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Effectiveness of a brief theory-based health promotion intervention among adults at high risk of type 2 diabetes: One-year results from a randomised trial in a community setting

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ABSTRACT

Aim: To examine the effect of a brief theory-based health promotion intervention delivered in the community on health behaviour and diabetes-related risk factors among Danish adults at high risk of diabetes.

Methods: A randomised trial was conducted among 127 individuals aged 28 to 70 with fasting plasma glucose: 6.1–6.9 mmol/l and/or HbA_{1c}: 6.0–<6.5% (42–<48 mmol/mol) recruited from general practice in Holstebro, Denmark. Participants were randomised to a control group or to receive the intervention delivered over four 2 h group sessions during five weeks, and two further sessions after one and six months. Questionnaire data and clinical measures were collected at baseline, three months and one year after intervention. Primary outcomes; total-fat intake <30% of energy intake; saturated-fat intake <10% of energy intake; fibre-intake≥15 g/1000 kcal; weight reduction >5%; changes in physical activity.

Results: 85% attended one-year follow-up. After adjusting for gender, age and education, Odds ratio (OR) (95% CI) intervention vs control: total-fat intake <30% energy intake: 0.52 (0.22;1.20), saturated-fat intake <10% energy intake: 1.22 (0.52;2.87), fibre intake ≥15 g/1000 kcal: 1.18 (0.48;2.92), weight reduction >5%: 2.47 (0.95;6.39). β(95% CI) between intervention vs control in changes from baseline: IPAQ, MET min/week: −236 (−2760; 2288), waist circumference,cm: −2.5 (−4.5; −0.5); systolic blood pressure, mmHg: −4.6 (−8.8; −0.3).

Conclusion: A brief theory-based health promotion intervention delivered in the community indicated effect on weight, waist circumference and systolic blood pressure at one year among Danish adults at high risk of diabetes. No effect was shown on diets or physical activity.

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1. Introduction

Intensive behavioural interventions aimed at high-risk individuals have halved progression to type 2 diabetes in randomised trials [1]. These trials typically focus on achieving goal-orientated changes in diet, physical activity and weight. For example, the Finnish Diabetes Prevention Study (DPS) [2] included five goals: 5% weight reduction, total-fat intake <30% of energy intake, saturated-fat intake <10% of energy intake, fibre intake ≥15 g/1000 kcal and physical activity >4 h per week. Interventions in these efficacy trials were extensive and resource demanding. Research on translating the results of these trials into "the real world"; in many different forms and contexts have been performed [3–5]. Only a minor part was evaluated in randomised trials, where effectiveness, however, was shown in a broad spectrum of contexts [6–10]. The interventions in these trials were still resource demanding in terms of time [6,8,9] or specialists [7,10]. The GOAL Implementation Trial [11] investigated the effect of a less resource-demanding group-based model that was underpinned by the same behavioural goals used in the Finnish DPS [2]. The effectiveness was evaluated in a before and after study, and the results suggested that health behavior change and risk reduction for prevention of type 2 diabetes could be achieved in routine health care with less resources [11].

In Denmark, local municipalities have been responsible for the prevention of chronic diseases since 2007. Most municipalities manage a local health care centre to provide preventive care. In the Holstebro Health Care Centre, health care staff developed a brief intervention with structure and content inspired by the GOAL study, but underpinned by learning theories; transformative learning [12], health literacy [13] and action competence [14], which were found relevant for the Danish context. The research question addressed was whether adding this brief diabetes risk reduction intervention in a Danish health care centre was beneficial compared to usual practice (visits in general practice, other health promotion programmes etc.). Hence, the aim of this study was to evaluate the effect of a brief theory-based health promotion intervention delivered via group sessions in the community on health behaviour and diabetes-related risk factors among Danish adults at high risk of type 2 diabetes.

2. Methods

2.1. Design and participants

In autumn 2010, 19 general practices in Holstebro, Denmark received two letters containing information about the trial. They were encouraged to opportunistically refer eligible participants to the Holstebro Health Care Centre when they attended appointments in their practice. Eligibility criteria were: resident in the Municipality of Holstebro, aged <70 years, and a measurement of fasting plasma glucose: 6.1–6.9 mmol/l (the thresholds for Impaired Fasting Glucose according to clinical guidelines) and/or HbA_{1c}: 6.0–<6.5% (42–<48 mmol/mol) within the previous six months. In 2011, the municipality of Holstebro had a population of 50.749 aged <70 years. A local general practitioner and a member of the study's advisory board also met the general practitioners from Holstebro on several occasions and gave them information about the trial. The health care staff from Holstebro Health Care Centre visited the general practices to give them more information. Furthermore, the study was advertised in the local press. Sixteen general practices recruited study participants between January 2011 and January 2013. All individuals who were referred from general practice to take part, agreed and were included in the study ($n = 127$) (Fig. 1). Participants were individually randomised 1:1 to the control group ($n = 64$) or the intervention ($n = 63$). The intervention was offered to control group participants after 12 months. The project-manager or the secretary at the Holstebro Health Care Centre administrated the random allocation sequence by block randomisation with a block size of 10 and by the use of sealed envelopes; Sets of 10 letters (five addressed to the intervention group and five addressed to the control group) were packed in sealed envelopes and mixed randomly. Participants sequentially arriving at the health care centre chose an envelope and the group allocation were recorded.

