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Research: Educational and Psychological Aspects

Theory-based diabetes self-management education with pre-selection of participants: a randomized controlled trial with 2.5 years' follow-up (ELDES Study)

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Abstract

Aims To evaluate the (cost-)effectiveness of Beyond Good Intentions (BGI), a 12-week group-based, nurse-led self-management programme, in terms of cardiovascular risk factors, self-management and quality of life, after 2.5 years of follow-up in pre-selected individuals with known Type 2 diabetes of up to 5 years' duration.

Methods A parallel randomized controlled trial comparing BGI with usual care, based on a self-management screening questionnaire, was conducted in 43 general practices after pre-selection of participants. After 2.5 years of follow-up, the between-group changes in the abovementioned variables were assessed using analysis of covariance.

Results A total of 108 participants (BGI group, n =56; control group, n =52) were included. Changes over time in BMI (–0.4 vs –0.5 kg/m^2) were similar in the two groups. Median HbA_{1c} [BGI group 47 mmol/mol (6.5%); control group: 49 mmol/mol (6.6%)] and mean systolic blood pressure (BGI group: 132±13 mmHg; control group: 133±14 mmHg) were well controlled at baseline and no intervention effect was found. LDL cholesterol levels decreased from 2.4 to 2.2 mmol/l in the control group and remained stable at 2.6 mmol/l in the intervention group (P=0.032). No intervention effect was found for self-management or quality of life.

Conclusion In contrast to the first BGI study, we did not observe significant effects of the BGI intervention, despite pre-selection of individuals. In diabetes populations with target levels for HbA_{1c}, systolic blood pressure and LDL cholesterol, no further beneficial effects can be expected from self-management programmes with regard to biomedical factors and quality of life.

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Introduction

Several programmes that offered support for diabetes self-management successfully improved individuals' health behaviour and significantly reduced cardiovascular risk [1–4]; however, their long-term (cost-)effectiveness was limited and disappointing [5], probably because they did not satisfactorily address the sustainability of behavioural changes over time [6]. In contrast, the DESMOND programme for people newly diagnosed with Type 2 diabetes was not designed to achieve long-term effects, but to start people on their journey and help them identify their long-term support needs. Surprisingly, illness beliefs regarding diabetes did result in sustained, long-term effects under this programme [7]. The diabetes self-management programme Beyond Good Intentions (BGI) focused on maintenance of changed health behaviour by encouraging resilience, and providing opportunities for gaining knowledge and skills for successful self-management via proactive coping; that is, the efforts undertaken in advance of a potentially stressful event to prevent or modify its form before it occurs [8]. BGI was originally designed for individuals with screen-detected Type 2 diabetes [9] and was based on the assumption that self-management is particularly difficult for people with screen-detected disease because they are generally asymptomatic, inexperienced and prone to downplay risks and treatment [9,10]. BGI resulted in a reduction of both BMI and systolic blood pressure (SBP) [11]. The effectiveness of the programme in individuals already diagnosed with Type 2

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What's new?

- Beyond Good Intentions (BGI), a 12-week group-based, nurse-led self-management programme, further improved BMI and blood pressure over and above intensive multifactorial treatment at 1-year follow-up in people with screen-detected Type 2 diabetes.
- The pre-selection of individuals who were unlikely to benefit from the programme led to the exclusion of 9% of all eligible participants.
- Despite pre-selection, the programme was ineffective in people with Type 2 diabetes of 3 months' to 5 years' duration. Neither BMI, HbA_{1c}, blood pressure, lipid levels, self-management, health status nor quality of life improved significantly.
- In diabetes populations with target levels for HbA_{1c}, systolic blood pressure and LDL cholesterol, no further beneficial effects on biomedical factors can be expected from self-management programmes.
- The challenge when designing a self-management educational programme for people with diabetes is customization to suit patient needs, and accommodation of specific phases during the course of the disease. One solution might be to develop educational programmes with individual modules that patients can then select.

diabetes is unclear. Furthermore, there is increasing recognition that the 'one-size-fits-all' approach in diabetes self-management education is obsolete, which is to say that not every person benefits equally from self-management programmes [2,12]. The self-management screening tool SeMaS can be used to identify barriers to effective self-management, such as lack of social support or the presence of depression or anxiety [13]. It might also be helpful to identify individuals who are unlikely to benefit from a diabetes self-management programme.

