document is available**

Data will be available for faculty and researchers.

**Under which criteria data/document could be used**

Available for similar research

**From where data/document is obtainable**

mail corresponding author: rnaimi@razi.tums.ac.ir

**What processes are involved for a request to access data/document**

E-mail should contain propose and aim of research then

author decides whether to share information or not

**Comments**