Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A community-based healthy lifestyle intervention amongst high risk adults to prevent type 2 diabetes in Malaysia (Co-HELP)- a translational research

Protocol summary

Summary

Although an intensive lifestyle intervention has been demonstrated to reduce the development of type 2 diabetes in high-risk individuals, it has yet to be widely adopted at the community level. There is little information about the feasibility of offering such intervention in community settings. This study is designed to translate the diabetes prevention approach for use in the community settings as an intervention administered through the Malaysia Diabetes Association (MDA), a local Non-Governmental Organization (NGO). This is a quasi-experimental study that will assess the effectiveness of lifestyle modification intervention as compared to the usual care in reducing the modifiable risk factors of type 2 diabetes in high risk adults. The population of this study is the adults with pre-diabetes status that will be recruited through the community-based screening events within the Ampangan and Senawang localities. The strategy of intervention is by using group-based approach, collaborative efforts between professionals and community volunteers as the facilitators. The general objective of this study is to assess the effectiveness of lifestyle modification intervention as compared to usual care in reducing the modifiable risk factors of type 2 diabetes in high risk adults. The primary outcome measure is change in fasting blood glucose, 2HPP and HbA1C. Whereas, the secondary outcomes include the cardiovascular risk factors, change in dietary intake, physical activity and health-related quality of life. The outcomes will be analyzed at regular intervals within a period of 6 months. The finding from this study will perhaps demonstrate that a community-based lifestyle intervention administered through partnership with a local Non-Governmental Organization such as Malaysia Diabetes Association may become a promising strategy for widespread dissemination of interventions at preventing type 2 diabetes in high risk individuals in Malaysia.

General information

Acronym

Co-HELP

IRCT registration information

IRCT registration number: **IRCT201104106163N1**
Registration date: **2011-06-05, 1390/03/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-06-05, 1390/03/15

Registrant information

Name

Norliza Ibrahim

Name of organization / entity

University of Malaya

Country

Malaysia

Phone

60-03-79676657

Email address

drliza@siswa.um.edu.my

Recruitment status

Recruitment complete

Funding source

POST GRADUATE RESEARCH GRANT FROM UNIVERSITY OF MALAYA, MALAYSIA

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-08-31, 1391/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A community-based healthy lifestyle intervention amongst high risk adults to prevent type 2 diabetes in Malaysia (Co-HELP)- a translational research

Public title

A community-based healthy lifestyle intervention amongst high risk adults to prevent type 2 diabetes in Malaysia (Co-HELP)- a translational research

Purpose

Prevention

Inclusion/Exclusion criteria

a)Inclusion criteria : -Adults of high risk groups age between 18 to 65 years old, Malaysian nationality -Able to read and write in Bahasa Malaysia or English language -Willing to give written consent and participate voluntarily has Impaired fasting glucose (IFG) between 5.6 to 6.9 mmol/L (100-125 mg/dL) and /or Impaired Glucose Tolerance (IGT) between 7.8 to 11.0 mmol/L (140-199 mg/dL) -Overweight (BMI> 23 kg/m²) with other risk factors like Waist Circumference (WC) > 80 cm in women and > 90 cm in men, history of diabetes in family members, presence of hypertension or dyslipidemia or physically inactive b)Exclusion criteria: -Not willing to give written consent and participate voluntarily or not interested to continue follow up -Has been diagnosed with Diabetes Mellitus -Has fasting plasma glucose ≥7.0 mmol/L(≥126 mg/dL). They will be referred immediately to the health care provider for confirmation of established Diabetes Mellitus during the screening process. -Has been diagnosed with other pre-existing co-morbidities that are contraindicated to adopt light to moderate physical activity (e.g; a recent cardiovascular event including myocardial infarction, angina, stroke, TIA, peripheral vascular disease, congestive heart failure, carotid and coronary vascularizations, severe chronic obstructive pulmonary disease, advanced arthritis, poorly controlled hypertension , any form of cancers that limit lifespan to less than 3 years and require treatment) -Pregnant, psychological disorder or physically disabled which can interfere with participation.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **328**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Iranian Registry of Clinical Trials (IRCT)

Secondary trial Id

A community-based healthy lifestyle intervention amongst high risk adults to prevent type 2 diabetes

Registration date

2017-05-11, 1396/02/21

Ethics committees

1

Ethics committee

Name of ethics committee

University Malaya Medical Centre (UMMC) Medical Ethics Committee

Street address

UMMC, Lembah Pantai

City

Kuala Lumpur

Postal code

59100

Approval date

2011-03-18, 1389/12/27

Ethics committee reference number

841.3

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Non-insulin dependent Diabetes Mellittus without complications

Primary outcomes

1

Description

Changes in blood glucose

Timepoint

Baseline,3 months, 6 months, 9 months,12 months

Method of measurement

Fasting bloood glucose (mmol/L), HbA1C (mmol/L)

