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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

Wieke H. Heideman [a,*], Maartje de Wit [a], Barend J.C. Middelkoop [b], Vera Nierkens [c], Karien Stronks [c], Arnoud P. Verhoeff [d,e], Frank J. Snoek [a]

[a] Department of Medical Psychology, The EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
[b] Department of Public Health and Primary Care, Leiden University Medical Centre, Leiden, The Netherlands
[c] Department of Public Health, Academic Medical Centre, University of Amsterdam, Amsterdam, The Netherlands
[d] Department of Epidemiology, Documentation and Health Promotion, Amsterdam Municipal Health Service, Amsterdam, The Netherlands
[e] Department of Sociology and Anthropology, University of Amsterdam, Amsterdam, The Netherlands

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ABSTRACT

Objectives: To test the efficacy of a low-intensive lifestyle education program (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, behavioral and psychological measures. Comparisons were made over time and between 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 ($P = 0.03$). Significant improvement of waist circumference sustained after 9 months in the intervention group (intervention: −4.33 cm, $P < 0.01$/control: −1.25 cm, $P = 0.08$). Systolic blood pressure improved within the intervention group (intervention: −8.77 mmHg, $P < 0.01$/control: −1.03 mmHg, $P = 0.60$). No effect was observed for biomedical and psychosocial outcomes.
Conclusions: Our low-intensive structured lifestyle education program 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.

1. 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% [1,2]. Raising public awareness and timely identification of high-risk individuals are therefore warranted. Therefore, easy-to-administer, non-invasive diabetes risk tests have been developed such as the FINDRISC [3]. 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 2–5 fold increased risk of developing diabetes compared to those without a FH [4,5] 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 [7], only few studies have addressed FH in diabetes prevention programs, taking the specific worries and needs of relatives into account.

Since the publication of the results of the Finnish Diabetes Prevention Study (DPS) and American Diabetes Prevention Program (DPP) [1,2], efforts have been made to translate the evidence into primary care and community settings. Meta-analyses have confirmed the feasibility of low intensive diabetes prevention interventions in a real-world setting, although with lower levels of weight loss compared to experimental trials

* Corresponding author at: Van der Boechorststraat 7, 1081BT Amsterdam, The Netherlands. Tel.: +31 204445682; fax: +31 204448230.
E-mail address: w.heideman@vumc.nl (W.H. Heideman).

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[8,9]. Pragmatic diabetes prevention interventions yield a clinically meaningful effect on prevention of diabetes and cardiovascular disease despite a drop in effectiveness on weight loss overt time [10], based on the DPP study that showed that each kilogram of weight loss is associated with a reduction of 16% in future diabetes incidence [11]. 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 [12]. 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 [13]. 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 behavioral theories that should be included in intervention programs for behavior change.

We are the first to have developed a low-intensive, structured group lifestyle education program specifically aimed at overweight first degree relatives of type 2 diabetes patients, named DiAlert [14]. In a pilot study DiAlert proved to be highly acceptable, feasible and promising with regard to increased motivation and action planning for lifestyle change [15].

The development of DiAlert was informed by the Health Action Process Approach (HAPA) [16], 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.

The primary aim of this study was to assess the efficacy of DiAlert in terms of body weight loss in order to prevent type 2 diabetes in Dutch overweight individuals with a FH of type 2 diabetes. Secondary outcomes were change in waist circumference, blood pressure, metabolic, behavioral and psychological parameters.

2. Methods

A detailed study protocol of the DiAlert trial has been reported elsewhere [17]. 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 eligible participants. The inclusion criteria were age between 25 and 65 years, at least one first degree relative with type 2 diabetes and being overweight (Body Mass Index (BMI) of $\geq$25 or waist circumference >88 cm for females and >102 cm for males). The focus of the trial was primary prevention; therefore, we excluded individuals diagnosed with type 1 or 2 diabetes. Further exclusion criteria were: current 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.

2.1. Reach

To maximize reach, we employed four different recruitment strategies: (1) 123 persons with a registered FH of diabetes and a BMI $\geq$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 to <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 form charts and invited for the study.

2.2. Procedures and setting

After signing informed consent, participants were randomly assigned to the intervention or control group. The concealed allocation sequence was generated by an independent researcher with serially numbered sealed envelopes. 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.

2.3. Intervention

The development of DiAlert was guided by the Health Action Process Approach (HAPA) [16], a social cognitive model with empirical evidence in the field of prevention. HAPA distinguishes two behavior 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 behavior change. The intervention build on the DESMOND-format [18] and consists of two interactive group sessions of 150 min delivered over 2 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 behavior 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 and 2) or at the outpatient clinic of VUMC (strategy 3 and 4).

