Health Economics and Outcome Studies on Type 2 Diabetes Education and Screening in a Chinese Population

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ACADEMIC DISSERTATION

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ABSTRACT

Type 2 diabetes occurs as a consequence of aging, family history, physical inactivity, unhealthy diet and obesity and it is an increasing public health problem worldwide. The condition is associated with high rates of mortality from co-morbid cardiovascular diseases and poor health-related quality of life (HRQoL). A large proportion of individuals with type 2 diabetes are not diagnosed for up to a decade after onset unless a screening programme has been implemented. The estimated prevalence of undiagnosed diabetes in China accounts for about 60-70% of the diabetes population. Diabetes education that is targeted at the general population is the key to increase public knowledge and awareness and is a fundamental building block for addressing the diabetes epidemic. Screening for identifying undiagnosed diabetes could lead to earlier identification and intervention, and postpone or prevent the onset of diabetes and its complications. However, there is a paucity of study on the impact of education and screening programmes on HRQoL, lifestyle modification of the targeted population, and the cost-effectiveness of such programmes.

The objectives of this study were to investigate 1) the cost and effectiveness of a population-based education programme to increase public knowledge and awareness of diabetes; 2) the cost-effectiveness of two different screening tools for undiagnosed diabetes; 3) impact of type 2 diabetes and its complications on individuals' HRQoL; 4) impact of a screening programme on individuals' overall HRQoL, depression dimension and lifestyle modification.

This study was based on data analyses of two population-based diabetes surveys conducted in 2006 (Survey A) and 2009 (Survey C), and a dataset of diabetes high-risk population identified through the Qingdao Diabetes Prevention Program (QD-

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DPP) between 2007 and 2010 in Qingdao, China (Survey B). The same stratified, random cluster sampling method was used in Surveys A and C to recruit a representative sample of the general population who had lived in Qingdao city for at least five years. A total of 5355 individuals in Survey A and 5110 in Survey C aged 35-74 years participated in the surveys. A total of 3108 rural participants who did not have diabetes at baseline in 2009 were invited for a re-examination and 1782 individuals attended the follow-up survey. A standard 2h 75g oral glucose tolerance test was administrated to all participants in both surveys. Diabetes education and health promotion information and activities under the framework of QD-DPP were given via printed and audio-visual media, the internet, free distribution of information booklets and diabetes risk score (DRS) flyers that targeted the entire population of 1.94 million who lived in the intervention areas. An adult with a DRS \geq 14 was considered at high-risk for diabetes and invited to a nearby community clinic for a free capillary blood glucose test.

The proportions of participants who correctly marked obesity, physical inactivity and positive family history of diabetes as the risk factors of diabetes were doubled in both urban and rural populations, irrespective of age and gender during the QD-DPP education campaign period. The cheapest way to inform 1000 individuals about type 2 diabetes was to distribute DRS flyers (\$54, \$ = Chinese yuan), followed by the newspapers articles (\$77), booklets (\$313) and by radio programmes (\$375) (1€ $\approx7\$$, for the year 2015). The fasting capillary glucose (FCG) test and Chinese DRS questionnaire were used as the first-line screening tools and these were evaluated for detecting undiagnosed diabetes in primary care settings. The sensitivity of FCG and DRS was 65.1% and 65.8%, whereas their respective specificity was 72.4% and 55.2%. The costs per undiagnosed diabetes identified at the optimal cut-off values of

6.1 mmol/l for FCG and 14 for DRS were ¥674 and ¥844, respectively. The area under curve (AUC) was higher for FCG than for DRS (75.3% vs. 63.7%, p<0.001). People with previously known type 2 diabetes reported that the symptomatic comorbidities had a strong negative impact on HRQoL; no significant difference was detected between people without diabetes and with newly diagnosed diabetes. The screening and labelling as pre-diabetes or normoglycaemia had no adverse impact on the participants' overall HRQoL and depression. An improvement in lifestyle as measured by the frequency of physical activity and vegetable intake was observed at 3 years post screening in both groups.

In conclusion, the QD-DPP education campaign efficiently increased public knowledge and awareness of diabetes. The DRS questionnaire is a simple, non-invasive and reliable first-line screening tool to identify undiagnosed diabetes at primary care settings. The diabetes screening programme in Qingdao generated positive changes towards a healthy lifestyle and did not result in any harm to the participants.

TIIVISTELMÄ

Tyypin 2 diabetes on kasvava kansanterveysongelma maailmanlaajuisesti. Syitä ovat ikääntyminen, perhehistoria, fyysisen liikunnan puute, epäterveellinen ruokavalio ja lihavuus. Tautiin liittyy huono terveyteen liittyvä elämänlaatu ja korkea kuolleisuus liitännäisiin sydän- ja verisuonisairauksiin. Suurta osaa henkilöistä, joilla on tyypin 2 diabetes, ei diagnosoida jopa vuosikymmeneen ilman seulontaohjelmaa. Kiinassa diagosoimattoman diabeteksen osuus on noin 60-70%. Väestölle suunnattu diabetesopetus on avainasemassa, kun halutaan lisätä tietoa ja tietoisuutta taudista ja rakentaa perustaa diabetesepidemian vastustukseen. Seulonta diagnosoimattoman diabeteksen löytämiseksi voisi johtaa varhaisempaan interventioon sekä diabeteksen ja sen komplikaatioiden puhkeamisen siirtämiseen tai ehkäisyyn. Koulutus- ja seulontaohjelmien vaikutusta kohdeväestön terveyteen liittyvään elämänlaatuun ja elämäntyylin muutokseen sekä sellaisten ohjelmien kustannusvaikuttavuutta on kuitenkin tutkittu vähän.

Tämän tutkimuksen tavoitteena oli selvittää Kiinassa 1) väestön diabetestiedon ja – tietoisuuden lisäämiseen tähtäävän väestön opetusohjelman kustannuksia ja kustannusvaikuttavuutta; 2) diagnosoimattoman diabeteksen kahden erilaisen seulontaohjelman kustannusvaikuttavuutta; 3) tyypin 2 diabeteksen ja sen komplikaatioiden vaikutusta ihmisten terveyteen liittyvään elämänlaatuun 15D:llä mitattuna; 4) seulontaohjelman vaikutusta ihmisten terveyteen liittyvään elämänlaatuun, masennukseen ja elämäntyylin muutokseen.

Tämä tutkimus perustuu kahteen diabetesta koskevaan väestökyselyyn, jotka toteutettiin vuonna 2006 (kysely A) ja 2009 (kysely C), sekä aineistoon diabeteksen suhteen korkeariskisestä väestöstä, mikä tunnistettiin vuosien 2007 ja 2010 välillä

Qingdaon diabeteksen ehkäisyohjelman (Qingdao Diabetes Prevention Program, QD-DPP) (kysely B) avulla Qingdaossa, Kiinassa. Kyselyissä A ja C käytettiin samaa ositettua ja satunnaistettua ryväsotantaa, jolla otettiin edustava otos väestöstä, joka oli asunut Qingdaon kaupungissa ainakin viisi vuotta. Kaikkiaan 5355 henkeä, iältään 35-74 vuotta, osallistui kyselyyn A ja 5110 kyselyyn C. Kaikkiaan 3108 maaseudun asukasta, joilla ei ollut diabetesta lähtötilanteessa vuonna 2009, kutsuttiin uusintatutkimukseen ja 1782 henkeä osallistui seurantakyselyyn. Kaikille molempien kyselyiden osallistujille tehtiin standardi 2 tunnin 75g:n suullinen sokerirasitustesti. QD-DPP:ssa toteutettiin diabetesopetusta ja terveyden edistämistä käyttämällä painettua ja audiovisuaalista viestintää, internetiä, sekä jakamalla maksutta informaatiolehtisiä ja diabeteksen riskilukeman (diabetes risk score, DRS) esitteitä interventioalueiden koko 1.94 miljoonan kohdeväestölle. Aikuisilla, joilla DRS≥14, katsottiin olevan korkea diabetesriski ja heidät kutsuttiin läheiseen terveyskeskukseen maksuttomaan verensokeritestiin.

QD-DPP:n opetuskampanjan aikana kaksinkertaistui ikään ja sukupuoleen katsomatta sekä maaseudulla että kaupungissa niiden osallistujien osuus, jotka merkitsivät oikein lihavuuden, fyysisen liikunnan puutteen ja diabeteksen perhehistorian diabeteksen riskitekijöiksi. Halvin tapa opettaa 1000 henkilöä oli jakaa DRS-esitteitä (\pm 54, \pm = CNY = kiinan yuan, vaihtokurssi EUR 1 = CNY 7.1396, elokuun 14, 2015), seuraavina olivat sanomalehdet (\pm 77), informaatiolehtiset (\pm 313) ja radio-ohjelma (\pm 375). Paastosokeritesti (Fasting capillary glucose, FCG) ja kiinalainen DRS-kyselylomake arvioitiin ensilinjan seulontamenetelminä etsittäessä diagnosoimatonta diabetesta perusterveydenhuollossa. FCG:n ja DRS:n herkkyys oli 65.1 % and 65.8 %, tarkkuus 72.4 % and 55.2 %, ja kustannus löydettyä diagnosoimatonta diabetesta kohti \pm 674 ja \pm 844, mainitussa järjestyksessä, kun optimaaliset raja-arvot olivat 6.1

mmol/l FCG:lle ja 14 DRS:lle. Pinta-ala käyrän alla (area under curve, AUC) oli suurempi FCG:lla kuin DRS:lla (75.3 % vs. 63.7 %, p<0.001). Ihmiset, joilla oli aiemmin todettu tyypin 2 diabetes, ilmoittivat oireellisia oheissairauksia ja niillä oli vahva negatiivinen vaikutus 15D:llä mitattuun terveyteen liittyvään elämänlaatuun; tilastollisesti merkitsevää eroa ei havaittu niiden välillä, joilla ei ollut diabetesta ja joilla oli äskettäin diagnosoitu diabetes. Seulonnan perusteella todetulla esidiabeteksella tai normaalilla verensokeritasolla ei ollut vaikutusta terveyteen liittyvään elämänlaatuun tai masennukseen. Fyysisen liikunnan useudella ja vihannesten syönnillä mitatussa elämäntyylissä havaittiin molemmissa ryhmissä parannus kolme vuotta seulonnan jälkeen.

Johtopäätöksenä voidaan todeta, että QD-DPP:n opetuskampanja lisäsi tehokkaasti väestön diabetestietoa ja -tietoisuutta. DRS-kyselylomake on yksinkertainen, kajoamaton ja luotettava ensilinjan seulontamenetelmä diagnosoimattoman diabeteksen löytämiseksi perusterveydenhuollossa. Diabeteksen ehkäisyohjelma Qingdaossa sai aikaan positiivisia muutoksia kohti terveellistä elämäntyyliä eikä aiheuttanut haittaa osallistujille.

LIST OF ORIGINAL PUBLICATIONS

The thesis is based on the following original articles.

- I. Zhang YL, Gao WG, Pang ZC, Sun JP, Wang SJ, Ning F, Song X, Kapur A, Qiao Q. Diabetes self-risk assessment questionnaires coupled with a multimedia health promotion campaign are cheap and effective tools to increase public awareness of diabetes in a large Chinese population. Diabet Med 2012 Nov;29(11):e425-9
- II. Zhang Y, Sun J, Pang Z, Gao W, Sintonen H, Kapur A, Qiao Q. Evaluation of two screening methods for undiagnosed diabetes in China: A costeffectiveness study. Prim Care Diabetes 2013 Dec;7(4):275-282
- III. Zhang Y, Sun J, Pang Z, Wang X, Gao W, Ning F, Ren J, Kapur A, Sintonen H, Qiao Q. The impact of new screen-detected and previously known type 2 diabetes on health-related quality of life: A population-based study in Qingdao, China. Qual Life Res 2014 Oct;23(8):2319-2326
- IV. Zhang Y, Ning F, Sun J, Pang Z, Wang X, Kapur A, Sintonen H, Qiao Q. Impact of a diabetes screening program on a rural Chinese population: a 3year follow-up study. BMC Public Health 2015 Feb 27, 15(1):198

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ABBREVIATIONS

ADDREVIATIONS	
15D	15 Dimensions
ADA	American Diabetes Association
AUC	area under (receiver operating characteristic) curve
BMI	body mass index
BP	blood pressure
CVD	cardiovascular disease
CBG	capillary blood glucose
DBP	diastolic blood pressure
DKQ	diabetes knowledge questionnaire
DRS	diabetes risk score
EQ-5D	European Quality of Life-5 Dimensions
FCG	fasting capillary glucose
FFQ	food-frequency questionnaire
FPG	fasting plasma glucose
HbA1c	glycated haemoglobin A1c
2hPG	2-hour plasma glucose
HRQoL	health-related quality of life
HUI	health utility index
ICT	information and communication technology
IDF	International Diabetes Federation
IFG	impaired fasting glucose
IGT	impaired glucose tolerance
NDM	newly diagnosed diabetes
OGTT	Oral Glucose Tolerance Test
PA	physical activity
PG	plasma glucose
PKD	previously known diabetes
QALYs	quality-adjusted life years
QD-CDC	Qingdao Center for Disease Control
QWB	quality of well-being
QD-DPP	Qingdao Diabetes Prevention Program
RBG	random blood glucose
RCG	random capillary test
ROC	receiver operating characteristic curve
SF-6D	Short form 6 Dimensions
SES	socio-economic status
SBP	systolic blood pressure
SD	standard deviation
TTO	time to trade-off
WC	waist circumference
WHO	World Health Organization

1. INTRODUCTION

Diabetes is a rapidly increasing public health problem throughout the world. There were 382 million people with diabetes worldwide in 2013, and this figure is expected to rise to 592 million by 2035 (International Diabetes Federation, 2013). The prevalence of type 2 diabetes is increasing at an alarming rate in China in recent decades. National surveys showed that the prevalence of diabetes was only 1% in the Chinese population in 1980 (National Diabetes Research Group, 1981), and had increased to 2.5% in 1994 (Pan et al., 1997a) and then to 5.5% in 2000-2001 (Gu et al., 2003). Two recent national surveys reported that the prevalence of diabetes was 9.7% in 2007 (Yang et al., 2010) and 11.6% in 2010 (Xu et al., 2013). Among the persons living in economically developed regions such as Qingdao, the prevalence of diabetes is even higher. The age-standardized prevalence of diabetes in Qingdao was significantly increased from 12.2% in 2002 to 16.0% in 2006 (Gao et al., 2009). The aging of the population, urbanization, changes in diets, physical inactivity, and obesity have probably contributed to the rapid increase in the prevalence of diabetes, especially in economically well-developed city of Qingdao.

