

gets 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.

Summary

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 underlining 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 heredity. A small, but non-significant change of the primary outcome of weight loss was observed in both treatment groups. The study demonstrated significant decrease of waist circumference in participants who received the two 150 minutes of structured education of DiAlert, after nine months (-4.33 cm, $P<0.01$). Moreover, significantly more participants in the intervention group reached 5% reduction of their initial body weight and a trend was observed for improvement of systolic blood pressure in the intervention group. No effects on biomedical outcomes (i.e. fasting

glucose, insulin total cholesterol, LDL, HDL and triglycerides) or determinants of behaviour change were 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.