

Three-year effects on dietary quality of health education: a randomized controlled trial of people with screen-detected dysglycaemia (The ADDITION study, Denmark)

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Background: Healthy diet is a core component in prevention and self-management of type 2 diabetes and cardiovascular disease. The long-term efficacy was assessed of a theory-based health education programme 'Ready to Act' on dietary quality in people with screen-detected dysglycaemia. **Methods:** Five hundred and nine adults with prediabetes (impaired glucose tolerance, impaired fasting glycaemia) or type 2 diabetes were recruited through screening for type 2 diabetes [the ADDITION (Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen-Detected Diabetes in Primary Care) study, DK] and then randomly assigned to health education or to a control group ($I=322$; $C=187$). The intervention group was offered a 12-week programme in health-related action competence including 2 one-to-one and 8 group sessions (18 h). Dietary quality was measured by the Dietary Quality Score_revised (0–8 points) at baseline and at one- and 3-year follow-up. Changes were analysed by multilevel analyses. **Results:** The analysis included data from 444 participants (87%). At the 3-year follow-up, the intervention group had significantly increased dietary quality compared with the control group (net change: 0.39 Dietary Quality Score_revised points, $P=0.04$). The intake of unsaturated fats used on bread and for cooking increased in the intervention group compared with the control group at the 3-year follow-up (net change: 31 g/week; $P=0.02$). A non-significant tendency toward an increased intake of vegetables in the intervention group compared with the control group was seen (net change: 111 g/week; $P=0.16$). No changes were seen in fish intake. **Conclusions:** Health education aiming at action competence improved the long-term dietary quality in a population with dysglycaemia, especially according to the intake of unsaturated fat. The ADDITION trial was registered at ClinicalTrials.gov ID no NCT00237549.

Introduction

The prevalence of type 2 diabetes continues to increase worldwide and diabetes-related morbidity and mortality are increasing health care burdens.^{1,2} Healthy dietary intake is an important factor in both the prevention and management of type 2 diabetes.^{3–5} Regardless of the widely recognized benefits of a healthy diet, effective interventions to help people achieve the right dietary behaviour demonstrate varied effects.^{6,7} A Cochrane review by Brunner et al⁸ concluded that dietary advice was effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 10 months among healthy adults, but the long-term effects are less clear. Moreover, reviews of diabetes self-management education studies reported effectiveness in short-term diet in people with diabetes, although methodology limitations, such as a lack of well-defined validated outcome measurements hinder clear conclusions.⁹

Behavioural prevention is already beneficial in the long 'silent or asymptomatic' period of type 2 diabetes, where complications gradually develop, although the individual is not aware of the disease.¹⁰ At the time of clinical diagnosis, approximately 30% may already have cardiovascular complications.² To our knowledge, only one Dutch study¹¹ with a short follow-up period provided health education in a population with screen-detected type 2 diabetes. This study reported no measurements of dietary intake, but a significantly reduced BMI (-0.77 kg/m²) and systolic BP (-6.2 mmHg) at the 9-month follow-up, regardless of medical

treatment. Acknowledging the increasing number of people with dysglycaemia, the inconsistent evidence of effective health education, and the specific needs of a newly diagnosed population, we developed a targeted health education intervention for people with screen-based dysglycaemia.¹²

This article aims to assess the efficacy of the 'Ready to Act' health education intervention to improve the dietary intake in people with screen-detected dysglycaemia. Our hypothesis was that the net change in dietary quality over a 3-year period would be significantly higher in the intervention group due to the systematically developed pedagogical approach used in the intervention.

Methods

Basic design

A pre-randomized study in primary health care was designed to investigate the health education in a subpopulation extracted from general practitioners (GPs) in one Danish county in the treatment arm of the ADDITION (Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen-Detected Diabetes in Primary Care) study, DK (figure 1).^{13,14} The ADDITION study investigated the effect of early prevention by a type 2 diabetes screening programme based on a high-risk, stepwise strategy in general practice followed by interventions. GPs in the ADDITION treatment arm were trained to provide target-driven intensive behavioural and pharmacological treatment for people with type 2