We hypothesized that by differentiating individuals who might or might not benefit from a self-management programme, an intervention could be designed that shows long-term (cost-) effectiveness. The aim of the present study, the Eindhoven Long-term Diabetes Education Study (ELDES), was to investigate the long-term (cost-)effectiveness of the BGI educational programme with regard to BMI, cardiovascular risk factors, quality of life and diabetes self-management behaviour in a pre-selected group of individuals with Type 2 diabetes.

Participants and methods

Setting and participants

The design of the study has been described previously [14]. In short, the ELDES study is a parallel randomized controlled trial (1:1) with an intended follow-up of 2.5 years (inclusion period 2014–2015), and randomization based on computer-generated random numbers, with sealed, opaque, sequentially numbered allocation envelopes. As participants in the intervention group attended an education programme, it was not possible to blind participants to treatment allocation. A total of 43 general practices with 89 general practitioners agreed to participate. Eligible individuals were adults aged 18–75 years, with a known diabetes duration of between 3 months and 5 years. Individuals were excluded from the BGI programme during a selection procedure as explained below. Other exclusion criteria were insufficient cognitive function and insufficient comprehension of the Dutch language. All included participants received standard diabetes care in accordance with guidelines from the Dutch College of General Practitioners [15]. Informed consent was obtained from all participants before pre-selection. The ELDES study was approved by the Medical Ethical committee of the University Medical Centre Utrecht. It was registered at the Dutch Trial Register (Nederlands Trial Register NTR5530).

Pre-selection

During pre-selection, the SeMaS questionnaire was used to assess a persons' self-management capabilities [13]. It was sent to all candidates and, upon completion and return to the research centre, was used to determine eligibility. The questionnaire consists of 27 items covering five psychosocial domains (locus-of-control, self-efficacy, social support, coping, anxiety/depression), three skills (computer, functioning in groups, self-care), perceived burden of disease, and level of education. Individuals scoring highly on anxiety (>4 points out of 8) and/or depression scales (>3 points out of 6) were excluded from the BGI programme, as treatment of these complaints was considered necessary before attempting improvement of self-management. The informed consent procedure indicated that reasons for exclusion would be reported to the treating general practitioner, and general practitioners were indeed informed about their patient's high SeMaS anxiety and/or depression scores. People without potential problems regarding self-management (the highest possible levels with regard to locus-of-control, self-efficacy, social support, and coping, combined with low anxiety (≤4 points) and depression (≤3 points) levels) were also excluded, as they were not expected to benefit from the BGI programme.

Intervention: Beyond Good Intentions

The ELDES study elaborates on the existing BGI programme and is based on the concepts of self-regulation and proactive coping [9]. BGI is a 12-week programme consisting of two individual and five group sessions: a 30-min individual session, followed by four 2.5-h group sessions, and completed with an individual evaluation session. An additional group booster session was scheduled 1 year after the