People with type 2 diabetes, especially those with diabetes complications, reported a worse quality of life compared to the general population (Alonso et al., 2004, Solli et al., 2010, Javanbakht et al., 2012). Diabetes constitutes a threat not only to health but also to global economics. The costs associated with diabetes include increased use of health care services, loss of productivity and disability. In 2013, the global health expenditure on diabetes in 2013 is estimated to be at least 548 billion United States Dollars (USD), and it accounts for 11% of world's total healthcare expenditures and will increase to USD 627 billion by 2035 (International Diabetes Federation, 2013).

About 6% of total health expenditure in China was accounted for by diabetes in 2010 and this equated to USD 115 expenditure per person (Zhang et al., 2010).

Diabetes can remain asymptomatic for up to a decade (Qiao et al., 2003b), and a large proportion of diabetic population will not be identified unless a screening test is provided. The proportion of people in China with undiagnosed diabetes is as high as 60-70% of the diabetes population (Gao et al., 2009, Yang et al., 2010, Xu et al., 2013).

Education and screening programmes have been implemented worldwide with the purposes to increase public awareness of diabetes, knowledge about healthy lifestyle, and early detection of diabetes and/or pre-diabetes. Mass media campaigns that are aimed at improving public awareness and health behaviours through broadcast, print, or the internet have become major tools in health promotion and disease prevention programmes (Randolph;Viswanath, 2004). Screening programmes for undiagnosed diabetes use a variety of different tools including fasting or random capillary blood glucose tests (Toscano et al., 2008, Zhou et al., 2010, Ritchie et al., 2011) and a number of risk assessment questionnaires (or scores) (Mohan et al., 2005, Sun et al., 2009, Zhou et al., 2013, Lindstrom;Tuomilehto, 2003) have been conducted in many countries. No study has hitherto evaluated the education and screening programmes for type 2 diabetes based on a large general Chinese population from health economics and outcomes perspectives.

We evaluated the cost and effectiveness of a primary education campaign to increase knowledge and awareness of type 2 diabetes in a large general Chinese population in this series of studies. A simple diabetes risk score (DRS) and fasting capillary glucose (FCG) test for screening undiagnosed diabetes in primary care settings were compared in terms of effectiveness (sensitivity of a screening method) and the cost per undiagnosed diabetes case identified. Finally, the impact of type 2 diabetes on the health-related quality of life (HRQoL) and whether screening for type 2 diabetes influence participants' HRQoL and lifestyle modification were investigated.

2. REVIEW OF THE LITERATURE

2.1 Epidemiology of type 2 diabetes

2.1.1 Definition and classification of type 2 diabetes

Diabetes mellitus is a group of metabolic diseases that are characterized by hyperglycaemia that result from defects in insulin secretion, insulin action, or both (American Diabetes Association, 2010). There are two main types of diabetes. Type 1 diabetes is mainly due to insulin insufficiency, which usually develops in childhood and adolescence. Type 1 patients require lifelong insulin injections for survival. Type 2 diabetes, on the other hand, usually develops in adulthood and represents 90% of diabetes cases worldwide. Type 2 diabetes occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces (insulin resistance). This leads to an increased concentration of glucose in the blood. A hallmark of type 2 diabetes is the decline in β -cell function and insulin sensitivity, which begins as early as 12 years before a clinical diagnosis is made and continues to decline throughout the disease process (UKPDS, 1995). The initial stages have been called 'pre-diabetes' or 'intermediate hyperglycaemia'. Both terms incorporate impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) when blood glucose levels are higher than normal, which indicates a high risk of developing type 2 diabetes (WHO/IDF Consultation, 2006). Individuals with IGT or IFG are between 10 and 20 times more likely to develop type 2 diabetes over a 5-year period than those with normal glucose tolerance over the same period (Magliano et al., 2008). About half of the people with IGT were reported to develop type 2 diabetes in the Indian population (Ramachandran et al. 2006) and in Chinese (Pan et al. 1997) during a 3-10-year follow-up.

The diagnosis of type 2 diabetes and other categories of glucose intolerance are based on blood glucose values. The diagnosis criteria for diabetes have been revised over the past decades. The first widely accepted diagnostic criteria for diabetes were set by the National Diabetes Data group in 1979, and since then the 2-hour 75 g oral glucose tolerance test (OGTT) was proposed as a standard test for diagnosis of type 2 diabetes (WHO, 1980, WHO, 1985). The American Diabetes Association (ADA) published its own criteria in 1997, which lowered the cut-off point of FPG from 7.8 mmol/l to 7.0 mmol/l for diagnosing diabetes (American Diabetes Association, 1997). Moreover, the ADA contemporaneously introduced a new category of IFG, which was redefined as fasting plasma glucose (FPG) concentration range of 6.1-6.9 mmol/l (American Diabetes Association, 1997). The ADA later recommended lowering the FPG cut-off point for IFG from 6.1mmol/l to 5.6 mmol/l in 2003 (Genuth et al., 2003). In 2009, the International Expert Committee recommended glycated haemaglobin (HbA1c) levels, which reflected average plasma glucose concentrations over the previous 8-12 weeks, to be used as a diagnostic test for diabetes. The HbA1c concentration of 6.5% was used as the cut-off point for diagnosing diabetes; and 5.7% to 6.4% range was used to signify a high risk for future diabetes (International Expert Committee, 2009). Current diagnosis and classification of diabetes are summarized in Table 1, and are based on the World Health Organisation (WHO) criteria in 2006 (WHO/IDF Consultation, 2006) and 2011 (WHO, 2011).

	Plasma glucose (mmol/l)	HbA1c (%)
Normoglycaemia	FPG < 6.1 and 2hPG < 7.8	<5.7
IFG	FPG 6.1 - 6.9 and 2hPG < 7.8 if measured	5.7 - 6.4
IGT	FPG < 7.0 and 2hPG 7.8 - 11.0	5.7 - 6.4
Diabetes	$FPG \ge 7.0 \text{ and/or } 2hPG \ge 11.1$	≥ 6.5

Table 1. Definitions of normoglycaemia, intermediate hyperglycaemia and diabetes based on WHO criteria

FPG, fasting plasma glucose; 2hPG, 2-hour plasma glucose; HbA1c, haemoglobin A1c; IFG, impaired fasting glucose; IGT, impaired glucose tolerance;

2.1.2 Risk factors of type 2 diabetes

Several risk factors are associated with the occurrence of type 2 diabetes. The genetic background, environmental factors and interaction between these factors have been linked to the risk of developing type 2 diabetes.

Aging

Type 2 diabetes occurrence increases with age and almost half of all adults with diabetes worldwide are between 40 and 59 years old (International Diabetes Federation, 2013). The age at peak incidence varies in different ethnic groups. The incidence of diabetes in the Pima Indian increases with age up to 40-50 years (Pavkov et al., 2007), whereas peak incidence occurs at over 65 in Caucasians (Ubink-Veltmaat et al., 2003, Monesi et al., 2012) and Chinese (Liu et al., 2007). The peak prevalence of diabetes of South-Asian (Indian) manifests at 10 years younger than for the Chinese and Japanese (Qiao et al., 2003a). The onset of type 2 diabetes is shifting to younger age groups with increasing levels of obesity and physical inactivity among adolescents and young people in many countries. Type 2 diabetes progresses more

rapidly among youths aged 10-19 years compared with type 2 diabetes in adults (TODAY Study Group et al., 2012).

Genetic predisposition and Ethnicity

Type 2 diabetes is a disease for which there are genetic predispositions. Several methods, which include linkage studies, candidate gene approaches and genome-wide association studies were used to find the diabetes susceptibility genes (Ahlqvist et al., 2011, Ribel-Madsen et al., 2012, Chang et al., 2014). Genome-wide association analysis has identified more than 40 genetic variants associated with type 2 diabetes, however, these variants accounted for only about 10% of the heritability of diabetes (Stolerman;Florez, 2009, Ahlqvist et al., 2011).

A family history of diabetes plays an important role in the development of type 2 diabetes. Individuals with a family history of diabetes have a 2 to 4-fold higher risk of diabetes than those with no family history of diabetes (Bjornholt et al., 2000, Ning et al., 2013). When an individual has a family history of diabetes, it may be difficult to determine whether the diabetes is due to lifestyle factors or to a genetic susceptibility or a combination of both.

The prevalence of diabetes is higher in certain ethnic groups than in others. According to results from the National Health and Nutrition Examination Survey in the US, Hispanic, Asian-Americans and non-Hispanic blacks are more likely to have diabetes than non-Hispanic whites (Sentell et al., 2012). At any given body mass index (BMI) or waist circumference in centimetres (WC) cut-off value, Asian populations have a higher prevalence of diabetes than Europeans (Nyamdorj et al., 2009, Nyamdorj et al., 2010).

Obesity

The increased prevalence of type 2 diabetes is strongly associated with obesity. The obesity indicators of BMI, WC, and waist-to-hip ratio have similar associations with the incidence of diabetes (Vazquez et al., 2007, Nyamdorj et al., 2009).

Weight gain is also positively associated with the incidence of type 2 diabetes (Wannamethee;Shaper, 1999, Resnick et al., 2000). On the other hand, weight reduction could prevent or delay the onset of diabetes among individuals with IFG/IGT (Pan et al., 1997b, Tuomilehto et al., 2001, Orchard et al., 2005, Lindstrom et al., 2013). Weight loss could also significantly reduce diabetes-related costs and a 1% weight change (increment or decrement) was associated with \$213 of total health care cost decrease (or increase) per year per patient with type 2 diabetes (Yu et al., 2007). A small loss in weight may significantly enhance HRQoL of persons at risk of type 2 diabetes (Nilsen et al., 2014).

Physical inactivity

Physical activity plays an important role in the prevention and control of type 2 diabetes. Physical activity increases total energy consumption and promotes both short- or long-term weight loss. Both obesity and physical inactivity are significant independent predictors of type 2 diabetes, but the magnitude of risk imparted by high levels of obesity is much greater than that of low levels of physical activity. The obese, physically active individuals are at a greater risk than normal-weight physically inactive individuals for type 2 diabetes (Goedecke; Micklesfield, 2014). Moderate or intensive physical activities reduce the risk of type 2 diabetes, with 17% - 60% risk reduction compared to those who are sedentary (Hu et al., 1999, Jeon et al., 2007).

Diabetes patients with structured exercise regimes, especially those who exercise for more than 150 min/week have a significant beneficial effect on glycaemic control and a 0.67% (0.49%-0.84%) decline in HbA1c levels (Umpierre et al., 2011). Similarly, a decline in blood pressure (BP) levels with 4.22 mmHg (2.56-5.89) decline in systolic blood pressure (SBP) and 2.07 mmHg (1.11-3.03) decline in diastolic blood pressure (DBP) have been reported for diabetes patients who exercise (Figueira et al., 2014). Those who already exercise at moderate intensity should increase the intensity of their exercise in order to obtain additional benefits in glycaemic control (Neetu, 2014).

Diet

Dietary patterns are important in the weight control, prevention and management of type 2 diabetes. There are several effective dietary patterns, e.g. the Mediterranean diet or eating more fresh vegetables, which are associated with low risk of onset of diabetes (Zhou et al., 2011, Schwingshackl et al., 2015). These dietary patterns share certain common characteristics: they are rich in whole grains, fruits, vegetables, legumes and nuts; moderate in alcohol consumption; and lower in refined grains, red or processed meats. The western-style diet, which is characterized by highly processed and refined foods, high contents of sugars, salt and high red meat consumption has been recognized as the major contributor to the development of type 2 diabetes and cardiovascular diseases (Steyn et al., 2004, Pan et al., 2013).

Cigarette smoking

The findings about associations between smoking and type 2 diabetes are inconsistent. Smoking is associated with an increased risk of developing of type 2 diabetes in men but much less so in women, as shown in some studies (Beziaud et al., 2004, InterAct Consortium et al., 2014). A protective effect of smoking against type 2 diabetes and elevated blood pressure was also reported by some studies (Onat et al., 2007, Imamura et al., 2001).