2.2. Intervention

Participants in the intervention group received the offer of four 2 h group sessions during five weeks, and two further sessions after one and six months. The attendance rates of the sessions were 95%, 88%, 87%, 73%, 67% and 51%, respectively. The course was delivered by health care staff in the Holstebro Health Care Centre, including a dietitian and an occupational therapist, both with health pedagogic competences. It was delivered to seven intervention groups, which varied in size from 5 to 15 participants. The intervention structure and the content were inspired by the GOAL study [15]. In Fig. 2, the intervention is depicted using a PaT Plot [16], showing the timeline and the characteristics of the intervention components. The Squares reflect the fixed and more reproducible elements. Circles reflect the activities that are flexible and maybe more difficult to reproduce, and open to variability depending on the context. The pedagogical approach was in line with modern health pedagogue/psychology, and the methods used were based on Mezirow's theory of transformative learning [12], Health Literacy Theory [13] and dimensions of health knowledge and action competence [14]. Mezirow describes how a disorienting dilemma (e.g. perceived high risk of type 2 diabetes) can induce a process including self-examination with feelings of fear, anger, guilt, or shame; a critical assessment of assumptions; exploration of options; planning and building competences of actions; and finally integration of these changes in one's life. At the beginning of each meeting, the participants were encouraged to reflect on own risk, resources, competences, experiences, and willingness to health behaviour change [12] The information provided at every meeting was presented in a number of ways to reach individuals with different levels of health literacy, including for individuals with low literacy, the use of pictures and short sentences. No exercises required writing from the participants [13,17] Through dialogue and discussions, the participants were encouraged to

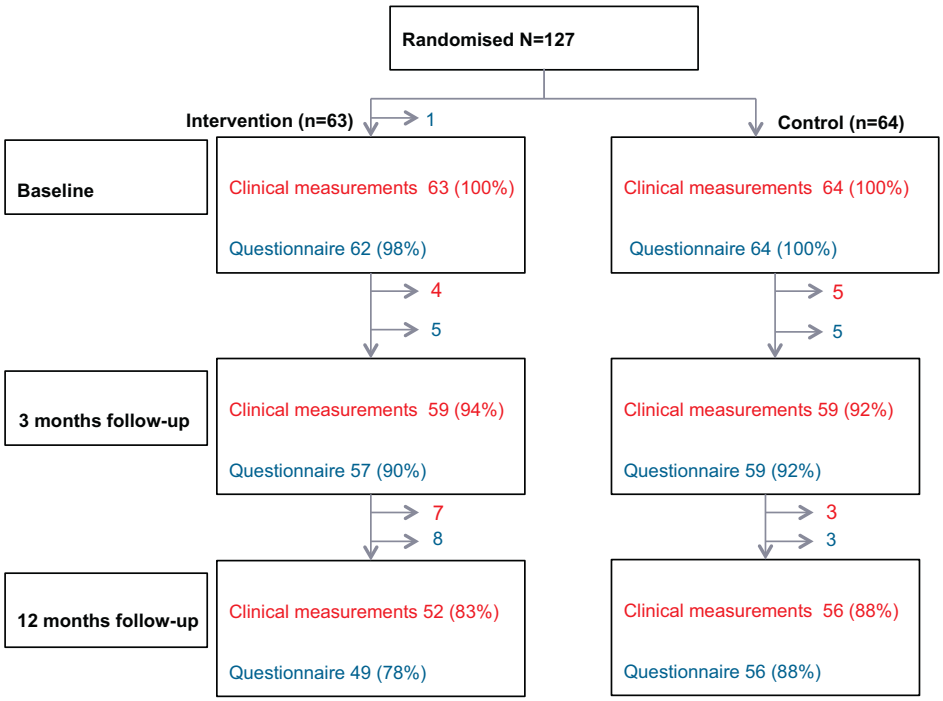

Fig. 1 – Trial profile for a trial evaluating the effectiveness of a brief theory-based health promotion intervention to adults at high risk of type 2 diabetes, Denmark 2011–2014.

find their own goals and make them concrete and attainable [14].

2.3. *Measurements and outcomes*

The primary outcome measures were the attainment of goals from the DPS [2] and the GOAL study [11]: weight reduction >5%, total-fat intake <30% of energy intake, saturated-fat intake <10% of energy intake, fibre-intake ≥15 g/1000 kcal, and changes in physical activity level. Secondary outcome measures included change from baseline to follow-up (three months and one-year) in patient activation, waist circumference, total energy intake, blood pressure, HbA_{1c}- and cholesterol values.