2.4. 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.

2.5. Measurements

Measurements were scheduled at baseline and at 3 and 9 months (see Fig. 1).

2.5.1. Anthropometric data

The primary outcome of body weight was measured with one calibrated digital scale (Seca 888). Participants were weighed 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 M5-I). Mean value of the two measurements was computed.

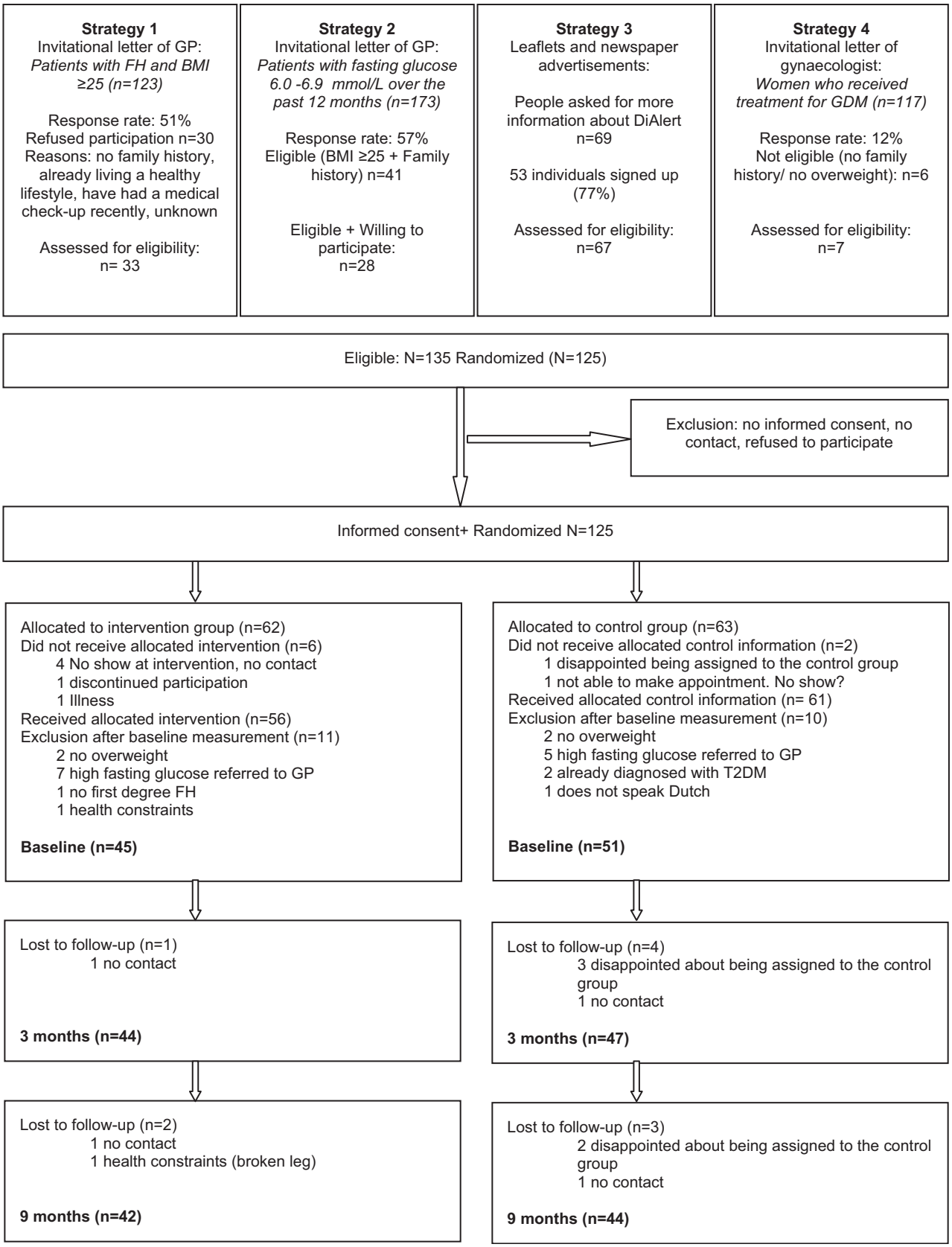

Fig. 1. Flow diagram.

2.5.2. Laboratory assessments

Blood samples were obtained and analyzed 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) [19].

