DIABETES PREVENTION EDUCATION aimed at Dutch and Turkish relatives at risk

Development and evaluation of DiAlert

WIEKE HEIDEMAN
Diabetes prevention education aimed at Dutch and Turkish relatives at risk:

Development and evaluation of DiAlert

Wieke Heideman
The studies presented in this thesis were conducted within the Department of Medical Psychology of the EMGO+ Institute for Health and Care Research, VU University Medical Center Amsterdam. The EMGO+ Institute participates in the Netherlands School of Primary Care Research (CaRe).

The research in this thesis was financially supported by the Dutch Diabetes Research Foundation (grant 2008.15.001).

Financial support for the publication of this thesis was kindly provided by VU University Amsterdam, Department of Medical Psychology, VU University Medical Center, Amsterdam and Novo Nordisk B.V.

ISBN: 978-94-6182-496-7

© 2014 W.H. Heideman

All rights reserved. No part of this book may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or by any information storage and retrieval system, without permission in writing from the author.

Cover design and lay-out: Rob Heideman
Printing: Off Page
Contents

Chapter 1 General introduction 9

Chapter 2 Changing the odds. What do we learn from prevention studies targeted at people with a positive family history of type 2 diabetes? 19
Published in Primary Care Diabetes 5 (2011) 215–221

Chapter 3 DiAlert: a lifestyle education programme aimed at people with a positive family history of type 2 diabetes and overweight, study protocol of a randomised controlled trial 31
Published in BMC Public Health 2011, 11:751

Chapter 4 DiAlert: a prevention program for overweight first degree relatives of type 2 diabetes patients: results of a pilot study to test feasibility and acceptability 45
Published in Trials 2012, 13:178

Chapter 5 Diabetes risk reduction in overweight first degree relatives of type 2 diabetes patients: effects of a low-intensive lifestyle education program (DiAlert) A randomized controlled trial. 67
Submitted for publication

Chapter 6 Diabetes prevention education for Turkish migrants with a positive family history in the Netherlands: first findings of the Turkish version of DiAlert (DiAlert-TR) 83
Submitted for publication

Chapter 7 General discussion 101

Summary 115
Samenvatting 121
Reference List 127
Publications 141
General introduction
Type 2 diabetes

Diabetes is a chronic disease that is characterised by high levels of glucose in the blood as a result of the inability of body cells to respond to insulin ('insulin resistance') or when the pancreas is no longer able to make insulin. Insulin is a hormone that is produced in the pancreas and it allows glucose to enter the body’s cells, where it is converted into energy. Insulin resistance leads to lower uptake of glucose by body tissues from the blood and therefore the pancreas starts to produce and secrete more insulin to clear blood glucose from the circulation. As a result of this overproduction, the pancreas becomes exhausted overtime and is unable to keep up with the insulin demands of the body. This leads to elevated blood glucose and in the end to development of type 2 diabetes.

The incidence of type 2 diabetes has rapidly evolved into a major public health problem. Worldwide, around 382 million adults (8.3%) have diabetes, and by the year of 2035 this figure is estimated to rise to 592 million adults[1] (see Figure 1). With the increasing prevalence of type 2 diabetes and the micro vascular and cardiovascular complications related to the disease, prevention is of eminent importance.

Figure 1. Millions of Cases of Diabetes in 2000 and projections for 2030 (Percent Changes). Map derived from Hossain et al. NEJM 2007, data are from Wild et al. Diabetes Care 2004
Prevention of type 2 diabetes

Well-known intervention trials in the field of diabetes prevention have demonstrated that lifestyle modification interventions could lower the incidence rates of type 2 diabetes in individuals with impaired glucose tolerance (IGT). Results from the Chinese Da Qing study showed reduction of diabetes incidence of 43% in the participants who received lifestyle counselling on diet and/or exercise [2]. Similar results from the Finnish Diabetes prevention study (DPS) and American Diabetes prevention program (DPP) showed that the risk of type 2 diabetes was reduced by 58% in those participants who received the lifestyle modification intervention with goals for weight loss, physical activity and diet [3,4]. In those trials, the reduction in the incidence of diabetes was directly associated with changes in lifestyle. In addition, results from the DPP confirmed that prevention or delay of diabetes with lifestyle intervention or metformin can persist for at least 10 years. Although participants regained weight overtime, the cumulative incidence of diabetes remained the lowest in the former lifestyle group as compared to the groups who received a placebo or glucose lowering drug metformin, during 10 years follow-up after the DPP [5]. Of note, among the participants in the American DPP, more than half of the participants had a first degree relative with diabetes and results from the Finnish DPS confirmed that the effectiveness of the lifestyle intervention in reducing the risk of type 2 diabetes in IGT individuals is independently of genetic or familial risk of type 2 diabetes [6].

Translation of findings from above mentioned landmark trials to routine health care or community settings is advocated, as avoidance or delay of progression to type 2 diabetes is of enormous benefit for both the individual at risk and for the society in terms of saved health-care costs. However, the interventions were highly intensive and carried out in experimental settings. In recent years, more research has focussed on translating the evidence to the ‘real world’ by implementing and testing interventions in primary care practice and community based settings, but it remains a major challenge to translate the evidence into practical programmes while retaining critical intervention components, such as behaviour change techniques, without overstretching budgets and available resources [7].

This thesis describes the development and evaluation of a low-intensive diabetes prevention education programme.

Risk factors for type 2 diabetes

Type 2 diabetes is multi-factorial in nature, this means that the onset is caused by the interplay between genetic, lifestyle and environmental risk factors. This paragraph summarizes the main risk factors that were targeted in the DiAlert education programme.

Family history of diabetes

Large epidemiological studies have provided evidence that a positive family history of type 2 diabetes is an independent risk factor type 2 diabetes depending on the number and type of probands [8-10]. Broadly, the chance of developing diabetes is two to five fold higher for people with a positive family history [11-13]. The risk is multi-factorial and can be explained by the same variations of genes, relatives are likely exposed to the same environmental factors and behaviours are commonly shared between family members [14].

Evidence of genome wide association studies have identified genetic variants that are associated with type 2 diabetes, but, until today the predictive value of individual relevant biomarkers is considered to be small [14,15]. However, it is suggested that family history can play an important role in motivation of relatives to engage in prevention education [14,15] and it can be used to inform decisions about screening and early treatment of type 2 diabetes [16].

Overweight and obesity

Overweight and obesity form potent and commonly known risk factors for type 2 diabetes. According to figures of the World Health Organization (WHO) the global prevalence of obesity has doubled over the past three decades, with more than 1.4 billion adults being overweight in 2008. In that year 35% of the adults were overweight and 11% obese [16]. There is conclusive evidence that overweight and obesity increases the risk of type 2 diabetes [20-22]. More specifically, the distribution of fat in terms of central obesity is an important predictor for the development of type 2 diabetes [23,24].

Yet, the good news is that the reversal of obesity decreases the risk of type 2 diabetes [25]. This is also confirmed by the famous diabetes prevention intervention studies that showed that modest weight loss reduces type 2 diabetes incidence with almost 60% in individuals at risk [26].

Diet and physical activity

Both nutrition and physical activity are important determinants of health. An imbalance between calories consumed and calories expended is a fundamental cause of overweight and obesity as result of an increased intake of energy dense foods and decreased levels of physical activity. There is compelling evidence that improvement of levels of physical activity reduce the risk of developing insulin resistance by improving glucose tolerance and insulin action in individuals predisposed to type 2 diabetes [27-29]. Moreover, the combination of diet and exercise in interventions results in major reductions in type 2 diabetes risk and incidence [30]. As mentioned earlier, clinical trials for prevention of type 2 diabetes (DPP and DPS) showed that changing to a healthier diet and increasing physical activity are important with regard to the delay and prevention of diabetes [31].

Ethnicity

Studies that were performed in multi-ethnic populations suggest that some ethnic groups have a particular predisposition to develop insulin resistance and type 2 diabetes as compared with
Chapter 1

General introduction

Type 2 diabetes is more prevalent among Turkish immigrants living in North-western European countries [29-33], and the age of onset of diabetes is a decade younger compared to the indigenous population, and only part of the difference can be explained by socio-demographic (e.g. low socioeconomic status) and lifestyle risk factors (e.g. higher rates of obesity) [30-33].

Psychosocial factors

It is suggested that psychosocial factors are related to development of type 2 diabetes. Generally, there is evidence for the suspected association between type 2 diabetes and psychological factors such as emotional stress [34] and depressive disorders [35,36]. However, the exact nature of this relationship remains unclear. During development of DiAlert, we learned that stress as causal factor for type 2 diabetes was an important topic for participants that warranted attention, especially for the Turkish target group.

Targeting diabetes prevention at individuals at risk

In 2007, consensus was reached by the International Diabetes Federation (IDF) that prevention of diabetes should target the entire population but importantly, special attention should be paid to those individuals at higher risk of type 2 diabetes [37]. In the Netherlands the national government adopted the goal to reduce the incidence of type 2 diabetes and enabled a National Action Plan (NAP) to achieve the ambitions of the government for prevention, advice, early diagnosis and lifestyle interventions for high-risk groups [38]. Specific target groups for primary prevention were identified, including people of >45 years of age, being overweight, people with a positive family history of diabetes, immigrants (namely people of Turkish, Moroccan or Hindustani origin), people with a low socioeconomic status, people with a depression and women with gestational diabetes.

The DiAlert-project

In 2009 we started with the prevention project called “DiAlert”. The target group for the DiAlert education programme were overweight individuals with a positive family history of type 2 diabetes, as it has been suggested that individuals with a positive family history of type 2 diabetes have higher risk awareness and a family history might promote risk-reducing behaviours [39]. Messages tailored to the family history of an individual at risk that emphasise approaches for diabetes prevention might more effective than general preventive messages [40].

Although, family history has often been mentioned as useful strategy to identify individuals at risk for type 2 diabetes, an approach of targeting relatives of type 2 diabetes patients is under explored in diabetes prevention interventions. In the period between 1998 and 2004, only three RCT studies were performed to evaluate the effectiveness of diabetes prevention interventions aimed at relatives of type 2 diabetes patients [41-43]. By targeting overweight first degree relatives of type 2 diabetes patients, we aimed to contribute to an effective strategy to promote lifestyle changes, rather than diabetes prevention aimed at ‘anyone at risk’.

Furthermore, we aimed to develop the DiAlert intervention as a low-intensive group intervention that is potentially feasible to be delivered into Dutch health care or community settings in terms of time and costs. Moreover, we believed that a low-intensive intervention of two group sessions was considerably more acceptable and attractive for individuals who are healthy, but at risk for type 2 diabetes, than an intensive programme with many group and/or individual sessions.

The goal was to develop and evaluate effectiveness of the short and structured education of DiAlert in both Dutch and Turkish first degree relatives of type 2 diabetes patients.

From development to evaluation

The Medical Research Council (MRC) [44] provided practical guidance on the development and evaluation process. For the DiAlert-project, the first three key elements of the MRC-framework (i.e. development, feasibility and piloting and evaluation) were performed (see Figure 2).

![Figure 2. Key elements of the development and evaluation process of DiAlert derived from the MRC-framework Craig et al. BMJ 2008](image)
Next, a randomized controlled trial (RCT) was performed to evaluate effectiveness of DiAlert. First degree relatives of type 2 diabetes patients were randomly assigned to the DiAlert education programme or the control group where participants received brief written information. The effect of the intervention was investigated by assessment of the primary outcome of body weight. Secondary outcomes included anthropometric, biomedical and psychological measures.

**DiAlert-TR for Turkish relatives of type 2 diabetes patients**

As it is suggested that culturally appropriate intervention may positively influence health behaviour change in ethnic minority groups, we aimed to develop a culturally appropriate version of DiAlert for overweight Turkish relatives of people with type 2 diabetes (DiAlert-TR). The first two steps of development and piloting of the MRC-framework were undertaken to develop DiAlert-TR and evaluate feasibility, fidelity, acceptability and comprehension in a pilot study with Turkish overweight relatives.

**Behaviour change techniques and theoretical framework of DiAlert**

Evidence showed that interventions to promote lifestyle change are more likely to be effective if they are based on established behaviour change techniques [1]. For DiAlert we used the format of the effective diabetes self-management education programme DESMOND (Diabetes Education for Self-Management in Ongoing and Newly Diagnosed) of the United Kingdom [2] that was adapted to PRISMA (Dutch acronym: PRo-actieve Interdisciplinaire Self-Management) for the Netherlands [3]. These short and structured group education programmes were based on psychological theories, including Leventhal’s common sense theory [4], the dual process theory [5] and the social learning theory [6] and encourages participants to review personal risk factors and benefits of behaviour change in a constructive atmosphere.

The Health Action Process Approach (HAPA) [7] provided the framework for development of the DiAlert education programme. This social cognitive behavioural model describes the process of adoption, initiation and maintenance of health behaviours as a sequence of two continuous self-regulatory processes, namely the motivational phase and the volitional phase. In the motivational phase, individuals form intentions to adopt or change certain risk behaviours. In this phase, risk perceptions set the stage for a contemplation process and elaboration of thoughts about consequences and competencies. Self-efficacy and outcome expectancies are considered as major predictors of intentions. Positive outcome expectancies are important to formulate intentions (e.g. losing weight helps to prevent diabetes). Self-efficacy beliefs are crucial in the process because the individual needs to believe in personal capability of performing the desired action [8].

In the volitional phase, the intentions for a particular health behaviour need to be transformed into actions. Research has shown that individuals are more successful in changing and maintaining behaviour if they plan their intended activity [9]. Action planning and maintenance are strongly influenced by perceived self-efficacy and individuals are more likely to change and maintain their behaviour if they believe in their ability to perform a specific action despite having to deal with barriers [10].

Details on implementation of HAPA and application of measurements are set out later in this thesis.

**Aim of this thesis**

The main aim of this thesis is to study the effectiveness of a theory-based and low-intensive diabetes prevention education programme for overweight first degree relatives of type 2 diabetes patients. Besides the effect of DiAlert on weight loss (primary outcome) the effects of other anthropometric measures including waist circumference, BMI and biomedical and psychosocial outcomes were studied in the RCT.

**Outline of this thesis**

Chapter 2 includes a review of the literature reporting on lifestyle interventions targeted at individuals with a positive family history of type 2 diabetes with the aim of type 2 diabetes prevention. Chapter 3 outlines the process of development of the low-intensive intervention and methods of the RCT. A detailed description of the DiAlert education programme is given as well as the evaluation plan for the assessment of outcome measures. Chapter 4 presents the lessons learned from a pilot study looking at acceptability, feasibility, fidelity and process of delivering the DiAlert education programme. Chapter 5 describes the effects of the DiAlert education programme on anthropometric risk factors, namely body weight and waist circumference as well as biomedical and psychological measures. Chapter 6 describes the adaptation process and the pilot-test of DiAlert-TR for Turkish first degree relatives of type 2 diabetes patients. Chapter 7 provides an overview of the main study findings, a general discussion on methodological strengths and weaknesses, and conclusions and future perspectives for research and implications for public health.

Finally, a summary of the main findings is given.
Changing the odds.
What do we learn from prevention studies targeted at people with a positive family history of type 2 diabetes?

Wieke H. Heideman,
Barend J.C. Middelkoop,
Vera Nierkens,
Karien Stronks,
Arnoud P. Verhoeff,
Suzanne C.M. van Esch,
Frank J. Snoek

Published in Primary Care Diabetes 5 (2011) 215–221
Abstract

People with a positive family history of type 2 diabetes (T2DM) are at high risk of developing diabetes. We set out to review the literature reporting on the development and/or evaluation of lifestyle interventions specifically aimed at prevention of T2DM in this group. Targeting people with a positive family history of T2DM seems so far an underutilized prevention strategy. They can and should be approached with the aim to raise risk awareness and promote healthy eating, weight loss and physical activity, thereby reducing their risk of developing diabetes.

Introduction

Type 2 diabetes mellitus (T2DM) is a multi-factorial disease, associated with several possible risk factors including lifestyle (i.e. obesity, unhealthy diet and physical inactivity), increasing age, insulin resistance, family history of diabetes and ethnicity. Family history (FH) is known to be an important independent risk factor for T2DM, and is ascribed to shared genes and shared environment. The chance of developing T2DM is two to fourfold higher for people with a positive FH compared to those without, depending on the number of and the distance to the affected family members. Family history is one of the key items in existing diabetes risk screeners to help identification of those at high risk.

Prevention studies in people at risk have provided compelling evidence that T2DM can be prevented or at least delayed with modest lifestyle changes. Significantly, among the participants in the Diabetes Prevention Program (DPP), more than half of the participants had a first degree relative with diabetes.

Translational research aimed at implementation of the knowledge of prevention trials is warranted. Evidence-based guidelines and a useful toolkit on T2DM prevention are now available and could help planning new prevention initiatives in individuals at risk.

FH is mentioned to be important to identify individuals at increased risk for diseases, for targeted interventions using knowledge of FH to guide risk-specific interventions for prevention and early detection, and to motivate changes in behaviour and adherence to lifestyle recommendations.

Focusing on first degree relatives of T2DM patients would indeed appear a suitable primary prevention strategy, with a potentially large public health impact. By addressing specific beliefs related to the vulnerability of these people, targeting health promotion programmes and prevention strategies to relatives of type 2 diabetes patients, rather than ‘anyone at risk’ could help to enhance reach and effectiveness.

The objective of the current narrative literature review was therefore to identify successful intervention strategies for diabetes prevention in this specific group, with a view to the identification, recruitment strategy employed, contents of the intervention, mode of delivery, health outcomes, and use of FH information to motivate lifestyle changes. The main aim of this study was to determine which lessons can be learned from diabetes prevention studies specifically aimed at relatives of type 2 diabetes patients.

Methods

Information sources

Electronic databases (EMBASE, Medline and PubMed) along with reference lists of relevant articles were searched for English language articles published over the past 15 years. In addition, international trial registers were searched. The terms used were: ‘diabetes’; ‘prediabetes’; ‘pre-diabetes’; ‘family history’; ‘relative’; ‘familial’; ‘offspring’; ‘prevention’; ‘intervention’.
Chapter 2
Prevention studies targeted at people with a positive family history

Viswanathan et al. [71] published results of a pre–post intervention study in 262 Asian Indians with a positive FH. The majority of the subjects was male (72%) and had one or two diabetic parents (95%); 3% had another FH and 2% appeared not to have a FH. Mean age was 39 years and mean BMI ranged from 25.1 to 26.5 kg/m$^2$.

Swartz et al. [72] carried out a small pre–post intervention study in the USA in 18 overweight or obese women aged 53 ± 7 years, with a FH of T2DM. Follow-up was 12 weeks.

Most recent, Nishigaki et al. [73] conducted a small nonrandomized study, comparing effects in offspring of T2DM patients (n = 10) and offspring of non-diabetes patients (n = 6). Mean age in the diabetes offspring group was 34 ± 8 years and mean BMI was 22.5 ± 3.8 kg/m$^2$, and 90% was female. Total follow-up was six months.

All studies were carried out among the host, and did not include or present data on immigrant groups.

Study selection

Studies with the purpose to prevent T2DM were included if they reported on lifestyle related inter-ventions, aimed at relatives of people with T2DM. Both prospective pre–post intervention studies and controlled studies, with or without randomization were included. Titles and abstracts of identified publications were screened for relevance by one researcher. Articles identified as qualify-ing were then reviewed by the first and last author (WH, FJS) on the following: setting, definition of FH and recruitment strategy, participants’ characteristics (including age, gender and ethnicity) study design and programme characteristics (including focus, modules, level of intensity, mode of delivery, theoretical basis), attrition rate, outcomes, and if applicable adoption and implementa-tion strategies that are employed. Only studies targeting people with a positive FH of T2DM were included. Studies in which FH was only one of a set of inclusion criteria were not included.

Authors were contacted by e-mail for additional information on recruitment strategies and content of the interventions.

Results

The initial electronic database searches identified 894 articles. Based on an initial screening of titles and abstracts, 75 articles were considered as potentially relevant. Eighteen full-text articles were checked for eligibility. Articles were excluded when FH or T2DM was not an inclusion criteria or when the FH was not diabetes specific. In addition, intervention studies without the aim to change lifestyle (e.g. drug treatment) were excluded.

In total 11 articles reporting on six different studies from January 1997 to May 2010 met our inclusion criteria. Three studies were randomized controlled trials, two were pre–post interven-tion studies, and the most recent study was a non-randomized comparative study. A description of study characteristics and intervention components of the RCT’s is presented in Table 1. The identified studies were conducted in India, Japan, Sweden, United Kingdom and United States of America (2x).

Participants characteristics and follow-up

The first RCT in relatives of T2DM patients was conducted in the USA by Wing et al. [42] including people with at least one parent with T2DM. Subjects (n = 154) were 46 ± 4 years of age, obese (BMI > 36 ± 4) and mainly female (79%). Follow-up was two years.

Brekke et al. [43,66,67] published the results of a 2-years RCT in Sweden (n = 77) that included people (77% female) who had two first-degree relatives or one first-degree and one second degree relative with T2DM. Age ranged from 41 to 44, and BMI ranged from 25 to 26 kg/m$^2$.

The ProActive trial [41,69,70] was conducted in the UK. This randomized controlled trial included participants (n = 365) with a parental FH and overweight (mean BMI > 27). Of the participants 62% was female, the majority Caucasian, with a mean age of 41 ± 6 years. Follow-up was one year.
Chapter 2

Prevention studies targeted at people with a positive family history

Prevention studies targeted at people with a positive family history

Table 1. Overview of all published randomised controlled trials on prevention of type 2 diabetes in people with a family history of type 2 diabetes

<table>
<thead>
<tr>
<th>Author, Year of publication</th>
<th>Location</th>
<th>Inclusion criteria</th>
<th>N (woman %)</th>
<th>Recruitment</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wing 1998</td>
<td>Area of Pittsburgh, PA, USA</td>
<td>Parental FH Age: 40-5</td>
<td>154 (79%)</td>
<td>Newspaper advertisements</td>
<td>24 months</td>
</tr>
<tr>
<td>Brekke 2003, 2004, 2005</td>
<td>Area of Göteborg, Sweden</td>
<td>Two 1st degree relatives or one 1st and two 2nd degree relatives age 25-55</td>
<td>77 (17%)</td>
<td>Newspaper Advertisements via T2DM patients from outpatient clinics</td>
<td>24 months</td>
</tr>
<tr>
<td>ProActive Williams 2004</td>
<td>Cambridge-shire, Essex and West Suffolk, England</td>
<td>Parental FH Age:30-50</td>
<td>321 (62%)</td>
<td>Via T2DM patients or letters to from GP clinics FH-records people with FH-records from GP clinics</td>
<td>12 months</td>
</tr>
<tr>
<td>Kinmonth 2008, 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study design</th>
<th>Focus</th>
<th>Mode of delivery, intensity</th>
<th>Main outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT (4 arms):</td>
<td>1. Diet (restriction of calories and fat)</td>
<td>Group sessions weekly (0-6 months)</td>
<td>The 3 lifestyle interventions differed in their initial effectiveness but not in the long-term effect. 17% of participants developed T2DM over 2 years. Weight loss from baseline to 2 years was significantly related to decreased incidence of T2DM.</td>
</tr>
<tr>
<td></td>
<td>2. Exercise</td>
<td>biweekly (6-12 months)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Diet+Exercise</td>
<td>2 refresher courses (12-24 months)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT (3 arms):</td>
<td>1. Diet</td>
<td>2 group sessions (weekly)</td>
<td>Significant dietary changes at 1 year. Positive changes in blood lipids and fasting insulin were achieved and maintained after 2 years.</td>
</tr>
<tr>
<td></td>
<td>2. Diet+Exercise</td>
<td>8 phone contacts (0-4 months)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT:</td>
<td>1. Telephone</td>
<td>Individual: 1) 6 phone contacts (0-5 months) monthly postal contact (5-12 months) 2) 6 home visits (0-5 months) monthly 30 minutes phone call (5-12 months)</td>
<td>No differences between control and intervention groups on physical-activity ratio.</td>
</tr>
<tr>
<td></td>
<td>2. Face to face</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Family history (FH) type 2 diabetes (T2DM) physical activity (PA) General Practitioner (GP)
Recruitment of relatives of diabetes patients

It is interesting to learn from the various studies how participants were recruited and to what extent the employed recruitment strategy was found to be successful. Basically, recruitment can be directly targeted at relatives, e.g. through advertisements, and/or via known diabetic patients, for example in primary care of outpatient clinics. Wing and associates recruited via newspaper advertisements and reported a relative ease to recruit participants. Brekke et al. used multiple recruitment strategies, including advertisements in local newspapers and recruitment of non-diabetic first degree relatives through T2DM patients from outpatient clinics. Diabetes patients having non-diabetic first degree relatives were sent an informational letter or were contacted by phone. In the ProActive trial, T2DM patients from 20 General Practitioner (GP) practices were asked to provide contact information for any offspring aged 30–50 years. Subsequently, the research team invited the offspring who gave consent to participate in the study. Due to a disappointing response rate, all patients aged 30–50 years from GP practices with a recorded FH of diabetes were approached.