All clinical measurements (weight, waist circumference, blood pressure and blood test) were performed at the Holstebro Health Care Centre by the same two trained health care staff following standard operating procedures with the same equipment throughout the study. Blood pressure was calculated as the mean of three measurements performed after at least 10 min rest, while participants were seated with the cuff on the right arm at the level of the heart. Height and weight were measured in light indoor clothing, without shoes. Waist circumference was recorded as the average of two measurements of waist circumference using a tape measure halfway between the lowest point of the rib cage and the anterior superior iliac crests when standing. Blood tests were analysed in a central laboratory.

All the self-reported data was collected using questionnaires sent to the participants by mail two weeks before the clinical measurement visits. Information on diet was obtained using a validated self-administrated 198-item food frequency questionnaire (FFQ), the Inter99 FFQ [18]. Portion size was set according to gender. Daily nutrient intake was translated into energy intake and nutrient intake using the Danish Food Composition Databank (version 7.01) [19] and the software program FoodCalc version 1.3 [20] was used for the calculations. Physical activity was measured using the International Physical Activity Questionnaire (IPAQ) [21] and patient activation using the Patient Activation Measure (PAM) [22,23]. SF12 [24] was used to measure self-reported health and the Perceived Stress Scale (PSS) [25] was used to measure stress-level. Education was categorised in three groups; (1) mandatory school and an optional 11th year of school at the most (≤11 years), (2) secondary education and/or vocational training <3 years at the most (>11 < 16 years) and, (3) secondary education and vocational training ≥3 years or tertiary education (≥16 years).

Questionnaire data and clinical measurements were collected at baseline, three months and one year (Fig. 2).

2.4. *Ethical approval*

The Danish Research Ethics Committee assessed the trial and concluded that it was not to be a biomedical intervention cf. The Committee Act no. 402 of the 28 May 2003 §7,1. Withdrawal from the study was a possibility at any time. The study was approved by the Danish Data Protection Agency (j.no:2010-52-0160).

2.5. *Statistical analysis*

The plan was to recruit at least 200 participants. However, recruitment to the study was slower than expected and

after two years, the members of the advisory board decided to stop inclusion. All measures were checked for normal-distribution. In case of not normal-distribution, the measures were reported as medians. The effect of the intervention on outcomes was assessed using between-arm intention-to-treat analysis, using linear and logistic regression for continuous and binary outcomes, respectively. Due to an unequal distribution of educational level at baseline and the assessment that education and also age and gender have an essential impact on the outcomes, regression models were adjusted for gender, age and educational level (≤11 years, >11 < 16 years, ≥16 years of education). Estimates were presented with 95% confidence intervals (CI) and p values, and p values of <0.05 were regarded as statistically significant.