2.5.3. Questionnaire

A detailed overview of the self-report measures was described elsewhere [17]. 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 behaviors (fruit, vegetable and snack intake per week), smoking status and alcohol intake and physical activity (using the International Physical Activity Questionnaire: IPAQ-short form [20]). Health-related quality of life was measured with the EQ5D [21]. We used The Kessler-10 scale (K10) [22] to assess psychological distress.

Determinants of behavior change based on HAPA were assessed with questions about risk perception, including perceived causal beliefs, consequences and control of diabetes [23] comparative risk, estimation of risk and emotional representation [24], 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 [25] (see Table 3 for exact wording of behavioral and psychological measures).

2.6. 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%, $P = 0.05$). We aimed to recruit 67 participants per group to allow for drop out (15%) and diagnosis of diabetes (10%).

2.7. Statistical methods

Statistical analyses were conducted using SPSS 20.0 software. Student's *t*-tests and χ^2 tests were employed to compare baseline characteristics between intervention groups. We performed generalized estimating equations (GEE) for anthropometric and biomedical parameters. Interaction effects of group (intervention versus control group) × time (baseline, 3-month and 9-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 behavioral and psychological variables were analyzed 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.

3. 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 Fig. 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 ≥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 4–7) 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 disappointment about not receiving the intervention.

3.1. Baseline characteristics

Mean age of the sample was 55 ± 8.6 years, 67.7% female ($n = 65$), 49.5% ($n = 47$) was lower educated. The study sample was 80% Dutch origin; others reported a variety of ethnic origins, including Suriname ($n = 4$, 4.2%), Antilles ($n = 2$, 2.1%) and Netherlands East Indies ($n = 4$, 4.2%). Most participants were offspring of a type 2 diabetes patient (89.6% ($n = 86$)) and obese, mean BMI was 30.5 ± 4.2 kg/m^2 (see Table 1). Mean fasting glucose was 5.6 ± 0.6 mmol/L. Elevated fasting plasma glucose (>5.6 < 6.9 mmol/L) was determined in 54.7% ($n = 52$). In both groups, attempts to loose weight in the past 5 years were frequently reported (median = 3). No significant differences were found for characteristics between the intervention and control group (except a borderline significant difference in anti-depressants ($P = 0.05$) which was higher in the control group).

Participants were moderately worried about developing diabetes (mean: 4.6 ± 1.8 on a 7-point Likert scale) and estimated their own risk to develop diabetes in the next 5 years to be only just slightly higher than for other people of their age (4.2 ± 1.5 on a 7-point Likert scale). Participants reported moderate to strong intentions to increase physical exercise (3.8 ± 0.7), improve dietary habits (3.6 ± 0.8) and to loose body weight 3.8 ± 0.8 (5-point Likert scale) (see Table 3).

3.2. Change in anthropometric variables

Weight changes over time were not significantly different between groups ($P = 0.48$), with a slight non-significant weight loss observed in the intervention group at 3 and 9 months (−0.88 kg, 95% CI −1.90:0.15 and −0.54 kg, 95% CI −1.86:0.79), versus a small weight gain in the control group (−0.24 kg, 95% CI −0.80:−0.33 and +0.38 kg, 95% CI −0.43:1.19) (Table 2). Significantly more participants in the intervention group versus controls lost at least 5% of their initial body weight after 9 months ($n = 11$ versus $n = 4$, $P = 0.03$).

GEE analysis confirmed a significant intervention by time interaction effect of waist circumference between the groups ($P = 0.01$). Both groups showed a significant decrease of waist circumference after three months (intervention: −4.24 cm, 95% CI −5.99:−2.49 versus control: −1.30 cm, 95% CI −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 versus 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 9 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.

Table 1
Baseline characteristics of participants of DiAlert.