The two pre–post intervention studies did not report how family members were recruited, but subjects of the study by Viswanathan et al. were registered at a diabetes centre. In the small study by Nishigaki et al. T2DM patients were asked whether they had any children meeting the inclusion criteria.

We additionally asked the authors of the aforementioned studies by e-mail, whether any information on FH, heredity and/or genetics was provided as part of the recruitment strategy. Only the ProActive trial and studies by Swartz et al. and Nishigaki et al. mentioned briefly that people were selected for the study because of a FH of diabetes which puts them at increased risk.

Content of interventions and mode of delivery

The focus and key components of the RCT’s are shown in Table 1. In the trial conducted by Wing et al. the three intervention arms consisted of either diet, exercise, or the combination of diet and exercise. All intervention arms had weekly group meetings during the first six months and biweekly meetings for the second six months, with two refresher courses during the second year. Group sessions were led by a behaviour therapist together with either a dietician or an exercise physiologist. Subjects in the control condition received a self-help behaviour manual.

Brekke et al. compared a diet versus a diet plus exercise against a control group. Both intervention groups received two education sessions between one and two hours, followed-up by unannounced telephone interviews every 10 days. Sessions consisted of a theoretical part, goal setting for behaviour change, recommendations and time for questions and discussion. Counselling was offered by a dietician in a group setting and participants were requested to bring a relative or a person in the same household. Participants of the ProActive trial were randomized into three conditions and received a behavioural intervention either by telephone (distance) or at home (face-to-face). The subjects in the control condition received only a leaflet. A range of self-regulatory skills (e.g. goal setting, action planning and social support) were introduced during telephone calls or home visits. The intervention programmes were delivered by trained health professionals (e.g. nurses, dieticians and health promoters). Subjects in Viswanathan’s study received individual diet prescriptions and advices for regular exercise, the exact content of the intervention nor the level of intensity or mode of delivery was mentioned. The goal of the intervention described by Swartz et al. was to increase the amount of steps per day to 10,000. The authors do not describe the content of the modules or mode of delivery. In the study by Nishigaki et al. personalized lifestyle advices were offered every three months by mail to a dietician and a medical fitness therapist.

Surprisingly, none of the six lifestyle programmes mentions to have specifically addressed the topic of FH of diabetes and related issues, such as causal beliefs and attitudes towards genetics, control beliefs, fatalism or anxiety.

Outcomes

Wing et al. described that weight loss from baseline to two years reduced the risk of T2DM with 31% in comparison to no change in weight. The achieved weight loss was maintained in respectively the Diet (D) group and the Diet + Exercise (DE) group (60% and 72%) after one year, which was significantly better than the Exercise and Control group. After two years the DE group continued to have significant better weight loss (P < 0.001). In participants of the ProActive trial the intention to be more physically active was stronger in both intervention groups than in the control group at six months, however at 12 months the amount of physical activity did not differ between participants who were delivered the intervention face-to-face or by telephone. In addition, no significant changes in weight, BMI, waist circumference, blood pressure or cholesterol were found between the intervention and control condition. Brekke et al. described that the DE group reduced respectively body weight, waist circumference and sagittal diameter significantly as compared to the control group. One year after the intervention the D and DE group showed significant changes in dietary adherence compared to the control group, which were sustained to a large degree at two years. Body weight was reduced in the DE group and sustained over two years.

Viswanathan et al. reported weight loss in people with good adherence to lifestyle prescriptions (in 72%), and weight gain occurred in those who did not comply with the prescriptions (in 80%). Swartz et al. showed that increasing physical activity was effective to significantly improve glucose tolerance (P < 0.05) and decrease the resting systolic and diastolic blood pressure in previously inactive overweight women. Nishigaki et al. showed significant decreased total energy intake in the diabetes offspring group. However, no significant changes were found in physical activity from baseline in both groups.

Most studies reported positive results, but comparison of outcomes is hampered by differences in design and methods. Some studies had limited power due to small sample sizes. Four studies observed body weight loss and increased amount of physical activity following the intervention, however only three maintained changes during follow-up, or long-term effects were not measured.

Interestingly, no attention was paid to the psychological effects of participating in the pro-
Discussion

The main aim of this review was to review the literature regarding prevention programmes specifically targeted at people with a FH of T2DM. Only six studies were identified, of which three were randomized controlled trials. Based on the publications, very little if any attention was paid to familial risk, based on heredity and shared environment. From contacting the authors of the respective studies, we learned that the ProActive trial and the studies by Swartz et al. and Nishigaki et al. did provide brief epidemiological information to the participants about the increased risk of relatives of T2DM patients, but not more than that. None of the interventions addressed anxiety, perceptions of controllability and fatalism related to FH of T2DM. Apparently FH was merely used as an identifier for the purpose of recruitment for the studies, rather than as a vehicle for enhancing intrinsic motivation to make lifestyle changes in this group, as a way of preventing diabetes or at least lower the risk. The fact that we found only three RCT’s aimed at relatives of T2DM patients suggests that FH is an underutilized potentially effective strategy to reach a defined group of people at risk.

The reviewed studies provide supportive evidence for the effectiveness of lifestyle interventions in relatives of T2DM patients, at least in terms of intention and health behaviours (diet and exercise). The greatest benefit was observed in interventions combining diet with physical activity, in line with a Cochrane review on the effects of exercise or exercise and diet on prevention of T2DM [6]. Lifestyle interventions with the goal to loose weight are more effective than blood glucose lowering medication in people at risk. The Diabetes Prevention Program (DPP)[5] and the Finnish Diabetes Prevention Study (DPS) [4] both showed that modest weight loss is sufficient to achieve an important reduction in the incidence of T2DM. Importantly, the DPS has shown to be equally effective in participants with or without a positive FH [9]. This finding allows us to inform people with a FH of diabetes of their increased risk and at the same time convey the positive message that lifestyle changes can effectively help to significantly reduce that risk, despite genetic susceptibility. When considering implementation of targeted diabetes prevention programmes in primary care, optimizing reach is of great importance. There is evidence to suggest that patients with T2DM recognize the need and are willing to give advice about preventive behaviour to their offspring. A role for patients with T2DM in discussing health risk in their family appears to be acceptable to many relatives [78].

Providing information on FH to relatives of diabetes patients to promote lifestyle changes is likely to be more effective than health messages in general [78]. Informsing people of their familial risk for diabetes and available preventive strategies enhances their control beliefs as regards prevention of diabetes and does not necessarily induce fatalism [66,70]. Short-term psychological

Conclusion

To date, intervention studies so far did not address the unique challenges faced by people with a FH and its implications for educational strategies. Recent findings confirm that both T2DM patients and relatives generally are willing to share information on diabetes risks and discuss opportunities of prevention [79].

Findings from this review suggest that existing diabetes prevention programmes, while aimed at relatives of type 2 diabetes patients, have not utilized the unique opportunities and challenges associated with FH and underlying hereditary factors.

It would seem worthwhile to develop and evaluate lifestyle education programmes specifically targeted at people with a positive diabetes FH, with the aim to promote family awareness around healthy behaviours and opportunities to reduce the risk of developing diabetes and its debilitating complications.
DiAlert: a lifestyle education programme aimed at people with a positive family history of type 2 diabetes and overweight, study protocol of a randomised controlled trial

Wieke H. Heideman,
Vera Nierkens,
Karien Stronks,
Barend J.C. Middelkoop,
Jos W.R. Twisk,
Arnoud P. Verhoeff,
Maartje de Wit,
Frank J. Snoek

Published in BMC Public Health 2011, 11:751
Abstract

Background: Family history is a known risk factor for type 2 diabetes (T2DM), and more so in the presence of overweight. This study aims to develop and evaluate the effectiveness of a new lifestyle education programme ‘DiAlert’ targeted at 1st degree relatives of people with T2DM and overweight. In view of the high risk for diabetes and cardiovascular disease in immigrants from Turkish origin living in Western Europe, a culturally appropriate Turkish version of DiAlert will be developed and tested.

Methods/design: In this RCT, 268 (134 Dutch and 134 Turkish) overweight 1st degree relatives of patients with T2DM will be allocated to either the intervention or control group (leaflet). The intervention DiAlert aims to promote intrinsic motivation to change lifestyle, and sustain achieved behaviour changes during follow-up. Primary outcome is weight loss. Secondary outcomes include biological, behavioural and psychological indices, along with process indicators. Measurements will take place at baseline and after 3 and 9 months. Changes in outcomes are tested between intervention and control group at 3 months; effects over time are tested within and between both ethnic groups at 3 and 9 months.

Discussion: The DiAlert intervention is expected to be more effective than the control condition in achieving significant weight loss at 3 months, in both Dutch and Turkish Dutch participants. Trial registration: Netherlands National Trial Register (NTR): NTR2036

Background

The prevalence of people with type 2 diabetes (T2DM) in the general population is reaching epidemic proportions in many countries, with the total number of people with T2DM projected to rise to 366 million in 2030 worldwide [84]. It is therefore imperative that strategies to prevent the disease are implemented, this might include targeting high-risk populations to increase effectiveness. The increased prevalence is associated with lifestyle dependent risk factors, including being overweight, physical inactivity and unhealthy diet. In addition, the chance of developing T2DM is two to fourfold greater for people with a positive family history (FH) compared to those without, depending on the number of and the distance to the affected family members [11, 12, 58]. Since members of families share the same variations of genes, environment and behaviour patterns, family history information could possibly be used for screening and as a vehicle to motivate people at risk for T2DM to change behaviour [17, 55]. However, targeting people with a positive family history of T2DM to promote lifestyle changes is an underexplored prevention strategy. In a review [85] we found only three randomised studies in the literature that have reported on the effectiveness of lifestyle-oriented interventions specifically targeted at individuals with a FH of diabetes. Remarkably, none of these trials addressed FH risk information and its implications for education strategies to change lifestyle. Risk information based on family history is of substantial importance in the DiAlert education programme.

Evidence from large prevention studies shows that the risk of developing T2DM can effectively be reduced by almost 60% in people at risk for diabetes as a result of lifestyle changes resulting in sustained modest weight loss [3, 4], with persistent benefits over a longer follow-up of at least 10 years [5]. Among the participants in the Diabetes Prevention Program in the US 66% of the male and 71% of the female participants had a first degree relative with diabetes [62]. Results from the Finnish Diabetes Prevention Study (DPS) have confirmed the effectiveness of weight loss by lifestyle changes to reduce the risk of diabetes independent of genetic or familial risk of T2DM [6].

To date, the majority of the diabetes prevention studies have evaluated intensive lifestyle and behaviour change interventions, most often including frequent sessions and one-to-one counselling. Translating the evidence to public health is a challenge, and there is a clear need for targeted interventions that balance feasibility and effectiveness to fit primary care and community settings [84]. Evidence from a pragmatic education programme (PREPARE) in the UK showed that 3 hours structured group-based education incorporating a pedometer is an effective strategy for improving glucose tolerance in people at risk, even after 24 months [87, 88]. This confirms the effectiveness of short theory based educational interventions aimed at people who are at risk for T2DM, yet not medically ill and unlikely to experience serious symptom distress or functional impairments to prevent T2DM.

Increasing evidence suggests that family history information could contribute to tailored health information, which is potentially more effective in promoting lifestyle changes than health information aimed at ‘anyone at risk’ [17]. We therefore developed DiAlert, a theory-based lifestyle
education program aimed at overweight first-degree relatives of patients with T2DM, to help them reduce their risk of diabetes and related cardiovascular disease. The group based intervention consists of two sessions of 150 minutes of education with focus on achieving moderate weight loss, by means of improved diet and physical activity.

Furthermore, we assume an attrition rate of approximately 15%. Therefore we aim to over sample (25%), and include 67 persons in each group (Dutch group: 67/67).

Turkish / Dutch group

Invitation people FH by:
- GP or outpatient clinic
- Advertisements, leaflets and brochures

Positive reply
N=134 (Dutch) / N=134 (Turkish)

Informed consent
Excluded
- Not meeting inclusion criteria
- Refused to participate
- Non response

Randomisation

Intervention group
N=67 (Dutch) / N=67 (Turkish)

Baseline measurement T0 (week 1)
Group sessions 2x 150 minutes (week 1-2)
Newsletter 1 (week 3)
Newsletter 2 (week 6)
Follow-up measurement T1 (week 13)
Newsletter 3 (week 21)
Newsletter 4 (week 30)
Follow-up measurement T2 (week 37)
Loss to follow-up

Control group
N=67 (Dutch) / N=67 (Turkish)

Baseline measurement T0 (week 1)
Written information + brochure heredity and diabetes (week 1)
Follow-up measurement T1 (week 13)
Follow-up measurement T2 (week 37)
Loss to follow-up

Exclusion:
screening of T2DM (10%)
Loss to follow-up

*The same study procedure is performed in both ethnic groups separately.

Figure 1. Participant flow. A detailed participant flowchart of the DiAlert study.
Study population
Eligible are first-degree relatives of T2DM patients (father, mother, brothers or sisters, sons or daughters), between 25 and 65 years of age, and overweight (Body Mass Index of ≥ 25 or waist circumference > 88 cm for females and > 102 cm for males) from ethnic Dutch or Turkish origin.

Exclusion criteria are: people diagnosed with type 1 or 2 diabetes, currently under medical treatment for ischemic heart disease or cancer, diagnosed with a psychiatric disorder, pregnancy or physically/mentally too impaired to participate in the study (e.g. unable to come to the location of the assessments and interventions) and not being able to write and read in Dutch or Turkish.

Setting
The study population will be recruited in the area of Amsterdam city, the Netherlands, through two strategies: First, GP practices and outpatient clinics will be approached. Patients from GP practices registered with a positive family history and known overweight will be invited by their GP. The second strategy involves an open recruitment strategy through advertisements in local newspapers, leaflets and posters in pharmacies, waiting rooms of GP practices and outpatient clinics. A website with information for participants and professionals to inform people about the study is made available on the internet ([http://www.dialert.nl](http://www.dialert.nl)). People can enrol in the study by sending an e-mail or completing a form to be sent by mail. Participation in the DiAlert study is free of charge for all participants. DiAlert group sessions will be delivered in local GP practices and in the outpatient clinic of the VU University Medical Center in Amsterdam facilitated by certified health educators of PRISMA (Pro-active Interdisciplinary Self-Management) [5], who received an additional 4 hours of specific DiAlert training.

Treatment allocation
After receiving a signed informed consent form from the participants, randomisation will be performed with sealed envelopes. Members of the same family or household participating in the study will be clustered. This will be done to stimulate cohesion in the intervention groups, and to prevent contamination of the intervention effect due to reciprocal communication about the intervention or control condition among family members.

Control group
Participants in the control group receive written information about diabetes risk and lifestyle advice to prevent T2DM and a brochure about heredity and diabetes from the Dutch Diabetes Foundation.

Intervention group
Participants allocated to the intervention group will be invited to take part in the group-based intervention. Group size is approximately ten participants and the programme consists of two sessions of 150 minutes over two consecutive weeks and 4 newsletters during the next 6 months. For the timing of newsletter mailings (see Figure 1) participants flow.

Intervention
The DiAlert intervention is based on the theory-based diabetes self-management programme PRISMA that was adapted from DESMOND (Diabetes Education for Self-Management in Ongoing and Newly Diagnosed) for the Netherlands [46,47]. DESMOND and PRISMA (hereafter: PRISMA) consist of two interactive group sessions and have shown to be successful at initiating behaviour change in individuals with T2DM [48]. To adapt the programme for participants at risk for T2DM we performed a review of existing lifestyle interventions for people with a positive family history of T2DM [49] and consulted different experts.

DiAlert is based on social cognitive behavioural theories, in particular the Health Action Process Approach (HAPA) [50]. HAPA identifies three key determinants of initial change: risk perception, self efficacy and outcome expectancies, leading to intentions and action for health behaviour change. Table 1 provides an overview of the DiAlert modules and aims. In brief, the sessions include explorations of knowledge, impact and concern about T2DM, discussing risk factors for T2DM, insulin resistance and loss of beta cell function, recommendations for balancing energy intake and energy expenditure, goals setting and action planning.

Like PRISMA, DiAlert encourages participants to consider their personal risk factors and choose specific goals of behaviour changes by using a non-didactic learning approach. Through eliciting personal stories and respectfully exploring and discussing participants ‘personal models’ [51] and barriers, the stage is set for reviewing the need for and benefits of behaviour changes, with a focus on healthy food choices and increasing leisure physical activities resulting in a personal action plan to change health behaviour.

A participant manual was developed after investigation of printed education materials of other lifestyle interventions and health promotion leaflets. The manual provides background to sessions and contains information about diabetes prevention, including risk information, tips and tricks to enhance self-efficacy and outcome expectancies for diet and physical activity, resources for the participants such as a table of caloric values and worksheets for the homework assignment and the participants’ action plan. In addition, four newsletters will be sent by mail during the follow-up (see Figure 1) providing information on health behaviour change, links to relevant websites, and ‘tips and tricks’ to stay on track with behavourial changes, physical activity resources in the neighbourhood and recipes for healthy cooking.

To enhance effectiveness and sustainability, participants will be informed about and encouraged to use existing local facilities for healthy lifestyle programmes. Participants will be stimulated to seek support after DiAlert from their GP, a dietician or physiotherapist to assist them with their goals to lose weight.
Table 1. Outline of the DiAlert programme for first degree relatives of people with type 2 diabetes

### Session 1

<table>
<thead>
<tr>
<th>Modules</th>
<th>Duration (min)</th>
<th>Sample activity</th>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Introduction</td>
<td>10</td>
<td>General introduction trainer and observers are introduced.</td>
<td>State aims and proceedings of the two group sessions.</td>
</tr>
<tr>
<td>• Participant topics</td>
<td>30</td>
<td>All participants are asked about family members with T2DM, and will be encouraged to explore their knowledge, concern and possible impact of T2DM.</td>
<td>Introduction of participants, personal models about T2DM are explored.</td>
</tr>
<tr>
<td>• View on personal risk factors</td>
<td>30</td>
<td>Participants share current knowledge of risk factors for T2DM and discuss modifiable and non-modifiable risk factors. Motives for participating and burning questions of participants are listed.</td>
<td>Increase risk perception.</td>
</tr>
<tr>
<td>30 Break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• How to prevent T2DM?</td>
<td>30</td>
<td>Participants learn about insulin resistance, loss of beta cell function and the positive effects of body weight loss and physical activity.</td>
<td>Increase outcome expectancies for weight loss and physical activity.</td>
</tr>
<tr>
<td>• Energy balance</td>
<td>10</td>
<td>Advice based on recommendations on nutrition and physical activity. Balancing calorie intake and energy expenditure per day.</td>
<td>Increase outcome expectancies for weight loss and healthy diet.</td>
</tr>
<tr>
<td>• Homework assignment</td>
<td>10</td>
<td>Self-monitoring diet and physical activity (diary).</td>
<td>Monitoring current lifestyle behaviour.</td>
</tr>
</tbody>
</table>

### Session 2

<table>
<thead>
<tr>
<th>Modules</th>
<th>Duration (min)</th>
<th>Sample activity</th>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reflections</td>
<td>10</td>
<td>Summary of session 1: Participants reflect on issues raised by the programme so far.</td>
<td>Discussing topics of the first session.</td>
</tr>
<tr>
<td>• Taking control: Nutrition and exercise balance</td>
<td>40</td>
<td>Introduction to calories by comparing different food products. Reading nutrition fact labels.</td>
<td>Knowledge and skills for food choices (calorie and fat intake) to reduce risk factors.</td>
</tr>
<tr>
<td>30 Break</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Personal action plan</td>
<td>45</td>
<td>Sharing experiences about losing weight. Exploring benefits and barriers for lifestyle change. Participants’ stories are used to summarise possibilities/facilities to lose weight. Participants formulate personal action plans to change lifestyle.</td>
<td>Action planning, coping planning and self efficacy for formulated goals.</td>
</tr>
<tr>
<td>• Burning questions</td>
<td>15</td>
<td>Check whether all questions raised by participants throughout the two group sessions have been answered and understood.</td>
<td>All questions of participants are answered.</td>
</tr>
<tr>
<td>• Conclusions</td>
<td>10</td>
<td>Summary</td>
<td>Conclusions of the two session are summarised.</td>
</tr>
</tbody>
</table>

### Newsletters

- 4 Newsletters: 4 newsletters are sent by mail with information about health behaviour change following HAPA framework and tips for healthy eating and increasing physical activity.

Focus of the 4 newsletters:
1. Outcome expectancies and self efficacy
2. Self efficacy, coping with barriers.
3. Intentions and maintenance
4. Maintenance
Pre-testing the intervention

Once the initial draft of the DiAlert intervention was completed, the intervention was pre-tested by a multidisciplinary panel of diabetes professionals, consisting of a registered dietician, a diabetes nurse specialist, two specialist diabetes psychologists, a research assistant, and an expert in the field of diabetes risk communication. The intervention was delivered by a trained psychologist and a health scientist (WH), both certified PRISMA trainers. The feedback from the professionals’ panel was overall positive with minor suggestions for further improvement.

Following a framework for development and evaluation of RCTs for complex interventions to improve health (MRC-framework) \(^{44}\), a feasibility and piloting stage was performed before embarking on a randomised controlled trial. Twenty first degree relatives of T2DM patients were invited to participate in a pilot study to evaluate feasibility, acceptability, participant appreciation, and questionnaire assessments. Based on the evaluation of the pilot the intervention modules were adapted before we set off the RCT.

Cultural adaptation

After implementation of DiAlert in the ethnic Dutch population, we will assess effectiveness and feasibility of DiAlert in a population of Turkish people who live in the region of Amsterdam in the Netherlands. Cultural adaptation and translations will be performed in order to target DiAlert for this group. By means of a needs assessment general information about the community, demographic data, health status, knowledge of health and cultural related information will be obtained \(^{95}\). Possible ‘mismatches’ in the ethnic Dutch intervention will be identified through literature review, interviews and focus group discussions with lay people from Turkish descent.

Study materials including participant information, newsletters and leaflets will be translated into Turkish with regard to core values, beliefs, norms and other significant aspects of the groups and lifestyles \(^{96}\). Questionnaires will be forward-translated by a bilingual health professional with knowledge of both the Dutch and Turkish culture, following guidelines of the WHO for translating instruments \(^{96}\). Conceptual rather than literal translations will be taken into account by natural and acceptable language. Backward-translations will be performed by an independent translator whose mother tongue is Turkish. Comparisons between the two translations will be performed and discrepancies will be discussed with both translators.

A pilot test of the culturally targeted intervention will be carried out in a sample of the target population to pre-test study materials and modules of DiAlert. Fidelity and appreciation will be evaluated with questionnaires and interviews.

Outcome measures

The main outcome measure is change in body weight. Secondary outcome measures include biological, behavioural and psychological outcomes and perceived health status. Predictors for weight loss and health behaviour change (e.g. participant characteristics: gender, initial BMI, SES, number of family members with diabetes, perceived risk and perceived seriousness of diabetes) will be assessed.

Measurements

Baseline measurements are planned after randomisation and follow-up measurements are planned at 3 and 9 months (see Figure 1 for a detailed flowchart). Baseline and follow-up measurements include physical measures, laboratory tests and questionnaires.

Physical measures

The anthropometric assessment will be performed in the GP practice or outpatient clinic by a trained research assistant. Calibrated scales will be used to measure body weight to the nearest 0.5 kg, wearing light indoor clothing and no shoes. Height in cm will be measured to the nearest 0.1 cm on bare feet. Waist circumference will be measured twice with a tape to the nearest 0.1 cm at the level midway between the lowest rib margin and the iliac crest. Systolic and diastolic blood pressure (in mmHg) will be measured in a seated position with a fully automated blood pressure monitor (OMRON M5-I). All measurements will be performed twice, mean values of the two measurements will be computed.

Laboratory tests

Fasting blood samples will be drawn at the laboratory to determine HbA1c, total cholesterol, LDL and HDL-cholesterol, triglycerides, glucose and insulin, to calculate HOMA \(^{95}\).

Questionnaires

All participants will be asked to fill out a questionnaire (20 minutes), either at home via the internet or on paper. The questionnaire consists of cross-cultural validated questionnaires when possible.

Participant characteristics

At baseline, socio-demographic data (marital status, highest level of completed education, current employment), reasons to participate in the study, complete family history of diabetes in first and second degree relatives, illness and co-morbidity in the past, and use of medication will be assessed. Ethnicity will be assessed by asking own and parents’ country of birth, duration of living in the Netherlands and self-reported ethnicity.