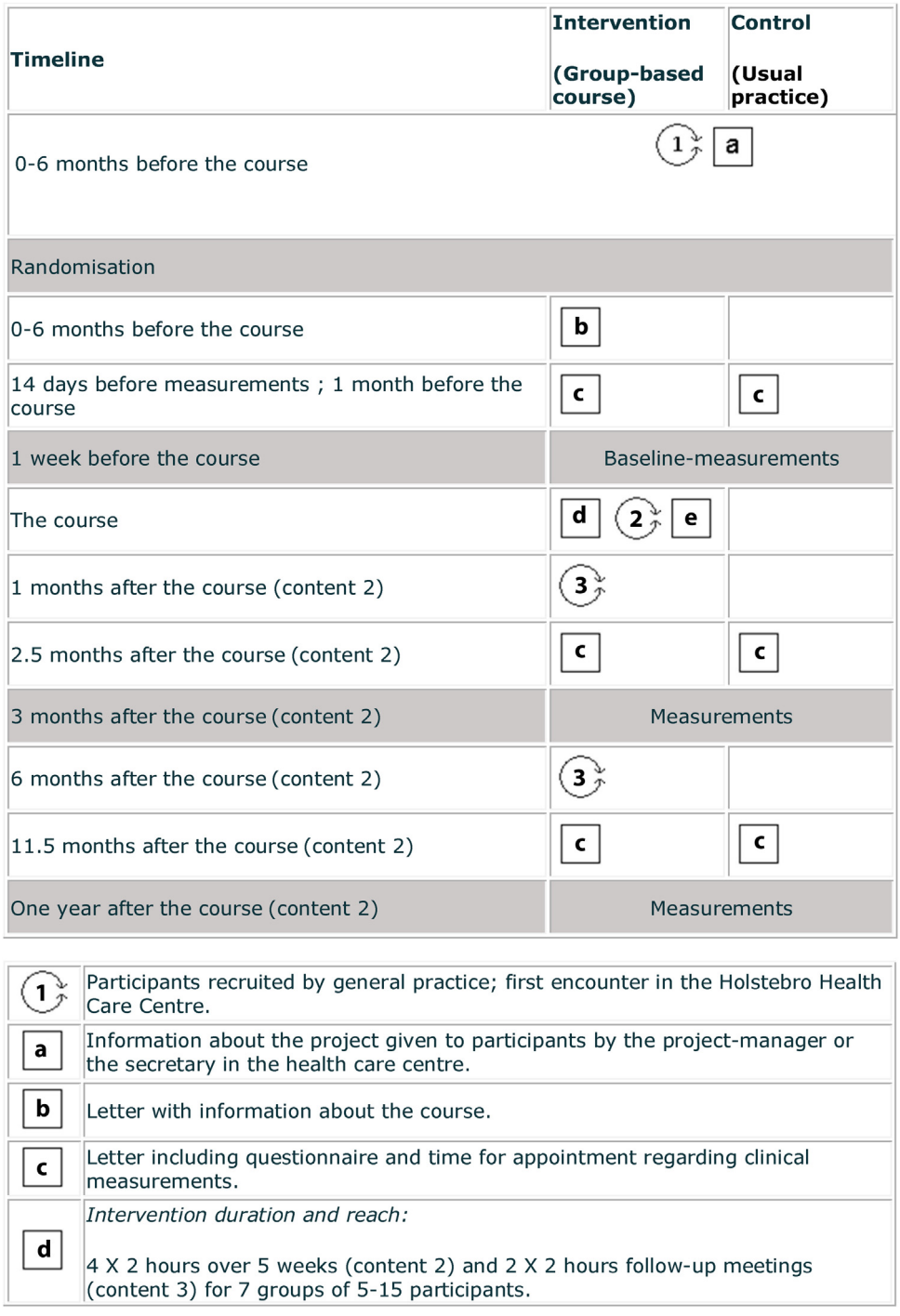

Fig. 2 – Graphical depiction of the timeline and the content of a theory-based health promotion intervention to adults at high risk of type 2 diabetes. (Squares reflect the fixed and more reproducible elements. Circles reflect the activities that are flexible and maybe more difficult to reproduce.).

2	*Content:* *Week 1: Introduction* Mutual introduction (30 minutes) Information about pre-diabetes and type 2 diabetes (45 minutes) Discussion: Personal visions and dreams and "the small-step-method" *Week 2: Physical activity* Dialogue about experiences and reflections (30 minutes) Information about the effect of physical activity for preventing type 2 diabetes; and how to integrate in daily life (45 minutes) Discussion: Habits and patterns *Week 3: Diet* Dialogue about experiences and reflections (30 minutes) Information about the effect of diet for preventing type 2 diabetes; ways to integrate recommendations regarding diet into daily life (45 minutes) Discussion: The cultural and sociological context *Week 4: Summing up and the opportunity for bringing a relative* Dialogue about experiences and reflections (30 minutes) Information about maintenance of changed behavior and risk situations (45 minutes) Discussion: Personal visions and strategies (45 minutes)
e	The presentations were supported by posters, and written materials were handed out. All the materials included many pictures and short sentences.
3	*Follow-up-meeting:* Dialogue about experiences and reflections (60 minutes) Information: topic chosen by the different groups (30 minutes) Discussion: topic chosen by the different groups (30 minutes)

Fig. 2 – (*Continued*).

3. Results

Fig. 1 shows the trial profile. A total of 127 participants were recruited to the study from 16 general practices and attended baseline measurements. Baseline characteristics of the study population are shown in Table 1. The median age was 58 years (range:33 to 70) in the intervention group; and 60 years (range:28 to 69) in the control group. The majority of the participants were women; 67% in the intervention group; and 70% in the control group. In the intervention group, 16% had ≤11 years of education, compared to 38% in the control group. The median BMI was 31 kg/m^2 in the intervention group; and 30 kg/m^2 in the control group and 67% and 59% of the participants reported being physical active in their leisure time in the intervention—and the control group, respectively. In contrast, the median MET/min/week was 2977 in the intervention group; and 4158 in the control group. 22% in the intervention group and 17% in the control group reported poor general health, whereas 30% in the intervention group and 33% in the control group reported a high stress-level. There were no deaths during the study period. Two persons in the intervention group and three persons in the control group had an HbA_{1c} ≥48 mmol/mol at one year. 83% of the intervention group and 88% of the control group returned for one-year

Table 1 – Baseline characteristics of participants taking part in a pragmatic, theory-based health promotion intervention trial in Holstebro, Denmark 2011–2013.