Alcohol consumption

Alcohol consumption has also been suggested to be relevant to the risk of type 2 diabetes. A U-shaped relationship was found between alcohol consumption and the risk of type 2 diabetes (Metcalf et al., 2014). Light-to-moderate alcohol drinking can reduce the risk of diabetes (Hodge et al., 2006, Wakabayashi, 2014b, Fagherazzi et al., 2014). However, heavy drinking is associated with an increased risk of diabetes (Wakabayashi, 2014a, Liang;Chikritzhs, 2014).

- 2.2 Primary education programme for type 2 diabetes
- 2.2.1 Public knowledge and awareness

Several studies that were conducted in many parts of the world, especially in the developing countries, suggested that there was a lack of sufficient public awareness and knowledge of type 2 diabetes. Of people over 60 years old in Jinan, China 40% and 30% did not know obesity and physical inactivity were risk factors of diabetes (Song et al., 2013). The total mean knowledge score in people with type 2 diabetes in Anhui Province of China was 5.48 with a standard deviation (SD) of 2.68 out of a maximum score of 12, and less than half of the study population had sufficient basic knowledge of diabetes or had adequate self-management skills (Zhong et al., 2011). Shafaee et al. reported that only 29.5%, 20.8% and 16.9% of local adult residents in a semi-urban setting of Omani identified the risk factors for diabetes of obesity, physical inactivity and a positive family history, respectively (Al Shafaee et al., 2008). The mean diabetes knowledge scores in Turkey were 62.9±17.9 out of a maximum score of 100 in the general adult population, and 83.7%, 78.9% and 92.3% of the

respondents correctly identified obesity, physical inactivity and a positive family history of diabetes as risk factors of diabetes (Gunay et al., 2006). About 50% of subjects in an urban adult Indian population scored less than 15 out of a maximum score of 65 and their knowledge regarding physical activity and healthy diet was poor as the scores were 2 out of a total of 7 and 9, respectively (Murugesan et al., 2007).

All these studies mentioned above highlight that there is an urgent need for educational programmes to increase public awareness and knowledge of diabetes. Increased knowledge of diabetes in the general population could raise public awareness and lead to early diagnosis and thereby facilitate the creation of supportive environments for diabetes prevention and intervention. Diabetes education targeting of type 2 diabetes patients aimed at improving the skills of self-management may also improve patients' quality of life (Ryan et al., 2013) and glycaemic control (Bains;Egede, 2011, Iqbal et al., 2008)

2.2.2 Approaches for delivering health education programmes

Health education activities occur in schools, working places, clinics and communities and include topics such as improving healthy eating, increasing physical activity, and cutting down on tobacco use etc. The purpose of such education is to improve health knowledge, improve attitudes, increase skills and modify behaviour. Health education programmes can be delivered by different approaches based on the main purpose of the programme and the target population. Generally, group education, one-to-one education, multi-media education are the most common delivery approaches used for diabetes patients and the general population in a diabetes education programme setting.

Group education

Teaching people in a group has been seen as an effective and also the most common intervention for diabetes since the 1970s (Carolé et al., April 2003). Education sessions that target groups of type 2 diabetes patients delivered diabetes-related knowledge and self-management skills (Raz et al., 1988, Rygg et al., 2012). Lifestyle intervention that focus on diet and physical activity when targeted at those people at high risk of diabetes can also be arranged as group education sessions, which take the forms of expert lectures, cooking lessons or a group-walking exercise etc. (Lindstrom et al., 2003, Balagopal et al., 2012). Group education has the potential of being efficient for dealing with the issues of blood pressure, glycaemia and weight control among diabetes patients (Heller et al., 1988, Deakin et al., 2005) and it could deliver medical cost savings (Fries;McShane, 1998, Christensen et al., 2004, Molsted et al., 2012). Smaller groups were reported to benefit more from group education than larger ones did, since there is more individual interaction between the tutors and patients in small size groups (Ooi et al., 2007).

One-to-one education

One-to-one education provides an individual relationship between health-care providers and participants. One-to-one education sessions are designed to meet the specific needs of each individual patient. A single episode of one-to-one education provided for the diabetic patients with poor glucose control was found to be effective at improving glycaemic control (Banerjee, 2012). The mean HbA1c level fell significantly from $9.2\pm0.5\%$ at baseline to $8.0\pm0.5\%$ at 6 months and to $8.3\pm0.7\%$ at 1 year final visit (p<0.05).

Both individual and group education can improve knowledge of participants and also improve their clinical outcomes, and each strategy has its advantages and disadvantages. Compared to individualized education, the group education programme setting may be more effective in delivering a lifestyle programme that focuses on diet and physical activity (Norris et al., 2001). Diabetes education delivered in a group setting is equally effective as the one-to-one approach at providing the equivalent or slightly greater improvements in glycaemic control (Norris et al., 2002, Rickheim et al., 2002).

Multi-media and other education approaches

Media education attempts to influence thinking, knowledge and beliefs at the individual and the group/population levels. It can reach large numbers of people at a relatively low cost. The knowledge about diabetes can be disseminated to the public through the existing media such as newspapers, radio and television. Printed material e.g. booklet or flyers play an important role as teaching or take-home material and it could be referred to repeatedly whenever the need arises.

New technologies (e.g. the internet, mobile phones, pedometers and self-monitoring of blood glucose devices) also have an effect in improving diabetes knowledge (Buis et al., 2013, Ramallo-Farina et al., 2015) and glucose control (Russell-Minda et al., 2009). Information and communication technology (ICT) offers the opportunity of efficiently supporting knowledge transfer and the management of diabetes (Alasaarela;Oliver, 2009, Fanning et al., 2012).

2.2.3 Cost and effectiveness of diabetes education programmes

Many education programmes have been initiated worldwide to increase public awareness of diabetes among the general population, and most of the studies demonstrated a significant improvement in the knowledge and awareness about diabetes. The effectiveness of education programmes to change diabetes knowledge and awareness was summarized in Table 2. Five well-documented cases were included in the summary based on the following criteria: (1) diabetes education campaigns using media education methods, 2) targeting of the general population, 3) using 'knowledge/awareness' changes as the main outcomes. The Diabetes Knowledge Questionnaire (DKQ) was developed in the mid-1980s to assess the knowledge of diabetes (Hess GE, 1983). The DKQ could be scored and compared before and after the education interventions. All the cases that were summarised in Table 2 indicated a significant increase in diabetes awareness and knowledge after the education campaign had been given.

Table 2. Summary of studies evaluating	ary of studies	evaluating the effectiveness of knowledge-based diabetes education programmes among the general	s education programmes among the general
	Time period	Education methods	Effectiveness
UK (Penn et al., 1992)	1 week	Local newspaper and radio; Public service announcement slots; Telephone help-line	The knowledge score rose from 5 before to 6 afterwards; score range 0-10, p<0.001
UK (Singh et al., 1994).	10 weeks	Poster advertising campaign	Correctly knowledge of diabetes symptoms increased from 5.1% to 7.1%; A reduction from 550 to 388 individuals lacking knowledge of any symptoms
India (Somannavar et al., 2008)	3 years	Education sessions in various locations; Local television, radio, printing media; Practitioners training	Awareness of a condition called diabetes increased from 75.5% before to 81% afterwards, $p<0.001$; Increases in knowledge of risk factors of diabetes: family history of diabetes (31.6% vs 38.9%); obesity (4.6% vs 10.7%); mental stress (4.0% vs 10.2%) and hypertension (6.8% vs 8.5%), $p<0.001$ for all
Cameroon (Fezeu et al., 2010).	3 years	Distribution of education materials; Meeting in market places or churches; Health education activities in schools; TV or radio broadcasts	94.7%, 90.4% and 77.3% of participants correctly recognized obesity, lack of physical activity and family history respectively as risk factors for diabetes after the campaign; Poor knowledge before the campaign
India (Balagopal et al., 2012)	6 months	Group and individual education; Personalized advice about their risk of developing diabetes; Distribution of education materials; Weight loss education for overweight and obese individuals; Blood glucose management education for diabetes and pre- diabetes individuals	Knowledge of diabetes and cardiovascular disease improved by 50% in high socioeconomic groups and doubled in the low socioeconomic status group; A reduction of blood glucose level in pre-diabetes, diabetes patients and general population

Although many diabetes education programmes have been implemented worldwide, few details on costs of these programmes have been reported (Bovet et al., 2011, Mash et al., 2015). Mass media campaigns for other conditions have been found to be cost-effective: for example the promotion of low-fat milk (Wootan et al., 2005), cessation of smoking (Farrelly et al., 2007), mental disease (Austin;Husted, 1998), stroke (Silver et al., 2003) and also diabetes prevention (George et al., 2015). Each education programme involves different numbers of education sessions provided by various health professionals. The unit cost, frequency and mode of the education delivery vary widely across different programmes and countries.

2.3 Screening for type 2 diabetes

2.3.1 Rationale for screening for type 2 diabetes

In the WHO report on the topic of screening for type 2 diabetes, screening was defined as the following: 'a process of identifying those individuals who may be at sufficiently high risk of a specific disorder to warrant further investigation or direct action. It [screening] is systematically offered to a population of people who have not sought medical attention on account of symptoms of the disease for which screening is being offered and is normally initiated by medical authorities and not by a patient's request for help on account of a specific complaint. The purpose of screening is to benefit the individuals being screened' (WHO, 2003).

Generally, screening for type 2 diabetes is considered to be necessary for several reasons. First, the prevalence of type 2 diabetes worldwide is increasing rapidly and it imposes a significant burden on individual's health and also on national health care systems. Second, type 2 diabetes develops gradually and there is a long, latent, asymptomatic period in which the condition can be detected (Harris et al., 1992).

Early identification with lifestyle intervention will postpone or even prevent the onset of diabetes. In addition, the risk of complications begins as early as in the pre-diabetic phase before blood glucose levels reach diagnostic cut-off points for type 2 diabetes (Haffner et al., 1990). Earlier diagnosis, intervention and treatment are believed to delay or even prevent such complications, improve health outcome and decrease the costs caused by the complications. Finally, some screening tools or tests (e.g. risk assessment questionnaires, portable capillary blood test and laboratory-based assessments) are valid, acceptable and reliable for detecting the preclinical stage of type 2 diabetes.

2.3.2 Screening approaches

Several potential approaches for diabetes screening have been used: population-based screening, selective or targeted screening, and opportunistic screening (WHO, 2003).

Population-based approaches attempt to screen every person in the entire population. It is not widely recommended, however, since it is costly and potentially inefficient except in populations that have a very high prevalence of diabetes. Epidemiological studies designed to assess the prevalence of diabetes often use this approach in a randomly selected population.

Selective screening target the subgroups of a population that have a high risk for diabetes. In selective screening, the first stage usually involves the identification of people at high risk (using general practice registers or self-evaluated questionnaires). The second stage for those with high risk could be a measure of blood glucose level, such as the HbA1c level, and/or the FPG and/or the OGTT (Waugh et al., 2013).

Opportunistic screening is an alternative to systematic screening. The screening is undertaken as patients attend medical practices for other purposes (which may be an acute problem or follow-up of a chronic disease or health promotion activity). Both selective and opportunistic approaches require fewer resources to conduct a screening programme than screening for the entire population.

2.3.3 Performance of screening tests

Performance of a screening test is usually evaluated against a 'gold standard' of sensitivity, specificity, positive and negative predictive values. A diagnosis for diabetes can be made on the basis of the standard 2-hour 75 g OGTT, which is widely accepted as the gold standard test. **Sensitivity** is defined as the proportion of people with the disease who have a positive test for the disease. **Specificity** is defined as the proportion of people without the disease who have a negative test. **The receiver operating characteristic curve (ROC)** curve is used to express the relationship between sensitivity and specificity for a given test. It is constructed by plotting the true-positive rate (sensitivity) against the false-positive rate (1-specificity) over the range of cut-off values. The area under the ROC curve (AUC) describes the overall accuracy of a test. The ROC curve is useful in (1) finding the optimal cut-off point to least misclassify diseased or non-diseased subjects, (2) evaluating the discriminatory ability of a test to correctly identify diseased and non-diseased subjects; (3) comparing the efficacy of two or more tests for assessing the same disease; (4) comparing two or more observers measuring the same test (inter-observer variability).

Many risk assessment algorithms that are used to screen for undiagnosed diabetes have been used around the world, and cover both modifiable and non-modifiable risk factors, such as age, sex, BMI, hypertension, family history of diabetes, physical activity, smoking and so on. The risk scores were developed and validated in Caucasian populations (Baan et al., 1999, Lindstrom;Tuomilehto, 2003), Indians (Ramachandran et al., 2005, Mohan et al., 2005), Chinese (Zhou et al., 2013, Gao et al., 2010, Sun et al., 2009) and other Asian populations (Aekplakorn et al., 2006). Most of these risk scores have a high sensitivity (above 70%) for predicting undiagnosed diabetes and these are set at the optimal cut-off points against the diagnostic test of a standard 2h 75g OGTTs or drug-treated diabetes. However, the specificities of the risk scores are relatively low or moderate, about 50% to 60%. The AUC for the respective ROCs vary from 70% to 85% (Baan et al., 1999, Lindstrom;Tuomilehto, 2003, Zhou et al., 2013).