Body weight

Questions about body weight include: a) weight loss history (number of attempts to lose weight, received weight counselling by a GP, dietician or physiotherapist during the past 3 months, desired body weight and body weight history over the past five years), b) body weight perception (description of own body weight: answer categories include ‘thin’, ‘average’, ‘somewhat overweight’ and ‘overweight’) and c) Importance of body weight, assessed by a 5-point Likert scale from very important to totally not important.
Lifestyle behaviours

Frequency and amount of fruit, vegetable and snack intake per week and nutrition habits will be assessed with a modified version of a frequently used food frequency questionnaire. Moderate, vigorous physical activity and the amount of walking per week will be assessed with the IPAQ short form. Smoking behaviour will be assessed by asking participants if they are a current smoker, an ex-smoker, or a never smoker. In case of a current smoker the number of cigarettes or other tobacco products will be assessed. Alcohol intake on weekdays and weekend days will be assessed separately.

Health status

Health outcome will be measured using the EQSD questionnaire. The Kessler-10 (K10) will be used to assess level of psychological distress (e.g. anxiety and depressive symptoms). The Dutch version of the K10 is appropriate for screening depressive disorders in primary care. In addition, life-events occurred in the past 6 months, and psychological treatment in the past will be assessed.

Determinants of health behaviour change

In the HAPA framework determinants of initial change have been identified: perceived risk, self-efficacy, outcome expectancies, leading to intentions and action planning.

Questions about risk perception will include perceived causal beliefs, consequences and control of diabetes, which were derived from the revised Illness Perception Questionnaire (IPQ-R). In addition, comparative risk (a lot lower to a lot higher), estimation of risk (very low to very high) and emotional representation (totally not worried to very worried) will be assessed with 7-point Likert scales (questions derived from Claassen et al.). Finally, participants will be asked to score whether they think that lowering the chance of diabetes is: ‘very important to totally not important’ and ‘very easy to very difficult’.

Self-efficacy for healthy eating and physical activity is assessed by ten questions using a 4-point Likert scale (very uncertain to very certain). Questions about risk perception will include perceived causal beliefs, consequences and control of diabetes, which were derived from the revised Illness Perception Questionnaire (IPQ-R) (Claassen et al., 2007). In addition, comparative risk (a lot lower to a lot higher), estimation of risk (very low to very high) and emotional representation (totally not worried to very worried) will be assessed with 7-point Likert scales (questions derived from Claassen et al.). Finally, participants will be asked to score whether they think that lowering the chance of diabetes is: ‘very important to totally not important’ and ‘very easy to very difficult’.

Outcome expectations for a healthy diet and increasing physical activity will be measured with 8 questions with a 5-point Likert scale (totally disagree to totally agree) (Claassen et al., 2007).

Intention and action planning to change health behaviours will be assessed on a 5-point Likert scale ranging from totally disagree to totally agree, asking participants whether they plan to consciously eat healthier/exercise more/lose weight and if they have formulated a detailed action plan (what, when, how) for changing diet and physical activity.

Process evaluation

To monitor programme implementation a process evaluation will be carried out following a structured process evaluation plan. Fidelity, reach, dose delivered and received of the intervention and materials will be assessed by means of a short questionnaire at the end of the second session.

In addition, the health facilitators will be asked to evaluate the group sessions, directly after each session.

Statistical analysis

Descriptive statistics will be applied to describe the study population at baseline. To determine the effect of the intervention on weight loss and to follow individual change over time we will use generalized linear mixed models and take into account different settings (e.g. intervention groups, trainers), clustering of family members and correlation between observations from same subject; i.e. using a three level structure. Potential confounders and effect modifiers (e.g. BMI at baseline, SES, gender and age) will be investigated. To test predictors of weight loss multiple regression analysis techniques will be performed. The level of significance is set at $P < 0.05$.

Ethical approval

The study protocol, information letters and informed consent form were approved by the Medical Ethics Review Committee of the VU University Medical Center.

Discussion

This randomised controlled trial is designed to evaluate the effectiveness of DiAlert in assisting overweight individuals with a family history of T2DM to lose weight in order to reduce their risk of developing T2DM. There is growing evidence for prevention of T2DM by lifestyle. However, an approach with a focus on family history combined with structured lifestyle education has not been utilized before. We assume that the DiAlert intervention will prove to be more effective than the control condition in achieving significant body weight loss at 3 months and 9 months. In addition, we expect to observe significant changes in metabolic, psychological and behavioural parameters following the intervention in both ethnic groups, resulting in reduced risk of developing T2DM.

The study has some limitations that should be mentioned. First, blinding of the participants will be impossible because they receive the intervention. To limit this bias, participants will not be informed about the outcomes of measurements, except when outcomes suggest diagnosis of diabetes based on guidelines. Furthermore, family history and overweight is not consistently recorded in patient registers of the GP in the Netherlands, which might hinder recruitment of participants. Therefore we will utilise different recruitment strategies. By recording the recruitment path of each participant, we will be able to take into account bias due to different motivations of participation in the study.

Despite the growing knowledge in the field of primary prevention, there is an urgent need for well-designed translational studies in populations at high-risk for diabetes. The challenge in offering an intervention in a primary care setting is to find the right balance between efficacy (intensity, follow-ups) and feasibility. Particularly, in the case of people who are just at risk for T2DM and not
yet medically ill and not meeting with disadvantages and complications of the disease. To increase feasibility, the intervention will be delivered in close proximity to participants’ homes, which could reduce barriers for participation. In addition, because DiAlert consists only of two interactive group sessions, we assume low drop-out rates. At last, delivery in GP practices or in the outpatient clinic could contribute to the perception of the reliability of the given information.

A group-based lifestyle education is a practical method for evidence-based prevention of T2DM in real-life settings. However, the group composition is important to consider, particularly with respect to mix of socio-demographics, health profile (previous health warnings, overweight) and cultural background. By targeting at a population of Turkish origin we will be able to reach a broader population at risk for diabetes in the Netherlands. However, we should take cultural competence of materials and facilitators into account.

**Future implementation**
This short, but comprehensive intervention could contribute to the knowledge of prevention of T2DM in public health. If DiAlert proves to be effective in reduction of body weight, implementation will be considered. The process evaluation will provide us with barriers and facilitators that can be used to determine the optimal implementation strategy.
Abstract

Background: Prevalence of type 2 diabetes mellitus is increasing due to lifestyle changes, particularly affecting those genetically at risk. We developed DiAlert as a targeted group-based intervention aimed to promote intrinsic motivation and action planning for lifestyle changes and weight loss in first degree relatives of patients with type 2 diabetes mellitus. The main objective of the pilot of the DiAlert intervention was to assess fidelity, feasibility and acceptability prior to starting the randomized controlled trial.

Methods: Individuals with a family history of type 2 diabetes mellitus were self-identified and screened for eligibility. DiAlert consists of two group sessions. Feasibility, fidelity, acceptability and self-reported perceptions and behavioural determinants were evaluated in a pre-post study using questionnaires and observations. Determinants of behaviour change were analysed using paired-samples t tests and Wilcoxon signed rank tests.

Results: DiAlert was delivered to two groups of first degree relatives of patients with type 2 diabetes mellitus (N = 9 and N = 12). Feasibility and fidelity were confirmed. Overall, the DiAlert group sessions were positively evaluated (8.0 on a scale of 1 to 10) by participants. The intervention did not impact perceived susceptibility or worry about personal diabetes risk. Action planning with regard to changing diet and physical activity increased.

Conclusions: DiAlert proved feasible and was well-accepted by participants. Positive trends in action planning indicate increased likelihood of actual behaviour change following DiAlert. Testing the effectiveness in a randomized controlled trial is imperative. Trial registration: Netherlands National Trial Register (NTR): NTR2036

Background

The increasing prevalence of type 2 diabetes mellitus (T2DM) is associated with high rates of morbidity and mortality and is a growing public health burden [34]. T2DM is a multifactorial disease and reflects an interaction between genetic susceptibility and lifestyle. Large trials have convincingly shown that lifestyle interventions with the aim to lose 5% to 7% body weight are associated with significant health benefits and more than 50% reduction of risk for developing T2DM [34]. However, these interventions are highly intensive and offered in experimental settings, and translating these findings to primary care with limited resources has proven to be challenging [30-31]. Less intensive diabetes prevention programmes targeted at high-risk individuals could increase the uptake and effectiveness, particularly if such programmes are linked to primary care and lifestyle services in the community. We developed DiAlert as a lifestyle education programme in primary health care settings, in response to the need for applicable, effective interventions for overweight people with a positive family history of T2DM, with the aim to prevent T2DM [112]. DiAlert is explicitly designed as a short, structured education programme, focusing on key determinants of health behaviour change, with a focus on promoting risk awareness and motivation for lifestyle changes. In this paper, we report on the development and first experiences with DiAlert in a pilot study. DiAlert is a theory-based group intervention, consisting of two interactive group sessions and a participant’s manual.

The aim of DiAlert is to reduce diabetes risk by means of weight loss. To this purpose, personal risk awareness and intrinsic motivation are enhanced, along with personal goal setting and action planning for lifestyle changes. The programme follows the format of the Diabetes Education for Self-Management in Ongoing and Newly Diagnosed (DESMOND) programme [47] that was adapted to PRo-active Interdisciplinary Self-Management (PRISMA) in the Netherlands [47]. The development of the DiAlert intervention included a review of existing lifestyle interventions for people with a positive family history of T2DM [85] and expert meetings.

DiAlert was informed by the Health Action Process Approach (HAPA) framework [45], a model based on social learning theories with strong empirical support. HAPA identifies three key determinants of initial change: risk perception, self-efficacy and outcome expectancies, which feed into intentions (motivation) that then need to be translated into action plans to achieve and maintain actual behaviour change. DiAlert targets all key determinants of the framework to help participants create a personal action plan to lose weight. In this pilot study, we seek to examine whether the DiAlert intervention has any effect on these determinants.

Following the Medical Research Council framework for complex interventions [44], which provides guidance on the development, evaluation and implementation of complex interventions in health care, we carried out an in-depth development fidelity and feasibility phase, to ensure that the design of the DiAlert intervention was appropriate for the target group and setting. The DiAlert intervention sought to help participants to lose weight to decrease T2DM risk. Formative evaluations were obtained to identify factors in the intervention that work well or are in need of improvement. Prior to commencing the main randomized controlled trial (RCT) to test the effec-
tiveness of the intervention, we set out to accomplish four objectives. The first three of these were to assess the fidelity (were intervention modules delivered as intended?), feasibility (was delivery of the intervention feasible in terms of time, group size, amount of sessions, etc.? and acceptability (did participants, observers and trainer evaluate positively the content and group format positively?) of the intervention sessions, by looking at the process of delivering the intervention. Fourth, we assessed pre-post changes following the DiAlert intervention on the specified determinants of behaviour change.

Methods
The pilot study was conducted at the outpatient clinic of the VU University Medical Center in Amsterdam in November 2010. The Medical Ethics Committee of the VU University Medical Center approved the study protocol. Inclusion criteria for participation were being a first degree relative of a patient with T2DM; age between 29 and 55 years; and being overweight (body mass index of ≥25 kg/m²).

Recruitment
We aimed to recruit sufficient participants (approximately 20) for two groups to be able to test the intervention twice. Approximately 250 flyers and information leaflets were posted in the hospital building and outpatient clinic of the VU University Medical Center in Amsterdam plus an advertisement run in a local newspaper in October 2010. In addition, announcements were posted on the project website (www.dialert.nl) and the website of VU University Medical Center (www.vumc.nl). To trigger attention, all recruitment materials included the sentence ‘Does diabetes run in your family?’ along with information about the pilot study and inclusion criteria. Participants were allowed to bring relatives who met inclusion criteria to participate in the pilot study. Participants received a small incentive and reimbursement of travel expenses.

Intervention
DiAlert is offered in two sessions of 150 minutes, and delivered over a period of two weeks by a trained health educator (WH), henceforth referred to as the trainer. The trainer was instructed according to a standardised training programme for the PRISMA (Dutch DESMOND) programme. Participants are encouraged to explore possibilities and resources for prevention in a positive atmosphere and using a constructive didactic approach. In view of the fact that participants are simply overweight and symptom free, with a family history of T2DM, we assume an interest in the programme but perhaps not a strong readiness for change, as one might expect in those who are medically ill. Therefore, DiAlert puts emphasis on promoting risk awareness and intrinsic motivation for changing lifestyle, while avoiding inducing psychological distress. The empowerment philosophy supports the educational process to develop awareness and autonomy to effectively assume responsibility for their decisions in relation to lifestyle behaviour. In line with this philosophy, the trainer is guiding rather than teaching. Following the format of PRISMA, a group size of 8 to 10 participants was considered to be ideal with ample opportunity for participants to interact with the trainer and the other group members.

The development of DiAlert was guided by the HAPA framework (Figure 1). HAPA builds on social cognitive theory, distinguishing two stages of behaviour change: motivation, and action and maintenance. The basic assumption underlying HAPA is that motivation is a necessary condition for behaviour change, but that goal setting and action planning are required for the change to actually occur. Throughout the process of behaviour change, feelings of self-efficacy play a key role.

In the first session, adequate risk perception is promoted by providing information and discussion of modifiable and non-modifiable risk factors for T2DM. To increase positive outcome expectancies for weight loss and physical activity, the trainer introduces the topic of combined insulin resistance and loss of beta cell function as the underlying pathophysiology of diabetes, using simple analogies and schemes. The benefits of weight loss and physical activity are discussed in that context. In relation to weight loss, energy balance (intake and expenditure) is discussed. At the end of the first session, participants are asked to record nutrition and physical activity behaviour in a diary on two separate days during the week in between the two group sessions. Self-monitoring of their health
Chapter 4

Pilot study DiAlert

50

Fidelity measures

- Coverage of the role of the trainer and the participants
- Engagement of participants
- Empowerment philosophy
- Do relatives of T2DM patients have:
  1. worries
  2. questions
  3. interests in relation diabetes prevention?
- percepts of worry
- personal control
- perceived consequences of T2DM

Checklist coverage: yes/no tick box
Observations
Participants have worries about:
1. Relatives (for example "worries about my mom/dad/children")
2. Own health: (for example "I'm afraid of getting diabetes myself"; "I think I'm too young to get it [diabetes]!")

Main themes of burning questions:
1. Diabetes causality and its relation to lifestyle (for example "What is the primary cause of T2DM? Does stress affect development of T2DM?"; "How important is eating healthy food, and what is considered to be healthy?")
2. Questions about diabetes treatment and complications (e.g. "Why do some people receive pills and others insulin treatment?"; "How can someone prevent getting polyneuropathy?").

Categories of reasons to participate:
1. Risk awareness and worry (for example "My risk of getting diabetes is high")
2. Information seeking (for example "How are lifestyle and diabetes risk related?")
3. Motivation (for example "Stimulates me to improve my exercise behaviour").

No significant changes for worry about personal risk and personal control of developing T2DM.

Significant increase of perceived consequences of getting T2DM. (major implications for life: baseline 4.2±0.8 follow-up 4.5±0.7 P=0.04, major financial implications: baseline 2.9±1.1 follow-up 3.4±1.0 P<0.01)
### Table 1. Analysis of Fidelity, Feasibility and Acceptability of the DiAlert intervention (continued)

<table>
<thead>
<tr>
<th>Category of measurement</th>
<th>Instrument and stage (by whom)</th>
<th>Topics measured</th>
<th>Scale</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility measures</td>
<td>Questionnaire &gt; at baseline (Participant)</td>
<td>- Which recruitment strategies were appropriate / How did participants knew about the study?</td>
<td>Multiple choice including 1 open-ended option.</td>
<td>Recruitment through flyers and advertisements n= 14 (66%), announcement on internet n= 3 (14.4%) and via a relative n=3 (14.4%)</td>
</tr>
<tr>
<td></td>
<td>Observations &gt; during the intervention sessions (Observer)</td>
<td>- time, duration of the modules/sessions</td>
<td>Minutes per module reported on checklist</td>
<td>All modules were delivered within 2x 150 minutes duration of modules deviated sometimes from planned time;</td>
</tr>
<tr>
<td></td>
<td>Questionnaire &gt; Follow-up 4 weeks (Participant)</td>
<td>- length of sessions was good</td>
<td>1= totally disagree - 4= totally agree</td>
<td>90% off the participants evaluated the length of the sessions &quot;good&quot; score ≥3</td>
</tr>
<tr>
<td></td>
<td>Evaluation form &gt; at the end of second session (Participant)</td>
<td>- group size</td>
<td>Multiple choice: too small, just right, too large</td>
<td>All participants evaluated the group size &quot;just right&quot;</td>
</tr>
</tbody>
</table>

| Acceptability measures  | Evaluation form > at the end of second session (Participant) | - generic grade for total intervention: (mean±SD) | 1 (lowest grade)-10 (highest grade) | 8.0 ± 1.0 |
|                         | | - usefulness of the separate modules: (mean ± SD) | 1=very useful - 5=totally not useful | Introduction 1.5 ±0.5; Risk factors: 1.3±0.5; Development of diabetes: 1.3±0.6; Homework: 1.8±0.9; Information about physical activity: 1.4±0.5; Information about diet: 1.5±0.8; Action plan: 1.7±0.4; Questions: 1.5±0.7 |
|                         | Questionnaire > Follow-up 4 weeks (Participant) | - participants manual: instructive and clear | 1= totally disagree - 4= totally agree | Instructive: 3.4±0.5; clear: 3.4±0.5 |
|                         | | - action plan: managed to make one and usefulness (mean±SD) | 1= totally disagree - 4= totally agree | "I managed to make an action plan": 2.8±0.5; "I think it is useful to create a personal action plan": 3.1±0.6 |
behaviours will help participants set personalized and realistic goals.

In the second session, self-efficacy beliefs, strategies to lose weight, coping strategies, goal setting and action planning are addressed.

Patients are provided with a written curriculum highlighting the key points and including the diary and action planning sheets. During group sessions, worries, discussions and clarifications put forward by the participants and trainer are written down on large flip-over sheets, visible for all participants, that stay there for the whole program. During the modules about healthy food choices, wrappings and containers of commonly used products are displayed and discussed. A more detailed description of the intervention development and outline is given elsewhere [102,103].

Measures

Participants were asked to fill out a questionnaire twice, one week before the first group session and four weeks later (that is, one week after the last group session). See Tables 1 and 2 for an overview of the measures and times of data collection. In addition, the flip-over sheets produced during the sessions gave information about main interests, questions and worries of the participants. All determinants were assessed with questionnaires at baseline and 4-weeks follow-up.

Participant characteristics

Characteristics of the study population were assessed by self-report, including socio-demographics, family history of diabetes in first and second degree relatives, body weight and lifestyle behaviour.

Fidelity measures

To assess whether the intervention was delivered consistently with the underlying theory and philosophy and to what extent the intervention was delivered as planned, the sessions were observed and findings recorded on a checklist. The checklist was created based on the objectives of the programme and trainers instructions. Two independent observers attended the group sessions and were instructed to check whether all modules were delivered and all objectives for participants were covered (see Additional file 1); to report on the engagement of participants by looking at interactions between trainer and participants and among participants; and to observe whether the sessions were delivered in a constructive, empowering atmosphere (that is, the trainer listens and is respectful and empathetic to all participants). The worries, questions and reasons for participation discussed in the first session provided insight into the extent to which the goals of the programme matched those of the participants. In addition, we measured worry about diabetes risk, feelings of personal control and perceived consequences by means of questionnaires at baseline and follow-up [103]. These outcomes could also show whether DiAlert had any adverse effects on these perceptions.

Table 2. Mean baseline and follow-up values for analysis of determinants of behaviour change

<table>
<thead>
<tr>
<th>Determinant of behaviour change (HAPA)</th>
<th>Domain and Instrument</th>
<th>Questions (scale)</th>
<th>Baseline N=17</th>
<th>Follow-up N=16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk perception</td>
<td>1. causal beliefs: (Revised Illness Perception questionnaire) [104]</td>
<td>Indicate the extent to which you believe that a given cause could be a cause of diabetes (1 = definitely not; 5 = definitely)</td>
<td>4.3 ± 0.7</td>
<td>4.4 ± 0.9</td>
</tr>
<tr>
<td></td>
<td>2. Comparative risk: adopted from Claassen et al. [105]</td>
<td>What is the chance of you getting diabetes compared with an average man/woman your age? (1 = a lot lower; 7 = a lot higher)</td>
<td>5.4 ± 1.0</td>
<td>4.7 ± 1.3</td>
</tr>
<tr>
<td></td>
<td>3. Risk estimation: [104]</td>
<td>How big is the chance of you getting diabetes within the next 5 years? (1 = very small; 7 = very big)</td>
<td>4.7 ± 1.5</td>
<td>4.7 ± 1.3</td>
</tr>
<tr>
<td>Outcome expectancies</td>
<td>For healthy diet and increasing physical activity: adopted from Schwarzer et al [104]</td>
<td>1. Diet: If I eat healthy foods: I feel healthy / I will lose weight / I will look better / I feel relaxed (1 = totally disagree to 5 = totally agree) (sum score 4 to 20)</td>
<td>16.0 ± 2.5</td>
<td>15.9 ± 1.7</td>
</tr>
<tr>
<td></td>
<td>2. Physical activity: If I exercise more: I feel healthy / I will lose weight / I will look better (1 = totally disagree; 5 = totally agree) (sum score 3 to 15)</td>
<td>12.2 ± 1.4</td>
<td>12.5 ± 1.4</td>
<td></td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>For healthy diet: adopted from Schwarzer et al [104]</td>
<td>1. Diet: I am confident that I can eat healthy food- even if I need a long time to develop the necessary routines / try several times until it works / have to rethink my entire way of nutrition / do not receive a great deal of support from others when making my first attempts / have to make a detailed plan (1 = very unconfident; 4 = very confident) (sum score 4 to 20)</td>
<td>13.8 ± 3.2</td>
<td>13.8 ± 3.1</td>
</tr>
</tbody>
</table>
Table 2 Mean baseline and follow-up values for analysis of determinants of behaviour change (continued)

<table>
<thead>
<tr>
<th>Determinant of behavioural change (HAPA)</th>
<th>Domain and Instrument</th>
<th>Questions (scale)</th>
<th>Baseline N=17</th>
<th>Follow-up N=16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-efficacy</td>
<td>For physical activity: adopted from Schwarzer et al. (106)</td>
<td>2. Physical activity: I can manage to carry out my exercise intentions even when I have worries and problems. / feel depressed. / feel tense / am tired / am busy. (1=very unconfident; 4=very confident) (sum score 4 to 20) b</td>
<td>12.0 ± 3.3</td>
<td>12.6 ± 4.0</td>
</tr>
<tr>
<td>Intentions</td>
<td>For healthy diet, physical activity and losing weight (106)</td>
<td>In the next three months I’m going to: (1=totally disagree; 5=totally agree)</td>
<td>3.7 ± 0.9</td>
<td>3.6 ± 1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. eat healthy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. exercise more</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. lose weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planning</td>
<td>For healthy diet and physical activity (106)</td>
<td>1. Diet: I have concrete plans… what / how to change nutrition habits / what to do in difficult situations in order to stick to my intentions. (1=totally disagree; 4=totally agree) (sum score 3 to 12) a,b</td>
<td>5.9 ± 1.8</td>
<td>7.1 ± 1.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Physical activity: I have concrete plans when / where / how / how many times / with whom I’m going to exercise / what to do in difficult situations in order to stick to my intentions (1=totally disagree to 4=totally agree) (sum score 6 to 24) b</td>
<td>6.9 ± 2.5</td>
<td>17.4 ± 3.5</td>
</tr>
</tbody>
</table>

Performed analyses were Wilcoxon signed rank tests, and t-test (a) in case of normal distributions. b Cronbach’s alpha of sum scores ≥ 0.8. c Cronbach’s alpha of sum scores of 3 items 0.67; d Cronbach’s alpha of sum scores > 0.9. e P < 0.05. HAPA: Health Action Process Approach.

Feasibility measures

Information on feasibility is essential before embarking on a RCT in a larger sample. For the aim of this pilot, we explored recruitment strategies, by asking participants how they knew about the intervention and why they were participating in the intervention. Length of the modules was timed with a stopwatch by the observers and recorded on the checklist and we examined whether all information could be delivered in two sessions of 150 minutes. Group size was informed by PRISMA and evaluated to confirm acceptability and feasibility (evaluation form: too small, just right, too large), observations (were all participants involved in the intervention?) and experiences of the trainer (was it feasible to deliver the intervention as intended with this number of participants?). Length of the sessions was assessed in the follow-up questionnaire.

