

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Aug 2026

### Assessing of an Intervention Based on 'Risk Communication and Community Engagement'(RCCE) for Enhancement of Framework Constructs and Preventing the Spread and Expansion of the Invasive Aedes Mosquito

#### Protocol summary

##### Study aim

Assessment of the efficacy of Intervention Based on 'Risk Communication and Community Engagement' for Enhancement of the Framework Constructs and Preventing the Spread of the Invasive Aedes Mosquitos

##### Design

This study is designed as a cluster randomized controlled trial (cRCT) with two parallel arms (intervention vs. usual health services) which will recruit about 400 households from each site for a total sample size of 800.

##### Settings and conduct

The study will take place in Bushehr port, Iran. The research will implement a multistage cluster sampling method and includes 20 clusters. The clusters will be assigned to two study arms by random allocation method at a 1:1 ratio between intervention and control groups. An independent statistician will perform the randomization process. The allocation sequence will be kept in sealed, opaque envelopes and will not be disclosed until clusters have been enrolled.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years old Residing in the intervention area Having a smartphone and virtual messengers. Exclusion criteria: Refuse to provide informed consent Having severe cognitive impairment

##### Intervention groups

Interventions: 1. Risk communication (culture specific messages) 2. Community engagement (community leaders, health volunteers and local organizations) 3. Behavioral motivation (practical steps towards preventive behaviors) 4. Creating communication channels (home visits, group sessions, printed and digital educational materials) All activities will be done by trained community health volunteers. The control group will get the routine vector control and health education services.

#### Main outcome variables

Level of acquiring appropriate communication and information; knowledge and awareness; risk perception; preventive behavior; impact of social and structural factors of the society; entomological indicators

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251127068127N1**

Registration date: **2026-02-28, 1404/12/09**

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

Last update: **2026-02-28, 1404/12/09**

Update count: **0**

##### Registration date

2026-02-28, 1404/12/09

##### Registrant information

##### Name

Adel Moqadas

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3484 3978

##### Email address

adelmoqaddass@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-02-20, 1404/12/01

**Expected recruitment end date**

2026-04-18, 1405/01/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Assessing of an Intervention Based on 'Risk Communication and Community Engagement'(RCCE) for Enhancement of Framework Constructs and Preventing the Spread and Expansion of the Invasive Aedes Mosquito

**Public title**

Assessing of an Intervention Based on 'Risk Communication and Community Engagement'(RCCE) for Enhancement of Framework Constructs and Preventing the Spread and Expansion of the Invasive Aedes Mosquito

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Be over 18 years of age. They must reside in the intervention neighborhood. The individual or their household must have a smartphone and virtual messengers.

**Exclusion criteria:**

Those who cannot give informed consent Individuals who have severe cognitive impairment

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **800**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research urban neighborhoods (mahallas) function as both the randomization units and the study's cluster boundaries. The study areas consist of 20 distinct clusters which create geographic boundaries that enable researchers to study them without interference from other study areas. The study included 20 clusters which consisted of 10 clusters from Kheybar Health Center and 10 clusters from Qods Health Center. The study used random allocation to assign clusters to the two study arms at a 1:1 ratio between intervention and control groups. The research study will invite all eligible households from the chosen clusters to participate in the research study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Clusters will be randomly assigned to either the intervention arm or the usual care arm using a computer-generated random sequence. An independent statistician who has no role in participant recruitment and intervention delivery will perform the randomization process. Allocation concealment will be ensured at the cluster level. The allocation sequence will be kept in sealed, opaque envelopes and will not be disclosed until clusters have been enrolled.

**Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Floor 6, Headquarters of Tehran University of Medical Sciences, Streetcorner of Quds Ave, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

141765383761

**Approval date**

2025-05-10, 1404/02/20

**Ethics committee reference number**

IR.TUMS.SPH.REC.1404.033

**Health conditions studied****1****Description of health condition studied**

Educational intervention using risk communication and social motivation framework to prevent the spread and spread of invasive Aedes mosquitoes

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The level of receipt of appropriate communication and information (information demand, information access,

information satisfaction, information trust, and infodemic risk) for promoting framework structures and preventing the spread and spread of invasive Aedes mosquitoes in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**2**

**Description**

The level of knowledge and awareness of study participants for upgrading framework structures and preventing the spread and spread of invasive Aedes mosquitoes in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**3**

**Description**

The risk perception of study participants for upgrading framework structures and preventing the spread and spread of invasive Aedes mosquitoes in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**4**

