

D-START: Information on the selected study design

Below you will find the framework of the study design on primary prevention of type 2 diabetes in a Low and Middle income Countries which you need to use to complete your application form. Please read this document carefully taking into consideration all the advices before completing the application form.

This framework has been developed by Dr Qing Qiao, Dr Markku Peltonen, Professor Jaakko Tuomilehto and Dr Weiguo Gao from the Department of Public Health, University of Helsinki (Finland). They can not be contacted by applicants during the application process.

Dr Qing Qiao and Professor Jaakko Tuomilehto will be part of the Advisory Board, together with representatives of IDF and experts in primary prevention, which will support the selected projects during the all duration of the project.

The proposed project is a lifestyle intervention to prevent type 2 diabetes. This intervention has already been successfully implemented in China. In your application, the objectives and design must be respected and adapted so they can fit the local environment.

When preparing the application, you must at least involve:

- A nutritionist
- A health educator
- A statistician
- Representatives of organizations where the project will take place in the different cities/areas
- Representatives of local authorities

Proposed duration of the project

Start date: July 1 st 2011	End date: June 30 th 2014
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This is an indication only, final dates and duration will be negotiated with the 2 selected implementation sites.

Please note that selected projects will be announced in March 2011 and the training will take place in June 2011. Also, the first installment will not be delivered before the letter of agreement is signed and, if necessary, ethical approval for the project has been sent to IDF. The procedure can take 4-6 months and should be taken into consideration when scheduling your project and activities. Finally, and for contractual reason, the project

Objectives of the selected study design

- 1- To implement a culturally tailored diabetes prevention program through lifestyle intervention into real life settings in communities in a LMCs for three years
- 2- To evaluate the effectiveness, cost-effectiveness, and the feasibility and the acceptability of the program at the end of the three-year implementation of the program using randomized controlled trial design
- 3- To check the impact of the dietary culture and city plan on prevalence of obesity and diabetes
- 4- To create and establish a partnership not only between the research teams but most importantly between the primary care workers and the local health authorities

Background

Type 2 diabetes increased fast in Low and Middle income Countries (LMCS) as a consequence of changes in lifestyle including physical inactivity and unhealthy diet (<http://diabetesatlas.org>).

Prevention through lifestyle intervention under strictly controlled trial conditions has been shown to delay the onset of type 2 diabetes worldwide(1-5), with a relative risk reduction ranged from 28% to 67%. A sustainable long-term effect of lifestyle intervention after trials was also reported (6, 7). But whether we can and how to transfer the trial experience to the real life settings are remained unknown.

In addition, with the economic development cities are full of skyscrapers and cars, almost no space is left for walking and biking particularly in the LMCs. This plus the abundant food supplies sedentary lifestyle is dominant. To evaluate the impact of city plan and unhealthy dietary habits on diabetes is important to convince policy makers and different stakeholders to invest on city plan and public health promotion to change unhealthy lifestyles

Advice for your application form : In your application, provide detailed background information on your country which explains why you are applying to D-START and the importance of carrying in such project in your country.

Study design

Targeting population

The prior condition to select the implementation sites **is the commitment of the local authorities.**

Advice for your application form : In your application, please provide information on how you will involve the local authorities should you project be approved. We also advice you to include, with your application, a letter of support from the local authorities stating that they are committed to support your project.

Sites

Two sites will be selected in two geographically separated towns with distinct dietary cultures and city plan. One town must have easy accesses to exercise parks, and another has no.

Two communities in each town/region will be selected, each with a community size about 10 000 (note: according to the community size in your region/country more communities may be recruited to achieve the number of 10 000), and **with similar economical development levels.**

One of the community is targeted for lifestyle intervention and another is considered as control.

Advice for your application form : In your application form, provide detailed information on the sites you will select, how and why you will select them. Also, you need to include information on how you will choose the community which will be used for the lifestyle intervention and the one for the control.

Inclusion criteria

Advice for your application form : In your application, include the inclusion criteria you will be using to select participants in the study (e.g: BMI, age.....)
Also, provide information on how you will develop/adapt/use a local diabetes risk score which will be use for the project.

Example provided by the Coordinating site

A Chinese diabetes risk score (8) developed in our team will be applied to the entire communities. It was estimated about 40% of the residents will have a score ≥ 14 , and 29% of these will have IFG/IGT. According to the national population census in 2000, 40% of the population are aged 35-74 years (targeting for intervention). Given a community size of 10 000, 4000 are aged 35-74 years and 1600 with a score ≥ 14 , 464 with IFG/IGT.

Power calculation and sample size

Advice for your application form : The sample size of the project should be calculated in order to give a 80% power and a two-sided significant level of 0.05 according to the method by Kelsey (<http://www.openepi.com/Menu/OpenEpiMenu.htm>).
Please use a statistician to help you in the power calculation and sample size

Example provided by the Coordinating site:

Power and Sample Size was calculated according to the recent data collected in China. In a ongoing survey in Qingdao, China the three-year crude incidence of diabetes among individuals with IFG/IGT at baseline was 20.7% (data not published); the prevalence of IFG/IGT in Chinese population is about 15.5%(9). To observe a relative reduction of 35% in incidence of diabetes in the Intervention Arm as compared with the Control Arm, a sample size of 812 individuals with IFG/IGT (406 in the Intervention Arm and 406 in the Control Arm) are required, given a 80% power and a two-sided significant level of 0.05 according to the method by Kelsey (<http://www.openepi.com/Menu/OpenEpiMenu.htm>). We will recruit 464 IFG/IGT to allow a 15% dropout.