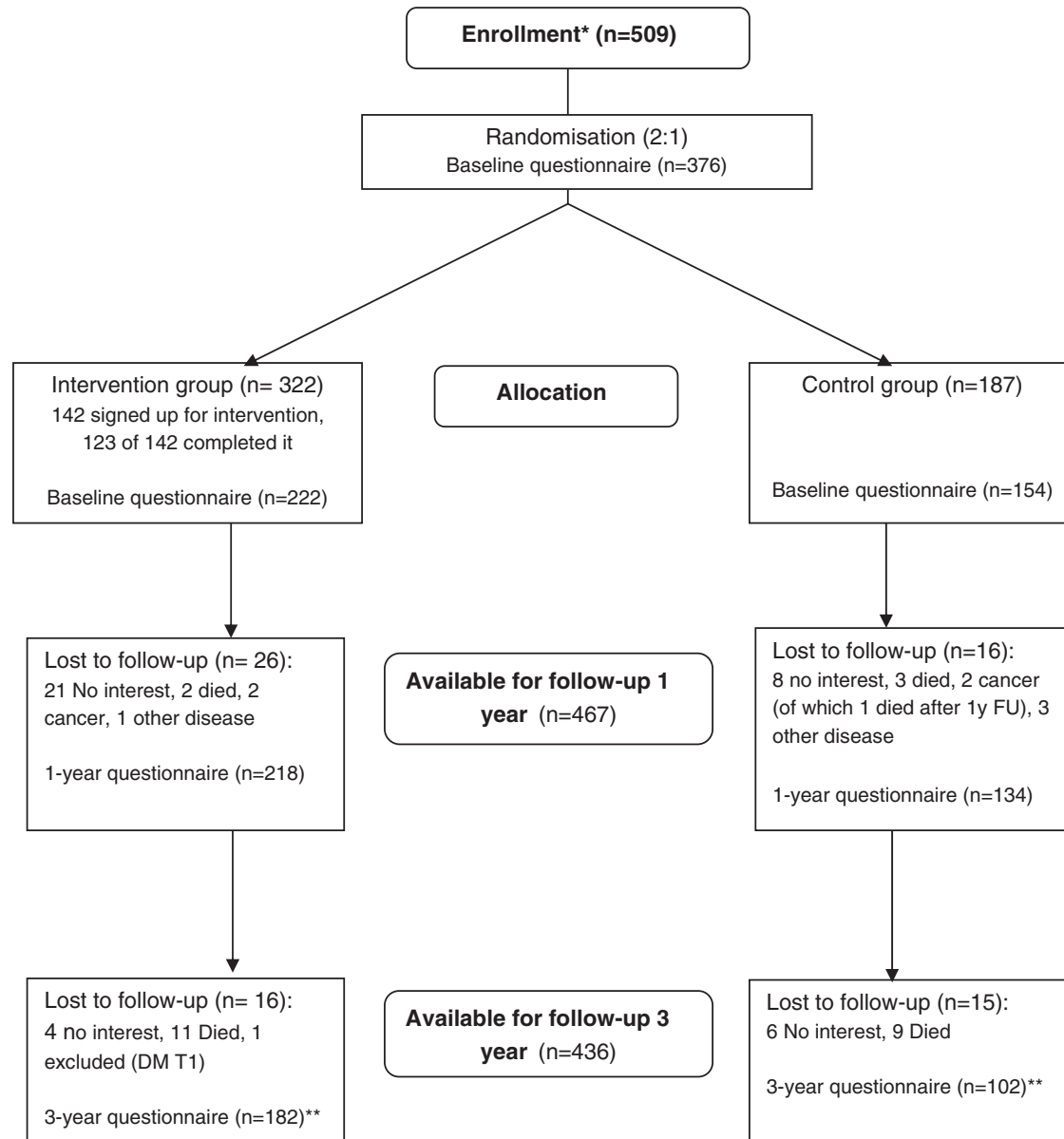


Figure 1 Flowchart of the 'Ready to Act' programme study

diabetes, whereas people with impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) were to be treated according to national clinical guidelines for CVD. The treatment targets and contents of the GP education have previously been published.

Population

The initial study population included 509 adults from the ADDITION treatment arm with IGT, IFG or type 2 diabetes from the county of Aarhus, Denmark. The inclusion period for this study was from January to September 2006. The follow-up times were scheduled for 1 and 3 years after end of intervention. The 509 adults with dysglycaemia were pre-randomly¹⁵ assigned to the 'Ready to Act' Health Education programme in addition to the GP treatment or to a control group (only GP treatment) (intervention = 322; control = 187). The pre-randomized design (randomized consent design) was chosen in order to protect the control group from unnecessary further 'project' burden. The pre-randomization was possible because the consent for providing data was given beforehand in the main trial, the ADDITION-study.