Acceptability measures

Participants’ views and experiences with the DiAlert programme were assessed using a short evaluation form at the end of the second group session and with the questionnaire at follow-up.

The evaluation form asked participants to give an overall grade between 1 and 10 for the whole intervention and to rate usefulness of each module of the intervention and the homework assignment on a five point Likert scale (see Table 1).

At follow-up, we assessed whether participants would recommend the DiAlert program to others. Participants were asked to respond to two statements about the manual: ‘In my opinion the information in the manual of DiAlert is…clear/instructive’ and to evaluate the action plan ‘I managed to create personal goals’ and ‘I think it is useful to create a personal action plan’.

Determinants of behavioural change

In line with the HAPA framework (Figure 1) determinants of behavioural change were made operational by questions at baseline and follow-up, derived from existing measures. Risk perception for diabetes was assessed on three different domains: causal beliefs, using a validated questionnaire (132); comparative risk; and risk estimation using questionnaires adopted from former studies in the field of family risk information (108). To assess the other determinants we adopted questionnaires from Schwarzer et al.: perceived self-efficacy for healthy eating and physical activity was assessed by 10 questions (106). Outcome expectancies for a healthy diet and increasing physical activity were measured with eight questions adopted from Schwarzer et al. (109). Intentions and action planning to change health behaviours were examined, asking participants whether they plan to consciously eat healthier, exercise more or lose weight and if they have formulated a detailed action plan (what, when, how) for changing diet and physical activity (109). See Table 2 for exact wording of the questions.

Data analysis

Fidelity, feasibility and acceptability measures were analysed descriptively, using data from the questionnaire at follow-up, the evaluation forms and observers’ checklists. Contributions of par-
Results

Participant characteristics
In total, 22 people signed up for the DiAlert pilot study and participated in two different groups; 10 and 12 participants respectively. Twenty participants had a first degree relative with T2DM; one participant had no first degree relatives but did have a number of second degree relatives with diabetes and was allowed to participate. Of the participants with a first degree relative with T2DM, two had a sibling with diabetes; all others reported parental family history of T2DM. One participant appeared not to have any relative with T2DM, and was therefore removed from the analyses, leaving 21 participants for baseline analyses. Characteristics of the participants are described in Table 3. The majority of participants was female (86%) with a mean age of 47.9 ± 9.7 years. Most participants were from Dutch descent (N = 15), others reported Surinamese, Moroccan, Hindustani, Indian, Polish and Chinese ethnicities. All participants spoke Dutch fluently. Mean self-reported body mass index was 29 ± 6.3 kg/m². More than half of the participants (N = 13) had attempted to lose weight in the past five years with a mean number of 5.9 ± 4.5 attempts. One participant dropped out after the first session, due to family circumstances.

Fidelity of the intervention
All topics of the intervention were covered in the two sessions as planned, in both groups, and all materials developed were used. All participants received the participant manual and took it home. In general, engagement of the participants was high in both groups – all participants were actively involved in both sessions. Participants were particularly engaged in the module discussing calories of displayed food products. Observers confirmed that the intervention was delivered in an empowering atmosphere.

As shown in Table 1, examination of the flip-over sheets showed that family risk information was an important topic of discussion and participants expressed concerns about their own risk of developing diabetes. Also, concerns were expressed about relatives, in most cases the parents who were having problems controlling their diabetes. In addition, the risk of diabetes in own offspring was raised in one group. Two main themes emerged from the list ‘burning questions’ at the beginning of the sessions. First, questions about causes of diabetes and its relation to lifestyle, and secondly, both groups raised questions about T2DM treatment and complications, see Table 1 for examples of quotes from participants.

No significant changes were found for the items on personal control and worry about personal risk, indicating that the intervention had no effects on these determinants. Perceived consequences of T2DM slightly increased at follow-up and participants more often disagreed with the statement: ‘I think I have little influence on getting type 2 diabetes’.

Table 3. Baseline characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>(N=21)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td>47.9 ± 9.7</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>18 (85.7 %)</td>
</tr>
<tr>
<td>Positive family history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- A First degree relative only</td>
<td></td>
<td>20 (95.2 %)</td>
</tr>
<tr>
<td>- A Second degree relative only</td>
<td></td>
<td>1 (4.8%)</td>
</tr>
<tr>
<td>- Both first and second degree relatives</td>
<td></td>
<td>6 (28.6)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td>81.1 ± 17.5</td>
</tr>
<tr>
<td>- BMI (kg/m²)</td>
<td></td>
<td>29.0 ± 6.3</td>
</tr>
<tr>
<td>- normal (18-25)</td>
<td></td>
<td>4 (19 %)</td>
</tr>
<tr>
<td>- overweight (25-30)</td>
<td></td>
<td>10(47.6 %)</td>
</tr>
<tr>
<td>- obese (≥30)</td>
<td></td>
<td>7 (33.3 %)</td>
</tr>
<tr>
<td>Reported elevated blood sugar in the past (yes)</td>
<td></td>
<td>7 (33.3 %)</td>
</tr>
<tr>
<td>Earlier attempts weight loss attempts (yes)</td>
<td></td>
<td>13 (61.9 %)</td>
</tr>
<tr>
<td>Mean number of attempts</td>
<td></td>
<td>5.9 ± 4.5</td>
</tr>
<tr>
<td>Current smoker (yes)</td>
<td></td>
<td>6 (28.5 %)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Lower</td>
<td></td>
<td>10 (47.6 %)</td>
</tr>
<tr>
<td>- Middle</td>
<td></td>
<td>4 (19.0 %)</td>
</tr>
<tr>
<td>- Higher</td>
<td></td>
<td>7 (33.3 %)</td>
</tr>
<tr>
<td>Employed (yes)</td>
<td></td>
<td>12 (57.1 %)</td>
</tr>
<tr>
<td>Marital state – living with partner</td>
<td></td>
<td>11 (52.4 %)</td>
</tr>
<tr>
<td>Self reported ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Dutch</td>
<td></td>
<td>15 (71.4 %)</td>
</tr>
<tr>
<td>- Other</td>
<td></td>
<td>6 (28.6 %)</td>
</tr>
</tbody>
</table>

Values are presented in number of participants (%) or mean ± SD. a Lower education = primary education or lower general secondary education; middle= intermediate vocational education or high school; high =higher vocational.
Feasibility

Recruitment resulted in a sufficient number of participants for two groups within a relatively short period of three weeks. Twenty-five people showed interest in participating in the pilot study and contacted the research team by email or telephone. Three people decided not to participate after receiving more detailed information. Both younger and older individuals showed interest in the DiAlert intervention, therefore we decided to include participants from 25 to 65 years old. Although the DiAlert intervention was targeted at overweight relatives, four participants had a normal body mass index (<25 kg/m²), and were included because the main aim of this pilot was to evaluate the process and feasibility of the group sessions. Most participants signed up after reading about DiAlert in flyers and the newspaper advertisement (63.7%). Main reasons for participating in the DiAlert pilot study were: ‘prevention of T2DM’ (N = 9) and ‘learning about the personal risk of diabetes due to a family history’ (N = 5). In addition, the three motives for joining the programme that were mentioned at the beginning of the first session were risk awareness and worry, information seeking and motivation to change behaviour.

The feasibility of the group sessions was confirmed in terms of duration of the modules and group size. All modules were delivered within the scheduled 150 minutes. Some modules exceeded the planned time with a maximum of 10 minutes, while other modules took less time.

The group size was evaluated as ‘just right’ by participants in both groups. Most participants (90%) stated that the duration of the interventions was good.

At the end of the sessions, observers and trainer confirmed that delivery of DiAlert is feasible in line with the empowerment philosophy and theoretical framework. In both groups, all participants were able to formulate goals and create a personal action plan to lose weight. The homework assignment was completed by almost all participants (N = 20) in between the two sessions.

Acceptability

Following the underlining empowerment philosophy, participants seemed to be encouraged to play an active role in the intervention, and came up with examples and questions to be answered during the sessions. High engagement of participants was noticed in both groups, especially sections with activities, where all participants were involved and came to the table to discuss calories and food choices together. After one week of follow-up, participants gave an overall mark of 8.0 ±1.0 on a scale from 1 (lowest) to 10 (highest). All participants would recommend the DiAlert programme to others. Overall, evaluation of the usefulness of the intervention modules showed a mean score of 1.5 ±0.4 (scale, 1 = very useful to 5 = totally not useful). The module ‘development of diabetes’ got the highest rating 1.3 ±0.6. In this module the development of diabetes is discussed with participants using a drawing to explain insulin resistance, loss of beta cell function and the positive effects of body weight loss and physical activity. Evaluation of the information in the manual and its clarity was good, 3.4 ±0.5 (scale, 1 = totally disagree to 4 = totally agree).

Determinants of behavioural change

Because the main objective of DiAlert is weight loss, post intervention analyses of the determinants of behaviour change were performed for the overweight participants only (N = 16). Analyses of baseline questionnaire scores showed that participants were aware of the main risks for developing T2DM at baseline, with mean scores of >4 (scale, 1 = definitely not to 5 = definitely) on the items nutrition, heredity, aging and lack of physical activity (Table 2). Not surprisingly, we found a relatively high baseline score for heredity (4.3 ±0.7). Participants perceived their risk (comparative risk and risk estimation) somewhat higher than average. Sum scores for outcome expectancies for a healthy diet and for physical activity were 16.0 ±2.5 (scale, 1 to 20) and 12.2 ±1.4 (scale, 1 to 15), respectively. This suggests that participants had quite positive outcome expectancies already for eating healthy foods and doing exercise.

Small non-significant increases in self-efficacy and outcome expectancies for diet and physical activity appeared at follow-up. Furthermore, at follow-up, all participants stated they were more aware of their risk, 65% said they ate more healthily due to DiAlert, and 40% improved their physical activity. Causal beliefs for the item ‘country of origin’ increased significantly (P=0.04), probably explained by discussion of heredity and the relation with genetic predisposition in the first session of the intervention.

With regard to action planning, significant positive changes were seen for both diet (P = 0.008) and physical activity (P <0.001). This means that the participants were more able to formulate concrete plans to change their dietary habits and physical activity pattern, including addressing coping plans to anticipate difficult situations in the future.

Discussion

The main aim of this pilot study was to evaluate fidelity, feasibility and acceptability of the DiAlert intervention before testing efficacy in a RCT. We took the opportunity to describe the development of a complex intervention and to share our lessons learned of developing an intervention in this specific target group at risk for T2DM. In our opinion, confirmation of content and delivery of the intervention is very important before conducting the intervention in a RCT setting.

The pilot study showed that the new lifestyle education programme DiAlert is attractive and feasible for relatives of patients with T2DM. Evaluation of fidelity showed no deficiencies and the intervention was delivered as theorized. All modules were delivered in time and the intervention was highly appreciated by participants. DiAlert helped participants to create personal action plans aimed at changing dietary habits and/or increasing physical activity to lose weight. This is an important finding since action planning is an important mediator of successful health behaviour change[11]. In all group sessions a positive atmosphere was noted, despite the topic of health risks and the need for lasting lifestyle changes. Moreover, our pilot study gave no indication that the risk information provided in the two group sessions resulted in fatalism or extreme worries.
This result together with previous studies suggests that targeted diabetes risk information for relatives of patients with T2DM can increase engagement in risk-reducing behaviours \cite{76,77,114} without causing psychological harm \cite{76,115}. An important finding was that some participants expressed concerns and worry about their family members developing T2DM and complications, and were for that reason more interested in learning about diabetes.

Most participants in this pilot study were overweight women who were sedentary and not meeting recommendations for a healthy diet or physical activity. We attracted both lower and higher educated participants for this pilot, which adds to the external validity of our findings. The results from the pilot seem to indicate that heterogeneity with regard to educational level, health profile (previous health warnings, overweight) and cultural background fits well with the programme.

In this pilot, not all participants were overweight. However, we were able to test the DiAlert intervention programme on its fidelity, because in this pilot phase we focused mainly on applicability of the intervention, delivery of the intervention and appreciation of participants.

Lessons learned from this pilot
Some issues relating to the conduct and management of the future RCT have been raised by this pilot study. First, interest in the topic was confirmed based on the finding that recruitment efforts proved effective to reach a sufficient number of eligible participants. However, mainly women were reached; therefore, in the RCT, we should take into account possible strategies to include both men and women and from a broad range of socioeconomic classes. In the RCT, we will apply a mixed recruitment strategy, involving general practitioners and diabetes specialists together with use of media and brochures to recruit participants with a positive family history of T2DM directly. As result of a direct recruitment approach (through general practitioners) we may expect participants with lower perception of risk, less positive outcome expectancies and lower self-efficacy for lifestyle changes. Another issue in relation to recruitment was that, although the DiAlert study was initially aimed at relatives 29 to 55 years of age, younger and older people showed interest and were enrolled. Therefore, the inclusion criteria for the upcoming RCT will be changed to 25 to 65 years of age to certify validity of the intervention. We plan to deliver a culturally-sensitive version of the DiAlert intervention to relatives of Turkish origin living in the Netherlands. The intervention will be pretested in this target group before we conduct the RCT in this group.

Second, discussion of risk information did not increase worries about personal risk. However, we should keep in mind that participants did express concerns and worries about their own family members with T2DM. Some participants clearly were in need of information on diabetes and its management with regards to their relatives rather themselves. In the RCT, the focus of DiAlert should stay on prevention and risk of developing diabetes due to family history, rather than discussing problems that may occur in their relatives with T2DM in the future. From this pilot, we learned that no changes to the intervention modules are anticipated before embedding DiAlert in a RCT.

Conclusions
DiAlert is a structured educational intervention based on principles of self-management that has been shown to be feasible and of interest to people genetically predisposed to T2DM. We demonstrated that participants were willing and able to formulate action plans after two group sessions. The DiAlert intervention was deliberately designed as a short and interactive intervention, to enhance the attractiveness of the programme for people at risk who are overweight and not yet medically ill. Finding the balance between attractiveness and high reach on the one hand and efficacy on the other is challenging, but preliminary results are promising. The group education approach could contribute to the implementation of primary prevention programmes in primary care to educate persons at risk in a cost-efficient way. Further investigation of DiAlert will involve a RCT, looking at both behavioural and metabolic outcomes.
### Additional file 1. checklist DiAlert intervention sessions

<table>
<thead>
<tr>
<th>Duration</th>
<th>Role of trainer</th>
<th>Objectives for participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First session</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. 5 min.</td>
<td>Introduction</td>
<td>Welcome to all participants and introduction of trainer and observers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stating aims of the intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Today’s modules</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respect to each other</td>
</tr>
<tr>
<td>B. 20 min.</td>
<td>Participant Topics</td>
<td>Facilitate participants to share experiences/worries about diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>List questions of participants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Everyone in the group gets the opportunity to tell his/her story</td>
</tr>
<tr>
<td>C. 35 min.</td>
<td>View on Personal risk factors</td>
<td>Risk factors for / causes of T2DM</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modifiable risk factors (overweight, diet, lack of physical activity, stress or worries)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-modifiable risk factors (genetics, age, ethnicity)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discuss personal risk profile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benefits of weight loss</td>
</tr>
<tr>
<td>D. 30 min.</td>
<td>How to prevent T2DM?</td>
<td>Discuss insulin resistance, loss of beta cell function and positive effects of weight loss and physical activity.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Differences between type 1 and type 2 diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diet: introduction of calories</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summarize information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trainer asks whether participant agree or doubt the information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowing what goes wrong in the body in the case of type 2 diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Know the term ‘insulin resistance’ and its relation to overweight and lack of exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Understand that there is decreased insulin production caused by exhaustion of the pancreas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowing positive effects of weight loss and exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Get familiar with the term “calories”</td>
</tr>
<tr>
<td>E. 15 min.</td>
<td>Homework assignment</td>
<td>Ask participants to fill out the diary for two days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trainer explains that the diary is for personal use</td>
</tr>
<tr>
<td>F. 5 min.</td>
<td>Conclusion</td>
<td>Positive take home message: Confirm trust that diabetes can be prevented</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Next session: topics, place, time and location</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Importance of second session</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summary</td>
</tr>
<tr>
<td><strong>Second session</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G. 10 min.</td>
<td>Reflections</td>
<td>Participants get the opportunity to express concerns and ask new questions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Encourage participants to address overweight as a modifiable risk factor for diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summary: opportunities for diabetes prevention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Appoint Today’s Topics</td>
</tr>
<tr>
<td>H. 40 min.</td>
<td>Taking control: nutrition balance</td>
<td>Ask about experiences with the diary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Promote active participation in the calorie game</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Encourages participants to reflect on options to lose weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Balance between energy intake and expenditure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summary</td>
</tr>
<tr>
<td>I. 45 min.</td>
<td>Personal actionplan</td>
<td>Stimulate participants to choose one personal risk factor they want to change encourage participants to seek which self-management behaviours they could change</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Identify success factors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Help participants create a SMART (specific, measurable, assignable, realistic, timely) goal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What, how, when, who, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Help participants to specify the formulated goal:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- How confident are you that it will work?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- What barriers are there?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summary</td>
</tr>
<tr>
<td>J. 15 min.</td>
<td>Burning questions</td>
<td>Make sure that participants know the answers to their questions or that they know where and from whom they can get these answers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Getting answers to all questions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knows where to get answers to remaining questions</td>
</tr>
<tr>
<td>K. 15 min.</td>
<td>Conclusion</td>
<td>Conclusions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thanks for participating</td>
</tr>
</tbody>
</table>
To support the empowerment philosophy in general during both sessions, the trainer:

- Makes no judgments of statements made by participants
- Uses open questions to ensure the participant’s understanding
- Gives each participant the opportunity to explore/express views the topic discussed
- Enables participants to reflect on topics discussed
- Adapts the pace of the modules to the learning of participants

Diabetes risk reduction in overweight first degree relatives of type 2 diabetes patients: effects of a low-intensive lifestyle education programme (DiAlert)
A randomized controlled trial.

Wieke H. Heideman,
Maartje de Wit,
Barend J.C. Middelkoop,
Vera Nierkens,
Karien Stronks,
Arnoud P. Verhoeff
and Frank J. Snoek

Submitted for publication
Abstract

Objectives: To test the efficacy of a low-intensive lifestyle education programme (DiAlert) for overweight first degree relatives of type 2 diabetes patients aimed at reducing diabetes risk.

Methods: Overweight first degree relatives of type 2 diabetes patients were randomly assigned to the DiAlert intervention (N=45) or control group who received leaflets (N=51). DiAlert consists of two group sessions and newsletters. Assessments were scheduled at baseline, three and nine months, with weight loss as primary outcome. Secondary outcomes included anthropometric, metabolic, behavioural and psychological measures. Comparisons were made over time and between study groups.

Results: Both groups showed modest weight loss with no difference between randomization groups. However, after DiAlert significantly more participants lost 5% of their weight compared to controls (P<0.05). Significant improvement of waist circumference sustained after nine months in the intervention group (intervention: -4.33cm, P<0.01 /control: -1.25cm, P=0.08). Systolic blood pressure improved within the intervention group (intervention: -8.77mmHg, P<0.01 /control: -1.03mmHg, P=0.60). No effect was observed for biomedical and psychosocial outcomes.

Conclusions: Our low-intensive structured lifestyle education programme helps overweight relatives to improve waist circumference and supports relevant weight loss. Practice implications: The family approach provides opportunities to reach and engage relatives at risk in diabetes prevention education.

Introduction

There is compelling evidence that modest lifestyle changes help to reduce the risk of developing type 2 diabetes in high-risk individuals by almost 60% [3,4]. Raising public awareness and timely identification of high-risk individuals are therefore warranted, for which purpose easy-to-administer, non-invasive diabetes risk tests have been developed such as the FINDRISC [5]. One of the well-known risk factors for type 2 diabetes is a positive family history (FH). First degree relatives of type 2 diabetes patients have a 2 to 5 fold increased risk of developing diabetes compared to those without a FH [10,12] and more so when overweight or obese. Effectiveness of lifestyle education to prevent diabetes in individuals at risk is independent of genetic or familial risk of type 2 diabetes [6]. Although health care professionals acknowledge the potential of FH for diabetes prevention [114], only few studies have addressed FH in diabetes prevention programmes, taking the specific worries and needs of relatives into account.

Findings from lifestyle education programmes based on the Diabetes Prevention Program (DPP) have been successfully translated for community settings by linking to existing community channels [117]. However, effective interventions based on health behaviour theory that are attractive and feasible to deliver are scarce. We are the first to have developed a low-intensive, structured group lifestyle education programme specifically aimed at overweight first degree relatives of type 2 diabetes patients, named DiAlert [85]. In a pilot study DiAlert proved to be highly acceptable, feasible and promising with regard to increased motivation and action planning for lifestyle change [118].

To assess the efficacy of DiAlert in Dutch overweight individuals with a FH of diabetes we conducted a randomized controlled trial. Primary outcome was weight loss. Secondary outcomes were change in waist circumference, blood pressure, metabolic, behavioural and psychological parameters.

Methods

A detailed study protocol of the DiAlert trial has been reported elsewhere [112]. Ethical approval was obtained from Medical Ethical Review Committee of VU University Medical Center (VUMC) in Amsterdam. Between April 2011 and June 2012 we recruited individuals between 25 and 65 years of age with at least one first degree relative with type 2 diabetes and being overweight (Body Mass Index (BMI) of ≥ 25 kg/m² or waist circumference > 88 cm for females and > 102 cm for males).

Recruitment strategies

To maximize reach, we employed four different recruitment strategies: 1) 123 persons with a registered FH of diabetes and a BMI ≥25, from five primary care practices (with in total 15,363 patients) were invited by their own GP by mail. 2) 173 patients with a documented fasting glucose >6.0 - <6.9 mmol/L over the past 12 months were invited by their own GP by mail. 3) Posters and leaflets
were distributed among several pharmacies in Amsterdam. Advertisements were published in free weekly newspapers (461,594 copies in Amsterdam region). We used the sentence: “Does diabetes run in your family? Reduce your risk!” to invite first degree relatives of patients with type 2 diabetes to participate. 4) Women who received treatment for gestational diabetes at the VUMC (n=117) were identified from charts and invited for the study.

Procedures and setting
After signing informed consent, participants were randomly assigned by an independent researcher with sealed envelopes to one of the parallel groups (intervention or control) and were invited for the baseline measurement. All laboratory analyses were conducted blinded to treatment group. Participants and trainers could not be blinded to treatment group because of the nature of the intervention.

Intervention
The development of DiAlert was guided by the Health Action Process Approach (HAPA) [45], a social cognitive model with empirical evidence in the field of prevention. HAPA distinguishes two behaviour change stages: intention formation (motivation), and the action-maintenance phase. For intention formation the perceptions of personal risk, outcome expectancies and self-efficacy beliefs are all three key determinants while self-efficacy is central throughout the process of behaviour change. The intervention build on the DESMOND-format [46] and consists of two interactive group sessions of 150 minutes delivered over two consecutive weeks. Through eliciting beliefs and worries about FH and diabetes, participants are encouraged to review personal modifiable and non-modifiable risk factors in a constructive atmosphere. Health benefits of lifestyle changes are clarified and participants are enabled to set a personal action plan to make healthy food choices or increasing physical activities. After the DiAlert intervention four newsletters with focus on relapse prevention and sustaining behaviour change, combined with 'fun facts' on diet and exercise were mailed after one, four, 19 and 28 weeks after DiAlert.

For this trial, a team of two experienced dieticians and two Master students (as co-facilitators) were trained by our research team to deliver DiAlert based on a detailed trainer’s manual. The group sessions were delivered by a dietician at the primary care practice (recruitment strategy 1&2) or at the outpatient clinic of VUMC (strategy 3&4).

Control group
Participants allocated to the control group received a brochure of the Dutch Diabetes Foundation about type 2 diabetes and heredity, and general information about diabetes risk factors. There were no contacts with the control group during the study other than the scheduled measurements.

Measurements
Measurements were scheduled at baseline and at three and nine months (see Figure 1).

Anthropometric data
The primary outcome of body weight was measured with one calibrated digital scale (Seca 888). Participants were weighted twice without shoes to determine the mean weight in kg. Body height in cm was measured on bare feet. Waist circumference (in cm) was measured twice with a measurement tape to the nearest 0.10 cm. Systolic and diastolic blood pressure were measured twice in sitting position with a fully automated blood pressure monitor (Omron MS-I). Mean value of the two measurements was computed.

Laboratory assessments
Blood samples were obtained and analysed at a regional certified laboratory or at VUMC. Serum concentrations of glucose, insulin and lipids (total cholesterol, LDL, HDL and triglycerides) were measured after an overnight fast. Insulin resistance was calculated by means of the homeostasis model assessment (HOMA-IR) [96].

