

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Evaluating the Effect of SMS-Based Feedback on Prescribing Indicators and Related Factors, and Explaining the Barriers and Facilitators Influencing Drug Prescribing Among General Practitioners in the Clinics of Tehran Province

Protocol summary

Study aim

The aim of this study is to evaluate the effect of SMS-based feedback on prescribing indicators among general practitioners in clinics of Tehran Province and to explain the barriers and facilitators influencing irrational drug prescribing.

Design

A randomized, parallel-group, non-blinded trial at the physician level with 1:1 allocation. All 645 eligible general practitioners will be included. Stratified randomization will be based on geographic area and clinic of practice using a computer-generated random sequence. This is a behavioral/health services intervention.

Settings and conduct

This study will be conducted in clinics affiliated with the Iran Health Insurance Organization in Tehran Province. In the quantitative phase, electronic prescribing data will be used and eligible general practitioners will be randomly assigned to intervention and control groups. The intervention includes three monthly feedback text messages. In the qualitative phase, semi-structured interviews will be conducted with selected physicians.

Participants/Inclusion and exclusion criteria

Participants are general practitioners in Tehran Province clinics registered in the Iran Health Insurance Organization electronic prescribing system. Eligible physicians must have at least 30 baseline prescriptions and at least one prescription during the study year. Others will be excluded.

Intervention groups

The intervention group received monthly feedback text messages for 3 months, showing each physician's prescribing performance, comparison with the provincial average and the WHO 20% antibiotic benchmark, plus a brief recommendation for rational prescribing.

Main outcome variables

The primary outcome variables are the mean number of drug items per prescription and the percentage of prescriptions containing antibiotics.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260611069750N1**

Registration date: **2026-07-15, 1405/04/24**

Registration timing: **prospective**

Last update: **2026-07-15, 1405/04/24**

Update count: **0**

Registration date

2026-07-15, 1405/04/24

Registrant information

Name

Nezam Armand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2816 5607

Email address

armandnezam@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2027-03-20, 1405/12/29 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	
Scientific title Evaluating the Effect of SMS-Based Feedback on Prescribing Indicators and Related Factors, and Explaining the Barriers and Facilitators Influencing Drug Prescribing Among General Practitioners in the Clinics of Tehran Province Public title Evaluating the Effect of SMS-Based Feedback on Prescribing Indicators and Related Factors, and Explaining the Barriers and Facilitators Influencing Drug Prescribing Among General Practitioners in the Clinics of Tehran Province	Target sample size: 645 Randomization (investigator's opinion) Randomized Randomization description The randomization method in this study is stratified randomization. The unit of randomization is the individual general practitioner, and allocation will be performed in a 1:1 ratio to the intervention and control groups. The randomization strata include the geographic area of practice based on the corresponding university of medical sciences and the physician's clinic of practice. Within each stratum, the allocation sequence will be generated using statistical software and a computer-based random number generator. The randomization sequence will be prepared by a person independent of the intervention implementation, and the allocation list will be kept confidential until assignment.
Purpose Health service research Inclusion/Exclusion criteria Inclusion criteria: The physician must be registered as a "general practitioner" in the Iran Health Insurance Organization electronic prescribing system. The physician must be working in clinics affiliated with the Iran Health Insurance Organization. The physician's workplace must be located in one of the catchment areas of Tehran, Iran, or Shahid Beheshti Universities of Medical Sciences. The physician must have at least 30 recorded drug prescriptions during the baseline period. The physician must have at least one recorded prescription during the study year. The physician's prescribing data must be retrievable and attributable to the physician in the system. A valid mobile phone number must be available for receiving feedback text messages. Exclusion criteria: The physician is simultaneously participating in another similar prescribing feedback program or intervention. No valid, usable mobile phone number is available to receive feedback text messages. The physician's identifying or prescribing data are incomplete or inconsistent in a way that affects allocation or analysis. Prescriptions cannot be reliably attributed to the physician or to the clinic of practice. The physician has left the clinic setting before randomization. The physician is on prolonged leave, assignment, or absence during the study period in a way that affects prescribing activity. The physician has unreliable or outlier records caused by major system or registration errors.	Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features Secondary Ids empty
Ethics committees <u>1</u> Ethics committee Name of ethics committee School of public health and allied medical sciences Tehran University of Medical Sciences Street address School of Public Health, Tehran University of Medical Sciences, Enqelab Square, Tehran, Iran. City Tehran Province Tehran Postal code 1417613151 Approval date 2026-06-10, 1405/03/20 Ethics committee reference number IR.TUMS.SPH.REC.1405.095 Health conditions studied <u>1</u> Description of health condition studied Irrational drug prescribing with a focus on polypharmacy and antibiotic prescribing in outpatient care	
Age From 26 years old Gender Both Phase N/A Groups that have been masked No information Sample size	ICD-10 code ICD-10 code description

Primary outcomes

1

Description

mean number of drug items per prescription

Timepoint

second half of the year before the intervention, and the post-intervention period in Azar, Dey, and Bahman.

Method of measurement

These variables are measured at the physician level using data recorded in the Iran Health Insurance Organization electronic prescribing system. The mean number of drug items is calculated by dividing the total number of prescribed drug items by the total number of prescriptions.