Characteristics	Total ($N=96$)		Control group ($n=51$)		Intervention group ($n=45$)		P-value
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	
Age	96	55.0 ± 8.6	51	54.5 ± 8.7	45	55.6 ± 8.6	NS
% (n) women	96	67.7% (65)	51	70.6% (36)	45	64.4% (29)	NS
% (n) Dutch	96	80% (76)	51	80% (40)	45	80% (36)	NS
% (n) married – with partner	96	69.5% (66)	51	72% (36)	45	66.6% (30)	NS
Education[a]	96		50			45	
Low		49.5% (47)		48% (24)		51.1% (23)	NS
Middle		18.9% (18)		18% (9)		20% (9)	NS
High		31.6% (30)		34% (17)		28.9% (13)	NS
1st degree family history	95		51			45	
% (n) with Parental FH		89.6% (86)		88.2% (45)		91.1% (41)	NS
% (n) with Siblings FH		34.4% (33)		33.3% (17)		35.6% (16)	NS
Self-reported medication use							
% (n) blood pressure		25.3% (24)		24% (12)		26.7% (12)	NS
% (n) cholesterol lowering		16.8% (16)		16% (8)		17.8% (8)	NS
% (n) anti-depression		11.6% (11)		18% (9)		4.4% (2)	0.05
Anthropometrics							
Body Weight (kg)	95	87.2 ± 14.8	51	88.2 ± 15.7	45	86.0 ± 13.7	NS
Body mass index (kg/m^2)	95	30.5 ± 4.2	51	31.1 ± 4.7	45	29.9 ± 3.6	NS
Waist circumference (cm)	95	101.3 ± 11.0	51	101.0 ± 11.6	45	101.6 ± 10.4	NS
Systolic blood pressure (mmHg)	94	140.1 ± 20.7	50	137.6 ± 19.0	45	142.8 ± 22.3	NS
Diastolic blood pressure (mmHg)	94	89.2 ± 12.6	50	88.6 ± 11.8	45	89.8 ± 13.6	NS
Laboratory							
Fasting Glucose (mmol/l)	95	5.6 ± 0.6	51	5.6 ± 0.5	44	5.6 ± 0.6	NS
Hemoglobin A1c (mmol/mol)	95	39.0 ± 3.7	51	39.5 ± 3.8	44	38.5 ± 3.6	NS
Hemoglobin A1c (%)	95	5.7 ± 2.5	51	5.8 ± 2.5	44	5.7 ± 2.5	NS
HOMA-ir	89	1.5 ± 1.3	49	1.6 ± 1.1	40	1.4 ± 1.5	NS
Total cholesterol (mmol/l)	95	5.5 ± 1.1	51	5.5 ± 1.0	44	5.5 ± 1.2	NS
HDL cholesterol (mmol/l)	95	1.5 ± 0.4	51	1.5 ± 0.4	44	1.5 ± 0.4	NS
LDL cholesterol (mmol/l)	95	3.3 ± 1.0	51	3.3 ± 0.8	44	3.3 ± 1.1	NS
Triglycerides (mmol/l)	95	1.5 ± 1.5	51	1.5 ± 1.6	44	1.6 ± 1.4	NS
Behavior							
% (n) current smoker	95	14.6% (14)	51	20% (10)	44	8.9% (4)	NS
Pieces of fruit/day	95	1.3 ± 0.9	50	1.2 ± 0.9	45	1.3 ± 0.9	NS
Glasses of alcohol/week	95	3.1 ± 5.0	50	3.9 ± 6.0	45	2.1 ± 3.4	NS
PA minutes per week	96	139.9 ± 123.1	51	158.5 ± 126.6	45	118.8 ± 116.9	NS
Total METs/min per week		2988.3 ± 3242.7	51	3320.6 ± 3195.5	45	2611.7 ± 3290.3	NS

Lower = primary education or lower general secondary education; middle = intermediate vocational education or high school; high = higher vocational education. HDL = high density lipoprotein; LDL = low density lipoprotein. METs = metabolic equivalents; PA = physical activity; NS = not significant.
[a] Values are presented in number of participants (%) or mean ± SD.

Table 2
Changes in anthropometric and biological measures after 3 and 9 months within and between study groups of DiAlert.