The capillary blood glucose (CBG) test has also been used to screen for undiagnosed diabetes. The optimal cut-off points for screening undiagnosed diabetes vary from 5.0 mmol/l to 7.9 mmol/l in different studies (Bortheiry et al., 1994, Husseini et al., 2000, Zhang et al., 2005, Somannavar et al., 2009). The sensitivities of the CBG values at the optimal cut-off points are about 80% and specificities about 70% in most of studies, using a 2h 75g OGTT as the gold standard test (Husseini et al., 2000, Zhang et al., 2005, Somannavar et al., 2009).

2.3.4 Cost per type 2 diabetes identified

The expenditures of diabetes screening programmes should be evaluated within the local context, since the costs may vary from one setting to another. The main resources demanded by diabetes screening include the costs associated with screening itself, specific diagnostic tests for people with positive screening results, and additional treatment due to an earlier diagnosis. Estimating the one-time screening cost and efficiency of each screening strategy include both medical and non-medical

costs. Medical costs include laboratory-based tests, the physician's time and other material costs. Non-medical costs include transportation to a health care provider and the patients' time spent on traveling and receiving the test. The total costs for each strategy is calculated as a sum of the costs associated with time and resources used by the screening test and subsequent diagnostic testing. The cost of per case identified is calculated as the total costs of a screening strategy divided by the total number of cases identified.

Eight well-documented studies assessed the cost per case identified by different screening strategies. These studies are reviewed and summarized in Table 3. The selection criteria for the chosen studies were the following: 1) screening for prediabetes and/or diabetes, 2) comparing various screening strategies in the same population, 3) using cost per case identified as the main outcomes. Testing by using OGTT alone or OGTT combined with HbA1c determinations were found to be the most effective strategies (Zhang et al., 2003, Icks et al., 2004) since OGTT is the gold standard for defining pre-diabetes or diabetes. The OGTT is costly and time consuming, and also the combination is not easy to apply in a large population screening setting. Capillary blood glucose test and risk score questionnaires were similar with respect to their effectiveness and efficiency for detecting pre-diabetes and undiagnosed diabetes (Zhang et al., 2003). Opportunistic screening was more efficient or as efficient when compared to population-based screening (Dalsgaard et al., 2010, Pereira Gray et al., 2012).

Study	Population	Screening methods and cut-off points	Gold standard diagnostic test	Unit costs	Cost per case identified
US (Zhang et al., 2003)	age 45-74 years screening for pre- diabetes and diabetes	2h PG \ge 140 mg/dl ; FPG \ge 95 mg/dl; A1c \ge 5.0%; CBG \ge 100 mg/dl; Risk assessment questionnaire	2h 75g OGTT	Physician time \$51 per visit; FPG \$5.24; OGTT \$17.22; Patient time \$8 per hour; Travel \$7 per trip	Single-payer/societal perspective: OGTT: \$196/299; FPG: \$192/319; A1c: \$236/332; CBG: \$176/247; Risk assessment questionnaire: \$179/263
Germany (Icks et al., 2004)	age 55-74 years screening for diabetes	FPG ≥ 7.0 mmol/l; FPG+OGTT, if FPG ≥ 6.1 and <7.0 mmol/l; Single OGTT; HbA1c+OGTT, if HbA1c >5.6%	2h 75g OGTT	Pre-selection $\notin 12.18$ per visit; FPG test $\notin 14.78$; HbA1c $\notin 16;$ OGTT $\notin 16.34$; Patient time $\notin 29.19$ per hour for employed $\notin 5.37$ for unemployed; Travel $\notin 7$ per trip;	Health insurance perspective: Single OGTT €4.9; HbAlc+ OGTT €21.44; Society perspective: FPG+OGTT €10.85; HbAlc+OGTT €31.77
US (Johnson et al., 2005)	age 45-74 years screening for diabetes	RPG for 100, 130 and 160 mg/dl at 1-3- and 5-year intervals over 15 years	2h 75g OGTT	Physician time \$51 per visit; RPG \$5.24; FPG\$5.24; OGTT \$17.22; Patient time \$8 per hour; Travel \$7 per trip;	Total costs of strategies ranged from \$6.9 billion (most specific strategy) to \$42.7 billion (most sensitive strategy) for screening 72 600 000 adults; RPG \ge 130 mg/dl every 3 years cost \$642 per true positive case identified
Brazil (Toscano et al., 2008)	age over 40 years screening for diabetes	FCG≥5.6 mmol/l or RCG ≥7.8mmol/l	Fasting venous glucose	Glucose test \$1.49; physician visit\$5.32; average monthly wage for nurse and doctor \$1362 and \$1915	Total screening and diagnostic costs were \$26.19 billion for screening 22 069 905 adults; cost per diabetes identified was \$76
US (Chatterjee et al., 2010)	mean age of 48 years screening for pre-diabetes and diabetes	RPG ≥100mg/dl and RCG ≥106 mg/dl; GCT-pl ≥138 mg/dl and GCT- cap ≥162mg/l; A1c ≥5.5%	2h 75g OGTT	RPG \$7.84 PCG \$4.06 GCT-pl \$10.13; GCT-cap \$7.54; A1c \$15.92	Health system/societal perspective: RPG \$937/\$1378; RCG \$1193/\$1713; A1c \$952/\$1383; GCT-pl \$728/\$1100; GCT-cap \$855/\$1259

Table 3. Summary of eight studies that assessed the cost per diabetes and/or pre-diabetes screening tests

Cost per diabetes identified: Mail-distributed: €1058 Opportunistic screening-direct: €707 Opportunistic screening-subsequent: €728	Sensitivities ranged from 71% to 92%; Cost of per abnormal fasting plasma glucose identified was \$59.12-\$69.62	Cost per diabetes identified was \$76	od glucose; OGTT, oral glucose random blood glucose; GCT-pl, T glucose challenge test without
No information	Questionnaire:1B per test; Physician's time: 284B per h; Nurse time: 170B per h; Secretary's time: 45B per h; Laboratory test: 8B; Mail: 5B; Transportation cost: 16B per trip (1B≈0.03\$)	blood glucose test £0.48; healthcare assistant cost £2.04; practice nurse costs £3.51; OGTT cost £20.81	haemoglobin A1c; CBG, capillary bloc RCG, random capillary glucose; RBG, ap, capillary glucose after 1h 50g OGT
2h 75g OGTT	FPG	2h 75g OGTT	bA1c, glycated pillary glucose; tt fasting; GCT-c
Mail-distributed (population-based): if risk score≥5 (at home), go to GP and offer screening test; if RBG ≥5.5mmol/1 or HbA1c ≥5.8%, invite to diagnostic test; Opportunistic screening-direct: if risk score≥5 (at GP's) subsequently offer screening test; if RBG ≥5.5mmol/1 or HbA1c ≥5.8%, invite to diagnostic test; Opportunistic screening subsequent: if risk score≥5 (at GP's), invite to diagnostic test	Four different diabetes risk assessment questionnaires	At least one risk factor of diabetes and random blood glucose test	FBG, fasting blood glucose; FPG, fasting plasma glucose; HbA1c, glycated haemoglobin A1c; CBG, capillary blood glucose; OGTT, oral glucose tolerance test; RPG, random plasma glucose; FCG, fasting capillary glucose; RCG, random capillary glucose; RBG, random blood glucose; GCT-pl, plasma glucose a 1h 50g OGTT glucose challenge test without fasting; GCT-cap, capillary glucose after 1h 50g OGTT glucose challenge test without fasting; GCT-cap, capillary glucose after 1h 50g OGTT glucose challenge test without fasting.
age 40-69 years screening for diabetes	age 35-60 years screening for abnormal fasting plasma glucose	age over 16 years screening for diabetes	FBG, fasting blood g tolerance test; RPG, plasma glucose a 1h fasting
Denmark (Dalsgaard et al., 2010)	Thailand (Srichang et al., 2011)	UK (Pereira Gray et al., 2012)	FI tol fas

2.3.5 Impact of a diabetes screening programme on subjects

The effects of screening and diagnosis of type 2 diabetes may have either a positive or negative impact on patients' perception of their well-being. Screening for identifying undiagnosed diabetes could lead to earlier identification and intervention, and postpone or prevent the onset of diabetes and its complications (Wareham;Griffin, 2001, Streets, 2001).

However, screening may also lead to a wrong diagnosis, inappropriate investigation and treatment and unnecessary psychosocial effects and a decline in HRQoL. Earlier studies reported minimal negative impacts of screening and suggested that the potential for 'labelling' was not an important barrier to diabetes screening (Edelman et al., 2002, Marrero et al., 2014). Screening for type 2 diabetes may be associated with higher levels of short-term anxiety among invited participants compared to their non-invited counterparts (Park et al., 2008). Other studies found that the screening programme had a limited adverse psychological impact on the screened participants after the initial blood glucose test, at 3-6 months and at 12-15 months follow-up (Adriaanse et al., 2004, Skinner et al., 2005, Eborall et al., 2007).

Unhealthy lifestyles that involve a lack of regular physical activity and consumption of unhealthy diets are related to many non-communicable diseases. Diabetes screening might provide the opportunities for initiating lifestyle modification, since the screening might be a 'teachable moment' for primary prevention measures to modify unhealthy lifestyles effectively (Fisher et al., 2002). However, another study showed the intentions to adopt healthy lifestyles were not increased in patients with a high perceived risk, even if the majority of patients agreed on the benefits of a healthy diet and exercise to prevent diabetes (Hivert et al., 2009). Negative screening results did not lower participants' intentions to reduce dietary fat and sugar intake and to increase physical activity after the first appointment or at 3-6 months or at 12-15 months follow-up (Paddison et al., 2009). Neither the subjects with a negative screening test for diabetes nor the subjects who were not offered a screening test made overt changes towards a healthier lifestyle after 4 years of follow-up (Willems et al., 2014).

2.4 HRQoL in people with type 2 diabetes

2.4.1 Definition and measures of HRQoL

The WHO has defined health as 'a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity' in 1948 (WHO, 1948). The theoretical framework of HRQoL is thus largely based on a multidimensional perspective of health, and it is broadly accepted that HRQoL is a multidimensional concept that encompasses the entire spectrum of physical, emotional and social components associated with illness and its treatment.

Several measures have been used to assess HRQoL. Two basic approaches that characterize the measurements of HRQoL are generic instruments and specific disease or aspect instruments (Guyatt et al., 1993). Specific-disease instruments e.g. Diabetes-39 (D-39) assesses individuals' HRQoL by taking into account specific issues in relation to diabetes. It is sensitive at detecting the differences that arise as a consequence of treatment strategies, which are compared in clinical trials. Generic instruments are applicable across all diseases and conditions, and assess the health of both general and specific populations. Generic instruments are further divided into two types, which are: health status profiles and health utilities.

Health status profiles attempt to describe a person's functioning for multiple domains. Each health status domain is scored separately. Currently, one of the most commonly used generic health status instruments is the Medical Outcome Study 36-item Short Form (SF-36), which encompasses 8 domains of health and further aggregated into physical and mental component summary scores (Ware et al., 1995).

Health utilities are preference-based numerical measurements that produce a single summary score for HRQoL (Lenert;Kaplan, 2000).

Both health status profiles and utilities measure and examine similar dimensions of health. The scaling of utility measures is made in terms of some absolute reference points (full health to death), whereas the population reference point is used in many health status measurements. A preference-based utility instrument can be used in estimating the quality-adjusted life years (QALYs), which is an outcome measure that is commonly used in health economics to estimate the overall burden the individual suffers over her/his lifetime.

Health utility measures are divided into 2 categories: direct and indirect measures (Khanna;Tsevat, 2007). The three most widely used techniques to measure utility directly are the rating scale (Froberg;Kane, 1989), the standard gamble, and the time to trade-off (TTO) (Torrance, 1986). Indirect measures, are also called multi-attribute health state classification systems, are exemplified by Quality of Well-being (QWB) (Kaplan et al., 1998), European Quality of Life-5 Dimensions (EQ-5D) from the EuroQoL group (EuroQol Group, 1990), Short form 6 Dimensions (SF-6D) (Brazier et al., 1998), Health Utility Index (HUI) (Furlong et al., 2001) and 15 Dimensions (15D) (Sintonen, 2001).

2.4.2 HRQoL in people with type 2 diabetes

When a person has a chronic disease such as diabetes, their overall and multiple dimensions of HRQoL will be adversely affected. Type 2 diabetes patients with complications have a reduced quality of life on multiple dimensions compared to those without complications, and the impairment is related to the number and severity of those complications (UKPDS, 1999, Maddigan et al., 2005, Cong et al., 2012, Tan et al., 2014). Diabetes is also independently associated with impaired HRQoL compared with the non-diabetic population regardless of comorbidities (Smith, 2004, Alonso et al., 2004, Choi et al., 2011). Eliminating diabetes would extend the life expectancy and health-adjusted life expectancy (Manuel;Schultz, 2004). The HRQoL is impaired in newly diagnosed asymptomatic diabetes patients (Chittleborough et al., 2006, Tapp et al., 2006, Seppala et al., 2013) and also in those people with IGT or IFG (Tapp et al., 2010) compared with those with normal glucose tolerance. These impairments are mainly due to adverse impacts in the physical dimension. Seven study cases related to the HROoL in people with diabetes or pre-diabetes are summarized in Table 4. The seven studies were selected using the following criteria: 1) assessment of the impact of diabetes among the general population 2) HRQoL was measured by either health status profiles or health utility measures.