Characteristics	Intervention ($n = 63$)	Control ($n = 64$)
Demographic		
Gender, men, *n* (%)	21 (33)	19 (30)
Age, median (q1, q3) (years)	58 (50, 63)	60 (51, 64)
Education, *n* (%)		
≤11 years	10 (16)	24 (38)
>11 < 16 years	41 (66)	31 (49)
≥16 years	11 (18)	8 (13)
Clinical		
BMI, median (q1, q3) (kg/m^2)	31 (27, 35)	30 (27, 33)
Weight, median (q1, q3) Kg	89 (77, 98)	85 (74, 95)
Waist circumference, mean ± SD (cm)	106 ± 14	104 ± 11
Systolic blood pressure, mean ± SD	134 ± 16	132 ± 12
Diastolic blood pressure, mean ± SD	84 ± 9	81 ± 8
HbA1c, mean ± SD (mmol/mol)	40.7 ± 3.5	40.6 ± 3.9
Total cholesterol, mean ± SD (mmol/l)	5.1 ± 1.1	5.4 ± 1.0
LDL-cholesterol, mean ± SD (mmol/l)	3.1 ± 0.9	3.3 ± 0.9
HDL-cholesterol, mean ± SD (mmol/l)	1.3 ± 0.3	1.3 ± 0.3
Self-reported health behaviour		
Total-fat intake, %energy, mean ± SD	31.8 ± 7.3	31.4 ± 5.5
Total-fat intake <30% energy, *n* (%)	29 (46)	24 (38)
Saturated-fat intake, %energy, mean ± SD	10.7 ± 3.2	11.2 ± 3.1
Saturated-fat intake <10%energy, *n*(%)	29 (46)	25 (39)
Fiber intake, g, mean ± SD	13.0 ± 3.0	12.3 ± 3.4
Fiber intake >15 g/1000 kcal, *n* (%)	16 (25)	12 (19)
IPAQ[a], MET min/week, median (q1, q3)	2977 (1506, 5292)[b]	4158 (1533, 5130)[c]
No exercise in leisure time, *n*(%)	21 (33)	26 (41)
Daily smoker, *n* (%)	7 (11)	11 (17)
Alcohol, units/week, median (q1, q3)	3 (0, 8)	4 (1, 8)
Patient activation, PAM[d], median (q1, q3)	60 (56, 69)	58 (53, 72)
Self-rated health and well-being		
Poor general health, SF-12, *n*(%)	14 (22)	11 (17)
Stress, PSS[e], median (q1, q3)	13 (9, 17)	14 (10, 17)
High stress-level (PSS[e] > 16), *n* (%)	19 (30)	21 (33)

[a] International physical activity questionnaire [b] based on 45/63 [c] based on 41/64.
[d] Patient activation measure [e] Perceived stress scale.

follow-up health assessment after a mean of 403 (SD 15) days from baseline in both groups. There was no significant difference in baseline characteristics between those who attended one-year follow-up health assessment and those who did not (data not shown).

3.1. *Primary outcomes*

Tables 2 and 3 show the outcomes of the DPS behavioural goals for this study. There was no significant difference in the proportion of participants reaching the total-fat intake <30% energy goal or the saturated-fat intake <10% of energy goal at three months and one year. While higher number of participants in the intervention group reached the fibre goal at three month (≥15 g/1000 kcal fibre), this was not maintained at one-year follow-up. Again, while changes from baseline in self-reported physical activity levels tended to be higher among intervention compared to control participants at three months, there was no difference at one year, but even a tiny difference in the unexpected direction (Table 3). In terms of weight loss, at both three month and one-year follow-up, significantly more participants in the intervention group had achieved a weight reduction of at least 5% compared to the control participants (OR at three months: 11.5;95% CI 2.53 to 52.66), (OR at one year: 2.54;95% CI 1.01 to 6.36). However, after adjustment of gender, age and education, the OR at one year was slightly attenuated (OR: 2.47(0.95;6.39) (Table 2).

3.2. *Secondary outcomes (Table 3)*

There was a significant reduction in waist circumference at three months (−2.5 cm; 95%CI −3.8 to −1.3) and one year (−2.8 cm;95%CI −4.4 to −1.1) in the intervention group. No significant changes were observed in the control group. The differences in changes between the groups were statistically significant. There were increases in patient activation in the intervention group at three months and one year, with no change observed in the control group. However, changes between the groups were not statistically significant. Self-reported daily energy intake decreased in the intervention group at three months (−471 KJ; 95% CI −1046 to 104/−112 kcal; 95% CI −250 to 25) and at one year (−691 KJ; 95% CI −1434 to 51/−165 kcal; 95% CI −343 to 12). Again, only minor changes were observed in the control group, but differences in changes between the two groups at three months (−677 KJ; 95% CI −1614 to 261/−162 kcal; 95% CI −385 to 62) and at one year

Table 2 – Primary outcomes by study group at three months and one year in a trial to assess the effectiveness of a brief theory-based health promotion intervention among adults at high risk of type 2 diabetes (Intention-to-treat analysis), Denmark 2014.