The 2:1 balance was chosen to secure a minimum of 8–10 groups in different local settings (approximately 100 participants). We predicted that 40–50% of those invited to the intervention would

participate. To minimize cluster effect between people from the same general practice, the enrolled participants were furthermore stratified according to practice, and diagnosis (IFG, IGT or T2D) to ensure that the group sessions involved both people with T2D and prediabetes. The randomization left us with 322 in the intervention group, and predictable 100–150 to participate in the programme. An independent biostatistician generated the random assignment, and the first author managed the dispatch of invitation letters. At the 3-year follow-up, 73 participants (I: 42; C: 31) had withdrawn ($n = 436$). The loss to follow-up differed in the two randomization groups as more people with prediabetes dropped out from the intervention group than from the control group ($P = 0.006$).

The health education intervention

The overall objective of the 'Ready to Act' health education programme¹² was to support the participants' competences in daily life and act appropriately with respect to their dysglycaemic condition. The achievement of action competence involved four learning objectives: intrinsic motivation, informed decision-making, action experience and social involvement. The programme was delivered in primary care settings (health centre or GP surgeries) by nurses, dieticians, physiotherapists and GPs. It consisted of 2

one-to-one sessions and 8 group sessions with 8–14 participants/group, totalling 18 h over 3 months. The group meetings were based on dialogues about understanding the risk condition and motivational issues, combined with practical, interactive exercises, mostly directed at diet and physical activity. The health professionals were urged to elicit and acknowledge the participants' perspectives and initiatives, offer relevant information including choices about treatment options, while minimizing pressure and control. All participants were encouraged to use self-directed action plans to support their health behaviour during and after the intervention. Three group meetings focused specifically on diet and were led by dietitians (9 h in total). Dietary recommendations were based on the Nordic Nutrition Recommendations 2004.¹⁶ The main emphasis was on decreasing sugar intake and total fat intake, substituting saturated fat for unsaturated fat, increasing the intake of fish and whole grain, and increasing the intake of vegetables and fruit, although fruit should be limited. Recommendations relevant for dysglycaemia such as meal frequency, macro nutrient composition, the distribution of carbohydrates, protein and fat, and the use of slow carbohydrates were also integrated. Before the intervention, the health professionals who delivered the intervention completed a training programme in participant-centred communication, autonomy support and action plan support given by experts in communication and health education (15 h). The content and the development of the 'Ready to Act' health education programme is described in detail elsewhere.¹²

Data

Clinical data including diagnosis, duration of diagnosis, HbA1c and BMI were collected at baseline by the GP. Self-reported data, including sociodemographic data, psychosocial conditions and health behaviour, was collected by questionnaires mailed to the participants at baseline and 1- and 3-year follow-up of intervention. After two weeks, reminders were sent out with a new copy of the questionnaire, if the first had not been returned.

Outcome measurement

Dietary intake was measured by a 38-item food frequency questionnaire. The overall dietary quality was estimated using a revised version of the Dietary Quality Score (DQS) [17]. In short, the original DQS score was developed as a crude index of the overall quality of the dietary habits. The score was based on questions regarding the intake of fruit, vegetables, fish and fats and was rated on a 9-point scale (0–8), with 8 as the optimal diet. The original DQS was created for cardiovascular disease prevention purposes and therefore included no upper limits for fruit intake. However, as this study focused on the management of dysglycaemia, a revised version of the DQS was developed (DQS_R) to account for a recommendation of maximum two pieces of fruit per day. This version was similar to the original DQS, except that in the DQS_R the category of an intake of 1–4 pieces of fruit was defined as the 'optimal' intake, whereas an intake of more than 4 pieces of fruit was only given a medium score (compared with a maximum score in the original version).

Ethics

Ethical approval of the study was attained from the local Science Ethics Committee of Aarhus County, Denmark (protocol no: 20000183). All participants gave informed content. The Danish Data Surveillance Authority permitted the collection and storage of data (journal no: 2000-41-0042). The ADDITION-study was registered as a Clinical trial (registration no: NCT00237549).

