Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 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
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 4293 3333
Email
ashoorkhani@gmail.com

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
Street address
Bushehr medical science, Moallem Street, Bushehr port, Bushehr, Iran
City
Bushehr
Province
Boushehr
Postal code
7514633341
Phone
+98 77 3484 3978
Fax
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