	Intervention								Control								P-between
	3 months				9 months				3 months				9 months				
	95% CI				95% CI				95% CI				95% CI				
	B	Lower	Upper	P	B	Lower	Upper	P	B	Lower	Upper	P	B	Lower	Upper	P	
Body weight (kg)	−0.88	−1.90	0.15	0.09	−0.54	−1.86	0.79	0.43	−0.24	−0.80	0.33	0.41	0.38	−0.43	1.19	0.36	0.48
BMI (kg/m^2)	−0.35	−0.71	0.02	0.06	−0.21	−0.69	0.28	0.41	−0.08	−0.30	0.13	0.44	0.11	−0.19	0.41	0.46	0.45
Waist circumference (cm)	−4.24	−5.99	−2.49	<0.01	−4.33	−6.33	−2.33	<0.01	−1.30	−2.28	−0.32	0.01	−1.25	−2.63	0.13	0.08	0.01
Systolic blood pressure (mmHg)	−5.42	−9.58	−1.27	0.01	−8.77	−13.93	−3.61	<0.01	−3.65	−6.90	−0.41	0.03	−1.03	−4.92	2.86	0.60	0.06
Diastolic blood pressure (mmHg)	−1.46	−4.23	1.32	0.30	−2.15	−5.55	1.26	0.22	−1.74	−4.22	0.73	0.17	−0.23	−2.63	2.16	0.85	0.44
Fasting glucose (mmol/L)	0.01	−0.17	0.20	0.90	0.06	−0.07	0.20	0.37	0.05	−0.07	0.18	0.40	0.15	−0.05	0.34	0.13	0.77
Hemoglobin A1c (HbA1c) (mmol/mol)	−0.15	−0.71	0.40	0.59	−0.38	−1.05	0.29	0.26	−0.36	−0.98	0.26	0.26	−0.57	−1.30	0.16	0.13	0.89
HOMA2-IR	−0.14	−0.42	0.14	0.32	−0.18	−0.43	0.06	0.14	−0.28	−0.61	0.05	0.09	−0.07	−0.42	0.27	0.68	0.31
Total cholesterol (mmol/l)	−0.02	−0.26	0.21	0.85	−0.19	−0.48	0.10	0.20	−0.14	−0.30	0.02	0.08	−0.14	−0.35	0.07	0.21	0.43
HDL cholesterol (mmol/l)	−0.07	−0.13	−0.01	0.02	−0.03	−0.09	0.03	0.28	−0.02	−0.08	0.04	0.49	0.01	−0.05	0.07	0.75	0.49
LDL cholesterol (mmol/l)	0.03	−0.19	0.24	0.79	−0.07	−0.33	0.19	0.60	−0.04	−0.18	0.09	0.54	−0.01	−0.21	0.18	0.88	0.59
Triglycerides	−0.03	−0.36	0.29	0.84	−0.03	−0.46	0.40	0.88	−0.09	−0.25	0.07	0.26	−0.11	−0.31	0.08	0.26	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.

Table 3
Adjusted mean intervention effect on 3-month and 9-month behavioral and psychological measures.

	Intervention group			Control group			*P*
	Baseline	3 months	9 months	Baseline	3 months	9 months	
Behavioral intentions (scale 1–5)							
Healthy diet	3.9 ± 0.6	4.0 ± 0.6	3.8 ± 0.8	3.7 ± 0.8	3.7 ± 0.8	3.8 ± 0.7	0.40
Physical activity	3.8 ± 0.9	3.9 ± 0.7	3.8 ± 0.8	3.6 ± 0.9	3.8 ± 0.7	3.7 ± 0.7	0.74
Losing weight	4.0 ± 0.8	3.8 ± 0.8	3.8 ± 0.8	3.5 ± 0.8	3.5 ± 0.7	3.6 ± 0.8	0.58
Self efficacy (sum 20 scale 1–4) [a]							
Diet	14.4 ± 2.4	14.2 ± 2.5	13.5 ± 2.9	13.6 ± 3.6	13.2 ± 3.1	13.9 ± 2.8	0.06
Physical activity	13.8 ± 2.9	13.0 ± 2.6	13.8 ± 3.1	13.5 ± 3.6	13.2 ± 3.6	12.7 ± 3.4	0.08
Outcome expectancies (sum 20 scale 1–5) [b]							
Diet	15.6 ± 3.2	15.9 ± 2.4	15.2 ± 3.3	14.5 ± 2.7	15.0 ± 2.8	15.1 ± 2.9	0.25
Physical activity	15.5 ± 3.5	16.0 ± 2.7	15.2 ± 3.2	15.3 ± 2.4	15.5 ± 2.5	15.7 ± 2.9	0.21
Action planning [a]							
Diet (sum 12 scale 1–4)	7.1 ± 2.1	7.8 ± 1.9	7.9 ± 2.1	6.1 ± 2.3	7.3 ± 2.4	7.0 ± 2.3	0.87
Exercise (sum 24 scale 1–4)	15.9 ± 3.6	16.4 ± 3.6	16.6 ± 4.6	13.9 ± 4.3	15.5 ± 4.6	14.7 ± 4.3	0.54
Personal control (sum 15 scale 1–5)[c]	6.0 ± 2.1	5.8 ± 1.7	5.8 ± 2.0	6.2 ± 1.9	6.4 ± 1.9	6.4 ± 1.9	0.40
Risk perception (scale 1–7)							
Comparative risk	5.1 ± 1.1	4.9 ± 1.2	4.7 ± 1.3	5.0 ± 1.3	5.0 ± 1.0	5.0 ± 0.9	0.37
Risk estimation	3.9 ± 1.6	3.8 ± 1.5	3.8 ± 1.4	4.3 ± 1.6	3.9 ± 1.5	4.0 ± 1.5	0.63
Worry about diabetes (scale 1–7)	4.2 ± 1.9	4.2 ± 1.7	4.2 ± 1.6	4.8 ± 1.7	4.8 ± 1.7	4.4 ± 1.7	0.74
Psychological distress (K-10)	16.4 ± 5.5	12.0 ± 7.0	10.2 ± 7.2	14.8 ± 5.2	13.0 ± 7.1	9.0 ± 7.8	0.31
Health outcome							
EQ5D	0.8 ± 0.2	0.9 ± 0.2	0.9 ± 0.2	0.8 ± 0.2	0.8 ± 0.2	0.8 ± 0.2	0.74
EQ5D cm	73.0 ± 21.7	75.7 ± 19.5	76.9 ± 18.3	74.1 ± 21.2	71.6 ± 21.1	74.6 ± 21.9	0.55