Study	Population	Instrument	Confounders	Impaired functions compared to normal glucose tolerance
Finland (Hiltunen;Keinanen- Kiukaanniemi, 1999)	age 273 years of an unselected non- institutionalised population	Nottingham Health Profile	age, sex	PKD: Impaired for energy, pain and physical mobility dimensions, Problems with performing jobs around the house, hobbies and holidays; NDM and IGT: no significant difference
Australia (Chittleborough et al., 2006)	age ≥18 years of a representative general population	SF-36	age, sex and cardiovascular disease	PKD: Impaired on all dimensions of the SF-36 except mental health; NDM and IFG: impaired on the physical functioning, body pain
AusDiab,Australia (Tapp et al., 2006)	age ≥25 years of a randomly selected general population	SF-36	age, sex, BMI, physical activity, current treatment for hypertension or lipid abnormalities	PKD: Impaired for all dimensions of the SF-36 except mental health; NDM: impaired for general health, physical functioning and role limitation; IGT: impaired for physical functioning and social functioning; IFG: no significant different
AusDiab,Australia (Tapp et al., 2010)	age ≥25 years, with 5 years follow-up of a randomly selected general population	SF-36	age, sex, BMI, total cholesterol, smoking, known CVD, medication for hypertension or a lipid abnormality	Incident DM: impaired on physical functioning, role-physical, body pain, general health, vitality, social functioning, role emotional and mental health at baseline; Incident IGT: impaired for physical functioning, role-physical, bodily pain, general health, vitality, social functioning and mental health at baseline; Incident IFG: impaired for bodily pain at baseline
Finland (Seppala et al., 2013)	at least one CVD risk; no PKD or CVD; age 45-70 years of a community apparently healthy population	SF-36	age, sex	NDM: impaired on physical functioning, general health, emotional role; IGM: no significant different
Finland (Vaatainen et al., 2014)	age 51-75 years of a general rural population	15D, SF- 6D, SF-36	age, sex, smoking, alcohol consumption, employment and marital status	The progression along the diabetes continuum (from NGM to PKD) was significantly associated with a decrease in overall HRQoL and health status, p for trend <0.001; IGT: impaired on physical dimensions of HRQoL
Iran (Ghorbani et al., 2014)	age 20 -78 years of a general population; no PKD	SF-36	age, sex	No association between quality of life domains and glucose metabolism status

2.4.3 Factors affecting the HRQoL score

Besides diabetes complications and comorbid diseases, HRQoL scores are associated with other predictors. Despite current diabetes treatment and management, a gender difference still exists and women report worse health status than men. In Germany, patients with type 2 diabetes have negative consequences on mental health in women only (Schunk et al., 2012). Newly diagnosed individuals with diabetes in Sweden had significantly impaired HRQoL scores in usual activity for all, but only women had reduced HRQoL scores for the dimensions of mobility, self-care, usual activities and discomfort. The duration of diabetes was found to be significantly associated with impaired HRQoL only for women (Sparring et al., 2013).

Differences in HRQoL scores between individuals with diabetes or pre-diabetes who are physically active also exist compared to those who are inactive. Sedentary diabetic patients have more depression symptoms and worse HRQoL (Daniele et al., 2013). People with pre-diabetes and who are physically active according to physical activity guidelines, report better physical health and mental health compared to those who do not meet the guideline for physical activity (Taylor et al., 2010).

HRQoL of patients with type 2 diabetes also has a strong association with patient's socio-economic status (SES). Patients with higher incomes and who are employed will have a better HRQoL than patients with lower incomes and who are unemployed (Brown et al., 2004, Hosseini Nejhad et al., 2013). Understanding the impact that diabetes and other risk factors have on HRQoL is important for diabetes management and also for public health policy initiatives in order to improve the long-term health outcomes of a population.

3. AIMS OF THE STUDY

The general aim of this study was to evaluate the feasibility, performance, and costeffectiveness of a population-based diabetes education programme and screening activities in Qingdao, China.

The specific aims were:

- To evaluate the costs and effectiveness of implementing a diabetes education programme to increase the public knowledge and awareness of diabetes in Qingdao (Study I).
- To compare the performance and cost-effectiveness of two screening methods at identifying undiagnosed diabetes (Study II).
- To determine and examine the HRQoL in people with previously known diabetes, newly diagnosed asymptomatic diabetes and people without diabetes at baseline screening (Study III);
- 4) To assess the impact of a diabetes screening programme on the overall HRQoL, depression dimension and lifestyle modification amongst those who underwent a screening programme three years previously and who were labelled either as prediabetes or normoglycaemia at baseline (Study IV).

4. STUDY POPULATION AND METHODS

4.1 Study population and design

This study was based on the health education and disease prevention programme conducted in Qingdao, China. Qingdao is located on the east coastline of China. There are 12 administration regions in Qingdao city, four urban and eight rural countries.

Qingdao Diabetes Prevention Program (QD-DPP) (Survey B)

Several studies based on clinical trials experience have shown that health education and lifestyle interventions can delay or even prevent the onset of diabetes in people with IGT across different ethnic groups around world (Eriksson, 1991, Pan et al., 1997b, Tuomilehto et al., 2001, Ramachandran et al., 2006). However whether the trial experience can be applied on the larger scale by targeting a large population under normal conditions remains unknown.

The QD-DPP has major goals of increasing public awareness and knowledge about the risk factors of diabetes. The QD-DPP also aims at promoting healthy living through diet and physical activity advice to high-risk groups and the general population in order to reduce the diabetes risk at population levels and prevent diabetes (Qiao et al., 2010).

The QD-DPP was launched in 2006 with support from the World Diabetes Foundation (WDF05-108 and WDF07-308), and it is administratively guaranteed and supported by Qingdao Health Bureau, Qingdao Centre for Diseases Control (QD-CDC) and the Qingdao Health insurance Center. The QD-DPP is led and run by professionals from the University of Helsinki and Qingdao CDC. The project office is located in the QD-CDC and is responsible for daily co-ordination of the project. The day-to-day running of the project mainly relies upon doctors and nurses whom work in the community or village clinics. In addition, more than 400 young volunteers were recruited by the local health bureau. The QD-DPP targets the two urban districts of Shinan and Shibei and two rural counties of Huangdao and Jiaonan, including 1.94 million citizens who live in 512 urban communities and 1128 rural villages. Both the population approach and the high-risk approach were applied in the QD-DPP.

Population approach

Diabetes education programmes and health promotion activities through printing and audio visual media, the internet, free distribution of information booklets and diabetes risk score flyers were targeted at the entire populations that were living in the intervention areas.

High-risk approach

An adult with a DRS \geq 14 was considered at high-risk for diabetes and invited to a nearby community clinic for a free capillary blood glucose test and interview by a community doctor or nurse. A total of 464 548 first-visit paper records were completed between 2007 and 2010. Of these, 162 709 first-visit records were converted into a digital format, and 77 389 individuals without a prior history of diabetes or who had missing data were also included in study I (Figure 1). The input of the paper records into digital records is random and is still ongoing. The goal is eventually to convert all paper records into digital form. The current digital record database can serve as a random sample of the high-risk population identified so far. At the end of the first clinical visit, the individuals received advice on how to change their dietary habits and increase their physical activity levels. In the follow-up survey, the changes in weight and in dietary and exercise habits were measured and new or modified suggestions on diet and exercise depending on the new outcome were provided.

Survey A

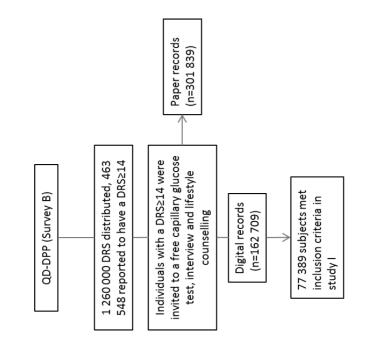
The baseline prevalence of diabetes and public knowledge and awareness of diabetes before the health promotion activities of QD-DPP started were investigated. This was accomplished by conducting a cross-sectional population-based epidemiological diabetes survey A. It was conducted from February to May of 2006 in six randomly selected urban and rural districts. Four of the six districts were intervention areas (Shinan, Shibei, Jiaonan, Huangdao) and two were non-intervention control areas. Five residential communities or villages from each district and 200-250 residents aged 35-74 years and lived in Qingdao for over 5 years were randomly selected. A total of 6100 individuals were invited and of these 5355 individuals participated in the survey, which gave a response rate of 78.6% (Figure 2).

Survey C baseline and follow-up

Another cross-sectional population-based diabetes survey was conducted in the same districts in Qingdao, China in April 2009. Survey C followed the same study procedure as survey A. A total of 7612 individuals in survey C were invited, of which 5110 individuals (1406 from the urban areas and 3704 from the rural areas) participated in the survey, which gave a response rate of 67.1%. The aim of survey C was to increase the number of individuals in both intervention and control study arms and add extra statistical power to facilitate detecting intervention effectiveness of the intervention. A total of 3108 rural participants who did not have diabetes at baseline in 2009 were invited for a re-examination. Of these, 1782 individuals attended the second examination and were included in study IV, with a follow-up rate of 57.3% (Figure 2). The timeline of the surveys are shown in Figure 3. Inclusion/exclusion criteria of the study population in each study are shown in Table 5.

Figure 1. The sampling procedures, participation rates and screening strategies in Qingdao Diabetes Prevention Program (QD-DPP,

Survey B)



DRS, Diabetes Risk Score

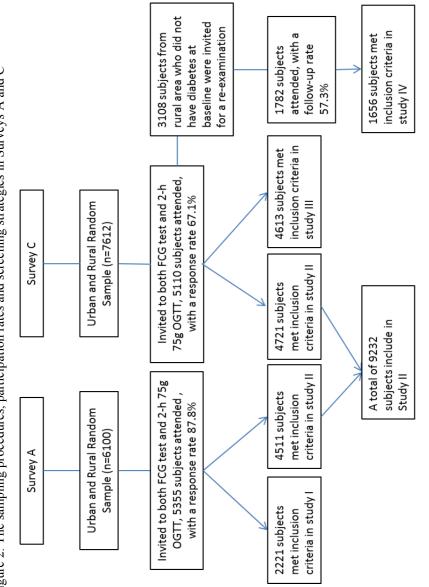


Figure 2. The sampling procedures, participation rates and screening strategies in Surveys A and C

FCG, fasting capillary glucose test; OGTT, oral glucose tolerance test

Figure 3. The timeline of Surveys A, B (QD-DPP) and C

2011 > 2012	 3-year follow-up of diabetes Survey C
> 2010	• QD-DPP (Survey B) Media campaign finishes
2009	 Population- based diabetes Survey C baseline
, > 2008	
2007	 QD-DPP (Survey B) Media campaign begins
2006	 Population- based diabetes Survey A

	Data source	Inclusion criteria	Exclusion criteria
Study I	Survey A and B	 Participants aged 35-74 years; 2) DRS≥14; 3) Valid diabetes knowledge 1) Previously known diabetes; questionnaire 	 Previously known diabetes; Missing required variables
Study II	Study II Survey A and C	1) Participants aged 35-74 years; 2) Undergoing a standard 2h 75g OGTT test or1) Previously known diabetes;HbA1c test; 3) Valid DRS questionnaire; 4) Undergoing FCG test2) Missing required variables	 Previously known diabetes; Missing required variables
Study III	Study III Survey C	1) Participants aged 35-74 years; 2) Previously known diabetes; or not having a prior history of diabetes with a standard 2h 75g OGTT test; 3) Valid 15D questionnaire	 Uncompleted 15D questionnaire; Missing required variables
Study IV	Study IV Survey C baseline and b	 Rural participants aged 35-74 years at baseline; 2) Undergoing a standard 2h 75g Previously known and newly OGTT test at baseline; 3) Valid 15D, depression and lifestyle questionnaire at both diagnosed diabetes at baseline; baseline and follow-up 	 Previously known and newly diagnosed diabetes at baseline; Missing required variables
FCG,	fasting capillary glucose;	FCG, fasting capillary glucose; DRS, diabetes risk score; OGTT, oral glucose tolerance test	

Table 5. Inclusion/exclusion criteria of the study population

4.2 Methods

4.2.1 The demographic and anthropometric measurements

Surveys A and C and follow-up used similar survey approaches. All eligible individuals were invited to a survey site near to their residential communities. Each participant was interviewed by a trained survey team of doctors and nurses.

Height and weight of subjects were measured with each individual wearing only light clothes and without shoes. When surveys were carried out in wintertime, a weight of 1 or 2 kg was deducted from the measured weight of individuals depending on the coldweather clothes participants wore to adjust for the individuals true weight. The subject's body mass index (BMI) was then calculated by dividing her/his weight in kilograms (kg) by their height in meters squared (m^2) . Waist circumference in centimeters (cm) was measured at the mid-point between the rib cage and the iliac crest. A family history of diabetes was defined as having at least one first degree family member (father, mother or sibling) with diabetes. Education was classified as illiterate, elementary school (1-6 years), junior high school (7-9 years) and high school or above ≥ 9 school years. Personal monthly income was classified as income <¥300/month, ¥300-999/month, or ≥¥1000/month (1€≈7.1¥, for the year of 2015). Three consecutive blood pressure readings that were separated by at least a 30 second interval, were taken from the right arm of subjects in the sitting position, and the mean of the three readings was calculated and recorded. A person having a systolic blood pressure \geq 140 mmHg and/or a diastolic blood pressure \geq 90 mmHg or with a history of hypertension defined by a physician was classified as having hypertension.