Questionnaire
A detailed overview of the self-report measures was described elsewhere [112]. In brief, data were collected on socio-demographics, FH of type 2 diabetes, perceived health status and medication use, perceptions of body weight and dietary behaviours (fruit, vegetable and snack intake per week), smoking status and alcohol intake and physical activity (using the IPAQ-short form [109]). Health-related quality of life was measured with the EQ5D [98]. We used The Kessler-10 scale (K10) [109] to assess psychological distress.

Determinants of behaviour change based on HAPA were assessed with questions about risk perception, including perceived causal beliefs, consequences and control of diabetes [112] comparative risk, estimation of risk and emotional representation [113], and importance of risk reduction. Furthermore self-efficacy beliefs, outcome expectancies, intentions and action planning for a healthy diet and increasing physical activity were assessed [116] (see Table 3 for exact wording of behavioural and psychological measures).

Sample size
Based on power calculations, 50 participants per group were required to detect a difference of at least 3.5% body weight at 3 months (SD 6%, power 80%, p-value 0.05). We aimed to recruit 67 participants per group to allow for drop out (15%) and diagnosis of diabetes (10%).

Statistical methods
Statistical analyses were conducted using SPSS 20.0 software. Students t-tests and $\chi^2$ tests were employed to compare baseline characteristics between intervention groups.
Figure 1. Flow diagram
We performed generalized estimating equations (GEE) for anthropometric and biomedical parameters. Interaction effects of group (intervention versus control group) \( \times \) time (baseline, three-month and nine-month follow-up) were calculated to test between group differences over time. The random part of both between-group and within-group models consisted of an adjustment for repeated measurements with an unstructured covariance matrix. Determined confounder variables were age, sex and site (GP practice/ VUMC) and entered in all GEE analyses. Self-reported behavioural and psychological variables were analysed using analysis of covariance (ANCOVA). All analysis were performed on intention-to-treat principles and adjusted for baseline values. A \( P < 0.05 \) was considered statistically significant.

**Results**

Response rates for the applied recruitment strategies using invitational letters (strategy 1, 2, 4) varied between 12 and 57%. Recruitment through advertisements (strategy 3) resulted in 53 participants; 77% of those who asked for more information signed up for the study (see Figure 1).

Eight participants dropped out after randomization, before the first appointment and 21 individuals were excluded after baseline measurement because they did not meet inclusion criteria. Of those, 12 participants had fasting blood glucose levels \( \geq 6.9 \) mmol/L, four participants appeared not to be overweight, two were already diagnosed with type 2 diabetes, one did not speak Dutch, one was not able to participate due to health constraints and one had no FH of type 2 diabetes. Resulting in a study sample of \( n = 96 \) (45 intervention / 51 control).

In the intervention arm, eight DiAlert groups with a median number of seven participants per group (range 4 to 7) were delivered between May 2011 and July 2012. Most participants attended both sessions; five participants attended only the first session due to sickness, but did participate in the follow-up measurements.

Study attrition was higher in the control group: six participants withdrew from the study due to health problems, one moved or was not able to participate due to health constraints, and one had no FH of type 2 diabetes. As a result, the study sample was reduced to \( n = 51 \) (45 intervention / 51 control). A response rate of 37.1% was established for the applied strategies using invitational letters (strategy 1, 2, 4).

**Baseline characteristics**

Characteristics of participants of DiAlert are shown in Table 1. Mean age of the sample was \( 55 \pm 8.6 \) years, 67.7% female \( (n=65) \), 49.5% \( (n=47) \) was lower educated. Most participants were offspring of a type 2 diabetes patient \( 89.6\% \) \( (n=86) \) and obese, mean BMI was \( 30.5 \pm 4.2 \) kg/m².

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control (n=51)</th>
<th>Intervention (n=45)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total METs/min per week</td>
<td>320.6 ± 3195.5</td>
<td>3290.3 ± 7</td>
<td>NS</td>
</tr>
<tr>
<td>Glass of alcohol/week</td>
<td>3.9 ± 0.6</td>
<td>3.4 ± 0.0</td>
<td>NS</td>
</tr>
<tr>
<td>Pieces of fruit/day</td>
<td>1.2 ± 0.9</td>
<td>1.3 ± 0.9</td>
<td>NS</td>
</tr>
<tr>
<td>Total METs/min per week</td>
<td>342.7</td>
<td>3427</td>
<td></td>
</tr>
<tr>
<td>Stabilized Hb (mmol/L)</td>
<td>8.8 ± 0.4</td>
<td>8.9 ± 0.4</td>
<td>NS</td>
</tr>
<tr>
<td>Total HbA1c (% or mmol/mol)</td>
<td>5.8 ± 0.4</td>
<td>5.5 ± 0.4</td>
<td>NS</td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L)</td>
<td>5.5 ± 1.0</td>
<td>5.5 ± 1.0</td>
<td>NS</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/L)</td>
<td>1.5 ± 0.4</td>
<td>1.5 ± 0.4</td>
<td>NS</td>
</tr>
<tr>
<td>LDL cholesterol (mmol/L)</td>
<td>3.3 ± 0.8</td>
<td>3.3 ± 0.8</td>
<td>NS</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>1.5 ± 1.6</td>
<td>1.6 ± 1.4</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with Parental FH</td>
<td>68.6 (86)</td>
<td>88.2 (45)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with Siblings FH</td>
<td>34.4 (33)</td>
<td>33.3 (17)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with siblings of a type 2 diabetes patient</td>
<td>80.0 (45)</td>
<td>91.1 (41)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>51.1 (23)</td>
<td>52.9 (10)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>52.9 (10)</td>
<td>51.1 (23)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
<tr>
<td>% (N) with FH of a type 2 diabetes patient</td>
<td>26.7 (12)</td>
<td>26.7 (12)</td>
<td>NS</td>
</tr>
</tbody>
</table>
Control -6.90 : -0.41) while significant improvement was only sustained in the intervention group after nine months (-4.33 cm, 95% CI -6.33 : -2.33). In both groups systolic blood pressure decreased after three months (intervention:-5.42 mmHg 95% CI -9.58 : -1.27 vs. control: -3.65 mmHg 95% CI -6.90 : -0.41 ). Again, further improvement after nine months was found only within the intervention group (-8.77 mmHg 95% CI -13.93 : -3.61). The P-value of 0.06 confirmed a trend for the intervention by time interaction effect between groups for systolic blood pressure.

Further examination of the association between changes in waist circumference and systolic blood pressure after nine months showed that 23 participants (59%) in the intervention group improved both waist circumference and systolic blood pressure versus 13 (31%) in the control group.

Changes in metabolic outcomes
No interaction effects between time and group were found for any of the metabolic outcomes (Table 2).

| Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| 3 months        | 9 months        | 3 months        | 9 months        | P-between |
| Body weight (kg)  | -0.88           | -0.54           | -0.24           | 0.38           | 0.06 |
| BMI (kg/m²)      | -0.35           | -0.21           | -0.08           | 0.03           | 0.48 |
| Waist circumference (cm) | -4.24 | -4.33           | -1.30           | -1.25           | 0.01 |
| Systolic blood pressure (mmHg) | -5.42 | -8.77           | -3.65           | -1.03           | 0.06 |
| Diastolic blood pressure (mmHg) | -1.46 | -2.15           | -1.74           | -0.23           | 0.44 |
| Fasting glucose (mmol/L) | 0.01 | 0.06           | 0.05           | 0.15           | 0.77 |
| Hemoglobin A1c (Hba1c ) (mmol/mol) | -0.15 | -0.38           | -0.36           | -0.57           | 0.89 |
| HOME2-IR         | -0.14           | -0.18           | -0.28           | -0.07           | 0.31 |
| Total cholesterol (mmol/l) | -0.02 | -0.19           | -0.14           | -0.14           | 0.43 |
| HDL cholesterol (mmol/l) | -0.07 | -0.03           | -0.02           | 0.01           | 0.49 |
| LDL cholesterol (mmol/l) | 0.03 | -0.07           | 0.04           | -0.01           | 0.59 |
| Triglycerides     | -0.03           | -0.03           | -0.09           | -0.11           | 0.93 |

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Regression coefficients with 95% Confidence Intervals. P-between (group * measurement time interaction) for the GEE-analysis regarding differences in change over time between the groups covariates: age, sex, site (GP practice or outpatient clinic), baseline value (accounting for baseline differences in outcome variables between subjects) CI= Confidence interval, HDL= High density lipoprotein, LDL= Low density lipoprotein

Table 2: changes in anthropometric and biological measures after within and between study groups of DiAlert
### Table 3. Adjusted mean intervention effect on 3-month and 9-month behavioural and psychological measures

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Behavioural intentions (scale 1-5)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthy diet</td>
<td>3.9 ± 0.6</td>
<td>3.7 ± 0.8</td>
<td>0.40</td>
</tr>
<tr>
<td>Physical activity</td>
<td>3.8 ± 0.9</td>
<td>3.6 ± 0.9</td>
<td>0.74</td>
</tr>
<tr>
<td>Losing weight</td>
<td>4.0 ± 0.8</td>
<td>3.5 ± 0.8</td>
<td>0.58</td>
</tr>
<tr>
<td>**Self efficacy (sum 20 scale 1-4) * **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>14.4 ± 2.4</td>
<td>13.6 ± 3.6</td>
<td>0.06</td>
</tr>
<tr>
<td>Physical activity</td>
<td>13.8 ± 2.9</td>
<td>13.5 ± 3.6</td>
<td>0.08</td>
</tr>
<tr>
<td>**Outcome expectancies (sum 20 scale 1-5) † **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>15.6 ± 3.2</td>
<td>14.5 ± 2.7</td>
<td>0.25</td>
</tr>
<tr>
<td>Physical activity</td>
<td>15.5 ± 3.5</td>
<td>15.3 ± 2.4</td>
<td>0.21</td>
</tr>
<tr>
<td>**Action planning * **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>7.1 ± 2.1</td>
<td>6.1 ± 2.3</td>
<td>0.87</td>
</tr>
<tr>
<td>Exercise (sum 24 scale 1-4)</td>
<td>15.9 ± 3.6</td>
<td>13.9 ± 4.3</td>
<td>0.54</td>
</tr>
<tr>
<td>**Personal control (sum 15 scale 1-5) ‡ **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>6.0 ± 2.1</td>
<td>6.2 ± 1.9</td>
<td>0.40</td>
</tr>
<tr>
<td>**Risk perception (scale 1-7) **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparative risk</td>
<td>5.1 ± 1.1</td>
<td>5.0 ± 1.3</td>
<td>0.37</td>
</tr>
<tr>
<td>Risk estimation</td>
<td>3.9 ± 1.6</td>
<td>4.3 ± 1.6</td>
<td>0.63</td>
</tr>
<tr>
<td>**Worry about diabetes (scale 1-7) **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diet</td>
<td>4.2 ± 1.9</td>
<td>4.8 ± 1.7</td>
<td>0.74</td>
</tr>
<tr>
<td>Physical activity</td>
<td>16.4 ± 5.5</td>
<td>14.8 ± 5.2</td>
<td>0.31</td>
</tr>
<tr>
<td>**Psychological distress (K-10) **</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EQSD</td>
<td>0.8 ± 0.2</td>
<td>0.8 ± 0.2</td>
<td>0.74</td>
</tr>
<tr>
<td>EQSD cm</td>
<td>73.0 ± 21.7</td>
<td>74.1 ± 21.2</td>
<td>0.55</td>
</tr>
</tbody>
</table>

Data are mean ± SD intervention effects adjusted for baseline measurement.

* = cronbach’s alpha >0.9 † = cronbach’s alpha >0.8 ‡ = cronbach’s alpha >0.6

Behavioural intentions: (1 = totally disagree to 5 totally agree) I plan to consciously eat healthier/exercise more/lose weight
Self-efficacy: (1 = very unconfident; 4 = very confident); Diet: I am confident that I can eat healthy food - even if I need a long time to develop the necessary routines/try several times until it works/have to rethink my entire way of nutrition/do not receive a great deal of support from others when making my first attempts/have to make a detailed plan. Physical activity: I can manage to carry out my exercise intentions even when I have worries and problems/feel depressed/feel tense/am tired/am busy.

Outcome expectations: (1 = totally disagree; 5 = totally agree) If I eat healthy foods / If I exercise more: I feel healthy / I will lose weight / I will look better / I feel relaxed.

Action planning: (1 = totally disagree to 4 = totally agree) Diet: I have concrete plans… what / how to change nutrition habits / what to do in difficult situations in order to stick to my intentions. Physical activity: I have concrete plans when / where / how many times / with whom I am going to exercise / what to do in difficult situations in order to stick to my intentions.

Personal control: (1 = totally disagree to 5 totally agree) I think I have little influence on getting T2DM / I think I have little control over my own health / I can reduce my risk of getting diabetes (reversed scored).

Comparative risk: (1 = a lot lower; 7 = a lot higher) What is the chance of you getting diabetes compared with an average man / woman your age?
Risk estimation: (1 = very small; 7 = very big) How big is the chance of you getting diabetes within the next 5 years?
Worry: (1 = not at all worried; 7 = very worried) Indicate your feelings when thinking about the chance of getting diabetes.
Reported perceptions and behaviour change

Table 3 shows no changes from baseline to 9 months in intentions to change behaviour. The intervention did not affect self-efficacy and outcome expectancies for lifestyle changes. Feelings of worry about diabetes or perceived risk of diabetes at follow-up were not different between groups. We observed a non-significant decrease of mean self-reported psychological distress (K-10) in both groups.

No changes for dietary behaviour, physical activity, smoking status and alcohol intake were reported in both groups.

Discussion

To the best of our knowledge we are the first to report on the effects of a low-intensive group lifestyle education programme specifically targeted at first degree relatives of type 2 diabetes patients, aimed to help them reduce their diabetes risk. Significantly more participants in the intervention group achieved a weight loss of at least 5% but the mean change in weight loss was not significantly different between both groups. Results of the Finnish and American diabetes prevention studies have shown that a weight loss of five to seven percent of the initial weight in high risk individuals is associated with marked clinical benefits. Furthermore, we demonstrated sustained improvement of waist circumference and systolic blood pressure in DiAlert participants. Reduction of these risk factors is important to prevent future cardiovascular disease and type 2 diabetes. The reported improvements were comparable to those found in previous diabetes prevention programmes designed for implementation in primary care. However, we did not find improvement in fasting glucose levels, nor in behavioural measures.

The absence of effect on self-reported determinants of behaviour change could be explained by a ceiling effect, i.e. already high scores at baseline in a sample of selected first degree relatives that were motivated to change their health behaviour. The initial study information offered on FH and relevance for diabetes risk prior to inclusion could have had an effect on motivation and risk perceptions in both the intervention and the control group.

The study succeeded in recruiting motivated overweight (obese) first degree relatives of type 2 diabetes patients, mainly Dutch and both higher and lower educated. Self-reported behavioural risk factors including smoking and alcohol intake were lower than the Dutch population average, suggesting a somewhat healthier lifestyle in our sample. However, most participants did not meet national recommendations for fruit intake and physical activity. Mean BMI was higher than previously reported in Dutch primary care settings but comparable to other European diabetes prevention trials. Moreover, most participants had raised blood pressure and elevated fasting glucose levels.

Utilizing the FH approach appears a feasible strategy to identify and reach people at increased diabetes risk who are motivated to engage in a low-intensity group programme. By using a mix of recruitment strategies we discovered that FH information was not systematically registered in medical records of the GP necessitating a time-consuming questionnaire approach. By contrast, open recruitment through advertisements in local newspapers proved to be successful and feasible and successful in attracting participants with an interest in diabetes risk reduction and seeking for advice. Participants' profiles were comparable across recruitment strategies, and we did not observe differences in delivery or uptake of the intervention between GP practice or open recruitment. This supports the idea that DiAlert can be integrated in primary care and is suitable to be delivered in a community setting.

This study has several limitations that need to be mentioned. First, the study is underpowered, as more participants dropped out before randomization than we had expected. In addition, besides the anticipated number of individuals (10%) with high fasting glucose levels at baseline we had to exclude people already diagnosed with type 2 diabetes and non-overweight individuals.

Second, the anthropometric measurements were not blinded to treatment allocation, and for pragmatic reasons the measurements were conducted before the group sessions. We can therefore not exclude experimenters' bias. Yet, automated measurement of systolic blood pressure showed more improvement in those individuals who successfully lost centimetres, suggesting actual improvement after DiAlert.

Finally, we could not demonstrate an association between improved lifestyle and change in anthropometric measures. To limit the burden of our assessments, we evaluated behaviour only with self-report questions about fruit and vegetable intake and used the short IPAQ for physical activity assessment. Future studies should use accelerometers for physical activity assessment for more accurate information.

Conclusion

In conclusion, overweight first degree relatives of type 2 diabetes patients who participated in the low-intensive structured lifestyle education programme showed improved waist circumference and reached relevant weight loss. We have demonstrated that the FH approach is feasible and a good starting point to engage relatives of type 2 diabetes patients in reflecting on their diabetes risk and achieve favourable outcomes in the context of diabetes prevention. It is of note that using family history as a starting point for reviewing risk factors and opportunities for prevention of type 2 diabetes in a constructive atmosphere had no negative psychological effects on the participants, confirming earlier findings.

We observed high acceptability, good attendance and engagement in all our intervention groups. Previous efforts to implement diabetes prevention interventions in a community or primary care setting showed decreased attendance rates after the first two counselling sessions. There-
fore, we believe that the short and structured approach is an important strength of the DiAlert intervention. Our results are supported by encouraging findings from a 3-hours structured intervention that was based on similar learning techniques and approaches for goal setting aimed to promote walking activity in individuals at risk in the UK [121].

Practice Implications
DiAlert is a structured, low-intensive educational group intervention that engages and supports overweight first degree relatives of type 2 diabetes patients reduce their diabetes risk. The study showed that family history is a feasible strategy to identify and reach relatives at risk of type 2 diabetes and engage them in diabetes prevention education. However, in view of our modest effects, we believe that it is worthwhile to consider linkage to existing (generic) lifestyle and weight management programmes to stimulate further adoption and maintenance of behaviour change following DiAlert.

Translation of landmark DPP-based interventions into community settings and primary care has found to be challenging [117,126]. In this context, finding a balance between efficacy and feasibility is crucial, particularly in high-risk subjects who feel relatively healthy and have no serious physical complaints.

Diabetes prevention education for Turkish migrants with a positive family history in the Netherlands: first findings of the Turkish version of DiAlert (DiAlert-TR)

Wieke H. Heideman,
Vera Nierkens,
Barend JC. Middelkoop,
Karien Stronks,
Arnoud P Verhoeff,
Maartje de Wit,
Frank J. Snoek

Submitted for publication
Abstract

Prevalence rates of type 2 diabetes (T2DM) among Turkish immigrants living in the Netherlands are higher than of the host population. Irrespective of ethnicity, a positive family history of diabetes is an important independent risk factor for the development of T2DM and offers opportunities for screening and primary prevention.

This study reports on findings of pilot testing a culturally adapted version of the diabetes prevention programme DiAlert in overweight Turkish overweight first degree relatives of T2DM patients (DiAlert-TR). Adaptations were informed by literature, expert opinion and pretesting in Turkish immigrants.

While keeping the core elements similar to the Dutch version of the intervention, necessary adaptations were identified, including: simplified risk information for T2DM, more extensive discussion of the role of stress as a risk factor for diabetes, inclusion of typical Turkish food products, simplified action plan worksheets and a bilingual Turkish-Dutch trainer to assist in formulating personal action plans.

A pilot was performed with two groups (N=16) to evaluate feasibility, fidelity, acceptability and comprehension of DiAlert-TR. Participants were recruited from the Turkish community in Amsterdam. Participants showed engagement group sessions and they were able to formulate personal action plans.

First findings demonstrate fidelity and acceptability of a short group-based diabetes prevention education programme in overweight Turkish immigrants with a positive family history. Future studies should evaluate the effectiveness of DiAlert-TR in the context of diabetes prevention and related cardiovascular disease.

Introduction

Modifiable risk factors such as overweight and physical inactivity contribute to the rapid rising prevalence of T2DM worldwide. Large diabetes prevention programmes have demonstrated that modest lifestyle modifications in order to lose weight can significantly reduce the risk of T2DM. Moreover, the prevalence of obesity, cardiovascular disease and T2DM is higher in some ethnic groups. In fact, among Turkish migrants living in North-western European countries T2DM is more prevalent, and the age of onset of diabetes is a decade younger than in the indigenous population. Today, Turkish people, who originally were labour immigrants, are among the largest group of immigrants living in the European Union and in the Netherlands accounting for approximately 2.3% (393,000 individuals) of the total population. Hence, it is important that this group will benefit from lifestyle programmes to prevent T2DM.

In addition, a positive family history (FH) or genetic predisposition of T2DM is an important non-modifiable risk factor, accounting for a two to five times higher risk of T2DM. Accordingly, screening for a FH of T2DM is an effective strategy to detect individuals at risk, can help raise awareness and target preventive initiatives to a specific population at risk.

We previously developed and tested a low-intensive structured lifestyle education programme (DiAlert) specifically targeted at overweight first degree relatives of patients with T2DM in the Netherlands with the aim to lose weight in order to prevent T2DM. We tested DiAlert in a Dutch sample and outcomes of the RCT proved encouraging findings of waist circumference loss and more participants of DiAlert reached a relevant weight loss as compared to the control group (publication under review). The DiAlert intervention consists of two interactive group sessions of 150 minutes with 7-10 participants and is delivered by trained dieticians. The intervention is theoretically based on the Health Action Process Approach (HAPA), a social cognitive model that guides health behaviour change through a motivational phase for intention formation leading to action and maintenance phase. HAPA identifies risk perception, self efficacy beliefs and outcome expectancies as key determinants for intention formation and action planning. Therefore participants are encouraged to elicit beliefs and worries about T2DM and FH and review personal risk factors for diabetes. Trainers employ a constructive learning approach with open questioning to clarify health benefits of lifestyle changes, increase self-efficacy beliefs for lifestyle change and enable participants to formulate time-set personal action plans to loose weight. The constructive approach stimulates group interaction, and enhances intrinsic motivation for practising skills for healthy food choices and improving physical activity.

In order for the DiAlert intervention to be effective for overweight Turkish relatives of people with T2DM as well, we adapted it to characteristics of the Turkish population (hereafter DiAlert-TR). It is suggested that culturally appropriate interventions help improve outcomes of diabetes education programmes in ethnic minority groups. Similarly, culturally appropriate lifestyle education
may positively influence health behaviour change in ethnic minority patients, but research in the field is scarce [131,132]. As defined by Hawthorne et al. culturally appropriate education is targeted to the cultural or religious beliefs and linguistic skills of the participants considering their literacy skills [13]. For DiAlert-TR it is crucial to account for socio-cultural factors to meet culturally unique needs for dietary and exercise behaviour change. This includes the concepts of diabetes specific knowledge, Turkish exercise and food habits, but also expectations regarding participation to group sessions and language preferences of the Turkish target group.

The adaptation process of DiAlert-TR was informed by the first three stages as described by Barrera and colleagues [133] 1) information gathering, 2) preliminary adaptation design and 3) preliminary adaptation tests. As the original DiAlert intervention was developed to reach a broad range of people with a structured and interactive approach, we aimed to preserve key aims and programme integrity of the DiAlert intervention, thereby replicating the core faithfully in the Turkish version.

Here we report on the identified adaptations for the Turkish target group, the adaptation process and pilot study that aimed to evaluate feasibility, fidelity, acceptability and comprehension of DiAlert-TR.

Table 1. Core components of the original DiAlert intervention

<table>
<thead>
<tr>
<th>Core setting components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inclusion criteria: Participants are overweight and have at least one first degree family member with T2DM</td>
<td></td>
</tr>
<tr>
<td>• Group intervention: two structured intervention sessions with approximately seven participants</td>
<td></td>
</tr>
<tr>
<td>• Intervention approach: following the underlying philosophy to support the educational process to develop awareness and autonomy to assume responsibility for decisions in relation to lifestyle behaviours: the role of the trainer is guiding, not teaching</td>
<td></td>
</tr>
</tbody>
</table>

Core topics

- Exploration of personal beliefs about T2DM.
- Increasing risk perception by reviewing risk factors (modifiable and non-modifiable).
- Increasing outcome expectancies for weight loss and physical activity by review of personal benefits of weight loss to prevent diabetes.
- Building on confidence (self-efficacy) to modify diet and/or exercise in order to lose weight and prevent diabetes.
- Increase knowledge and skills for food choices to reduce risk factors
- Monitoring current lifestyle behaviour.
- Creating an action plan to change lifestyle (planning).

