Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

The Effect of Individualized Counseling, Phone Line Follow up, and Nicotine chewing Gum on Smoking Cessation in Smokers: A clinical Trial Study

Protocol summary

Summary

Objective:The Effect of Individualized Counseling, Phone Line Follow up, and Nicotine Chewing Gum on Smoking Cessation in Smokers. Design: A clinical trial, pre and post test design with randomized control group. Setting and Conduct: The study population is all Gorgan city smokers recruited through sending of short message system (sms). Then,they randomly were allocated to control and treatment groups. Participants:Smokers are in preparation stage of smoking behavior. The inclusion criteria are readiness to quit; age between 12-80 years old; not to be Pregnant; and not suffer from MI or CVA in last 3 weeks. There is no limitation for exclusion. Interventions: Five sessions of personally counseling that will take about 45 minutes .Using nicotine chewing gum for 2 months along with phone line follow up including two times in first week of the nicotine chewing gum using.Then once a week till three months and finally quarterly untill the end of sixth months. Main outcomes: It is expected smoking cessation for at least six month after intervetion begining.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011025074N1**
Registration date: **2012-06-05, 1391/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

Name

Abdurrhman Charkazi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2011-07-16, 1390/04/25

Expected recruitment end date

2011-10-17, 1390/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Individualized Counseling, Phone Line Follow up, and Nicotine chewing Gum on Smoking Cessation in Smokers: A clinical Trial Study

Public title

The Effect of Individualized Counseling, Phone Line Follow up, and Nicotine Chewing Gum on Smoking Cessation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Appeasing in preparation stage of

smoking behavior; being in readiness to quit; age between 12-80 years old; not to be pregnant; and suffer from MI or CVA in last 3 weeks. Exclusion criteria: There is no limitation for the participants exclusion.

Age

From **12 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Committe of Isfahan University of Medical Sciences

Street address

No 4 Building, Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan , Iran.

City

Isfahan

Postal code

Approval date

2011-07-16, 1390/04/25

Ethics committee reference number

390076

Health conditions studied

1

Description of health condition studied

smoking cessation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

smoking cessation stability

Timepoint

baseline, 3 and 6 months after intervention

Method of measurement

Fagerstrom test, Diclemente and et al. Stages of change questionnaire

Secondary outcomes

1

Description

Relapse in smoking cessation

Timepoint

Baseline, 3 and 6 months after intervention

Method of measurement

Self reporting

Intervention groups

1

Description

Two milligrams of nicotine chewing gum will used based on subjects nicotine dependency for 2 months, five consulting sessions along with one booklet. The using dose of nicotine gum is basis on the subjects nicotine dependency that will divided in 3 groups: low dependency group (score1 - 4) according to Fagerstrum test), middle dependency(score 5-7), high dependency (8-10). Low, middle, and high depended people will receive the maximum daily gums by 6, 9, and 12 gums, respectively. For all three groups nicotine chewing gum doses will tapered 2 gums biweekly.

Category

Treatment - Drugs

2

Description

Control group will not received any drug or intervention except recommendation for cessation.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

No 6 Health Center, 1 st Mordad Alley, 32 nd Edalat Street, Gorgan, Iran.

Full name of responsible person

Abdurrahman Charkazi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences, Vice Chancellor for Research
Full name of responsible person
Doctor Mehdi Amin
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No 4 Building, Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan, Iran.
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences, Vice Chancellor for Research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code

empty

Data Dictionary

empty