Statistical methods

We examined the disparities between responders and non-responders with regard to sex, age, education, cohabitation, diagnosis, HbA1c-level, BMI and perceived competence in healthy diet. The chi-square test was used for comparison of categorical variables, and the non-parametric Mann-Whitney test or the Student's *t*-test with unequal or equal variances was used for continuous variables. Multilevel regression analyses with repeated measurements were used to determine the effect on dietary intake over time. Proc Mixed in SAS (SAS statistical software, version 9.1, SAS Institute Inc., Cary, NC, USA) was used with normally distributed random intercepts. In all analyses, the parameter of interest, development in dietary intake, was an interaction term between intervention group and time. In the analyses, time was included as a random effect, whereas intervention group and confounders were included as fixed effects. The multilevel regression models were adjusted for the variables that were either differently distributed between the intervention and control group at baseline and/or differently distributed at baseline between responders and non-responders at baseline, and the 1- and 3-year follow-ups. In this study, adjustments were therefore made for sex, age, vocational education (yes or no), dysglycaemic condition (prediabetes or type 2 diabetes) and perceived competence associated with dietary habits measured by the Perceived Competence Scale.¹⁸ The effect was described as a net change meaning the difference between the change in the intervention group and the change in the control group. Participants that reported dietary intake at least once were included in the analyses. Overall, 65 of the 509 included participants (Intervention: *N*=48; Control: *N*=17) had missing information on dietary habits at all three occasions, leaving 444 subjects for the analyses. Dropouts were defined as missing information on dietary quality at baseline or follow-up, because the participant did not complete the questionnaire or dropped out of the study. Additional analyses of the differences in the crude estimates at baseline and at 3-year follow-up were tested by unpaired *t*-tests in the total population. The null hypothesis was rejected at a 5% level. Post-intervention analyses showed that the actual participation of 444 responders available for the 3-year analyses yielded an unadjusted difference of 0.11 of the DQS_R measure. Given the standard deviations (1.29 and 1.35) measured in the randomization groups, we would have been able to detect a difference at 0.375 on a 5% level.

Results

Characteristics of the participants at baseline are shown in table 1. The age of the 509 participants ranged from 43 to 75 years (mean=61.8 years; SD=7.2), and 46.8% were women. Four hundred and forty-four participants (87.2%) contributed to the analysis. The drop-outs (*n*=65) differed from the responders (*n*=444) according to the dysglycaemic condition, as the individuals who were diagnosed with type 2 diabetes had a higher response rate

Table 1 Baseline characteristic of participants, the Ready to Act study, Aarhus, Denmark

Characteristic	Randomization groups			
	Intervention	<i>n</i>	Control	<i>n</i>
Age, mean (SD) (years)	62.2 (6.9)	322	61.2 (7.6)	187
Sex, female (%)	47.2	322	46	187
Cohabit, living alone (%)	24.7	316	26	185
Vocational education, yes (%)	68.5	302	66.3	178
Dysglycaemic condition, IFG and IGT (%)	46.0	322	50.3	187
Body mass index, mean (SD) (kg/m ²)	29.9 (5.1)	315	30.2 (5.8)	186
Glycated haemoglobin, mean (SD) (%)	6.0 (0.8)	322	6.1 (0.9)	187

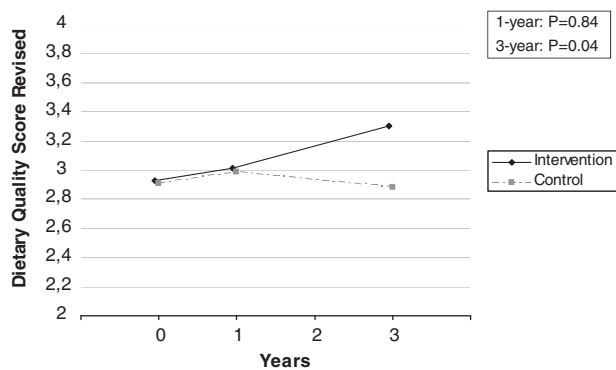
Table 2 Crude dietary intake at baseline, 1- and 3-year follow-up, the Ready to Act study, Aarhus, Denmark