Methods

Before starting the adaptation process we identified the essential core elements based on theoretical underpinnings of DiAlert to be able to keep the content and aims similar to the original intervention after adding cultural content. (Table 1 shows the core components of DiAlert). The original DiAlert intervention was deliberately developed as a short and low-intensive group education intervention, we aimed not to increase the intensity of the intervention by adaptations.

Needs assessment for adaptations

We performed literature research and consultation of experts to identify needs for adaptations of the intervention. A Turkish bilingual/bicultural dietician, with experience in culturally adapting educational interventions joined the research team and assisted the process of adaptations. A meeting was organised with four experts (a Turkish health educator, a Dutch diabetes prevention worker of Amsterdam Public Health Service, a Turkish social worker/trainer and a Turkish psychologist) to identify the cultural relevance and discuss potential adaptations, facilitators and barriers for the Turkish target group.

Pilot

The next step involved a pilot test with two groups of Turkish first degree relatives of T2DM patients. Group sessions were audio taped and observed by an independent bilingual observer who used a checklist to evaluate delivery and uptake of the intervention. Based on our own experience of the first pilot [118] and guidance on process evaluations [106,134] and cultural adaptations [135] the following goals were identified for the pilot:

Assessment of acceptability, by testing effective recruitment strategies, evaluation of measurement, evaluation of participants that were reached and feasibility of delivery of the short and structured intervention programme to the Turkish participants in terms of group size, time management of modules and length of the total intervention.

Evaluation of fidelity, whether DiAlert-TR was delivered as planned following the core elements of DiAlert (see Table 1) and evaluation of the trainers’ behaviours to guide discussions in a positive atmosphere, rather than teaching.

Investigation of the acceptability of DiAlert-TR, i.e. whether the family history approach for diabetes prevention education was applicable for overweight Turkish first degree relatives; assessed with observations by looking at discussions, disclosure of FH and beliefs about T2DM prevention. In addition, participants were asked to give a general evaluation of the whole intervention.

Assessment of comprehension, referring to understandable content that is matched to the linguistic, educational and developmental needs of the target group [134]. And evaluation of spoken language during the session.
To ensure consistency of delivery we consulted a dietician who was trained to deliver the Dutch DiAlert intervention in the main RCT. The co-trainer was a Turkish dietician who was able to translate if necessary. The process of delivery was evaluated immediately after each session with the trainers. We aimed to perform the pilot with two groups of overweight Turkish first degree relatives of T2DM patients between the age of 25-65 years. For recruitment, a bilingual leaflet in the Dutch and Turkish language, providing information about the intervention, dates and locations was provided to a number of primary healthcare centres and mosques in Amsterdam West. Acquainted health care professionals volunteered to distribute leaflets among their clients. We consulted a Turkish health educator with access to the Turkish community in Amsterdam for assistance with recruitment.

The pilot study was delivered at the outpatient clinic of the VU University Medical Center in Amsterdam (VUMC).

Characteristics of participants
To evaluate the characteristics of the participants that were reached for the pilot, participants were asked to fill in a questionnaire before the first group session covering age, education, employment, FH of T2DM and years living in the Netherlands and determinants of behaviour change of HAPA with questions on risk perceptions, outcome expectancies, self-efficacy and planning of behaviour change were assessed. The questionnaire was available in Dutch or Turkish (forward and backward translated from the Dutch questionnaire). Assessment of the risk profile included measurement of body weight, height and waist circumference. Fasting blood samples were drawn before the second session to determine HbA1c, total cholesterol, LDL and HDL cholesterol, triglycerides and glucose.

Results
Adaptations based on needs assessment
Based on formative research, evidence from literature and insights gained at the expert meeting, we identified major needs for adaptation. Table 2 shows the adapted modules per core element of DiAlert, we illustrate the five main adaptations below.

1. Bi-lingual trainer
Clarifications and translations of a bi-cultural/lingual trainer appeared to be necessary for participants with limited command of the Dutch language.\[137\].

2. Simplified risk information
Increasing adequate risk perception is a core element of DiAlert. The information about diabetes risk factors was simplified because we expected participants with low socioeconomic status in the Turkish group. Low health literacy is a known barrier to diabetes self management in groups with low socioeconomic status.\[138,139\]. Experts confirmed that an interactive approach to discuss risk factors could possibly help to engage participants to consider personal risk factors. In addition, Turkish immigrants with T2DM living in Berlin ascribed diabetes causation to external factors, including a FH of T2DM\[140\]. Therefore, the terms “modifiable and non-modifiable risk factors for T2DM” were explained through an interactive assignment with a container filled with coloured balls to discuss risk factors for T2DM. The amount of coloured balls illustrated the level of risk. Removing a coloured ball (e.g. losing weight, increase exercise, eating healthy) symbolized a lower risk of T2DM. The information and objective of the original module were not changed. With the adapted module we aimed to stimulate active involvement to the discussion about risk factors for T2DM.

3. Stress and diabetes
An important finding of the formative research was that stress is suggested as preliminary cause of developing diabetes by Turkish immigrants living in Germany, Australia and Belgium\[141,142\]. In addition, based on their experience with education for Turkish T2DM patients living in the Netherlands, the experts confirmed that stress is often mentioned in relation to diabetes causality. Therefore, we developed an extra module about diabetes and stress. A drawing of a water tap and an overflowing bucket illustrated causes and consequences of too much stress. The aim of this module was to increase self-efficacy beliefs by early identification of signs of stress and learning strategies to cope with stressful situations and learning that stress can be a barrier to adopting or maintaining a healthy lifestyle.

4. Turkish food products
Turkish people living in the Netherlands value their traditional food culture and hold on to their traditional recipes\[143\]. This supported the need for culturally appropriate dietary advices in DiAlert-TR. Typical Turkish products, such as nuts, seeds, helva and baklava were therefore introduced. Although consumption of alcohol is prevalent among Turkish immigrants, the experts advised us to remove alcoholic beverages from intervention materials, because it might interfere with Islamic rules. The products were pre-tested in a group of Turkish volunteers to establish a set of familiar food products that are frequently consumed by the target group. Moreover, the information in the manual about nutrition was adapted to the Turkish diet and pictures of Turkish products were included.

5. Action plan worksheet
Literature research did not provide us information on action planning in Turkish immigrants. Experts confirmed the importance of a systematic approach for action planning, but advised us to increase guidance by trainers (i.e. take a more directive approach), because of the expected lower education level of the target group, people might be less familiar with individual goal setting and action planning. In addition, we were advised to provide less written information and develop...
<table>
<thead>
<tr>
<th>Core topics of DiAlert</th>
<th>Intervention component</th>
<th>Cultural adaptations</th>
<th>Evaluation pilot (Trainers/ Observations/ Flip-over sheets)</th>
<th>Reflections on cultural relevance / adaptations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exploration of personal beliefs about T2DM</td>
<td>Discussing family members with T2DM</td>
<td>Participants have multiple family histories and their relatives have severe complications (T/O)</td>
<td>• Participants have multiple family histories and their relatives have severe complications (T/O)</td>
<td>• Disclosure of diabetes family history not a taboo.</td>
</tr>
<tr>
<td></td>
<td>Exploration of worries and possible impact of T2DM</td>
<td>Participants are worried about diabetes and show anxiety to develop diabetes (T/O)</td>
<td>• Participants are worried about diabetes and show anxiety to develop diabetes (T/O)</td>
<td>• Turkish participants were willing to share their beliefs and experiences about T2DM and their relatives with T2DM.</td>
</tr>
<tr>
<td></td>
<td>Burning questions</td>
<td>Prominent discussion on stress and diabetes (O)</td>
<td>• Prominent discussion on stress and diabetes (O)</td>
<td>• Worries and anxiety to develop diabetes were present in both groups.</td>
</tr>
<tr>
<td></td>
<td>Motives for participating</td>
<td>Worries (F):</td>
<td>• Worries (F):</td>
<td>• Participants set great importance to the relation between stress and diabetes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Anxiety to develop diabetes</td>
<td>- Anxiety to develop diabetes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Worries about symptoms of diabetes (physical complaints, fatigue, headache)</td>
<td>- Worries about symptoms of diabetes (physical complaints, fatigue, headache)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Impact (F):</td>
<td>- Stress, because life has changed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Burning Questions (F):</td>
<td>- Burning Questions (F):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diabetes causality (e.g. “Are body weight and diabetes related? My father has diabetes, do I get it too? Is it hereditary? How can someone get diabetes without being overweight?”)</td>
<td>- Diabetes causality (e.g. “Are body weight and diabetes related? My father has diabetes, do I get it too? Is it hereditary? How can someone get diabetes without being overweight?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Diet and weight loss (e.g. “Is it true that you need to eat small amounts of food five times a day when you have diabetes? Do you put on weight if you eat fruit after 10 p.m.? Stress-eating. How can I stop the yo-yo effect?”)</td>
<td>- Diet and weight loss (e.g. “Is it true that you need to eat small amounts of food five times a day when you have diabetes? Do you put on weight if you eat fruit after 10 p.m.? Stress-eating. How can I stop the yo-yo effect?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Personal risk (e.g. “I would like to know if I have diabetes, What are the odds? How can I recognize it?”)</td>
<td>- Personal risk (e.g. “I would like to know if I have diabetes, What are the odds? How can I recognize it?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Family risk (e.g. “How can I prevent my children from getting it [diabetes]?”)</td>
<td>- Family risk (e.g. “How can I prevent my children from getting it [diabetes]?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Diabetes treatment and complications (e.g. “Does diabetes affect the eyes? Is there a relation between diabetes and organ dysfunctions? What are the consequences of diabetes on cholesterol? Is there a alternative for insulin?”)</td>
<td>- Diabetes treatment and complications (e.g. “Does diabetes affect the eyes? Is there a relation between diabetes and organ dysfunctions? What are the consequences of diabetes on cholesterol? Is there a alternative for insulin?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Motivation for participation (F):</td>
<td>Motivation for participation (F):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- knowledge and information (“What is diabetes? How to prevent it?”)</td>
<td>- knowledge and information (“What is diabetes? How to prevent it?”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Get motivated to change (“I would like to eat healthy and exercise more/ losing weight”)</td>
<td>- Get motivated to change (“I would like to eat healthy and exercise more/ losing weight”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Support (“How to cope with diabetes – for myself and environment/ social support”)</td>
<td>- Support (“How to cope with diabetes – for myself and environment/ social support”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Join for the sake of company</td>
<td>- Join for the sake of company</td>
<td></td>
</tr>
<tr>
<td>Increasing risk perception</td>
<td>Discussing risk factors for T2DM (modifiable and non-modifiable)</td>
<td>Simplified risk information using a container with coloured balls</td>
<td>• Engagement and interaction between participants was stimulated by the assignment (T).</td>
<td>Trainers acknowledge beneficial effect of the assignment: participants were engaged in the discussion and identified risk factors. Unclear whether the assignment with the container clarified the information about risk factors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Differences between modifiable and non-modifiable factors was difficult for some participants of the first group (O)</td>
<td>• Differences between modifiable and non-modifiable factors was difficult for some participants of the first group (O)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Participants of the 2nd group were better aware of risk factors for T2DM and trainers explained the assignment better (O).</td>
<td>• Participants of the 2nd group were better aware of risk factors for T2DM and trainers explained the assignment better (O).</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 6

Reflections on cultural relevance / Intervention component

Cultural adaptations

<table>
<thead>
<tr>
<th>Core topics of DiAlert</th>
<th>Intervention component</th>
<th>Cultural adaptations</th>
<th>Evaluation pilot (Trainers/ Observations/ Flip-over sheets)</th>
<th>Reflections on cultural relevance / adaptations</th>
</tr>
</thead>
</table>
| Increasing outcome expectancies for weight loss and physical activity by review of personal benefits of weight loss to prevent diabetes | Interactive education about insulin resistance, loss of beta cell function and the positive effects of body weight loss and physical activity. | No adaptations | - Participants are in need of simple explanations and expressions therefore participants had difficulties to understand the relation between lifestyle and diabetes (T).  
- The module was repeated at the second session.  
- Translation into Turkish was necessary for participants to understand the module (1st group)(T/O)  
- Trainers use simple words, but the information is difficult for some participants (O). | The relation between stress and diabetes was important to all participants, they appreciated the information about stress. Trainers had an important role to help participants identifying coping strategies and discuss problem solving techniques. Negative stories about stress can affect the positive atmosphere. |
| Monitoring current behaviour and increase knowledge and skills for food choices to reduce risk factors. | Calories game: reading labels to determine calorie load of product and discussing healthy alternatives. | Typical Turkish food products were included | - Engagement in the games was high: all participants actively participated in the games and discussed the products together (T/O)  
- Participants recognized all products (T/O)  
- Misconceptions about food were discussed (e.g. participants believed that natural product like nuts and seeds do not contain calories or that the calories disappear when nuts are roasted) | Turkish products were recognized by all participants. High engagement. |
| Homework: record nutrition and physical activity behaviour in a diary | | No adaptations | - Participants used the diary and were positive about monitoring their own behaviour (T/O).  
- Participants became aware of low activity levels and high intake of food in evenings. | The diary was clear, all participants monitored their dietary intake and physical activity. |
| Building on confidence (self-efficacy) to modify diet and/or exercise in order to loose weight and prevent diabetes) and creating an action plan to change lifestyle (planning) | Sharing experiences about losing weight. Exploring benefits and barriers for lifestyle change. Participants formulate personal Action plans to change lifestyle. | Simplified action plan worksheet with pictures. Ten prepared action plan examples with cultural sensitive goals: 1. Walking together with a neighbour/friend three times a week. 2. to swimming in the pool with friends. 3. Take the stairs to the 3th floor when I come home from work instead of using the elevator. 4. Doing groceries by foot twice a week. 5. Eat only one piece of bread at dinner. 6. Eating less olive oil by using a spoon to measure amounts. 7. Drink water instead of juices at weekdays. 8. Dish up lettuce and vegetables first on my plate. 9. Telling friends that I eat less sweets and snacks for my own health. 10. Eating two pieces of fruit per day. | - Formulation of specific and time-set goals is difficult for participants, they need assistance of trainers (T)  
- Participants became aware that an action plan can assist in planning activities. (O) | Participants had no experience with lifestyle change, they were therefore not able to share barriers and facilitators of behaviour change. Prepared examples of action plans that fit the target group were helpful to create a personal action plan with assistance of trainers. |
pictures that support simple texts and to prepare cultural sensitive examples of action plan worksheets for inspiration (e.g. detailed plan to go walking with their children in the park, instead of cycling, since cycling is not appropriate for all Turkish people). Trainers were instructed to adapt the discussion on the personal actions in response to the participants’ level, and facilitate participants to adapt the prepared plans to their personal situation. We redesigned the action plan worksheet, formulated simple questions and added pictures for a stepwise approach to formulate goals along the constructs of HAPA (self-efficacy and outcome expectancies, action and coping planning).

Results pilot

Feasibility

Recruitment
We visited three mosques and two meetings of women in several districts of Amsterdam to distribute leaflets and to promote the pilot study. This strategy resulted in one participant, others were not interested for various reasons (e.g. “I have diabetes, not my children”, “I'm not ill”, “My parents have diabetes, they are in need of a course”, “I don't have time”). Collaboration with the Turkish health educator who knew the community was more successful and resulted in 17 potential participants of whom 14 were eligible and 11 participated in the intervention.

Four participants were recruited by an enthusiastic woman who invited other women of her own social network. One participant brought his mother with T2DM to the intervention, she participated actively in the sessions, but did not participate in measurements (Table 3 provides participants characteristics of N=16). The recruitment via primary healthcare centres yielded no participants.

Participants reached
Table 3 shows the characteristics of the participants, mostly female (N=14) with a mean age of 43.9 ± 6.7 years. Twelve participants had a first degree relative with T2DM, four had only second degree relatives (grandparent or uncle). All participants were lower educated and mostly unemployed, 56% reported being a housewife (N=9). Only one participant was born in the Netherlands, the others in Turkey. Mean years that they had lived in the Netherlands is 28.8±8.8 years. Most participants (N=12) were obese (≥30 kg/m²) with a mean BMI of 34.2 ± 7.1 kg/m². Mean fasting glucose was 5.6±0.6 mmol/l, HDL cholesterol was 1.5±0.3 mmol/l and LDL cholesterol 3.0±0.7 mmol/l.

Intervention delivery
The programme was conducted in two groups of participants (N=9 and N=8) in February and March 2013.

<table>
<thead>
<tr>
<th>Table 3. Characteristics participants pilot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics (N = 16)</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Lower Education a</td>
</tr>
<tr>
<td>Employed (yes)</td>
</tr>
<tr>
<td>Mean years living in NL† b</td>
</tr>
<tr>
<td>First degree family history</td>
</tr>
<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
</tr>
<tr>
<td>Overweight (25 to 30 kg/m²)</td>
</tr>
<tr>
<td>Obese (≥30 kg/m²)</td>
</tr>
<tr>
<td>Current smoker (yes) a</td>
</tr>
<tr>
<td>Metabolic profile b*</td>
</tr>
<tr>
<td>Fasting glucose (&lt;5.6 mmol/l)</td>
</tr>
<tr>
<td>HbA1C (&lt;42 mmol/mol)</td>
</tr>
<tr>
<td>Total cholesterol (&lt;5 mmol/l)</td>
</tr>
<tr>
<td>HDL cholesterol (&gt;1.2 mmol/mol (in women))</td>
</tr>
<tr>
<td>LDL cholesterol (&lt;2.5 mmol/l)</td>
</tr>
<tr>
<td>Triglycerides (&lt;1.7 mmol/l)</td>
</tr>
</tbody>
</table>

Values are presented in number of participants (%) or mean ± SD.

a= information missing N=14, b= information missing N=12
†=1 participant 2nd generation (born in the Netherlands)
* reference values between brackets are based on European Guidelines on cardiovascular disease prevention in clinical practice [149]

One participant was not able to attend the second session. Overall, the participants showed high engagement. All participants were enthusiastic to share their beliefs and questions about diabetes prevention in the group sessions. This resulted in longer, but good, group discussions. We learned from evaluations with the trainers that the first group with nine participants was large; all participants took the opportunity to participate in discussions and translations were time-consuming. In addition, the sessions were delivered in the Dutch language, but in the first group almost every module had to be simultaneously translated into Turkish. So we noticed in the first group that 150 minutes per session was too short to deliver the whole programme. To enhance time for more personal attention, we scheduled 180 minutes for the second pilot group. Participants
of the second group spoke mainly in Dutch and the group was smaller. Delivery of the complete programme proved feasible in 180 minutes, confirming the need for longer sessions.

**Measurements**
Anthropometric measurements were performed with all participants before the first session. Blood samples were drawn before the second session in N=12, because one participant dropped out after the first session and three participants did not show up for the measurement. The questionnaires were poorly filled in, resulting in an incomplete dataset. Especially the questions about health behaviour change were skipped and data could therefore not be analysed.

**Fidelity**
Defined core components of the intervention (shown in Table 1) were helpful to assess the minimum requirements for the intervention. We did not manage to recruit only first degree relatives of T2DM patients; four participants had a second degree relative with T2DM. Engagement of participants was high, trainers confirmed that all participants were actively involved in the discussions. The observer noticed a positive atmosphere and trainers used open questions to invite participants to share their beliefs, worries and questions about diabetes. However, duration of talking by the trainers (and participants listening) increased as a result of Turkish translations.

As shown in Table 2, all core topics of the intervention were delivered, we report here findings from the pilot in relation to the five main adaptations.

1. **Translations of a bilingual trainer**
Level of command in the Dutch language was lower in participants of the first group. For them, Turkish translations of all modules were necessary to clarify information. In the second group the language spoken was Dutch, but translations were necessary to clarify specific information.

2. **Simplified risk information**
Participants of both groups were able to identify their personal risk factors. Trainers reported that the simple and interactive approach stimulated participants to consider modifiable and non-modifiable risk factors. The observer noticed that the aim of the module was not clear to all participants of the first pilot group. The interactive explanation of risk factors and causes of diabetes was better appreciated in the second group, because trainers used their experience from the first session to better explain the assignment the second time.

3. **Stress and diabetes**
The implementation of the extra module about stress was successful. From the beginning, participants underscored the importance of the link between stress and diabetes. The image of a water tap was understood by all participants and triggered participants to express their anxiety and worries to develop diabetes. They were convinced that both stress and grief were important causes of diabetes and mentioned their history of migration to the Netherlands, family relations and work as most important stress factors.

Trainers had to guide the discussions to avoid a negative atmosphere as result of sharing emotions, but the observer noticed good uptake of the module with participants discussing various effective strategies for coping with stressful situations.

4. **Turkish food products**
Participants were highly engaged in the modules about diet. All products were familiar to the participants. They confirmed that they used the products at home and learned about the (unexpected) high amounts of calories of some products, for example, some participants believed that ‘natural’ products like nuts and seeds do not contain calories or that the calories disappear when nuts are roasted.

5. **Action plan worksheet**
As expected, personal goal setting was new to most participants, though they were enthusiastic and willing to complete their personal action plan. All participants of both groups completed a personal action plan, however they needed personal assistance from the trainers to formulate detailed action plans on what, when, where, how they want to change. The examples of action plans were recognized and used for inspiration by participants. Due to time constraints, a good group discussion on action planning was left out in the first pilot group.

**Acceptability**
The family history approach proved to be applicable to Turkish relatives who participated in the pilot study. Participants of both groups were willing to disclose their FH and personal stories proved to be a good starting point to explore personal beliefs about diabetes. The trainers noticed that almost all participants had multiple relatives with severe complications and they had worries and anxiety about developing diabetes themselves. The participants generated many questions about diabetes causality, risk factors, family risk, diabetes treatment and lifestyle (see Table 2). In general, the participants were engaged in all modules showed by active participation in the discussions. In addition, we asked participants to rate the total intervention, they gave a mean overall mark of 8.7±1.2 on a scale from 1 (lowest) to 10 (highest).

**Comprehension**
Most modules matched the educational and developmental needs of the target group illustrated by highly engaged participation and good discussions between participants and trainers. The interactive approach, using flip-charts to identify participants’ personal beliefs in their own words proved to be applicable in the Turkish group. However, some modules deserved more attention.

First, the Turkish relatives appeared to have less basic knowledge about health and disease than the participants in our Dutch trial. Therefore, the discussion about development of diabetes...
and prevention was difficult for the participants because the trainers had to repeat that module at the second session and had to use more analogies to express the functions of the human body (e.g. bricks of a house to explain cells of a human body). According to the trainers and the observer, the participants better understood the module the second time, because participants were able to discuss the importance of losing weight in relation to diabetes prevention.

Second, the Turkish participants needed more assistance in creating their personal action plans, as compared to Dutch participants. Trainers confirmed that Turkish participants had little experience with changing lifestyle behaviour in the past; the discussion about barriers and facilitators for lifestyle change with regard to self-efficacy for lifestyle change was therefore difficult.

Discussion

The current study focussed on the development of a culturally adapted DIAlert-TR intervention and a pilot study to evaluate feasibility, fidelity, acceptability and comprehension for Turkish relatives of T2DM patients. Based on literature and experts opinion, we identified five important adaptations including a new module about stress and diabetes, simplified diabetes risk information, inclusion of Turkish food products, simplified action plan worksheets and delivery of the intervention by a bi-lingual trainer.

Adapted modules were pretested and a pilot study that was performed in two groups of participants confirmed that the family history approach was acceptable for Turkish relatives of T2DM patients, because they were willing to disclose their FH of T2DM. Like in the original DIAlert intervention, DIAlert-TR proved that the constructive approach stimulated group interaction and engagement in diabetes prevention education with a positive atmosphere. Participants showed engagement and enthusiasm to discuss the information of the intervention. Basic knowledge about health and diabetes was lower in the selected Turkish participants as compared to participants of the Dutch intervention and therefore requiring more attention.

(Reached) participants

Although we succeeded in enrolling a sufficient number of participants for two pilot groups recruitment of participants was challenging, many potential participants refused participation, because they believed that they had no influence on the development of T2DM. This is in line with studies reporting on religious fatalism in British Muslim migrants. Furthermore we reached mainly low-educated females who were born in Turkey and migrated to the Netherlands in the 1980’s. In the Netherlands, 50% of the 393.000 Turkish individuals are born in the Netherlands (second generation migrants) however, only one participant of the pilot study was born in the Netherlands.

Mean age of the participants was more than a decade younger as compared to the Dutch participants of the DIAlert trial (Dutch mean 55±9 years). An epidemiological study among immigrants living in Amsterdam confirmed that the age of onset of diabetes in Turkish immigrants being one to two decades younger than in the indigenous population.

Insights from other adaptation studies showed that utilizing community resources increases intervention accessibility and recruitment for an exercise programme through ethnically specific channels contributed to the reach of a target group, however the authors concluded that the success of recruitment depends on the characteristics of the target community such as close-knit, highly organized ethnic communities with limited fluency in the local language. This could be a possible explanation for the finding that we reached a selective group of motivated females.