	Three months				One-year			
	Intervention	Control	OR (95% CI)		Intervention	Control	OR (95% CI)	
Outcomes	*n*(%)	*n*(%)	Crude	Adjusted[a]	*n*(%)	*n*(%)	Crude	Adjusted[a]
Total-fat intake <30% energy	24(42)	25(42)	0.99(0.47;2.07)	1.00(0.47;2.12)	17(35)	26(46)	0.61(0.28;1.35)	0.52(0.22;1.20)
Saturated-fat intake <10% energy	27(47)	26(44)	1.14(0.55;2.37)	0.96(0.45;2.06)	18(37)	16(29)	1.45(0.64;3.30)	1.22(0.52;2.87)
Fibre intake ≥15 g/1000 kcal	21(37)	13(22)	2.06(0.91;4.68)	2.12(0.92;4.90)	14(29)	13(23)	1.32(0.55;3.18)	1.18(0.48;2.92)
Weight reduction > 5%	17(29)	2(3)	11.5(2.53;52.66)	10.17(2.18;47.46)	17(33)	9(16)	2.54(1.01;6.36)	2.47(0.95;6.39)

[a] For gender, age and educational level.

Table 3 – Outcomes by study group and between group differences at three months and one year in a trial to assess the effectiveness of a brief theory-based health promotion intervention among adults at high risk of type 2 diabetes (Intention-to-treat analysis), Denmark 2014.

	Three months						One-year					
	Intervention		Control		Δ between groups β (95%CI)		Intervention		Control		Δ between groups β (95%CI)	
Outcomes	Mean (SD) or Median (q1, q3)	Change from baseline Mean (95%CI)	Mean (SD) or Median (q1, q3)	Change from baseline Mean (95%CI)	Crude	Adjusted[a]	Mean (SD) or Median (q1, q3)	Change from baseline Mean (95%CI)	Mean (SD) or Median (q1, q3)	Change from baseline Mean (95%CI)	Crude	Adjusted[a]
IPAQ[b], MET (min/week)	4629 (2351, 7965)	1631 (75; 3188)	2613 (1611, 6342)	−254 (−2036; 1528)	1886 (−414; 4185)	1825 (−664; 4315)	3778 (1866, 5118)	223 (−1256; 1702)	4251 (2301, 7359)	−114 (−2000; 1772)	337 (−2008; 2681)	−236 (−2760; 2288)
PAM[c]-score	68.5 (56.4,77.5)	4.0 (0.1;7.9)	66.0 (49.9, 75.3)	0.2 (−3.7;4.1)	3.8 (−1.6;9.3)	3.0 (−2.4;8.4)	60.0 (56.4,77.5)	3.4 (−2.1;8.8)	60.0 (49.9,72.0)	−0.1 (−3.7;3.5)	3.5 (−2.8;9.8)	3.2 (−3.1;9.4)
Energy intake (kJ)	8264 (6277, 10233)	−471 (−1046; 104)	8425 (6896, 10358)	205 (−542; 953)	−677 (−1614; 261)	−656 (−1621; 308)	7704 (6233, 9421)	−691 (−1434; 51)	7749 (6739, 9933)	−122 (−1165; 920)	−569 (−1868; 730)	−519 (−1857; 819)
Weight (kg)	86 (76, 96)	−2.5 (−3.3; −1.7)	82 (75, 93)	−0.7 (−1.3; −0.16)	−1.8 (−2.7; −0.9)	−1.5 (−2.5; −0.6)	85 (73, 97)	−2.4 (−3.4; −1.3)	81 (75, 94)	−1.1 (−2.3; 0.2)	−1.3 (−2.9; 0.3)	−1.1 (−2.8; 0.5)
Waist circumference (cm)	102.7 (13.3)	−2.5 (−3.8; −1.3)	103.7 (12.0)	−0.1 (−1.0;0.8)	−2.4 (−3.9; −0.9)	−2.5 (−4.0; −1.0)	102.7 (14.5)	−2.8 (−4.4; −1.1)	103.1 (11.5)	−0.5 (−1.7;0.6)	−2.2 (−4.2; −0.3)	−2.5 (−4.5; −0.5)
Systolic blood pressure (mmHg)	131.8 (15.9)	−2.3 (−5.0;0.5)	130.3 (12.2)	−2.0 (−4.8;0.8)	−0.3 (−4.1;3.6)	−0.1 (−4.1;3.8)	132.1 (15.3)	−4.1 (−7.2; −1.0)	132.5 (10.9)	0.3 (−2.5;3.2)	−4.4 (−8.6; −0.2)	−4.6 (−8.8; −0.3)
Diastolic blood pressure (mmHg)	82.1 (9.2)	−1.5 (−3.1;0.1)	80.2 (9.0)	−1.0 (−2.7;0.8)	−0.5 (−2.9;1.8)	−0.2 (−2.6;2.2)	81.4 (8.3)	−3.1 (−5.0; −1.2)	80.2 (7.5)	−1.1 (−2.6;0.4)	−2.1 (−4.4;0.3)	−1.9 (−4.4;0.5)
HbA_{1c} (mmol/mol)	40.1 (3.5)	−0.6 (−1.0; −0.1)	40.4 (4.0)	−0.0 (−0.5;0.4)	−0.5 (−1.2;0.1)	−0.5 (−1.2;0.1)	41.2 (10.6)	0.8 (−1.8;3.4)	40.5 (4.3)	0.1 (−0.6;0.7)	0.8 (−1.8;3.3)	0.7 (−2.0;3.4)
Total cholesterol (mmol/l)	5.0 (1.0)	−0.0 (−0.2;1.2)	5.3 (0.9)	0.0 (−0.2;0.2)	−0.0 (−0.3;0.2)	0.0 (−0.3;0.3)	5.0 (1.1)	0.0 (−0.2;0.2)	5.2 (1.0)	−0.1 (−0.3;0.1)	0.1 (−0.2;0.4)	0.1 (−0.2;0.4)
LDL-cholesterol (mmol/l)	3.0 (0.8)	−0.0 (−0.2;0.2)	3.3 (0.9)	−0.0 (−0.2;0.1)	0.0 (−0.2;0.2)	0.0 (−0.2;0.3)	3.1 (0.9)	0.1 (−0.1;0.3)	3.2 (0.8)	−0.0 (−0.2;0.1)	0.1 (−0.1;0.3)	0.1 (−0.1;0.4)
HDL-cholesterol (mmol/l)	1.3 (0.3)	0.0 (−0.0;0.0)	1.3 (0.3)	0.1 (0.0;0.1)	−0.0 (−0.1;0.0)	−0.0 (−0.1;0.0)	1.3 (0.4)	0.0 (−0.0;0.1)	1.3 (0.4)	0.0 (−0.0;0.1)	0.0 (−0.1;0.1)	−0.0 (−0.1;0.1)

