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Intervention phase of the Tehran Lipid and Glucose Study (TLGS phase II)

Submission date 11/10/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 27/11/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 20/11/2018	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Noncommunicable disorders (NCDs) are long-term diseases that are not passed from person to person. NCDs include heart disease, cancer, lung disease and diabetes. This study is a long-term community-based programme which aims to evaluate lifestyle modification interventions to prevent or postpone the development of NCDs.

Who can participate?
Residents of District 13 of Tehran, aged 3 years and over

What does the study involve?
Participating areas are randomly allocated to either the intervention or the control group. Residents in the intervention areas receive interventions that aim to improve their lifestyle (e.g., diet, smoking and exercise) through education, leaflets, brochures, school programme alterations, and treating patients with NCD risk factors. Data is collected every 3 years to assess the effects of the different interventions on the prevalence of NCDs in the intervention areas as compared to the control areas, where residents do not receive the interventions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Research Institute for Endocrine Sciences (Iran)

When is the study starting and how long is it expected to run for?
March 1999 to March 2020

Who is funding the study?
1. National Research Council, Ministry of Health (Iran)
2. Research Institute for Endocrine Sciences (Iran)

Who is the main contact?
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Study website
http://endocrine.ac.ir/English/study.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prevention of non-communicable disease in a population in nutrition transition: Tehran Lipid and Glucose Study Phase II

Acronym
TLGS II

Study objectives
The Tehran Lipid and Glucose Study (TLGS) is a long term integrated community-based programme for prevention of non-communicable disorders (NCD) by development of a healthy

lifestyle and reduction of NCD risk factors. The primary research goal is an evaluation of the feasibility and effectiveness of lifestyle modification interventions in preventing or postponing the development of NCD risk factors and outcomes in a population in nutrition transition. Secondary research goals include determining differences in the prevalence of major NCD risk factors and outcomes between intervention and control groups with special focus on angina pectoris, myocardial infarction, cerebrovascular events, diabetes mellitus, hypertension and dyslipidaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Research Council of the Islamic Republic of Iran (ref: 121); performed with the approval of the Human Research Review Committee of the Endocrine Research Centre, Shahid Beheshti University (MC).

Study design
Randomised community intervention (controlled field trial)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Non-communicable diseases (NCD)

Interventions
Primary, secondary and tertiary interventions were designed based on specific target groups including school children, housewives, and high-risk persons. Officials of various sectors such as health, education, municipality, police, media, traders and community leaders were actively engaged as decision makers and collaborators. Interventional strategies were based on lifestyle modifications in diet, smoking and physical activity through face-to-face education, leaflets and brochures, school programme alterations, training volunteers as health team and treating patients with NCD risk factors. Collection of demographic, clinical and laboratory data will be repeated every 3 years to assess the effects of different interventions in the intervention group as compared to control group.

Intervention Type
Behavioural

Primary outcome measure
Major NCD risk factors including the following:
1. Glucose disorders (oral glucose tolerance test, fasting blood sugar)
2. Dyslipidaemia: serum total cholesterol, triglycerides, low density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C)
3. Obesity: a body mass index (BMI) of 25 to 29.9 kg/m^2 in adults is considered as overweight and a BMI equal to or more than 30 kg/m^2 is defined as obesity. Obesity and overweight in children and adolescents are defined according to international cut-off points for body mass index. Truncal obesity is defined as a waist-hip ratio (WHR) more than 0.95 in adult men and more than 0.8 in adult women.
4. Smoking, assessed by a 110-item questionnaire and Modifiable Activity Questionnaire (MAQ)
5. Hypertension (HTN)
6. Level of physical activity, assessed by a 110-item questionnaire and Modifiable Activity Questionnaire (MAQ)
7. Nutritional status, assessed by interviews

The primary outcomes are assessed every 3 years.

Secondary outcome measures
1. Any significant medical events
2. Mortality

The secondary outcomes are assessed annually.

Overall study start date
01/03/1999

Completion date
01/03/2020

Eligibility

Key inclusion criteria
1. Individuals aged 3 years and over, either sex
2. Residents of the District 13 of Tehran
3. Under the coverage of three medical health centres, selected using multistage cluster random sampling method
4. Agree for all members of each family, including those not having risk factors, to be enrolled

Participant type(s)
All

Age group
Other

Sex
Both

Target number of participants
15,005 (5,630 cases for intervention group)

Key exclusion criteria
Mentally disabled persons

Date of first enrolment
01/03/1999

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
Iran

Study participating centre
Research Institute for Endocrine Sciences
Tehran
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Sponsor information

Organisation
Research Institute for Endocrine Sciences (Iran)

Sponsor details
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Sponsor type
University/education

Website
http://endocrine.ac.ir

ROR
https://ror.org/01kpm1136

Funder(s)

Funder type
Government

Funder Name
National Research Council, Ministry of Health (Iran)

Funder Name
Research Institute for Endocrine Sciences (Iran)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		15/06/2000		Yes	No
Results article	results	01/01/2002		Yes	No
Results article	results	14/11/2007		Yes	No
Results article	assessment of alternative definitions results	01/05/2008		Yes	No
Results article	nested case control study results	05/06/2008		Yes	No
Results article	prospective study results	01/10/2008		Yes	No
Results article	anthropometric parameter results	01/11/2008		Yes	No
Results article	nutritional intervention results	01/11/2008		Yes	No
Protocol article	phase II protocol	25/01/2009		Yes	No
	results				

Results article		01/06/2010	Yes	No
Results article	results	01/02/2018	Yes	No