**Description**

The performance of study participants to improve framework structures and prevent the spread and spread of invasive Aedes mosquitoes in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**5**

**Description**

The level of social factors of the target community (stigma, social norms, social motivation) for promoting framework structures and preventing the spread and expansion of the invasive Aedes mosquito in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**6**

**Description**

The level of structural factors of the target community for improving framework structures and preventing the

spread and expansion of the invasive Aedes mosquito in the intervention and control groups

**Timepoint**

Beginning and end of the study

**Method of measurement**

Researcher-made questionnaire

**Secondary outcomes**

**1**

**Description**

Container Index (CI)

**Timepoint**

Beginning and end of the study

**Method of measurement**

Standardized observational checklists and entomological inspection tools

**2**

**Description**

Breteau Index (BI)

**Timepoint**

Beginning and end of the study

**Method of measurement**

Standardized observational checklists and entomological inspection tools

**3**

**Description**

House Index (HI)

**Timepoint**

Beginning and end of the study

**Method of measurement**

Standardized observational checklists and entomological inspection tools

**Intervention groups**

**1**

**Description**

Intervention group: The intervention will establish a community-based program which depends on the Risk Communication and Community Engagement (RCCE) framework as its foundational element. The program will run for 2 months and it will include these program components: 1.Risk communication: Delivery of culturally tailored messages addressing Aedes mosquito risks, dengue and other Aedes-borne diseases, modes of transmission, symptoms, and prevention strategies. 2.Community engagement: The community leaders together with health volunteers and local organizations will actively work to create a situation where people will join together to share accountability. 3.Behavioral motivation: The manual offers people practical steps which will help them remove mosquito breeding areas that include stagnant water near their homes while teaching them how to continue their preventive practices. 4.Communication channels: The program will

use household visits and group sessions together with printed educational materials and digital and social media platforms which are suitable for the local community. The program will provide all activities through trained community health workers CHWs and primary health care staff who will implement activities according to standardized manuals and supervision protocols.

**Category**

Behavior

**2**

**Description**

Control group: The usual care group will receive ongoing standard vector control and health education services which the local health system provides. The health centers use passive information delivery to their customers together with standard environmental health methods which do not include community engagement and do not use RCCE framework for their environmental health work.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Bushehr medical science

**Full name of responsible person**

Adel Moqaddas

**Street address**

Bushehr medical science, Moallem Ave, Bushehr port

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7514633341

**Phone**

+98 917 621 2197

**Email**

Adelmoqaddass@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ramin Kordi

**Street address**

Department for Research and Technology, Fl 6,  
Tehran University of Medical Sciences Headquarters  
Bldg, Corner of Quds Ave, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

141765383761

**Phone**

+98 21 8163 3698

**Fax**

**Email**

vcr@tums.ac.ir

**Web page address**

<https://vcr.tums.ac.ir/>

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Bushehr University of Medical Sciences

**Proportion provided by this source**

30

**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**

Mahnaz Ashourkhani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

School of Public Health, Tehran University of Medical  
Sciences, Poursina street, Ghods street, Enqelab  
Avenue, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Phone**

+98 21 4293 3333

**Email**

Ashoorkhani@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahnaz Ashourkhani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

**Street address**

School of Public Health, Tehran University of Medical Sciences, Poursina street, Ghods street, Enqelab Avenue

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**Province**

Tehran

**Postal code**

1417613151

**Phone**

+98 21 4293 3333

**Email**

ashoorkhani@gmail.com

**Email**

adelmoqaddass@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**

Despite of anonymity of the obtained consent from participants, we assured them that their personal information would not be made public.

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

The study protocol will be published as an article. The statistical analysis plan, the informed consent form, and the clinical study report will also be published in another article after the study is conducted and the results are summarized.

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

After publication of the relevant article in the journal in 2026, the study protocol will be available. Also, access to the statistical analysis plan, informed consent forms, and the clinical study report will be possible in the second half of 2027.

**To whom data/document is available**

The data will be available to all academic and non-academic researchers.

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

Using the results of this study is possible only by citing the reference and following the copyright.

**From where data/document is obtainable**

Applicants can send their request to the following email: adelmoqaddass@gmail.com

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

The request must include the applicant's personal and organizational details along with a statement of the purposes of use.

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

Tehran University of Medical Sciences

**Full name of responsible person**

Adel Moqadas

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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