Not all participants had at least one first degree relative with T2DM, but carried multiple risk factors for diabetes, including obesity, elevated fasting glucose levels and poor levels of LDL and total cholesterol. This indicates that we reached participants that could benefit from lifestyle changes in order to decrease their diabetes and related cardiovascular risk.

Process (feasibility/ fidelity/acceptability/comprehension)

With regard to delivery of DIAlert-TR we reported that the content of the intervention was acceptable for the participants; they showed high engagement in discussions. Based on literature about other immigrant groups living in the Netherlands we had expected that Turkish participants might not want to disclose the diabetes status of their relatives. Interestingly, the pilot proved the opposite; it appeared that the participants were likely to elaborate on all topics. However, disclosure of diabetes FH might has been a reason for relatives to refuse participation.

Feasibility of delivering the intervention in terms of time was hindered by longer group discussions, translations into Turkish and the need for repeated information at the second session to improve uptake of information.

A limitation of the pilot study was that data on lifestyle behaviour and determinants of behaviour change was missing from the questionnaire. Although the questionnaire was available in Turkish some questions, particularly, the last about the determinants of behaviour change were missing. Possibly the questionnaire was too long or questions were difficult. A structured face-to-face interview based on the questionnaire that matched the literacy level of participants could have provided better information for the participants that had a low educational level.

Recommendations for further development of the intervention:

Beforehand we aimed not to change the amount and the duration of the group sessions, but more time was spent on group discussions, translations into Turkish and repeating information because level of knowledge about health related to diabetes was lower than expected. We therefore suggest to add an extra session; this may improve uptake with possibilities to repeat information and help participants to create and adjust personal action plans.
Delivery of the intervention with a guiding approach of the trainers was successful in stimulating engagement and lively discussions. Translations by a bilingual trainer were essential, but time consuming. Delivery of the intervention by trained Turkish trainers might therefore be more efficient.

Although participants were aware of modifiable risk factors including overweight, low levels of physical activity and an unhealthy diet, they considered stress and anxiety to be the main causes of diabetes. Interestingly, the trainer reported that participants had higher levels of worry and anxiety about their risk of developing T2DM in the sessions, as compared to the Dutch participants of DiAlert. We believe that the extra module on stress and stress management satisfied the need for recognition and discussion of socio-cultural beliefs about stress and diabetes. However, we could not determine whether self-efficacy to cope with these feelings and developing positive outcome expectancies of physical activity and relaxation were achieved.

FH was not a taboo and the discussions were appreciated by the participants of this pilot. Results from a recent qualitative study among Turkish patients with T2DM suggests that fatalism (i.e. the perception that someone is not responsible for an undesirable situation and is unable to change it) is an important belief in relation to perceived causality of T2DM[142]. Considering further development of the intervention, assessment of risk perceptions and the potential impact of fatalistic beliefs of participation in preventive education is important. With regard to the recruitment, specific strategies to attract participants with fatalistic beliefs should be considered.

**Conclusion**

The pilot study confirmed acceptability and fidelity of DiAlert for the Turkish target group. We conclude that FH is a good starting point to engage Turkish relatives into diabetes prevention education. Homogeneous groups with only low-educated participants are in need for basic health education supporting accurate risk perceptions, to enhance positive outcome expectancies and increase self-efficacy beliefs for relevant behaviour changes.

Further research is necessary to evaluate effective recruitment strategies to reach a representative group of Turkish immigrants and to establish the effectiveness of DiAlert-TR, in terms of health outcomes, and weight loss in particular. If proven effective, dissemination of DiAlert in other ethnic minority groups at high risk for diabetes may help to bridge the cultural gap that still accounts for significant health inequalities between host and immigrant populations.
Type 2 diabetes has become one of the most important chronic diseases and has a huge impact on patients and health care costs globally. Large clinical trials have provided evidence that modest changes in diet and increase of physical activity can reduce the incidence of type 2 diabetes. In addition to lifestyle related risk factors, evidence has shown that genetic predisposition contributes to the development of type 2 diabetes. A positive family history of type 2 diabetes is recognized as an indicator for susceptibility for the disease and it is often used as a marker to identify individuals at risk. Furthermore, it is suggested that individuals with a family history may be more motivated to engage in preventive behaviour as result of raised perceived susceptibility.

This thesis described the development and evaluation of effectiveness of DiAlert: a structured diabetes prevention education programme targeted to overweight first degree relatives of type 2 diabetes patients. The primary aim of the intervention was body weight loss in order to prevent type 2 diabetes. Secondary outcomes included biomedical, anthropometrical and psychosocial measures.

In addition, because the prevalence of type 2 diabetes is higher in Turkish immigrants living in the Netherlands, we believed that overweight Turkish relatives of type 2 diabetes are an important target group for diabetes prevention programmes. Hence, we aimed to develop a culturally appropriate version of DiAlert for overweight first degree Turkish immigrants (DiAlert-TR). The objective was to identify necessary cultural adaptations, develop and evaluate feasibility, fidelity, acceptability and comprehension of DiAlert-TR in a pilot study.

The development and evaluation of DiAlert included several stages that were set out in this thesis.

First, a literature review was performed to summarize existing literature about diabetes prevention trials that were specifically aimed to motivate individuals with a positive family history of type 2 diabetes (chapter 2).

Second, a description of the rationale for the intervention and the design of the randomised controlled trial (RCT) were reported in chapter 3.

Third, in a pilot study, the feasibility and fidelity of delivery of DiAlert were assessed together with the acceptability of the intervention for people with a positive family history of type 2 diabetes (chapter 4).

Fourth, the effects of the DiAlert education programme on the primary outcome of weight loss and other anthropometrical, biomedical and psychological outcomes were reported in chapter 5.

Finally, a description of the development and pilot-testing of DiAlert-TR for Turkish people with a positive family history of type 2 diabetes was given in chapter 6.

This chapter provides a reflection on the main results of the DiAlert project and discusses implications for further research.

Discussion

The main aim of the DiAlert-project was to study the effectiveness of the DiAlert intervention. The RCT showed no significant effect on the main outcome of body weight loss, meaning that the intervention was not superior to the control group for this outcome. However, significantly more participants reached 5% loss of their initial weight in the intervention group than in the control group. The significant effects on waist circumference and a trend in the improvement of systolic blood pressure suggest an improvement of the metabolic profile of the intervention group, as waist circumference is an indicator of central adiposity and a good predictor for type 2 diabetes (154). Yet, conclusions should be drawn with caution, as the sample size was small and the follow-up relatively short.

Since the publication of the results of the well-known diabetes prevention trials, researchers have tried to translate the evidence into non-experimental settings, including primary care and community settings. Although most interventions in these settings produced lower levels of weight loss, two meta-analyses have highlighted the potential impact and the feasibility of less intensive interventions on diabetes prevention interventions delivered in community and healthcare settings (151,152). Recently, a meta-analysis on pragmatic diabetes prevention interventions confirmed the clinically meaningful effect on prevention of diabetes and cardiovascular disease despite a drop-off in intervention effectiveness on weight loss (154), as the American Diabetes Prevention Program (DPP) study showed that each kilogram of weight loss is associated with a reduction of 16% in future diabetes incidence (154). However, traditional diabetes prevention programmes that employed intensive counselling strategies showed to be effective, but the total cost and cost per case of diabetes avoided was high (135). With regard to feasibility, DiAlert was explicitly developed to be delivered in routine health care or a community setting and we aimed to evaluate the low-intensive intervention of only two education sessions of 150 minutes, that was targeted at healthy, but overweight, first degree relatives of type 2 diabetes patients diabetes.

The studies reported in this thesis confirmed that family history proved to be a good starting point to review personal risk factors and discuss opportunities for prevention of type 2 diabetes without negative psychological effects in Dutch relatives of type 2 diabetes patients. The interactive group sessions stimulated participants to elicit beliefs and worries about family history and diabetes and they were motivated to consider personal modifiable risk factors and create personal action plans to change lifestyle behaviour in a constructive atmosphere.

Based on a previous study among immigrants groups we anticipated that the Turkish participants might not want to disclose their family history of diabetes in the group sessions (149). However, findings from the pilot study of DiAlert-TR showed that discussion of family history was not a taboo for the Turkish participants (chapter 5). The pilot study of DiAlert-TR did not provide information on risk perceptions, diabetes causality and beliefs of control over the risk. A qualitative
study in Turkish type 2 diabetes patients in Belgium suggests that fatalistic beliefs are important in relation to perceived causality of diabetes [142]. Research has demonstrated that family history information is effective as a tool for risk assessment, screening uptake and prevention of type 2 diabetes [143,144]. Moreover, it is suggested that it can raise awareness for diabetes risk and contributes to promotion to adopt diabetes risk-reducing behaviours in relatives at risk [144]. A systematic review that evaluated the impact of communicating personalized genetic risk information on perceived control over the risk showed that the information does not result in fatalism [145]. Therefore, future studies should evaluate the impact of religion and the role of fatalistic beliefs in the uptake of prevention programs are evaluated.

Finally, evidence from a recent meta analysis on pragmatic diabetes prevention trials showed that the effectiveness of interventions can be improved by maximizing adherence to international guidelines on intervention content and delivery [146]. A good example is the European Evidence-Based Guideline for the prevention of type 2 diabetes (IMAGE) that was developed by a European multidisciplinary consortium after systematic review of evidence on the effectiveness of interventions for type 2 diabetes prevention [64]. The consortium recommends a high risk approach for prevention of type 2 diabetes, by targeting individuals that are at the highest risk and identified the essential elements based on social cognitive behavioural theories that should be included in intervention programs for behaviour change. As the development of DiAlert was informed by HAPA, the intervention covered the essential elements of self-monitoring, self-regulation, goal-setting, action planning, coping strategies and problem solving to support changes in diet and physical activity. Furthermore, the participants were supported to undertake behaviour change while it was acknowledged that behaviour change is not simple and requires appropriate training.

**Process of development and evaluation of DiAlert**

Despite the small effects of the DiAlert intervention on the primary outcome, this thesis provides insights into future pragmatic diabetes prevention aimed at specific individuals at risk. The extensive procedure of development and pilot testing of the intervention provided valuable lessons learned before the RCT was conducted. As described by the revised framework of the Medical Research Council (MRC- framework) the phases of development of a complex intervention allow a cyclical sequence to adapt and understand processes (Figure 1).

For the development of the DiAlert education programme we benefited from previous experiences with diabetes education in the VU University Medical Center (VUMC), because we used the format of the effective diabetes self-management education program PRISMA that has established philosophy and didactics (i.e. an interactive learning approach to stimulate participants to consider their own personal risk factors and to choose a specific goal of behaviour change [146,147]).

A pre-test of the intervention performed with a multidisciplinary panel of diabetes professionals who were familiar with PRISMA provided some minor suggestions for improvement (e.g. changing the sequence of modules). And the pilot study showed to be useful to test procedures for recruitment and outcome measurements. Determination of the sample size for the RCT was not based on results of the pilot study, as the main aim of the pilot was to evaluate the process and feasibility of the group sessions, rather than examine changes of weight loss.

Subsequently, the RCT was performed to assess effectiveness and evaluation of change processes. The group sessions were delivered by skilled diabetes dieticians with good experience in delivery of the PRISMA programme. The trainers received extra training to deliver DiAlert and they used a detailed manual that provided structure and guidance which contributed to a standardised delivery of the intervention.

Following the MRC-framework, the next stage would be implementation of the intervention. Results of the RCT were encouraging in terms of feasibility and acceptability of delivery of the intervention and uptake by participants. However we believe that implementation of the programme in its current form is not recommendable, because the RCT did not show significant effects on weight loss (primary outcome), biomedical outcomes and determinants of behaviour change. Further research is necessary to identify strategies to improve long-term effects on weight loss and cost effectiveness.

For the Turkish target group, we performed just the first two steps of the MRC-framework to develop and pilot DiAlert-TR. More research is needed to determine effectiveness of DiAlert-TR in a representative group of Turkish immigrants living in the Netherlands. However, we concluded that
the short and structured intervention and the family history approach is acceptable for the Turkish target group.

The findings of the study on DiAlert-TR might provide guidance for other target groups at risk. With regard to immigrants from Moroccan and Hindustani origin or people who share same socio-demographic characteristics and low socioeconomic status, some of the adaptations might be appropriate. For example, the pilot study confirmed that basic knowledge about health and diabetes of the Turkish participants was lower than in the Dutch participants of the RCT. Therefore we recommended to add an extra group session to DiAlert-TR to provide opportunities to repeat information and increase uptake of low-educated participants. Furthermore, we suggested that delivery of the intervention by trained bilingual trainers would be more efficient than time-consuming translations.

In addition, the Turkish participants perceived that stress is an important causal factor for type 2 diabetes. In line with other studies that were performed in immigrant populations, high levels of stress related to migration, family and issues at work are often mentioned as cause of a chronic disease. With regard to recommendations for evaluation and implementation of a culturally appropriate version of DiAlert in future, we believe that the short and structured diabetes prevention education programme of DiAlert can provide a good base for a broad range of target groups. However, identification of specific needs is necessary for adaptations targeted at different groups.

**Methodological issues of the randomized controlled trial**

**Study design**

Effectiveness of the DiAlert intervention was evaluated in a RCT, which is traditionally regarded as gold standard for judging the benefits of an intervention. However, some limitations with regard to the methodology of the trial merit attention.

**Blinding**

A major limitation of the study was that the anthropometric measurements were performed by a non-blinded researcher. As a result of this, the measurements of, for example, waist circumference could have been biased because subjective experimenter’s bias could have led towards a result expected by this researcher. Furthermore, the randomization was performed on individual level. In one occasion we had to cluster two participants of the same household to avoid contamination. Baseline characteristics between participants of the intervention and control group were not significantly different. It is, however, possible that participants of different groups knew each other, especially the participants who were recruited by their own general practitioner (GP) were likely to live in the same neighbourhood. Participants could not be blinded for the treatment group but their GPs were only informed about participation of their patient, allocation to the randomization group was not disclosed to them.

When the study was designed, we planned not to inform participants about outcomes of the measurements (as described in the study protocol, chapter 3). Nevertheless, the study information raised awareness and because participants were stimulated to evaluate their health status, the outcomes of the biomedical measurements were provided to the participants. All participants of the trial were referred to their own GP when they were in need for more personal information about diabetes, medication or screening for related (cardiovascular) diseases. This could have contributed to behaviour change in both randomization groups, eliminating possible bias.

**External validity**

The trial was performed in two different settings, namely at a GP practice and an outpatient clinic. We did not observe differences between participants that were invited to participate by their own GP or self-referred to the study after reading an advertisement or leaflet in terms of socio-demographic characteristics nor in risk perceptions or intentions to change behaviour at baseline. This is in favour of the external validity of the study, meaning that the outcomes can be generalized to both settings. Yet, the setting was considered as a potential confounder variable in the statistical analysis, because participants of the different settings could have been differently motivated to participate, but this was not measured objectively.

With regard to the study sample, the study attracted individuals that were (higher) at risk for type 2 diabetes: besides being overweight (or obese) and having a positive family history of type 2 diabetes, multiple other risk factors for diabetes were observed including high blood pressure and elevated glucose levels. This indicates that individuals that could benefit from the intervention were reached.

Furthermore, with the structured and interactive approach of DiAlert, we aimed to reach a broad range of people. The divergence in education level suggests a heterogeneity in socioeconomic status. However, most participants of the RCT were of Dutch origin (80%).

**Sample size**

The Finnish Diabetes prevention study (DPS) and American Diabetes prevention program (DPP) have shown that the aim to loose five to seven percent of the initial body weight is associated with significant health benefits and diabetes risk reduction of more than 50% for developing type 2 diabetes in individuals with Impaired Glucose Tolerance. Power calculations for the DiAlert trial were based on these results because specific data on overweight individuals with a positive family history of type 2 diabetes were not readily available from the pilot study. Taking into account the lower intensity of the intervention and a shorter follow-up time, the study was powered to detect a mean body weight loss of 3.5% at three months follow-up. With the results of the RCT we concluded that the study was underpowered to detect significant changes in weight. The mean weight loss of participants who received the intervention was 1.2% (±4.1%).
Drop-out
More participants in the control group dropped-out from the study as compared to the intervention group (intervention: 6.6% n=3; control: 13.7% n=7). All participants received consent information about the aim of the study and the allocation process prior to randomization. Despite this information, five participants of the control group were disappointed about not being assigned to the intervention group and discontinued participation. Disappointment after allocation to a control group is common in clinical trials[161]. It has been shown that participants can get confused by the concept of randomization[161,162], and participants frequently express a feeling that allocation to the control group is of no benefit to them[162]. Overall the attrition rate in the trial was low suggesting good engagement in the study. However, follow-up of the DiAlert-trial was relatively short. The low numbers hampered a proper analysis of characteristics of the participants that were lost to follow-up.

Measurements
A combination of assessments was used to evaluate characteristics and progress of the participants, including anthropometric measurements, biomedical outcomes from blood samples and questionnaires.

Anthropometric assessment: Anticipated experimenters bias is a major limitation of the anthropometric assessments because the measurements were not blinded for randomization group. As most of the measurements were conducted by one researcher, subjective bias could have led towards a result expected by the experimenter. Technical challenges in obtaining waist circumference could have contributed to lower inter and intra-rater reliability for waist circumference measurements. For example, difficulties in locating anatomical landmarks in obese individuals and/or stabilizing the measuring tape are described in literature[164,165]. However, for the main outcome of weight loss a calibrated scale was used and blood pressure was examined by a fully automated blood pressure monitor.

Questionnaires: Self-report could have led to social desirable answers and recall bias of the participants. One could argue that participants involved in a trial with the aim to change lifestyle are highly motivated and they would give desirable answers. However, it is assumed that this bias was eliminated by randomization.

To assess health status and lifestyle behaviours, mostly validated questionnaires were used. For assessment of the determinants of health behaviour change as defined by HAPA, validated questionnaires were used to assess intentions, self-efficacy beliefs, outcome expectancies and action planning for lifestyle changes. To measure risk perceptions a set of questionnaires was used to assess control beliefs and perceived susceptibility of type 2 diabetes. It should be noted that reliability and validity were not tested for all scales.

With regard to lifestyle behaviour, physical activity was evaluated with the short form of the International Physical Activity Questionnaire (IPAQ)[166] to limit the burden of the assessments. This questionnaire is frequently used and widely validated in research and measures physical activity in a range of settings. Nevertheless, it was designed for large surveys and might not be responsive enough to detect small changes following an intervention[166]. Additional to a questionnaire, the use of accelerometers could have provided more objective and accurate information about the level of physical activity and discrimination of activity patterns[167,168].

Intervention delivery
With regard to the delivery and uptake of the intervention some limitations should be mentioned.

First, the group sessions were delivered by two different trainers. Although, the trainers confirmed feasibility, fidelity and acceptance of the intervention, differences between the trainers (e.g. attitude, communication style, guiding) could have existed. Unfortunately, the number of groups was too small to examine differences in outcomes between trainers.

Second, as action planning is important in the process of health behaviour change in bridging the gap between intentions and behaviour, a major aim of the intervention was assisting participants to formulate personal action plans. Based on evaluations of trainers we know that most participants created a personal action plan, however detailed information about the content and quality of the action plans was not collected. Evaluation of the created action plans can provide information on compliance to the intended behaviour and fidelity of the intervention[164]. Tools to rate the quality of written goals and action plans are now available and could potentially address the gap between intervention fidelity and outcomes[169].

Third, the four newsletters that were mailed to participants after the group sessions were not evaluated with participants. The newsletters were developed following the HAPA framework and focussed on maintenance of behaviour change through discussing self-efficacy beliefs, relapse prevention and provided information on diet and exercise. Evidence from a study that aimed to promote exercise maintenance[170] demonstrated that reflection on experiences with planned actions, as well as, evaluation of action plan adherence in booster sessions can improve maintenance of behaviour and increase levels of satisfaction, and improve self-efficacy beliefs for long-term behaviour change. Delivery of booster information to participants through the internet could provide opportunities to promote and engage participants in maintenance of behaviour change without increasing the intensity of the group intervention.

Reaching relatives at risk for type 2 diabetes
We aimed to recruit first degree relatives of type 2 diabetes patients that were ‘just’ overweight, yet healthy and symptom free. Therefore, we assumed some an interest in the programme but not a strong motivation to engage in diabetes preventive education and readiness to change behaviour, as one might expect in those who are medically ill.
Research has suggested that a positive family history of type 2 diabetes can play a role in motivation of relatives to engage in prevention education \[16,17\] and it can be used to inform decisions about screening and early treatment of type 2 diabetes \[18\]. The literature review (chapter 2) showed that previous diabetes prevention studies aimed at relatives have not utilized family history information as educational strategy for prevention. With regard to recruitment of relatives of type 2 diabetes patients, the review provided insight into successful strategies. Broadly, two different approaches were employed: 1) direct targeting relatives at risk with leaflets and newspaper advertisements, and 2) targeting at relatives via patients with type 2 diabetes registered in health care centres.

**Direct targeting**

For the RCT (chapter 5) different direct strategies were explored to recruit a sufficient number of participants, including invitational letters of GP’s and open recruitment strategies with newspaper advertisements and leaflets. In order to maximize reach of participants, women who were treated for gestational diabetes at the VUMC were identified by their gynaecologist and invited for the study when they were overweight and had a first degree relative with type 2 diabetes. This strategy had a low response rate of 12% and it resulted in only seven eligible participants for the trial. Together, the different strategies were successful to reach 125 participants for the trial. Evaluation of the recruitment process can provide guidance for future prevention programmes that target at individuals with a positive family history of diabetes.

As weight loss and primary prevention of type 2 diabetes was the main goal of DiAlert, primary health care was considered to be the right setting for the RCT. However, it proved to be challenging to find cooperation with GP’s for this project. Although the managers of collaborating GP’s were convinced that prevention of type 2 diabetes was important, the doctors often mentioned limited time and the lack of financial reimbursement to identify potential participants as a barrier for partnership in the trial. Fortunately, five primary care practices with in total 15,363 patients participated in the trial and provided approximately half of the total group of participants in the trial.

A major barrier to the identification of patients at risk for type 2 diabetes in primary care was that risk information (e.g. BMI and family history of diabetes) was not systematically coded in the electronic medical records of the GP’s. This finding was also confirmed by a study with the aim to identify people at risk for undiagnosed type 2 diabetes in Dutch primary care \[19\]. To obtain more information on risk factors in a pragmatic way, patients who got an influenza vaccination were asked to fill out a short questionnaire that assessed weight, height and diabetes family history. Subsequently, the medical records were updated and a selection of patients that met the inclusion criteria for the DiAlert trial was performed (i.e. positive family history, age between 25-65, BMI ≥25 and no other diseases, as described in chapter 3), and the patients were invited by their own GP. The disadvantages of this approach were that patients who receive the influenza vaccination in the Netherlands are relatively old (≥60 years) or they have a disease \[17\], the information was based on self-report and entering the information into the electronic medical records was laborious. However, response rates to the letter were relatively good (51%) and many of the eligible patients were motivated to participate in the trial.

The advantage of recruitment through newspaper advertisements was that we could reach a broad group of people within a small timeframe with relatively small effort. Many individuals at risk were triggered by the advertisement and asked for more information about the study. Apparently, the relatives of type 2 diabetes were aware of their own diabetes risk and were motivated to participate in the trial. This awareness and interest in diabetes prevention could possibly be explained by the increased incidence of diabetes, i.e. more people become a relative of a type 2 diabetes patient and many people are overweight. In addition, in recent years, public attention for prevention of overweight and non-communicable diseases including diabetes and cardiovascular disease has grown. For example, mass media campaigns of the Dutch diabetes foundation and the Dutch diabetes Federation that were specifically targeted at groups at risk, including ethnic minority groups and people with a positive family history could have contributed to improved risk awareness in the general population.

**Targeting relatives via patients with type 2 diabetes**

As previous studies have demonstrated that relatives of patients with diabetes are generally receptive to being informed via the family system about their diabetes risk \[17,17,17\], a strategy to recruit participants via patients with type 2 diabetes was explored. However, the leaflets and information letters that were distributed among type 2 diabetes patients treated in the outpatient clinic of VUMC did not result in participation of their first degree relatives. As described by van Esch et al., coaching of patients to carry out a messengers’ role in the family and providing recommendations about how, when and which relatives to inform is important when family system is utilized in diabetes prevention \[17\], but the written information about the DiAlert trial provided by the physicians was not accompanied by such information.