4.2.2 Screening for undiagnosed diabetes

Both the FCG test and the DRS questionnaire (**Appendix**) were given to all survey participants in surveys A and C. The FCG measurement was taken between 07.00 and 09.30 hours. The DRS questionnaire was filled in during the same morning with other survey questionnaires at the survey sites. The DRS included three categorical variables of age, waist circumference and family history of diabetes. The range of DRS was from 3 to 32, and a score of \geq 14 was defined as high risk (Gao et al., 2010). The standard 2h 75g OGTT was also administrated to all participants on the same morning.

4.2.3 Classification and diagnosis of type 2 diabetes

Every participant was asked during the interview whether he/she had been previously diagnosed with diabetes. If the answer was 'yes', the glucose level at the diagnosis and the treatment for diabetes was checked and reviewed by a doctor, and the subject was classified as having previously known diabetes.

Individuals with a FPG \geq 7.0 mmol/l and /or 2hPG \geq 11.1 mmol/l were classified as having newly diagnosed diabetes. An FPG 6.1-6.9 mmol/l value range and/or 2hPG 7.8-11.0 mmol/l range were classified as IFG and/or IGT, according to the WHO/IDF 2006 criteria (WHO/IDF Consultation, 2006). Both IFG and IGT were considered as pre-diabetes. Normoglycaemia was defined when a FPG <6.1 mmol/l and a 2hPG <7.8 mmol/l was obtained. In study II, HbA1c \geq 6.5% values or values between the 5.7% and 6.4% range was also used to define the newly diagnosed diabetes or pre-diabetes (WHO, 2011).

4.2.4 Cost of screening for undiagnosed diabetes

We estimated the total cost associated with the screening programme from the societal perspective in study II, which covered direct costs included for the laboratory tests, the physician's time and the direct costs of other materials (e.g. cost of blood glucose strips, capital cost of glucose measuring equipment, needles, printing DRS, etc.) and indirect costs (e.g. subjects off work to participate the screening and money/time spent for transportation to a health care provider site).

We estimated that it took about 20 min for community/village doctors or nurses to measure the weight, height and WC at first-line screening and to double check the self-administrated questionnaire or to execute the capillary blood glucose test. The cost of laboratory diagnostic tests in tertiary hospitals was based on local medical service prices. The labour costs regarding patient and the physician were based on national statistics of the average physician salaries and also taking into account the local payment levels.

The total cost (TC) of screening all individuals was calculated as

TC = (all individuals screened * screening cost per person) + (individuals with a positive screening test * diagnostic cost per person)

TC per 1000 persons = TC/ all individuals screened *1000 [Equation 1]

The effectiveness of screening methods was measured by the proportion of people with newly diagnosed diabetes who have a positive test result at a first-line screening, which is equal to the sensitivity of a screening method. The number of undiagnosed diabetes identified by each screening method was calculated thus: The number of undiagnosed diabetes identified per 1000 persons = prevalence * sensitivity *1000 [Equation 2].

The mean cost per undiagnosed diabetes identified was obtained by the total screening cost divided by the number of undiagnosed diabetes identified (Eq1/Eq2). The incremental cost per undiagnosed diabetes identified = (Cost1-Cost2) / (Eff1 – Eff2), which indicates the cost that decision makers are willing to pay for one more diabetes case identified compared with other screening strategies.

4.2.5 Assessment of physical activity and diet

We evaluated the individual physical activity (PA) in study IV by estimating the daily steps walked by the individual by using a questionnaire recommended by Physical Activity Guideline for Chinese Adults (People's Republic of China Ministry of Health, Bureau of Disease Control and Prevention, 2011). The questionnaire investigated five major types of daily physical activity patterns of Chinese adults: walking, housework, leisure time PA, cycling, and occupational PA. Four types of daily physical activity patterns except for occupational PA were considered in the current study. Each type of PA includes specific activities such as walking, cooking, taking care of children or group dancing etc. that are the most common among Chinese adults. Participants reported the minutes per day of PA and the frequency per week of each specific activity during the past week. Each specific activity based on the total amount and intensity was then converted into 'walked steps'. The calculation was based on the Compendium of Physical Activities (Ainsworth et al., 2011), which is a coding scheme that classifies specific PA by the rate of energy consumption of a specified activity. The energy consumption of 1000 walk steps was equal to walking at 4 km/hour (METs= 3) for 10 minutes (1000 steps = 1/2 MET-hr). The physical activity

level was classified on this basis as low (<6000 steps per day), moderate (6000-9999 steps per day), and high ($\geq 10\ 000$ steps per day).

The consumption of fresh vegetables was evaluated by an interviewer-administered 54-item food quantitative frequency questionnaire (Li et al., 2006) that incorporated 54 kinds of food, beverage and other items that are commonly consumed in China. Participants reported the intake frequency and amount of fresh vegetables during the past year on a daily, weekly, monthly or yearly basis. Each participant was classified into three categories of fresh vegetable consumption of <7 times, 7-13 times, and ≥ 14 times per week.

4.2.6 Public knowledge and expenditures on diabetes education programmes

The evaluation of the effectiveness of the mass media campaign included changes in knowledge, summarizing the number of diabetes booklets, DRS flyer and newspaper articles that had been distributed, and the number of radio programmes that had been broadcasted. The costs associated with the media campaign were also tracked. The media campaign was further assessed by evaluating the cost per1000 individuals covered.

Knowledge of diabetes risk factors and the need for a healthy diet and regular physical activity were the core messages of the QD-DPP education campaign. The changes in the knowledge about diabetes were based on the answers recorded in two similar diabetes awareness questionnaires i.e, survey A and B. The proportions of participants who correctly identified the major diabetes risk factors of obesity, family history of diabetes and physical inactivity in both surveys were counted and compared before and after the education and the differences were regarded as the changes in diabetes awareness. Incremental costs of conducting the education campaign were calculated. Costs of each education tool were obtained from the actual expenditures in the project. The costing has two elements: quantities of resources used (q) and unit prices (p). We interviewed 90 randomly selected adults from a suburban area in Jiaonan district in July 2011, to estimate the number of individuals exposed to different education strategies. The following questions were asked during the interview: (1) 'Did your family subscribe to the Qingdao Morning newspaper during the period of 2007-2010'? (2) 'Do you ever listen to a radio programme on lifestyle and diabetes'?, (3) 'Have you received a booklet on diabetes or a DRS flyer'? The exposure rates to the media in this district as indicated by the interviews were as follows; 34% for the newspaper articles, 33% for radio, 83% for the booklet and 56% for the single diabetes risk score flyer.

4.2.7 HRQoL and depression measures

We used an interview-based 15D instrument to measure the overall HRQoL in surveys C and follow-up surveys (Sintonen, 2001). The 15D utility system consists of 15 following dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. Each dimension is divided into five ordinal levels, by which more or less the attribute is distinguished. The single index score (15D score), representing the overall HRQoL on a 0-1 scale (1= full health, 0= being dead) and was calculated from the health state descriptive system using a set of population-based preference or utility weightings. The minimal clinically important change or difference in the 15D score is ± 0.015 (Alanne et al., 2015).

The Zung Self-rating Depression Scale questionnaire was used to survey depressive symptoms (Zung et al., 1965). The scale consists of 20 items using a four-pointgrading system, ranging from 'none or a little of the time' to 'most of or all the time'. The completed scale ranged from 20 to 80, and depression level was defined on the basis of the Zung depression scores: 20-44 normal range, 45-59 mildly depressed, 60-69 moderately depressed, and \geq 70 severely depressed.

4.3 Statistical analyses

The differences between the groups in means of continuous variables were tested with independent sample t-test and the differences between the groups in categorical variables were tested by using the Pearson Chi-square test. All statistics were performed using PASW statistics, with statistical significance defined as two-tailed p-values < 0.05 (Version 18.0.2, Chicago: SPSS Inc; April 2, 2010). The specific statistical methods in each study are described as follows:

In study II, C-statistics were used to compare the AUC of the ROC by using R (Version 2.10.1, 2009-12-14).

In study III, a Tobit (censored regression) model was constructed to assess the effect of diabetes or pre-diabetes on HRQoL, and controlled for different confounding effects. Modeling was performed with LIMDEP 8.0 econometric software.

In study IV, changes over time in the continuous variables (HRQoL, Zung depression score, BMI, weight) within each group were analysed using the paired-t test and in categorical variables using the McNemar's test (binary) or Marginal homogeneity test (multinomial), respectively. Differences in parameters between the two groups were

determined by analysis of co-variance (ANCOVA), adjusting for the corresponding baseline values of HRQoL, Zung depression score, BMI and weight.

5. RESULTS

5.1 Baseline characteristics of the participants

Characteristics of all the participants in surveys A, B (the QD-DPP), C are summarized in Table 6. The urban participants in all the surveys reported a positive family history of diabetes and better social-economic status more often than the rural participants did.

Survey B (QD-DPP)	Survey A (n=53	355)	Survey C (n=5	110)	Survey B (Q (n=77 389)	D-DPP)
	Urban (N=2568)	Rural (N=2787)	Urban (N=1406)	Rural (N=3704)	Urban (N=38 139)	Rural (N=39 250)
Men (%)	36.4	40.5	32.1	42.3	47.7	53.9
Age (years)	51 (10.1)	49 (10.2)	54 (10.6)	52 (10.8)	62 (8.3)	59 (9.4)
Family history of diabetes (%)	24.2	12.2	20.1	6.5	14.4	7.6
School years (%)						
Illiterate	1.9	15.9	1.1	20.4	2.7	28.8
Elementary school (1-6 years)	9.6	23.8	7.5	34.7	21.9	48.2
Junior high school (7-9 years)	35.9	33.6	35.9	37.4	44.7	20.0
High school or above $(\geq 9$ years)	52.6	26.7	55.5	7.5	30.7	3.0
Personal income level (%)						
<300 ¥	17.9	29.9	9.7	43.8	6.4	27.4
300-999¥	55.3	47.5	17.9	39.5	16.3	54.0
>1000¥	26.8	22.6	72.3	16.7	77.3	18.6
BMI (kg/m ²)	25.5 (3.5)	26.0 (3.5)	25.6 (3.8)	24.8 (3.6)	25.3 (3.2)	24.8 (3.0)
Waist circumference (cm)						
men	88.9 (9.2)	87.1 (10.0)	91.5 (9.5)	83.4 (10.3)	86.6 (15.5)	88.2 (12.1)
Women	81.1 (9.6)	83.5 (10.0)	84.1 (10.3)	82.5 (10.4)	83.0 (15.1)	85.2 (12.5)
Systolic blood pressure (mmHg)	130 (24)	133 (28)	131 (20)	135 (22)	134 (16.7)	129 (15.0)
Diastolic blood pressure (mmHg)	84 (14)	85 (16)†	83 (12)	82 (12)	83 (9.8)	82 (10.7)
Total cholesterol (mmol/l)	5.4 (1.0)	5.2 (1.1)	5.4 (1.2)	5.2 (1.0)	-	-
Triglycerides (mmol/l)	1.4 (1.1)	1.3 (0.8)	1.7 (1.2)	1.4 (1.4)	-	-
HDL-C (mmol/l)						
Men	1.5 (0.4)	1.6 (0.5)	1.4 (0.3)	1.7 (0.4)	-	-
Women	1.7 (0.5)	1.6 (0.5)	1.6 (0.4)	1.6 (0.3)‡	-	-

Table 6. Baseline characteristics of all participants (aged 35-75 years) in Surveys A and C and Survey B (QD-DPP)

 $^{\text{ho}}$ significant difference between the participants of the urban and rural areas in the survey A, otherwise p<0.05 for all other comparisons, $^{\text{ho}}$ significant difference between the participants of the urban and rural areas in the survey C, otherwise p<0.05 for all other comparisons; BMI, body mass index; HDL-C, high-density lipoprotein cholesterol

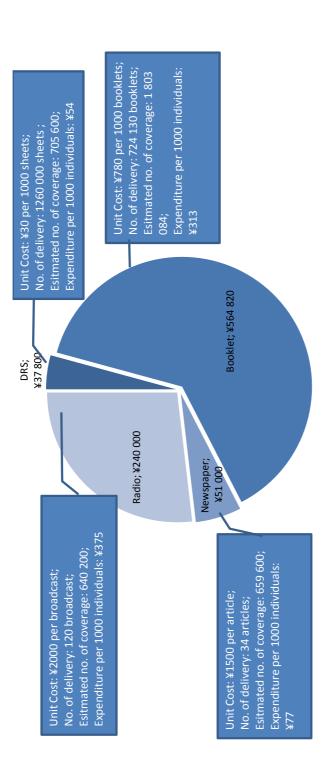
5.2 Cost and effectiveness of the diabetes education campaign (Study I)

The QD-DPP programme framework administered over the 2007 to 2010 period distributed 724 130 education booklets (57 pages including one page bearing a Chinese DRS questionnaire) and another 535 870 single DRS flyers were distributed to citizens through primary care doctors and nurses, schoolchildren, volunteers and during public events including walks to mark World Diabetes Day. The booklets that were sent to each family contained information about the diabetes risk score sheet, diabetes diagnosis, prevalence, risk factors, and complications. In addition, 34 educational articles were published in Qingdao Morning, a local newspaper. A 30-min radio programme about healthy lifestyle and prevention of diabetes was broadcasted every Monday at 12.00 h between September 2006 and 2009. These scheduled radio spots reinforced the campaign's message and facilitated the project with its aim to deliver more detailed information about the diabetes and its cause.