2

Description

Percentage of prescriptions containing antibiotics

Timepoint

second half of the year before the intervention, and the post-intervention period in Azar, Dey, and Bahman.

Method of measurement

These variables are measured at the physician level using data recorded in the Iran Health Insurance Organization electronic prescribing system. The percentage of prescriptions containing antibiotics is calculated by dividing the number of prescriptions containing at least one antibiotic by the total number of prescriptions and multiplying by 100.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: **The intervention in this study is SMS-based feedback on prescribing performance among general practitioners. Physicians in the intervention group will receive one feedback text message per month for three consecutive months from the Iran Health Insurance Organization. The content of each message will be prepared based on each physician's electronic prescribing data from the previous month and will include the mean number of drug items per prescription, the percentage of prescriptions containing antibiotics, comparison with the provincial average and the World Health Organization benchmark of 20% for antibiotic prescribing, and a brief, respectful, non-punitive recommendation to improve rational drug prescribing.***In the first month, corrective feedback will be sent based on baseline prescribing performance. In the second and third months, the content of the message will be determined based on the physician's prescribing performance in the previous month. If the indicators are higher than the reference values, a

corrective comparative message will be sent; if the physician reaches the desirable level, an encouraging message will be sent. The control group will not receive any feedback text messages during the study period.**

Category

Behavior

2

Description

Control group: The control group will not receive any feedback text messages regarding their prescribing performance during the three-month study period. Physicians in this group will continue their usual prescribing practice, and no additional educational, feedback-based, or managerial intervention will be delivered by the research team. Electronic prescribing data for physicians in the control group will be extracted, similar to the intervention group, during the baseline period and throughout the study months to compare changes in prescribing indicators.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated with the Iran Health Insurance Organization in Tehran Province

Full name of responsible person

Iran Health Insurance Organization

Street address

No.1 ,Shajarian st (N Falamak St) , Eivanak Blvd, Qods (West) Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1948744851

Phone

+98 21 2816 5607

Email

armandnezam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi- Deputy for Research and Technology

Street address

Enqelab Street, Qods Street, Pour Sina Street, School of Public Health**

City

Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 4293 3333

Email
sph@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
Nezam Armand

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Health Service Management

Street address
Enqelab Street, Qods Street, Pour Sina Street, School of Public Health

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 2816 5607

Email
armandnezam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Nezam Armand

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Health Service Management

Street address
Enqelab Street, Qods Street, Pour Sina Street, School of Public Health

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 2816 5607

Email
armandnezam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Nezam Armand

Position
PhD candidate

Latest degree
Master

Other areas of specialty/work
Health Service Management

Street address
Enqelab Street, Qods Street, Pour Sina Street, School of Public Health**

City
Tehran

Province
Tehran

Postal code
1417613151

Phone
+98 21 2816 5607

Email
armandnezam@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

De-identified electronic prescribing data from the Iran Health Insurance Organization and coded qualitative interview files will be available after study completion. The final study protocol, including objectives, methods, intervention, outcomes, and statistical analysis, will be available for dissemination after finalization. The statistical analysis plan, including outcomes, variables, statistical models, and primary and secondary analyses, will be available after finalization. The final clinical study report, including methods, main results, interpretation of findings, and study conclusions, will be available after study completion.

When the data will become available and for how long

Data will be available after study completion and publication of results, for a limited period, subject to approval by the research team and the relevant organization. The protocol will be made available after final study registration and required approvals. The statistical analysis plan will be available after protocol finalization and before the final data analysis. The clinical study report will be available after completion of the study and finalization of the results.

To whom data/document is available

Qualified researchers for scientific purposes may access the data upon formal request and approval by the research team and the Iran Health Insurance Organization. Researchers, reviewers, and individuals with scientific or academic purposes may access the protocol upon approval by the principal investigator. Researchers, reviewers, and individuals with scientific purposes may access the statistical analysis plan upon approval by the principal investigator. Researchers,

reviewers, and individuals with scientific or academic purposes may access the clinical study report upon approval by the principal investigator.

Under which criteria data/document could be used

The data may be used only for scientific and research purposes, in de-identified form, after approval of the request and compliance with confidentiality requirements. The protocol may be used only for scientific, research, and academic dissemination purposes with proper citation of the source. This document may be used only for scientific, research, and methodological review purposes with proper citation of the source. The clinical study report may be used only for scientific, research, and educational purposes with proper citation of the source.

From where data/document is obtainable

Applicants should submit their request to the principal investigator and, if required, to the Tehran Provincial Office of the Iran Health Insurance Organization. Applicants should contact the principal investigator to request access. Applicants should contact the principal investigator to request access. Applicants should contact the principal investigator to request access.

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

After formal submission, the request will be reviewed for scientific purpose, confidentiality compliance, and approval by the principal investigator and the relevant organization; if approved, limited access will be granted. After submission, the request will be reviewed by the principal investigator, and if approved, the protocol will be provided. After review by the principal investigator, and if approved, the statistical analysis plan will be provided. After review by the principal investigator, and if approved, the clinical study report will be provided.

Comments