[a] For gender, age and educational level [b] International Physical Activity Questionnaire [c] Patient Activation Measure.

(−569 KJ; 95% CI −1868 to 730/−136 kcal; 95% CI −446 to 174) were not statistically significant. There was a significant reduction in systolic blood pressure at one year in the intervention group (−4.1 mm Hg; 95% CI −7.2 to −1.0), compared with no change in the control group (0.3 mm Hg; 95% CI −2.5 to 3.2). The difference in changes between the groups was statistically significant. The difference in the changes in diastolic blood pressure between the groups was −2.1 mm Hg (95% CI −4.4 to 0.3) at one-year follow-up. No change or differences were observed for HbA_{1c}- and cholesterol within or between the groups.

4. Discussion

4.1. *Main findings and comparison with existing literature*

A brief theory-based health promotion intervention provided in the community indicated positive effect on weight, waist circumference and systolic blood pressure over one year among Danish adults at high risk of type 2 diabetes. However, there were no statistically significant differences in the primary outcomes of the DPS behavioural goals at one year. The dietary goals on saturated fat and fiber were in the expected direction at one year, whereas the total-fat goal went into the unexpected direction. It may be appropriate to have a high unsaturated fat-intake, while decreasing the total energy intake maybe by decreasing the intake of carbohydrates. The small between-group difference in MET-minutes/week in favour of the control group at one year is difficult to explain.

In the DPS, statistically significant differences in dietary and physical activity behaviour between the intervention- and the control group were observed at one-year follow-up [26]. Our results suggest that some health behaviour changes did occur, because of the small improvements in weight, waist circumference and systolic blood pressure, and our hypothesis is that the weight loss is mainly explained by decreased energy intake in this study. However, it was noticeable that the health behaviour changes except the total energy intake were highest at the three months follow-up and then decreased. A hypothesis could be that a more extensive intervention and/or ongoing support are necessary for maintaining health behaviour change in the long-term. The effect on weight loss and HbA_{1c} of the individual-based DPS-intervention, which was intensively delivered during the first year and every three months thereafter, was maintained at the three years follow-up [26]. A translation of the Diabetes Prevention Project (DPP) [27] in an American community setting showed an effect on weight loss and reduced weight circumference at two years follow-up [28]. This intervention was a peer-led group-based intervention delivered over weekly meetings during the first six months, and monthly meetings from months 7 to 24. Hence, there was substantial more intervention than our intervention. In our study, contact with participants after the delivery of the course was scarce, and after six months, there was no further contact. The NICE public health guidance 38 also recommends more extensive interventions [29].