Table 1. Randomization of individuals with IFG/IGT and time schedule

	Time table	Implementation Site 1 with city plan for exercise parks Dietary culture A		Implementation Site 2 no city plan for exercise parks Dietary culture B	
		Community 1 No intervention	Community 2 Intervention	Community 1 No intervention	Community 2 Intervention
Community recruiting N \approx 10 000 each	May-June 2011				
Screening using risk score (entire community)	July 2011- Feb.2012	N \approx 10 000	N \approx 10 000	N \approx 10 000	N \approx 10 000
Risk score ≥ 14 & Age 35-74 years	July 2011- Feb.2012	N \approx 1 600	N \approx 1 600	N \approx 1 600	N \approx 1 600
OGTT test	July 2011- Feb.2012	N \approx 1 600	N \approx 1 600	N \approx 1 600	N \approx 1 600
IFG/IGT arms Randomization	July 2011- Feb.2012	Control N=464	Intervention N=464	Control N=464	Intervention N=464
Health tips after screening		Yes	Yes	Yes	Yes
Lifestyle counseling	July 2011- June 2014	No	Yes	No	Yes
Outcome evaluation OGTT test	June-Dec. 2014	Yes	Yes	Yes	Yes

Lifestyle counselling every three months in the 1st year and every 6 months in the 2nd and the 3rd years.

Measurable indicators during the study

BRIDGES, an IDF project supported by an educational grant from Eli Lilly and Company

Advice for your application form: as HBA1c measurements are not available in some countries, please explain which indicators you will be using. You also need to explain clearly how you will develop the questionnaire, how you will manage the data

At enrolment, interim and at the end of the project a 2-h OGTT and Hba1c (if available in your country) will be applied to diagnose diabetes and IFG/IGT. Lipids profile will be measured. Others such as CRP, fasting insulin, retinal photograph and ECG may be examined according to the budget obtained then (note if the IDF funds the project local resource may be obtained). A questionnaire containing demographic characteristics, occupation, education and income, smoking and drinking habits, disease history and medication, exercise questionnaire, 24-hour dietary recall and a 54-items food frequency table, and 15D (<http://www.15d-instrument.net>) to measure health-related quality of life (HRQoL) will be filled in at each examination. Individual use of health care and other resources in the past three months are also recorded.

Lifestyle counseling targeting at all individuals with a risk score ≥ 14

Group counseling sessions will be provided within the community every three months in the 1st year and every 6 months in the 2nd and the 3rd years targeting all individuals with a risk score of ≥ 14 . Changes in energy intake (kcal) and physical activities as well as weight, risk score and glucose levels will be recorded electronically for data analysis. Intervention kits and medical records developed in the QD_DPP will be applied with modification (details see appendix). People diagnosed as diabetes will be referred to the higher level hospitals for management and treatment.

Advice for your application form:

The risk factor provides here is an example and should be adapted based on the local environment.

This is the core of your application in which you need to provide clear information on:

- Who will be developing the group counseling sessions? Information about the content of the group counseling sessions and how there will be adapted to local culture.
- How you will recruit participants
- Your strategy to avoid an important dropout rate
- How you will monitor participation
- Where do the sessions will take place? How often? How many groups? How many people per group.....
- How will be involved in running the sessions? Qualification of these persons.....
- How will you measure the outcomes

Any other information you feel will be important to strengthen your application.

Measurable outcome: Primary outcomes: Incidence of type 2 diabetes, according to OGTT and HbA1c levels.

Secondary outcomes: Cost-effectiveness, by assessing the incremental costs and benefits per case of diabetes prevented and per quality-adjusted life-year (QALY) In addition, the impact of dietary culture and city plans on prevalence of obesity and diabetes will be analyzed. Feasibility and the acceptability of the major intervention components (or tool kits) applied to the prevention project will be evaluated

Advice for your application form: If HBA1c measurements are not available in your country, please explain which outcome indicators you will be using

Data analysis and expected results: Data will be managed and analyzed in the Department of Public Health, University of Helsinki in Finland following the standard statistical approaches. All results will be published in national and international peer-reviewed journal and communicated in the professional meeting.

In your application, please explain how you will liaise and communicate with University of Helsinki concerning data and data transfer. Also explain how you will bring your local expertise to support the data analysis.

Sustainability and future impact of the project: The health lifestyle may remain in the communities after the project. But this is not the only milestone. To incorporate the prevention program into regular public health activities in policy level nationwide is the greater milestone. To achieve this goal the involvement of the health authorities from the Ministry of Health to the implementation of the program from the beginning of the project with the help of the IDF is extremely important

In the application, please explain your strategy to ensure the sustainability of the project after the grant period.

Good luck

Brussels, June 15th 2010
Ronan L'heveder