The levels of diabetes awareness were increased significantly during the diabetes education campaign, irrespective of age, gender and place of residence (urban/ rural). The respective awareness rates in the urban population increased to as much as, 85%, 82% and 76% for the correct identification of obesity, family history of diabetes and physical inactivity as important risk factors for diabetes in the QD-DPP education campaign survey. The awareness rates for the initial survey (survey A) in this same population were only 43%, 46%, and 25%, (p < 0.001). The corresponding figures among rural participants were 65%, 63% and 53% in QD-DPP; and 29%, 22% and 11% in survey A (p < 0.001). There was no significant increase obtained from 2007 to 2010, in spite of the rising number of information media being used.

The main expenditure items of education campaign are shown in Figure 4. The total direct cost of media education and printed materials were $\$291\ 000$ and $\$602\ 620$, respectively ($1 \notin \approx 10 \$$, for the year 2008). The distribution of booklets accounted for the largest part of the budget. The cheapest way to cover 1000 individuals was to distribute DRS flyers, followed by the newspapers, booklets and the radio programmes.

Figure 4. Unit cost, resource use, and total expenditure of different means of disseminating information under the QD-DPP framework



5.3 Performance and cost-effectiveness of FCG and DRS (Study II)

Among the 9232 participants in the pooled cohort (combined surveys A and C), 1349 (14.6%) were newly diagnosed with diabetes and 3342 (36.2%) of the participants had pre-diabetes. The sensitivity of FCG at the optimal cut-off value of 6.1mmol/l was 65.1% and the optimal cut-off value of 14 for DRS was 65.8%. The specificity cut-off values for FCG and DRS were 72.4% and 55.2% (Figure 5). The AUC was higher for FCG than for DRS (75.3% vs. 63.7%, p<0.001). At the optimal cut-off values, the number of undiagnosed diabetes identified was 95 per 1000 persons for FCG and DRS was 51 and 50 per 1000 persons.

The costs considered in study II included expenditures on each screening test and diagnostic tests, from a societal perspective. Direct medical costs included the physician's time (¥4 per visit for screening test and ¥5 per visit for diagnostic test), FCG tests (¥6), DRS questionnaire (¥1) and diagnostic tests of OGTT (¥10) and HbA1c (¥70). Indirect costs included the cost of the patient's time (20 minutes for screening test and 3 hours for diagnostic tests, ¥12 per hour) and travel (¥20 per trip) (1€≈10¥, for the financial year 2007/2008). The total cost of screening per 1000 persons was ¥64 000 for FCG test and ¥81 000 for DRS, from the societal perspective. The cost per undiagnosed diabetes identified was ¥674 for FCG at optimal cut-off point value of 6.1mmol/1 and ¥844 for DRS at the cut-off score of 14. The incremental cost per case identified for DRS over FCG was ¥17 000.

We assumed all the screening positive individuals had both the OGTT and HbA1c test as diagnostic tests in base case. If they had received only a single fasting plasma glucose test, or a standard 2h 75g OGTT or a single HbA1c determination as a

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diagnostic test, then the cost per undiagnosed diabetes identified will be decreased. The decreased costs would be ¥342, ¥405 and ¥569 for FCG followed by single diagnostic test; and ¥373, ¥463, ¥697 for DRS followed by single diagnostic test. The dominant relationship between the two screening strategies remained with all the changes in the sensitivity analysis.

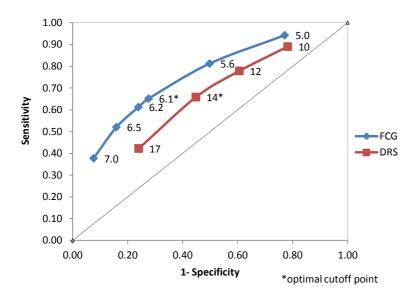


Figure 5. Receiver operating characteristic (ROC) curves for fasting capillary glucose (FCG) test and Diabetes Risk Score (DRS) for predicting undiagnosed diabetes

5.4 HRQoL in the people with/without diabetes (Study III)

The HRQoL of 4613 individuals in Survey C, which included 220 individuals with previously known diabetes and 531 individuals with newly diagnosed diabetes, was measured by using the 15D instrument. The mean 15D scores estimated by using the Tobit regression model to adjust for age, gender and BMI were 0.975 in urban participants without diabetes, 0.975 in those with newly diagnosed diabetes and 0.964 in those with previously known diabetes, respectively. The corresponding mean values for the rural population were and 0.971, 0.972, and 0.960 respectively. People

with previously known diabetes had a relatively lower HRQoL compared to those with newly diagnosed diabetes and those without diabetes for all the dimensions (p<0.05) except for hearing, eating and speech. There was no significant difference in the mean total 15D score between people without diabetes and with newly diagnosed diabetes for all age groups, except that people with newly diagnosed diabetes had lower scores on the dimension of usual activity (p<0.05) (Figure 6.).

The people with previously known or newly diagnosed diabetes had a reduced HRQoL scores but the impact on the score diminished after adjustment for comorbid diseases and other confounders. Self-reported history of dyslipidaemia, kidney disease, eye disease and cardiovascular disease were all negatively associated with the HRQoL score (p<0.01). Aging and low socio-economic status were also associated with impaired HRQoL.

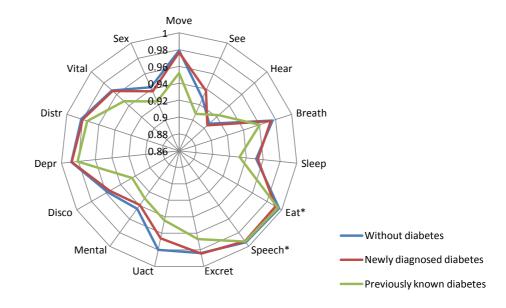


Figure 6. The 15D health profiles of participants stratified by diabetes status, estimated mean using Tobit model adjusted for age, gender and BMI.

*No significant difference between people with previously known diabetes and newly diagnosed diabetes/without diabetes

+p<0.05 between people with newly diagnosed diabetes and without diabetes

5.5 Impact of a diabetes screening programme on the overall HRQoL, depression dimension and lifestyle (Study IV)

A total of 1656 rural participants who did not have diabetes at baseline screening in survey C attended the re-examination after 3 years in study IV. Their means of 15D scores, Zung depression scores at baseline and at follow-up and also their changes in physical activity and vegetable intake Table 7. Compared to the baseline, the HRQoL was slightly lower at 3 years for all groups but the changes were only statistically significant for women with normoglycaemia (p<0.05), and were thus not considered to be clinically important. There was a small but significant increase in the Zung depression scores for the women of both the normoglycaemia and the pre-diabetes groups, but not in corresponding groups of men. No significant changes in BMI were found, but weight increased slightly in the normoglycaemia group for both men and women (p<0.05). Physical activity increased in both men and women, but an increase in frequency of vegetable intake was observed in women only.

Normolgycaemia (n=376) Baseline Follow-up 0 974 0 973										
Baseline 0 974	(0/6	Pre-diabetes (n=272);	s (n=272)‡		Normoglyc	Normoglycaemia (n=633)	()	Pre-diabete	Pre-diabetes (n=375);	
0 974	up Δ (SD)	Baseline	Follow-up	Δ (SD)	Baseline	Follow-up	Δ (SD)	Baseline	Follow-up	Δ (SD)
	-0.001 (0.06)	0.971 (0.05)	0.966 (0.06)	-0.005 (0.08)	0.973 (0.05)	0.963 (0.06)	-0.010 (0.07)†	0.959 (0.06)	0.954 (0.07)	-0.005 (0.09)
Zung depression 29(7.7) 29(7.1) score	0.5(10.1))	29(7.9)	30(7.1)	0.6(10.6)	29(8.0)	31(7.2)	1.6(10.4)†	30(7.7)	32(7.1)	1.7(10.7)†
BMI (kg/m ²) 24.1(3.1) 24.2(3.4)	(1.9) (1.9)	24.9(3.7)	24.9(3.8)	0.04(2.3)	24.7(3.4)	24.9(3.4)	0.1(1.9)	26.0(3.6)	26.0(4.0)	-0.03(2.4)
Weight (kg) 67.2(10.5) 67.8(11.3)	.3) 0.6(4.5)†	69.3(11.9)	69.6(12.3)	0.2(5.7)	61.4(9.4)	62.0(9.8)	0.6(4.1)	63.2(9.8)	63.2(10.0)	-0.1(4.4)
Physical activity (%) Low 61.7 59.8†		66.5	51.5†		34.1	16.1†		36.3	17.3†	
Moderate 22.1 14.1		23.9	19.9		11.5	15.6		11.7	17.1	
High 16.2 26.1 Vegetable- intake (/inmac/vroat 0.0)		9.6	28.7		54.3	68.2		52.0	65.6	
<14 26.6 30.9		31.6	31.6		32.9	24.5†		36.3	27.2†	
≥ 14 73.4 69.1		68.4	68.4		67.1	75.5		63.7	72.8	

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6. DISCUSSION

6.1 Summary of the main findings

The QD-DPP conducted a multi-media education campaign whose purpose was to increase public awareness and knowledge of diabetes from 2007 to 2010. This campaign was in addition to the regular health-education programmes that are organized by local health authorities. A significant improvement in public knowledge on diabetes risk factors has been achieved since the start of the education campaign. The diabetes self-risk assessment questionnaire incurred the lowest costs per thousand people reached, compared to the other education means of newspaper, radio programmes and booklets.

The screening for type 2 diabetes in primary care settings requires a two-step screening strategy that uses DRS or the FCG test as a first-line screening tool were evaluated in two population-based diabetes surveys in Qingdao. The more effective screening strategy was to use DRS because of the high sensitivity (65.8% for DRS vs. 65.1% for FCG test). However, the total costs and the cost per diabetes case identified were lower when screening with the FCG test. The decision about which is the more favourable strategy to use depends on the screening objective and the budget. We used the DRS in the QD-DPP project, because it is non-invasive, easy to implement in a mass population and most importantly the DRS includes all the major diabetes risk factors that were also used in education and health promotion activities. The screening and labelling as pre-diabetes or normoglycaemia had no adverse impact on the overall HRQoL and depression. Moreover, it generated positive changes towards a healthy lifestyle in the screened population.

People with previously known type 2 diabetes reported symptomatic comorbid conditions which had a strong negative impact on HRQoL. The overall HRQoL was, however, not different between people without diabetes and people with newly diagnosed asymptomatic diabetes.

6.2 The QD-DPP

6.2.1 Impact on diabetes knowledge and lifestyle modification

Diabetes education and health promotion activities that were implemented under the framework of QD-DPP targeted the entire population of 1.94 million who were living in the intervention areas. The intervention programme together with increased education activities that had been organised by government and other stakeholders contributed to some extent to the positive changes in the population's knowledge and lifestyle. All participants were in a free living condition had received a public education, had been given health advice from the survey doctors and/or nurses during the interview and also when they were contacted again with their screening test results.

Some health behaviour theories hypothesized that higher perceived risks will lead to higher motivations to adopt healthy behaviour (Brewer et al., 2004) and a willingness to engage in a diabetes prevention lifestyle intervention (Pinelli et al., 2010). Some other behavioural change theories, in contrast, hypothesized that higher perceived risk did not translate into intentions to adopt healthier lifestyles even when associated with higher actual risks (Hivert et al., 2009). These heterogeneous hypotheses suggest that changing peoples' behavior is a complex challenge.

The process of lifestyle modification starts with the acknowledgement of the problem and its significance. Simply giving information of an association between specific habits and diabetes and repeating this several times will lead to increased public

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awareness and encourage some to make an effort to change their behaviour, but this measure alone is insufficient to actually implement or maintain a modified lifestyle of a whole target population. A mass media campaign can influence knowledge and beliefs, but it needs to be supplemented over a period of time by personal contact methods, such as delivered education booklets to home, group education, telephone conversations, family support etc. Easily access to the playground, exercise equipment and facilities, and healthy food will also increase physical activity and eating habits.

The long-term sustained funding and the development of a permanent health education infrastructure within the community are critical to maintain a modified lifestyle and it is also a vital investment. Like so many countries around the world, China's economy suffers severe consequences from battling chronic diseases such as diabetes, obesity, stroke and others. The WHO has estimated that China will lose US\$550 billion over the next 10 years, due to the effects of heart disease, stroke and diabetes (WHO, 2005). Early intervention and delay or avoidance of progression to type 2 diabetes is of enormous benefit, both to patients in terms of increasing life expectancy and quality of life, and in economic potential for society and healthcare payers (Herman et al., 2005, Ramachandran et al., 2007, Bertram et al., 2010, Ramallo-Farina et al., 2015).