Data are mean ± SD intervention effects adjusted for baseline measurement.
Behavioral intentions: (1 totally disagree to 5 totally agree) I plan to consciously eat healthier/exercise more/loose 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 expectancies: (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/how many times/with whom I'm going to exercise/what to do in difficult situations in order to stick to my intentions.
Personal control (1 = totally disagree; 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 = totally not worried; 7 = very worried). Indicate your feelings when thinking about chance of getting diabetes.
[a] = chronbach's alpha > 0.9.
[b] = chronbach's alpha > 0.8.
[c] = chronbach's alpha > 0.6.

3.3. Changes in metabolic outcomes

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

3.4. Reported perceptions and behavior change

Table 3 shows no changes from baseline to 9 months in intentions to change behavior. 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 behavior, physical activity, smoking status and alcohol intake were reported in either group.

4. Discussion and conclusions

4.1. Discussion

To the best of our knowledge we are the first to report on the effects of a low-intensive group lifestyle education program specifically targeted at first degree relatives of type 2 diabetes patients, aimed to help them reduce their diabetes risk [14]. 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 groups. Results of the Finnish and American diabetes prevention studies have shown that a weight loss of 5–7% of the initial weight in high risk individuals is associated with marked clinical benefits [1,2]. 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 programs designed for implementation in primary care [26,27]. However, we did not find improvement in fasting glucose levels, nor in behavioral measures.

The absence of effect on self-reported determinants of behavior 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 behavior. 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 behavioral risk factors including smoking and alcohol intake were lower than the Dutch population average [28], 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 [29,30], but comparable to other European diabetes prevention trials [31,32]. 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 program. By using a mix of recruitment strategies we discovered that FH information was not reported 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, although all participants of the study had a positive family history of type 2 diabetes, the sample included both offspring and siblings of type 2 diabetes patients. This heterogeneity might have had an effect on the outcome of intentions to change lifestyle and/or weight loss. However, including the type of family history in the analysis had no significant effect on the outcomes.

Third, 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 centimeters, suggesting actual improvement after DiAlert.

Fourth, we could not demonstrate an association between improved lifestyle and change in anthropometric measures. To limit the burden of our assessments, we evaluated behavior 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.

Finally, feasibility, fidelity and acceptability of the intervention were confirmed in the pilot study [15]. In this study, every session was evaluated with the principal researcher (WH) and documented, but fidelity of the intervention was not measured objectively. The trainers confirmed feasibility, fidelity and acceptance of the intervention based on their experiences. The trainers were experienced and qualified to deliver diabetes education, but differences between the trainers (e.g. attitude, communication style, guiding) could have existed. The number of groups was too small to examine differences in outcomes between trainers.

4.2. Conclusion

In conclusion, overweight first degree relatives of type 2 diabetes patients who participated in the low-intensive structured lifestyle education program 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 favorable 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 [33].

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 counseling sessions [26,29,32]. Therefore, 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-h 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 [34].

4.3. 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 programs to stimulate further adoption and maintenance of behavior change following DiAlert.

Translation of landmark DPP-based interventions into community settings and primary care has found to be challenging [35,36]. 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.

Authors' contributions

WH researched data, and wrote, reviewed, and edited the manuscript. MdW contributed to data analysis. MdW, FJS, KS, VN, BM contributed to the discussion and reviewed and edited the manuscript.

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Conflicts of interest

No potential conflicts of interest relevant to this article were reported.

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