Secondary outcomes

1

Description
changes in weight
Timepoint
Baseline, 3 months, 6 months, 9 months , 12 months
Method of measurement
Weight (kg)

2

Description
changes in BMI
Timepoint
baseline, 3rd, 6th, 9th and 12th mth
Method of measurement
BMI (kg/m2)

3

Description
changes in waist circumference
Timepoint
baseline, 3rd, 6th, 9th and 12th mth
Method of measurement
Waist circumference (cm)

4

Description
changes in total cholesterol
Timepoint
baseline, 3rd, 6th, 9th and 12 mth
Method of measurement
Total cholesterol (mmol/L)

5

Description
changes in HDL
Timepoint
baseline, 3rd, 6th, 9th and 12th mth
Method of measurement
HDL (mmol/L)

6

Description
changes in Triglycerides
Timepoint
baseline, 3rd, 6th, 9th and 12th mth
Method of measurement
TG (mmol/L)

7

Description
changes in Blood pressure
Timepoint
baseline, 3rd, 6th, 9th and 12th mth
Method of measurement
BP (mm Hg)

Intervention groups

1

Description
A) Lifestyle modification intervention group The lifestyle modification intervention sessions will be conducted in group format, coordinated and facilitated by the peer educators. The intervention will focuses on empowerment of participants to change their lifestyle. This intervention will incorporates diet, physical activity and healthy behaviour modification. The contact schedule occurs in three phases, with an early 3- month intensive phase (1 group session every 2 weeks) followed by a 6-month non-intensive phase (1 group session every month) and a 3-month maintenance phase. The goals set for this intervention is based on what is outlined in the Clinical Practice Guidelines by Ministry of Health Malaysia, Management of type 2 Diabetes Mellitus, 4th edition 2009 to produce modest but yet achievable outcomes as below: • Reduction of 5-10% of initial body weight for all overweight and obese participants • Reduction of calorie intake (20-25 kcal/kg body weight) • Increase light to moderate physical activity to at least 150 minutes/ week The group will have series of different sessions with professionals like Physicians, Dietician/ Nutritionist and Physical trainer specialist during the intensive phase. Throughout the intervention, the participants will have a continuous support from Diabetic Educators (Nurses) and Peer Educators that acts as program facilitators. Facilitators will consult the professional health providers if any problems arise during the intervention sessions. Participants will also be referred to relevant health providers if the problem could not be handled by the program facilitators. i) 0 to 3rd month: Intensive intervention -2 weekly sessions for 3 months. Total 6 sessions, deliver by Professionals (Doctor, Nurse, Dietician, Sport Medicine Physician, Diabetic Educator or Community Health Nurse ii) 4th to 6 month: Non-intensive intervention-1 monthly sessions for 3 months. Total 3 sessions, deliver by Peer Educators with supervision by professionals. iii) 7th to 9th month: Non-intensive intervention- 1 monthly sessions for 3 months. Total 3 sessions, deliver by Peer Educators with supervision by professionals iv) 10th to 12th month: Maintenance of intervention- Follow up of participants by peer educators via phone, e-mail or home visits • Session with physician: To increase knowledge of the participants about the disease, sign and symptoms, common risk factors and complications associated with the disease. • Session with dietician or nutritionist: Not only focusing on food pyramid but also on healthy food choice. Might also conduct practical session on how to prepare healthy meals. • Session with sport medicine physician or physical trainer: Encourage participants to do light to moderate exercises at the beginning but later will encourage them to do moderate to high intensity exercises. The prescription is according to the participant’s age and health status. • Session with

Diabetes Educators and Peer Educators: The session with Diabetes Educators and Peer Educators will be conducted on monthly basis with intention to ensure all participants are able to continue lifestyle modification activities that have been taught earlier. On the other hand this will also benefits the participating MDA's members to continue and sustain the activities at their organization even after the study is over. The activities will be conducted in big group and small groups. For example; if the activity is in the form of one and half hour lecture, the participants will be grouped in large group of 50 people. But if the activities involve group-work or discussion, they will be grouped in smaller group of 10 to 15 people.

Category

Lifestyle

2

Description

B) Conventional intervention group : Participants in the conventional intervention group will receive general verbal and written information about diet and exercise during baseline investigation and subsequent blood taking visits.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Malaysian Diabetes Association

Full name of responsible person

Professor Dato Dr Ikram Shah bin Ismail

Street address

Malaysian Diabetes Association, No 2 Lorong 11/4E

City

Petaling Jaya

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University Malaya

Full name of responsible person

Dr Moy Foong Ming

Street address

Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya

City

Kuala Lumpur

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University Malaya

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

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya

Full name of responsible person

Dr Norliza binti Ibrahim

Position

MPH, DrPH candidate, Principal investigator for this research

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr Moy Foong Ming

Position

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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