6.2.2 Comparison of different education approaches applied in Qingdao

The dissemination of knowledge about diabetes was delivered by different approaches under the framework of the QD-DPP. The multimedia campaign had the capability of rapid dispersion of knowledge, but unfortunately newspaper or radio education programme reached only a third of the targeted population in a suburban area as shown by our interview data. These estimates may be variable due to the limits of estimation procedures and the small sample size (n=90). Most people in the world have access to different kinds of mass media. However, the newspaper articles only can be read by those who have the reading habit and who could get access to newspapers. The radio programme was repeatedly broadcasted at the same scheduled time and on the same channel, which could also partly contribute to the low exposure rate of newspapers and radio. A wider audience and also a greater exposure to health promotion messages could be ensured by using different channels and times for radio broadcasts health promotions in the future. The distribution of health information by printed media is slow by contrast but does reach a higher proportion of the targeted population. It took about three years to deliver 724 130 booklets and 1.26 million DRS flyers to subjects of the targeted population. However, these printing materials are specific, targeted and likely to provide recipients with easy access to facts as written information. It has the drawback that it can only be used widely in populations with high literacy rates. The regional differences in levels of knowledge of diabetes could be attributed to differences in the education levels. People with higher education attainments were more likely to have knowledge about diabetes than those with lower education levels (Caliskan et al., 2006, Song et al., 2013). A slump in the knowledge of diabetes was observed in 2009 in study I and was more noticeable in the rural population. The exact reason for this slump is not clear. It may be related to a diversion in the attention of local health workers who were constrained to dealing with other acute issues such as outbreaks of foot-and-mouth disease and H1N1 flu in 2009, or because of changes in the local leadership.

6.2.3 Diet and physical activity assessment methods

Habitual dietary intake and physical activity are complex behaviours with large dayto-day variations, which make it challenging to accurately measure these factors. We used self-reported methods including food-frequency questionnaires (FFQs) and physical activity records: the latter of which can be translated into walked-steps. The FFQ is a widely-accepted method for quantitative assessment of usual dietary intake of free-living individuals. The FFQ is easy to obtain data from large proportion of the population and it is sensitive to the behaviour changes targeted by the intervention. Compared to the short-term reports such as 24-hour recall, FFQ is more representative of the long-term behaviour. Since the Chinese way of eating is by consuming prepared meals from shared dishes instead of separating portions of food for each individual, it is very difficult to evaluate the portion size for an individual and we only considered the frequency in this study.

We used Chinese physical activity self-report questionnaire to tackle the trends of physical activity within the population. Self-reported physical activity questionnaires may lead to over-reporting of subject's physical activity and under-reporting of sedentary behaviour since physical activity is a socially desirable behaviour and its benefit is well-known (Adams et al., 2005). Agreement between the physical activity questionnaire and objective measurement by using a pedometer when walking or running was weak (Sequeira et al., 1995, Schmidt et al., 2003, Colpani et al., 2014).

6.3 Screening for type 2 diabetes

6.3.1 Evidence on benefits and harm of diabetes screening

The necessity of screening for type 2 diabetes is debatable as it has not been directly determined whether screening for type 2 diabetes among asymptomatic adults improves health outcomes (Selph et al., 2015). Screening for type 2 diabetes was reported to be feasible, acceptable and effective even in poor resource settings (Unnikrishnan; Mohan, 2015). However, there was no difference between an

invitation to screening and no invitation to screening for either risk of all-cause mortality or diabetes-related mortality after approximately 10 years (Simmons et al., 2011, Simmons et al., 2012, Rahman et al., 2012b). Moreover, no improvement in self-rated health and health-related behaviour were reported in two other studies (Lauritzen et al., 2000, Echouffo-Tcheugui et al., 2015).

Only one trial in Daqing, China with a 23-year follow-up showed that screening with subsequent lifestyle intervention reduced the incidence of cardiovascular and allcause mortality and diabetes (Li et al., 2014). Several modelling studies that analyzed the potential benefits of opportunity or mass screening suggest that early detection of type 2 diabetes may postpone the onset of diabetes and increase the quality of life years, reduce both diabetes-related and overall mortality, reduce the lifetime's occurrence of microvascular disease and could thus be cost-effective (The C.D.C Diabetes Cost-Effectiveness Study Group, 1998, Chen et al., 2001, Hoerger et al., 2007, Chatterjee et al., 2010). Further studies are therefore needed to confirm the benefits of screening on health outcomes.

Our study of the screening programme indicated that screening had no adverse effect on the overall HRQoL, physical or emotional state after 3 years at population level. The short-term effect of screening cannot be determined since we did not assess the HRQoL of participants within 1 or 2 weeks after the screening test results had been disclosed. Other studies found that there is no negative psychological effect associated with an invitation to screening or notification of positive diabetes status after initial blood glucose test, at 2 weeks or at a longer follow-up period (Adriaanse et al., 2004, Eborall et al., 2007, Paddison et al., 2011). Two studies reported that the wellorganized stepwise population-based screening for pre-diabetes or type 2 diabetes was considered by participants to be useful and acceptable and the psychological impact of screening was limited (Ludvigsson et al., 2002, Adriaanse et al., 2002). Self-rated health quality is similar between the screened and unscreened populations after 13-year follow-up (Rahman et al., 2012a).

6.3.2 Comparisons with different screening methods

The use of a risk score questionnaire as a first-step screening tool was aimed at reducing the number of individuals that need to undertake invasive glucose testing. The risk assessment questionnaires are non-invasive, relatively cheap, fast and easy to apply among a large population unlike the other blood glucose tests. The Chinese DRS was developed in and for the Chinese population, and is very sensitive. The Chinese DRS is also orientated towards the layperson as it includes only three major diabetes risk factors of age, WC and family history of diabetes. Obesity is a strong modifiable risk factor for diabetes, and WC included in the risk score could educate and encourage people to reduce weight and change lifestyle. Almost all adult Chinese people know their own WC as it is required to buy pants of a suitable size. The diabetes risk score is simple but effective among Chinese (Gao et al., 2010). In Qingdao, the DRS questionnaire was introduced to the local healthcare providers and integrated into Qingdao urban residents' electronic health record system in 2012 with the purpose of identifying and educating people at high risk of diabetes as a routine part of primary care practice.

Fasting/random capillary blood glucose may be another alternative screening tool since it is relatively inexpensive and fast, and requires no lab equipment, unlike venous glucose tests or HbA1c. The FCG performed better as a screening tool for undiagnosed diabetes than either DRS or HbA1c in the general Chinese population (Zhou et al., 2010).

6.4 Impact of type 2 diabetes on HRQoL

6.4.1 Methodology considerations

The Tobit regression model is a frequently used tool for modelling censored variables. It has superior performance in the analysis of continuous measures of health status with a ceiling effect (Austin et al., 2000). The Censored Least Absolute Deviations (CLAD) regression has been proposed as a robust alternative. In study III, the distribution of 15D scores is skewed and censored at 0 and 1. There were 54.3% of participants at the upper limit of 1 (full health). Both Tobit and CLAD approaches were applied and compared and the results showed they have a good agreement in study III. Another study used both Tobit and CLAD regression to investigate the impact of 29 chronic conditions on HRQoL measured by 15D instrument. The estimates of regression coefficient of the two models were similar and the differences did not exceed the minimal clinically important change of ± 0.015 (Alanne et al., 2015).

6.4.2 Factors associated with HRQoL

Type 2 diabetes patients with symptomatic comorbid conditions such as cardiovascular disease, kidney disease, and eye disease have a significantly lower overall HRQoL score (Clarke et al., 2002, Maddigan et al., 2005, Alva et al., 2014). A study reported the magnitude of impact of 6 different complications of type 2 diabetes on HRQoL measured by EQ-5D and VAS score instruments: myocardial infarction (effect on tariff values by Tobit model, β = -0.055), blindness in 1 eye (β =-0.074), ischaemic heart disease (β =-0.090), heart failure (β =-0.108), stroke (β =-0.164), and amputation (β =-0.280) (Clarke et al., 2002).

Hypertension and dyslipidaemia are very common in the citizens of Qingdao as shown in this study and in our previous studies (Ning et al., 2009, Zhou et al., 2010). Most of the people with hypertension and/or dyslipidaemia were asymptomatic and therefore unaware of their conditions before the survey. These people's daily life and activities were not affected by these hitherto undiagnosed comorbid conditions. This finding is consistent with previous studies, which showed that people who suffered from diabetes and hypertension had similar HRQoL scores as those people with diabetes but without comorbidities (Miksch et al., 2009). Moreover, self-reported symptomatic comorbid conditions were reported to be more strongly associated with lower quality of life than asymptomatic conditions (Wexler et al., 2006).

Numerous social-demographic factors, culture and ethnicity differences influence the HRQoL. Education and income are associated with HRQoL. Poor quality of life is likely to be associated with low education or low income, and these factors may also increase the likelihood of developing type 2 diabetes (Kazemi-Galougahi et al., 2012). Conversely, type 2 diabetes may cause poor quality of life and may impose a heavy economic burden leading to poverty. Many studies have suggested that Chinese individuals subjectively consider their health quality to be better (Avis et al., 2003, Wang et al., 2005). The differences in culture, expectations, interpretation of life and happiness, living standards and environment, access to medical care and other social circumstances can influence the perceptions of health status.

6.5 Limitations of this study

This study consisted of two population-based diabetes surveys, with response rates of 87.8% in survey A and 67.1% in survey C, and 57.3% the 3-year follow-up of survey C. Although there have been reported benefits of health intervention, not everyone

was willing or could participate in all the surveys. The main reasons for those individuals who did not participate were: lost contact due to urbanization or not arriving at the survey site because of various reasons such as being busy, missed the date, ill or not being informed by the local community organizers. All the selected residents of Qingdao were invited by organizers from their local residents/villagers committees by telephone or home visits in order to increase the participant rates of diabetes surveys. In China, the tasks of a resident committee include assisting the local government and its agency in its work related to the interests of the residents such as public health, family planning, special care and so on. The organizers of residents committees have frequent contacts and communication with the local residents, which helped the residents to trust our programme. Small gifts, travel subsidies and other compensations were also provided as incentives to increase the participation. The non-participants were slightly younger, more men and had better HROoL at baseline than the participants of subsequent visits in both survey A and C. There was no significant difference in the distribution of participants and nonparticipants between the urban and rural areas. Given the large sample size and a random cluster sampling approach including both urban and rural areas, our study population is fairly representative of the general population that lives in Qingdao city.

When a non-diabetic individual living in one of the QD-DPP intervention areas was found to have a high risk (DRS \geq 14) for diabetes, he/she was invited to two free capillary blood glucose tests at a primary clinic: the first at baseline and second one at the end of the programme in 2014 to 2015. The participants were mostly volunteers and so they may probably have been more health-conscious than the general population. All clinical visits were required to be recorded on paper. Only one-third of

visiting records were randomly entered into digital forms in study I and the ultimate goal is to convert all paper records into digital form when the QD-DPP ends.

A Chinese version of the 15D questionnaire was used to measure the people's HRQoL. Deriving the 15D score with the valuation algorithm requires a response to each question (dimension). We considered answers of 'don't know' to be missing data in studies III and IV. Most missing data occurred for the dimension of sexual activity. We used the data imputation procedure to replace the missing data, as recommended by the 15D instrument developer and by using this procedure the probability of getting the level of the dependent variable right was 70-80% (Harri Sintonen,2015).

7. CONCLUSIONS

- The population-based education campaign carried out under the framework of the QD-DPP efficiently increased public awareness and knowledge of diabetes. It provided a feasible scheme in diabetes education targeting at a large general population.
- A simple non-invasive DRS questionnaire was not only a cheap and effective sensitization tool to raise public awareness of diabetes, but was also a reliable and effective first-line screening tool for undiagnosed diabetes in Qingdao.
- HRQoL was impaired in people with previously known diabetes who had comorbid conditions, but it was largely unaltered in people with newly diagnosed asymptomatic diabetes compared to people without diabetes.
- Screening and labelling individuals as either pre-diabetes or nomorglycaemia has no adverse impact on overall HRQoL or psychology.
- Diabetes screening can be regarded as a 'teachable moment' that can be used to generate positive changes towards a healthy lifestyle in the Chinese population.

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APPENDIX

Diabetes Risk Score Q	Juestionnaire (Chinese and English v	version)

腰围(尺)			
男性	分数	女性	分数
≤2.3	1	≤2.0	1
2.4-2.6	4	2.1-2.3	3
2.7-2.9	8	2.4-2.6	6
≥3.0	12	≥2.7	9
年龄 (岁)			
≤35	1		
36-45	3		
46-55	6		
56-65	9		
≥65	12		
糖尿病家族史(父母兄弟姐妹	任一人或以上患糖尿病)	1	分数
有家族史			8
无家族史			1
您的风险积分为多少?			()分

糖尿病风险积分自评表

市民姓名:

如何计算?

糖尿病风险积分=年龄分+腰围分+家族史分

当糖尿病风险积分大于等于 14 分时,个体糖尿病患病风险显著增加,建议咨询医务人员,恰当干预以预防糖尿病的发生。

- 举例:
 - 某居民,男性,年龄 50岁,腰围 3尺,有糖尿病家族史,查上表计算其糖尿病风险积分为 6+12+8=26分,高危个体,建议进行干预。
 - 某居民,女性,年龄 52岁,腰围 2尺 3寸,无糖尿病家族史,查上表计算 其糖尿病风险积分为 6+3+1=10分,低危个体。

A simple Chinese Diabetes Risk Score Questionnaire

Waist (Chinese chi*)				
Men	Score	Women	Score	
≤ 2.3	1	≤ 2.0	1	
2.4-2.6	4	2.1-2.3	3	
2.7–2.9	8	2.4-2.6	6	
≥ 3.0	12	≥ 2.7	9	
Age (years)	Score			
≤ 35	1			
36–45	3			
46-55	6			
56-65	9			
≥ 65	12			
Diabetes in parents and/or siblings			Score	
Negative			1	
Positive			8	
Score range			3-32	