	Intervention ^a	Control ^b
Use of saturated fat on bread or for cooking, mean (SD), (g/week)		
Baseline	61 (78)	65 (76)
1-year follow-up	55 (72)	58 (69)
3-year follow-up	71 (97)	64 (88)
Use of unsaturated fat on bread or for cooking, mean (SD) (g/week)		
Baseline	91 (66)	95 (65)
1-year follow-up	96 (70)	96 (72)
3-year follow-up	132 (118)	109 (89)
Fruits, servings, mean (SD) (week)		
Baseline	12.6 (11.9)	13.2 (12.6)
1-year follow-up	14.3 (12.3)	14.0 (12.4)
3-year follow-up	14.2 (11.9)	16.8 (13.0)
Vegetables, mean (SD) (g/week)		
Baseline	988 (521)	996 (544)
1-year follow-up	949 (522)	994 (556)
3-year follow-up	1014 (507)	938 (476)
Fish, mean (SD) (g/week)		
Baseline	258 (164)	241 (149)
1-year follow-up	232 (157)	249 (185)
3-year follow-up	238 (174)	232 (148)
DQS_R mean (SD), points		
Baseline	4.61 (1.58)	4.62 (1.40)
1-year follow-up	4.70 (1.42)	4.69 (1.42)
3-year follow-up	4.86 (1.29)	4.75 (1.35)

Comparisons of differences in intake between groups were analysed by Wilcoxon's two-sample test. No significant differences were found for the crude intakes.

a: N = 222 (baseline), N = 218 (1-year FU), N = 182 (3-year FU)

b: N = 154 (baseline), N = 134 (1-year FU), N = 102 (3-year FU)

**Figure 2** Development in the DQS_R from baseline to the 3-year follow-up, the Ready to Act-study, Aarhus, Denmark

of 91.0 versus 83.1 among those with prediabetes ($P=0.007$). One hundred and twenty-three accepted to take part in the interventions offered and completed the entire programme (38%). Details of the reach of the programme are reported elsewhere.^{19,20}

Table 2 shows the crude intake of fats, fish, fruits and vegetables, and the DQS_R score at baseline, 1- and the 3-year follow-up. At baseline, no significant differences were found in dietary intake between the intervention group and the control group. The multi-level analyses showed that at 3-year follow-up, participants in the intervention group had significantly improved the overall quality of their dietary intake compared with the control group (net change: 0.39 DQS_R points, $P=0.04$) (figure 2). Furthermore, there was a statistically significant increase in the intake of unsaturated fat from baseline to the 3-year follow-up in the intervention group compared with the control group (net change: 31 g/week; $P=0.02$). A non-significant tendency of an

increased intake of vegetables was additionally seen in the intervention group at the 3-year follow-up compared with the control group (net change: 111 g/week; $P=0.16$) (data not shown). No significant differences were found at the 1-year follow-up, except for a significantly lower increase of fish intake in the intervention group compared with the control group (data not shown). However, this difference attenuated and became insignificant at the 3-year follow-up. No significant effect was found on fruit intake.

Discussion

Findings

The aim of this study was to assess the effect on dietary quality of a theory-based health education programme as part of a multifactorial intervention offered to people with screen-detected dysglycaemia. The intention-to-treat analysis revealed a statistically significant higher net change in dietary quality, favouring the intervention group. The intervention comprised a flexible, individual and group-based curriculum focusing on the personal action competence rather than a fixed curriculum. The intervention appeared to be able to, not only sustain, but improve dietary quality 3 years after intervention. The long-term effects in dietary intake are in line with the applied behavioural theories, which state that autonomous motivation, self-efficacy and informed decisions are important steps of sustainable behaviour changes to be integrated into everyday life.^{21,22} These findings are supported by our 1-year follow-up results of the 'Ready to Act' programme, which showed statistically significant improvements on perceived competence/self-efficacy in achieving a healthy diet as well as the motivation for behavioural treatment, but yet no measurable effect on the DQS_R.¹⁹ In addition to a significantly improved overall dietary quality, a significant increase in the use of unsaturated fats on bread and for cooking was found in the intervention group compared with the control group. This change in behaviour might indicate that participants in the intervention group in general choose healthier types of fats, and the recent The Prevención con Dieta Mediterránea (PREDIMED) study²³ showed how a diet including increased intake of unsaturated fat reduced the incidence of type 2 diabetes.

The change in overall dietary quality was small and the actual clinical impact of the achieved increase is not clear. However, an earlier randomized intervention study, Inter99, reported that the DQS was associated with risk of cardiovascular disease¹⁷. The DQS showed a significantly positive association with HDL-cholesterol and a significant negative association with total cholesterol, triglyceride, LDL cholesterol, homocysteine, waist circumference and the absolute risk of cardiovascular disease measured by The Copenhagen Risk Score. The association was shown with the unrevised version of DQS.