Weight loss is assumed to be the predominant factor for preventing type 2 diabetes in high risk groups [30]. In the DPS, the odds ratio for developing type 2 diabetes within three years for the participants in the intervention group who had achieved >5% weight loss at the one-year follow-up was 0.3 (95% CI 0.1 to 0.7) compared with those in the intervention group who had lost less weight or none at all [2]. The proportion of participants in the intervention group who achieved at least 5% weight loss at one-year follow-up in our study (33%) was in between the proportion achieved in the DPS [2] and in the effectiveness trial, GOAL [11]. Similarly, the magnitude of improvement in waist circumference and systolic blood pressure from baseline to one year was in between the sizes of change that was achieved in the DPS and in the GOAL study. Furthermore, a recent review including 22 translational diabetes prevention programs reported significantly reduced weight in the intervention arms by a mean of 2.3 kg (95%CI: 1.7 to 2.9) at one-year follow-up [31]. In our study, the mean weight reduction from baseline to one-year follow-up in the intervention group was 2.4 kg (95% CI: 1.3 to 3.4) (Table 3). Hence, the change observed in the intervention group in our study is similar to results from international translational studies.

4.2. *Strengths and limitations*

A translation of the DPS by health care staff in a Danish municipality, and the delivery of the intervention in routine practice, was evaluated using a randomised design. This is a strength as it adds knowledge about whether adding a brief diabetes risk reduction intervention in a community health care centre is beneficial compared to usual practice (e.g. visits in general practice or other health promotion programmes). The use of different outcomes collected by use of validated questionnaires, especially the comprehensive food frequency questionnaire, and clinical measurements at different times over one year is also a strength of our study. While we assessed gender, age and education to be potential major confounders, all estimates were adjusted for these variables. This adjustment tended to show that the crude results overestimated the effect of the intervention to a minor extent.

Despite substantial effort, recruitment to the study was slower than expected. It is unclear whether this was related to general practitioners, who did not offer referrals to relevant individuals, or to individuals themselves who did not accept the offer. In the study period, the criteria for the diagnosis of Type 2 diabetes changed to be based on HbA_{1c} instead of plasma glucose. Practical procedures concerning measurement and discussions about the diagnostic term "pre-diabetes" might have influenced the recruitment of participants. Furthermore, the choice of using the thresholds for Impaired Fasting Glucose as inclusion criteria and not lower levels of fasting glucose as in the DPP [27] or as recommend by the NICE public health guidance 38 [29] may have reduced the recruitment of participants. Moreover, the NICE public health guidance 38 recommend to use validated risk assessment tools to identify people at high risk for type 2 diabetes, who should be offered a blood test [29]. Implementing such a tool could potentially have improved recruitment to the study and may be useful to include in future studies. An ongoing Danish study investigating collaboration between general practice

and the municipalities will illuminate the challenges of participant recruitment. Our findings highlight the challenges of reaching the intended target population, and suggest that focusing exclusively on individual-level interventions should not be the only approach to tackling the diabetes epidemic.

A large proportion of the participants reported being physically active in their leisure time, but a large number also reported a high stress-level and reduced well-being compared with the general population in the Municipality of Holstebro [32]. We are not able to compare the characteristics of the study population with the total population of people at high risk of type 2 diabetes, but the included study population may be a selected group reducing the generalisability of the study results. Likewise, as in similar intervention studies [2,11,27], the majority of the study population was women (Table 1).

The absence of effect regarding the health behaviour outcomes in the present study may be explained by a low statistical power in combination with self-reported behavioural measurements, as opposed to the objectively measured clinical outcomes; weight, waist circumference and blood pressure. Self-reported measures are often imprecise and we suppose e.g. the energy intake to be underestimated. Well-known that intervention might further influence this underestimation, we assume that the indication of difference in energy intake may be the most obvious explanation of the weight loss. Regarding the IPAQ-questionnaire on physical activity, there were lots of missing data indicating that these questions may have been difficult to understand or answer. Recent studies have also found that the IPAQ is not a valid measurement compared with objective physical activity measurements e.g. Actigraph accelerometer [33]. Due to systematic bias and large standard errors from the IPAQ measure and minimal detectable change, the IPAQ may only be suitable for intergroup comparisons [34]. Blinding was impractical in this study, and is a limitation, as the Holstebro Health Care Centre is a small unit. However, standard operating procedures were followed. Contamination of the intervention to the control group may have occurred and influenced the results towards the null. Information about the study in the local press may by itself have induced some health behaviour change among participants in the control group. The increase in number with at least 5% weight loss in the control group from three months to one-year follow-up is notable (Table 2).

4.3. *Conclusion*

This small randomised trial evaluating a brief theory-based health promotion intervention in the community setting indicated effect on diabetes-related risk factors; weight, waist circumference and systolic blood pressure at one year among Danish adults at high risk of type 2 diabetes. To maintain or improve the effectiveness, ongoing support or multi-level interventions may be required.

Conflict of interest

The authors declare no conflicts of interests.

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