**Targeting Turkish relatives of type 2 diabetes patients**

An important aim of the pilot was to evaluate effective recruitment practices to reach overweight Turkish relatives of type 2 diabetes patients in the Netherlands. Recruitment was performed with the help of a Turkish health educator, because research has shown that the use of ethnically matched recruiters can result in higher receptivity \[17\], it can be of importance for trust building \[17\] and delivery of tailored messages that are culturally appropriate \[17\]. Recruiting participants, especially those of minority descent and lower educated, is frequently described as a difficult aspect of conducting health promotion research \[17,17\].

A qualitative study that performed focus group discussions with Turkish migrants living in Germany identified barriers and facilitators for participation in research. The barriers included a lack of knowledge (e.g. attributed to low education and knowledge levels as well as a lack of desire to obtain an education and to increase their general knowledge), mistrust, anxiety and concerns about data privacy protection. The company of friends or people who know each other was identi-
Implementation of prevention targeted at relatives at risk

In the Netherlands the number of people with diabetes is expected to rise to 1.3 million people in 2025. It figures that prevention is an important theme in healthcare policy documents published by the Dutch government over the past decade. In 2003, the Dutch ministry of Health, Welfare and Sport prioritized prevention of chronic disease with focus on lifestyle and behaviour changes for individuals at risk. In 2007, the ministry advocated that embedding prevention in routine (primary) care is evident. Currently, the government promotes the ‘national programme prevention’ (in Dutch: Nationaal Programma Preventie 2014-2016) together with different public health-, municipality-, commercial-, educational- and welfare-partners. Long term aims for 2030 were formulated with a prominent role for health promotion and prevention of chronic diseases through an integrated approach.

Traditionally, the GP has an important role in the identification of individuals at risk because all Dutch citizens are registered with a GP. Results from a survey study among 156 Dutch GPs in 2011 confirmed that 88% of them believed that they have a responsibility to discuss a healthy lifestyle with patients and 75% confirmed that the GP has the task to prevent future health problems in their patients. A qualitative study that we performed with 19 Dutch health care professionals gave insight into opportunities to use diabetes family history information in diabetes prevention. The professionals expressed positive attitudes to the use of family history as an important risk factor in opportunistic screening for type 2 diabetes and promotion of health behaviour change. Targeting preventive education to at risk relatives of patients with type 2 diabetes was desired by professionals in primary care, but feasibility of the approach was considered to be low as family history information is often not present in medical records.

Implementation of the new guideline ‘The Prevention Visit’ (in Dutch: het Preventieconsult) for primary prevention of cardio metabolic diseases in Dutch primary care could contribute to tailored health promotion advice. Following this guideline, individuals at risk for type 2 diabetes, cardiovascular disease and/or kidney disease are identified through an eight-item self-report questionnaire that assesses age, gender, body mass index, waist circumference, current smoking, family history of myocardial infarction or stroke and family history of type 2 diabetes. Individuals with a high risk score are advised to visit their GP for a complete risk assessment and tailored advice or treatment according to the Dutch College of General Practitioners’ guideline ‘Cardiovascular Risk Management’. When this guideline is common practice in Dutch primary care, data about family history of type 2 diabetes and cardiovascular disease will become available for the GP. This provides perspectives for targeting primary prevention to relatives at risk for chronic diseases in future. However, when implementing an intervention for relatives at risk for a chronic disease, it should be low intensive in order to be feasible to deliver and attractive to participants. As shown by the DESMOND intervention trial, a short intervention that helps participants to formulate personal goals for behaviour change (e.g. weight loss) is likely to be cost effective. To improve the effect on behaviour change outcomes, cooperation with existing facilities is warranted.

Recommendations for future research

The worldwide high prevalence of type 2 diabetes stresses the need for diabetes prevention programmes that are effective but feasible to be delivered in terms of costs and attractiveness for individuals who are at risk, but not yet diagnosed with a chronic disease. To find a balance between efficacy and feasibility, investigation of low-intensive and structured group diabetes prevention education programmes that are grounded in behaviour change theories and employ self-regulation strategies to formulate realistic and individually tailored action plans to change health behaviour are needed.

Regarding the small effects of the DiaAlert intervention on the primary outcome of weight loss, future studies should explore techniques to improve performance of action plans after the group sessions of DiaAlert, for example by obliged referral of participants to existing facilities for healthy lifestyle programmes (e.g. sports facilities). Evaluation of follow-up counselling through internet should be considered to optimize personal action planning and reformulation of plans to increase uptake and maintain long term health behaviour change.

The studies in this thesis showed that the family history approach was feasible to reach overweight individuals at risk due to their positive family history of diabetes. Both Dutch and Turkish first degree relatives of patients with type 2 diabetes were willing to discuss family history in relation to prevention of diabetes. The discussions at the group sessions of DiaAlert provided much information about worries, interests and questions of the relatives at risk for diabetes. Analysing this quantitative data about the specific beliefs might provide opportunities for dissemination of diabetes risk information that is targeted to relatives at risk in future. For example, the question asked by the participants can guide information delivery, or the beliefs expressed by participants could be used as peer support in texts for diabetes prevention materials.

As the family is a fundamental social network, a family-oriented intervention approach that tar-
get more members of one family with a positive first or second degree family history of diabetes should be considered. For example, a type 2 diabetes patient can be asked to invite his/her relatives with their own families to participate in lifestyle education together. With such an approach, participants of the group sessions are familiar to each other and this could contribute to social support and by that increase self-efficacy for health behaviour change. Furthermore, relatives could be stimulated to formulate action plans together. Disclosure of diabetes family history and worries was not an issue for the Turkish participants in our pilot study, but targeting a whole family might facilitate recruitment and participation in prevention programmes, because information will be discussed with relatives only.

Finally, blinded trials with large sample size and long follow-up are required to be able to draw valid conclusions on effectiveness of feasible lifestyle education programmes aimed at relatives to prevent type 2 diabetes in terms of morbidity and mortality rates and cost-efficiency.

**Conclusion**

This thesis suggests that the new short and structured diabetes prevention education programme called “DiAlert”, that was targeted at first degree relatives of type 2 diabetes with overweight is promising to reach a relevant weight loss and decrease waist circumference. Development and evaluation of the DiAlert intervention was extensive and provided insights into developmental processes. As the effectiveness of the intervention compared to the control condition was unsatisfactory, further research is needed in order to increase effects on weight loss.

This thesis showed that family history was a good starting point to reach and engage relatives at risk from different ethnic backgrounds in diabetes prevention, making individuals at familial risk for chronic diseases an interesting population for further study.
Type 2 diabetes has become one of the most important chronic diseases and has a huge impact on patients and health care costs globally. Large clinical trials have provided evidence that modest changes in diet and increase of physical activity can reduce the incidence of type 2 diabetes. In addition to lifestyle related risk factors, evidence has shown that genetic predisposition contributes to the development of type 2 diabetes. A positive family history of type 2 diabetes is recognized as an indicator for susceptibility for the disease and it is often used as a marker to identify individuals at risk. Furthermore, it is suggested that individuals with a family history may be more motivated to engage in preventive behaviour as result of raised perceived susceptibility.

This thesis described the development and evaluation of effectiveness of DiAlert: a structured diabetes prevention education programme targeted to overweight first degree relatives of type 2 diabetes patients.

**Development of DiAlert**

As outlined in chapter 2, a review provided an overview of the literature about diabetes prevention interventions targeting people with a positive family history of type 2 diabetes. We found six studies, reporting on three RCT’s, two pre-post intervention studies and a non-randomized comparative study, that were performed in Europe, the United States and Asia. The studies included overweight relatives of type 2 diabetes patients, most of the studies targeted at first degree relatives. For the review, we had special interest in the recruitment strategies performed, the content of the interventions and whether family history information was used to motivate the participants to engage in lifestyle change in order to prevent type 2 diabetes.

First, the recruitment strategies that were employed in the studies varied from direct recruitment of individuals at risk by contacting patients with a registered family history from medical records and through advertisements in newspapers to invite participants. The other recruitment strategy involved utilisation of index patients with type 2 diabetes who were asked to invite their relatives to participate. Only three of the six studies mentioned briefly that the intervention was aimed at relatives because a positive family history of diabetes puts them at increased risk of type 2 diabetes.

Second, we evaluated the content of the interventions that were included in the review. Although the design of the studies differed, all studies reported on lifestyle counselling techniques with focus on healthy diet and/or physical activity. Our main finding was that family history information was only used as an identifier of individuals at risk for type 2 diabetes. To our surprise, the information was not utilised to enhance motivation for lifestyle change by for example, addressing perceptions of risk, controllability, worries or beliefs of fatalism related to a positive family history of type 2 diabetes.

In chapter 3, a description of the development of the DiAlert education programme is given. Findings from the literature review and evidence of diabetes prevention trials informed development of the intervention. The programme follows the format of the existing theory based diabetes self-management programmes in the United Kingdom (DESMOND) and the Netherlands (PRISMA Dutch acronym: Pro-actieve Interdisciplinaire Self-Management) that have shown to be successful in initiating behaviour change in patients with type 2 diabetes.

DiAlert is based on social cognitive behavioural theories, specifically on the Health Action Process Approach (HAPA) that identifies three key determinants of health behaviour change: risk perception, self efficacy beliefs and outcome expectancies. In chapter 3, a detailed overview of the modules of the DiAlert group sessions is provided. Briefly, the sessions include exploration of diabetes knowledge, identification of concerns and worries about type 2 diabetes, a discussion of risk factors and development of type 2 diabetes, practical recommendations and interactive skills training for balancing energy intake and expenditure to prevent type 2 diabetes.

An important aim of the intervention is personal goal setting and action planning for health
behaviour change with focus on a healthy diet and physical activity. According to the study protocol and the design of the RCT, we hypothesized that for overweight individuals with a first degree relative with type 2 diabetes DiAlert is effective to promote weight loss and thereby reduce the risk of type 2 diabetes development.

Pilot: testing feasibility, fidelity & acceptability of DiAlert

After development of the intervention, a pilot study was performed. As described in chapter 4, the main aim of pilot study, was to evaluate the feasibility, fidelity and acceptability of the DiAlert education programme to ensure that the design and setting of the DiAlert intervention was appropriate for the target group prior to commencing a RCT. Furthermore, pre-post changes of the determinants of health behaviour change that were based on HAPA were assessed.

In the pilot study, 22 participants were recruited and assigned to two different intervention groups. Feasibility of the group sessions was confirmed; all modules were delivered in time and the intervention was highly appreciated by participants. The intervention was delivered as planned following the underlying philosophy and participants discussed family risk information and they expressed their concerns about their risk of developing diabetes, both for themselves and for their offspring confirming fidelity. The intervention had no effect on personal control beliefs and worries about development of type 2 diabetes, indicating that the risk information did not result in fatalism or extreme worries. The pilot confirmed that no changes of the intervention were anticipated for the proposed RCT. However, recommendations were formulated to recruit a representative sample of men and women from a broad range of socioeconomic classes for the RCT. In addition, the focus of the intervention should stay on prevention of type 2 diabetes rather than discussing problems and complications of relatives with type 2 diabetes.

Evaluation of effectiveness of DiAlert

In chapter 5, results of the RCT are described. Effectiveness of the DiAlert education programme was tested by comparison of the DiAlert intervention (N=45) against a control group (N=51) who received only written information about diabetes prevention and a leaflet about diabetes and their relatives’ cardiovascular disease. A small, but non-significant change of the primary outcome of weight loss was observed. Different recruitment strategies were necessary to reach overweight first degree relatives of type 2 diabetes patients for the trial. The structured, low-intensive group intervention demonstrated good attendance and engagement and participants were supported to reduce their diabetes risk.

Development of DiAlert-TR: a culturally appropriate version of DiAlert for Turkish overweight relatives of type 2 diabetes patients

Chapter 6 describes the development and pilot-test of a culturally appropriate version of DiAlert for overweight Turkish first degree relatives (DiAlert-TR). Turkish people, who originally were labour immigrants, are among the largest group of immigrants living in the Netherlands accounting for approximately 2.3% (393,000 individuals) of the total population. As the prevalence of obesity, cardiovascular disease and type 2 diabetes is high among Turkish migrants it is important that this group will benefit from lifestyle programmes to prevent type 2 diabetes. As it is suggested that culturally appropriate interventions help improve outcomes of diabetes education programmes, we adapted the DiAlert intervention in order to be effective for overweight Turkish relatives of people with type 2 diabetes.

Adaptations were informed by literature, expert opinion and pretesting in Turkish immigrants. Essential core elements based on theoretical underpinnings of DiAlert were identified to keep the content and aims similar to the original intervention after adding cultural content. Five major adaptations for DiAlert-TR were identified, including: simplified risk information, more extensive discussion of the role of stress as a risk factor for diabetes, inclusion of typical Turkish food products, simplified action plan worksheets and a bilingual Turkish-Dutch trainer to assist with translations of modules. Mainly low-educated females who were born in Turkey and migrated to the Netherlands were reached for the a pilot study. First findings demonstrate fidelity and acceptability of a short group-based diabetes prevention education programme in overweight Turkish immigrants with a positive family history. Participants showed engagement in group sessions and were able to formulate personal action plans to improve their health behaviours. However, the assistance and translations of a bilingual trainer proved essential to ensure successful action planning. Future studies should evaluate the effectiveness of DiAlert-TR in the context of diabetes prevention and related cardiovascular disease.
Conclusion

This thesis suggests that the new short and structured diabetes prevention education programme called “DiAlert”, that was targeted at first degree relatives of type 2 diabetes with overweight is promising to reach a relevant weight loss and decrease waist circumference. Development and evaluation of the DiAlert intervention was extensive and provided insights into developmental processes. As the effectiveness of the intervention compared to the control condition was unsatisfactory, further research is needed in order to increase effects on weight loss.

This thesis showed that family history was a good starting point to reach and engage relatives at risk from different ethnic backgrounds in diabetes prevention, making individuals at familial risk for chronic diseases an interesting population for further study.

Samenvatting

Diabetespreventie educatie gericht op Nederlandse en Turkse familieleden van patiënten met diabetes type 2: de ontwikkeling en evaluatie van DiAlert.
Diabetes type 2 is een chronische ziekte waarbij het lichaam de bloedsuikerspiegel niet meer goed binnen de normale grenzen kan houden. Dit is het gevolg van een tekort aan het hormoon insuline in het lichaam en bovendien reageert het lichaam niet meer goed op insuline. Wereldwijd hebben ongeveer 382 miljoen volwassenen diabetes. Onderzoekers verwachten dat dit aantal zal stijgen naar 592 miljoen in het jaar 2035.

Welbekende risicofactoren voor diabetes type 2 zijn een ongezonde leefstijl en overgewicht in combinatie met ouderdom. Daarnaast blijkt uit onderzoek dat familieleden van patiënten met diabetes type 2 een verhoogd risico hebben om zelf diabetes te ontwikkelen. Voor hen is de kans om diabetes type 2 te krijgen twee tot vijf keer groter dan voor mensen zonder een familiegeschiedenis. Onderzoek naar preventie van diabetes type 2 toont aan dat het verbeteren van leefstijl door gezond te eten en regelmatig te bewegen en af te vallen de kans op diabetes kan verlagen. Door het groeiende aantal patiënten met diabetes type 2 is er behoefte aan interventies die effectief en haalbaar zijn in de praktijk.

In de periode 2009-2014 ontwikkelden en evalueerden we een korte leefstijlinterventie, genaamd DiAlert. Deze interventie is speciaal gericht op mensen met overgewicht die een eerste- of tweedegraadsfamilielid (d.w.z. vader, moeder, broer of zus) hebben met diabetes type 2. Het doel van DiAlert is mensen helpen hun gewicht te verminderen om hun risico op diabetes te verlagen.

In dit proefschrift zijn de studies naar DiAlert beschreven.

**Literatuur over diabetespreventie voor familieleden (hoofdstuk 2)**
Allereerst voerden we een uitgebreid literatuuronderzoek uit om de wetenschappelijke literatuur over diabetespreventie speciaal gericht op familieleden van patiënten met diabetes type 2 in kaart te brengen. Zes verschillende studies werden gevonden en samengevat in een review. Aan alle studies deden mensen mee met overwegend bij wie diabetes type 2 in de familie voorkomt.

Het doel van de review was tweeëndertig. Ten eerste waren we geïnteresseerd in de strategieën die werden gebruikt om familieleden van diabetes type 2 patiënten te werven voor onderzoek. De wervingsstrategieën variëren van directe tot indirecte strategieën. Patiënten met een familiegeschiedenis werden direct geselecteerd uit medische dossiers of ze werden geworven door middel van advertenties in kranten. Indirect werd er gewerkt door een familieled met diabetes type 2, zij werden gevraagd om hun familieleden te informeren over de studie.

In slechts drie van de zes studies vertelden de onderzoekers aan de familieleden dat zij gevraagd werden om deel te nemen aan onderzoek omdat zij een hoger risico hebben om de ziekte te krijgen.

Ten tweede wilden we de inhoud en aanpak van de interventies evalueren. Alle zes de studies richtten zich op het verbeteren van leefstijl door middel van adviezen over gezonde eetgewoontes en het stimuleren van bewegen. Een belangrijke bevinding was dat de informatie over familiegeschiedenis alleen werd ingezet om mensen mee met een verhoogd risico op diabetes type 2 te identificeren. Verassend genoeg werd de informatie niet gebruikt om de familieleden te motiveren om hun leefstijl aan te passen, bijvoorbeeld door het bespreken van risico (perceptie), zorgen over diabetes en fatalistische gevoelens over het voorkomen van diabetes in de familie.

**De ontwikkeling van DiAlert (hoofdstuk 3)**
De resultaten van de review (hoofdstuk 2) en ervaringen uit andere diabetespreventie onderzoeken werden gebruikt voor de ontwikkeling van DiAlert, een diabetespreventie educatieprogramma. DiAlert is gebaseerd op sociaal cognitieve gedragstheorieën en bestaat uit twee groepsbijeenkomsten van 150 minuten. Het doel is het verhogen van de intrinsieke motivatie voor gedragsverandering, vertaald in een concreet persoonlijk actieplan voor gewichtsafname door leefstijlaanpassingen. Kort samengevat, wordt er in de groep sessies van DiAlert aandacht besteed aan kennis van diabetes, zorgen en vragen over diabetes, risicofactoren voor diabetes type 2, praktische adviezen voor het aanpassen van eetgewoonten en bewegen door interactieve opdrachten gericht op de balans tussen energie-inname en verbruik. De hypothese is dat het DiAlert educatieprogramma effectief is om mensen met overgewicht die een eerste- of tweede graadsfamilieled zijn van een patiënt met diabetes type 2 te laten afvallen en daarmee hun risico op diabetes type 2 te verkleinen.

**Pilot: testen van de haalbaarheid, geschiktheid en acceptatie van DiAlert (hoofdstuk 4)**
Nadat DiAlert was ontwikkeld voerden we een pilot uit om de interventie te testen. In hoofdstuk 4 staan de resultaten van deze pilot beschreven. Het doel van de pilot was om de haalbaarheid, de geschiktheid en de acceptatie van het DiAlert educatieprogramma voor de doelgroep te testen voordat we een grotere gerandomiseerde studie zouden uitvoeren.

Aan de pilot deden tweeëntwintig familieleden mee in twee verschillende groepen. Op basis van de pilot concludeerden we dat de interventie haalbaar was. Alle modules werden binnen de geplande tijd gegeven en de deelnemers waren enthousiast. De deelnemers bespraken hun zorgen en vragen over hun risico op diabetes. De interventie had geen negatief effect op gevoelens van controle en zorgen over het persoonlijk risico op diabetes. Met andere woorden, de informatie over het risico op diabetes veroorzaakte geen fatalisme of ernstige zorgen bij de deelnemers.

Op basis van de pilot studie bleken geen verdere aanpassingen aan de interventie noodzakelijk.

**Evaluatie van het effect van DiAlert (hoofdstuk 5)**
De effectiviteit van het DiAlert educatie programma werd getest in een zogenaamde Randomised Controlled Trial. Hiervoor werd de DiAlert interventie (45 deelnemers) vergeleken met een controlegroep (51 deelnemers). Deelnemers in de interventiegroep namen deel aan twee DiAlert bijeenkomsten en deelnemers in de controlegroep kregen een folder met informatie over diabetes en erfelijkheid en diabetespreventie aan te bieden. Op basis van lichamelijk onderzoek naar gewicht, middelomtrek en bloeddruk concludeerden we dat DiAlert geen effect heeft op de gemiddelde gewichtsafname. Deelnemers in zowel de interventie als de controlegroep bereikten een klein, maar niet significant, gewichtsverlies na negen maanden. Toch zijn de resultaten van het onderzoek hoopgevend, omdat meer deelnemers uit de interventiegroep 5% van hun startgewicht verloren in vergelijking met deelnemers uit de controlegroep. Daarnaast was er een significante verbetering van de middelomtrek en een relevante verbetering van de systolische
Conclusie
Het traject van ontwikkeling tot evaluatie van DiAlert is beschreven in dit proefschrift. Op basis van de resultaten van de studies, opgenomen in dit proefschrift concluderen we dat het korte en gestructureerde diabetespreventieve programma “DiAlert” dat gericht is op eerstegraads familieleden van patiënten met diabetes type 2 kansrijk is. Deelnemers van DiAlert bereikten een Relevant gewichtsverlies en verminderden hun middelomtrek. Echter, meer onderzoek is noodzakelijk om het effect op de gewichtsafname te vergroten.

Het gebruik van informatie over familiegeschiedenis is een goed startpunt om familieleden met een verhoogd risico op diabetes met een verschillende etnische achtergrond te bereiken en hen te motiveren deel te nemen aan diabetespreventie. Naaste familieleden van patiënten met diabetes type 2 vormen daarom een interessante doelgroep voor onderzoek naar diabetespreventie in de toekomst.

De ontwikkeling van DiAlert-TR: een cultureel specifieke versie van DiAlert voor Turkse familieleden van patiënten met diabetes type 2 en overgewicht. (Hoofdstuk 6)
De Turkse bevolking vormt de grootste groep allochtonen in Nederland, met 393.000 personen vormen zij 2,3% van de totale Nederlandse bevolking. Het is bekend dat overgewicht, diabetes en hart- en vaatziekten vaker voorkomen onder de Turkse bevolking. Daarom is het van belang dat deze doelgroep wordt bereikt met diabetespreventieprogramma’s. Er wordt verondersteld dat aanpassingen van de interventie aan specifieke culturele waarden van een etnische minderheids-groep de resultaten van diabetes educatie positief beïnvloedt. Daarom ontwikkelden we een cultureel specifieke versie van DiAlert voor Turkse familieleden van patiënten met diabetes type 2. In hoofdstuk 6 is de ontwikkeling en pilot test van DiAlert-TR beschreven.


De pilotstudie werd uitgevoerd met twee groepen Turkse familieleden. We bereikten met name laagopgeleide vrouwen die geboren waren in Turkije (eerste generatie allochtonen). Op basis van de pilot concludeerden we dat de aangepaste interventie werd geaccepteerd door de Turkse deelnemers. Ze waren erg betrokken in de groep sessies en ze formuleerden allemaal een persoonlijk actieplan om hun leefstijl aan te passen. Echter, het bleek noodzakelijk om modules te vertalen in het Turks en de deelnemers hadden hulp nodig van de trainers om een actieplan op te stellen. Om meer te kunnen zeggen over de effectiviteit van DiAlert-TR op diabetespreventie en gerelateerde hart- en vaatziekten is verder onderzoek noodzakelijk.


131. Renzaho AM, Mellor D, Boulton K, Swinburn B: Effectiveness of smoking interventions aimed at smoking cessation, diet, and/or physical activity in ethnic minorities. a systematic review. PLoS One 2013, 8: e73373.


Publications


Wieke Heideman was born in Naarden on May 14, 1984. She grew up in Weesp, a small historic town south-east of Amsterdam, on the river Vecht. After secondary school at Het Goois Lyceum in Bussum, she studied physical therapy at the Hogeschool van Amsterdam. In 2005 she obtained her bachelor degree and worked as a part-time physical therapist for two years.

In 2005 Wieke was admitted to the pre-master of General Health Sciences of the VU University Amsterdam and obtained her Master of Science degree in 2007. The focus of her Master thesis was body weight changes in breast cancer survivors. She started working as a research assistant on several research projects at the Dutch Cancer Institute, department of cancer epidemiology.

In February 2009 she started as a PhD-student at the Diabetes Psychology Research Group at the VU University Medical Center in Amsterdam. The research project includes a lifestyle intervention in first degree relatives of persons with type 2 diabetes (the DiAlert Project). Wieke developed the short structured DiAlert intervention for Dutch and Turkish relatives of type 2 diabetes patients and coordinated data collection and analyses. She wrote publications about the findings and presented them at several (inter)national conferences and meetings.