Participation

The 38% completion rate in our programme may seem low, but it is comparable with other studies that provide health education for people with screen-detected and/or other populations with type 2 diabetes.^{24,25} The low rate should be interpreted with the pre-randomized design in mind including the eligible population, and not only the motivated. The pre-randomization permitted the analyses of predictors for acceptance of the intervention, with vocational education proving to be the most decisive factor for attending, compared with no education. No education was followed by comorbidity measured by Charlson's comorbidity score, which predicted a decreased probability of participating in health education.²⁰

Studies comparable with ours in intervention length and content targeted people in risk of or with diabetes very often lack dietary outcomes.^{9,11,26,27} The DESMOND study,²⁸ a randomized controlled

trial assessing a group education intervention for people with newly diagnosed type 2 diabetes emerged from the British part of the ADDITION study. The intervention included 6 h.

Comparison with other studies

No other studies have addressed health education in a group of people with either prediabetes or type 2 diabetes. We decided to do so because the target of reducing risk is similar, and the educational needs seem to be very similar.²⁹ Health education of contact between patients and trained healthcare professionals in the primary care. None of the aforementioned studies measured dietary changes, whereas a few Danish studies measured dietary quality.^{24,30} In a type 2 diabetes lifestyle study, the achieved changes were in line with the effect in this study²⁴ as the total dietary quality improved in the intervention group, whereas the intake of unsaturated fat increased. In the Inter99-study, which was a five-year lifestyle intervention study in a general population, a borderline significant improvement in the DQS was found.

Strength and limitations

Only few studies have studied the effects in dietary quality of a health education programme across different conditions and targeting action competence in living with a risk of diabetes development and/or cardiovascular complications. It is notable that the intervention seemed to attract people with both prediabetes and type 2 diabetes. The attendees had a similar proportion of prediabetes (46.3 %) as the invited intervention group (46.0 %).¹⁹ The primary strength of this study is the long follow-up period that made it possible to reveal sustained behavioural changes, and the possibility of accounting for non-responses in the analysis. An important limitation of the study is the incomplete number of responders at each measurement point. The loss to follow-up differed in the two randomization groups according to the dysglycaemic condition as more people with prediabetes dropped out from the intervention group than from the control group. However, the use of multilevel regression analyses with repeated measurements and random effects made it possible to take into account the loss to follow-up,³¹ by including covariates associated with missing information on dietary habits at follow-up. Because baseline intake and other relevant characteristics were taken into account in the model, the fact that these to some degree varied between responders and non-responders should therefore not bias the results. Furthermore, other important advantages of the applied method include that individuals with missing data at some of the follow-ups can be included in the analyses and that we could control for the dependencies among the repeated measurements.³²

Dietary habits are complex and difficult to measure. We used a crude score that only can be interpreted as an indicator of the dietary quality in general. Therefore misclassification must be considered. The validation study showed reasonable classification of the individuals.¹⁷ Furthermore, the observed significant improvement in dietary intake in the intervention group could partly be due to desirability bias because individuals in the intervention group more so than in the control group may tend to report the diet they were taught to eat.³³ Although probably smaller, desirability bias could also be present in the control group because of the focus of increasing the intake of fruit, vegetables, fish, and decreasing fat intake in the public nutritional campaign at the same time as the intervention in Denmark. More objective measures for diet than the ones we used, e.g. the calculating of daily diet, may be better suited for measuring changes. The limitation of this method is the need for contact with the participants, making the data collection an intervention in itself. Concerning the data quality in general, no patterns of missing values to single items or scales were found.

Conclusions

Health education aiming at health-related action competence improved the long-term dietary intake in a population at high risk of cardiovascular disease and diabetes measured by a validated crude index. The findings add to the knowledge base of health education content, and contribute to the future planning of preventive strategies after screening procedures and other behavioural interventions, taking into account the possible barrier among specific target groups.

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Key points

- Health education aiming at broad health-related action competence improved the long-term dietary quality in a population with dysglycaemia.
- The results confirm the theoretical assumption that motivation and perceived competence leads to behavioural changes; and that changes are long in the making.
- This study acknowledge the increasing number of people with early detected dysglycaemia and offer evidence of effective health education for implementation in future public health strategies.

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