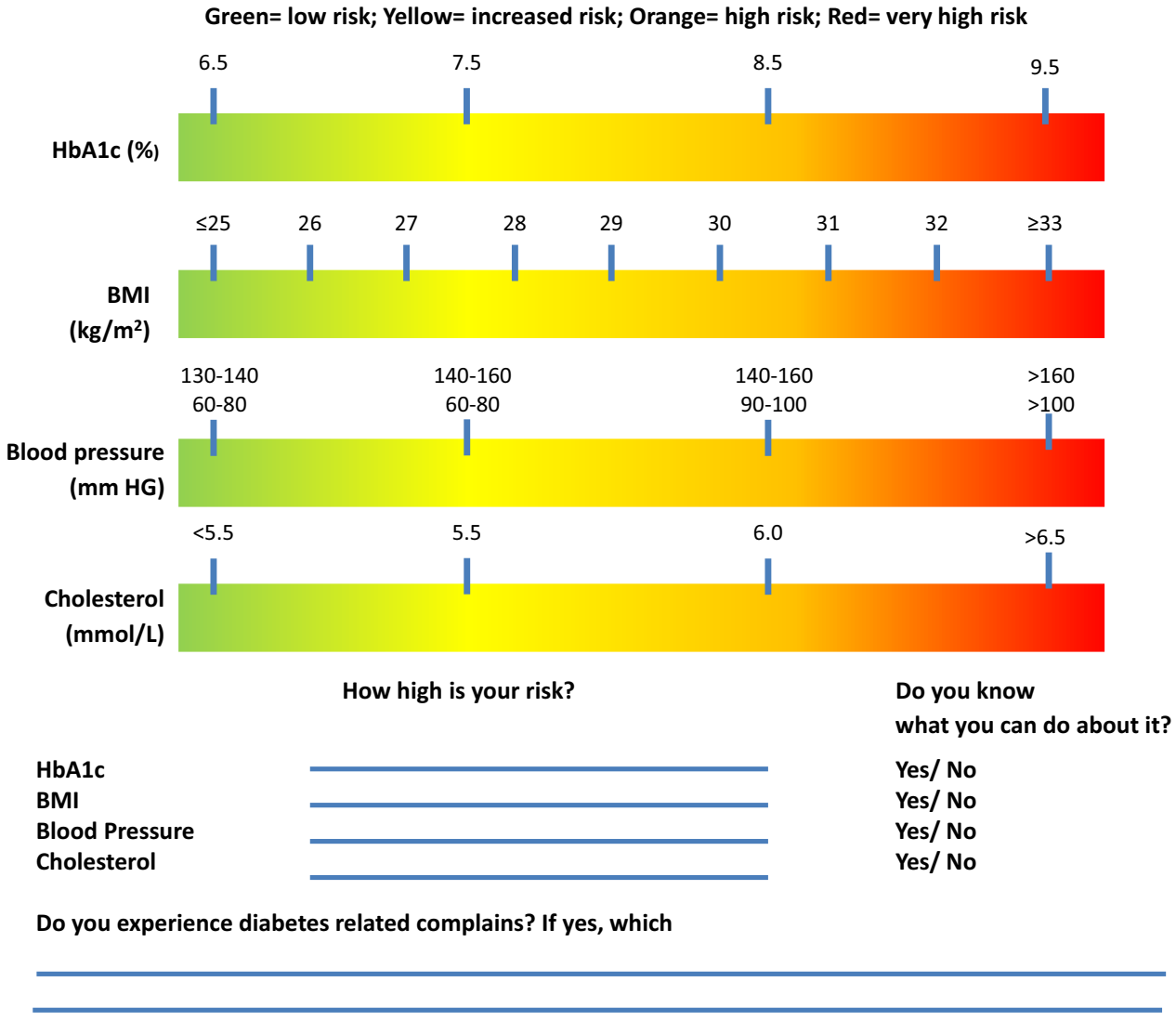

FIGURE 1 Diabetes profile chart used during the individual session to explain the individual risk profile.

evaluation. The programme was structured as described below.

1. Individual session

The practice nurse and the participant discuss the participant's knowledge and attitudes regarding diabetes management. A 'diabetes profile' was specifically designed to support participants in gaining insight into their diabetes risk factors and relative risk for long-term complications (Fig. 1). Glycaemic control, BMI, SBP and lipid profile were discussed. Participants were encouraged to set personal goals and asked to articulate a goal for the next session.

2. Group sessions

These included eight to 10 participants and took place close to the participants' homes. Participants from the same practices attended different group sessions to minimize a practice-based cluster effect. The first three sessions covered topics relevant to all individuals with Type 2 diabetes, including physical exercise, diet, medication and blood glucose self-monitoring. The fourth session was dedicated to the participants' personal goals. Every session started with the introduction of the topic, after which participants shared their opinions, emotions and experiences. Participants then drew up their own individual plan of action for the coming 2 weeks, using a proactive five-step approach:

Step 1: Articulate a concrete, achievable goal.

Step 2: Identify necessary conditions and potential barriers.

Step 3: Develop strategies for overcoming potential barriers.

Step 4: Articulate the final plan: what, how, where, when, whom?

Step 5: Specify the method of evaluation and specific targets; discuss with peers for final improvements

Participants were encouraged to gather information about diabetes themselves and take responsibility for their disease. At the end of every session the homework for the upcoming 2 weeks was explained.

3. Evaluation

Two weeks after the fourth group session, the programme was evaluated in an individual session with each participant in which personal benefits of the programme were discussed.

4. Booster session

With the same group composition and trainer as during the original programme, the preceding year was discussed. Existing goals were evaluated and new goals were formulated.

Nurse training

Three nurses were trained in two 3-h sessions, via the teach-the-teacher principle, by the psychologist who designed the original BGI programme. The programme was conducted by three trained practice nurses, who assumed the role of coach and facilitator. They encouraged participants to support each other and to gain self-confidence in gathering information to facilitate the design of individual goals. In addition, the three trainers met (on an irregular basis) in order to swap experiences.

Control group

Participants in the control group received only usual diabetes care, in accordance with the guidelines from the Dutch College of General Practitioners [15]. No other diabetes self-management educational programmes were offered by the general practices during the study.

Outcome measures

As in the original BGI study, the primary outcome measure, BMI, was retrieved from electronic medical records. A change of 0.77 kg/m^2 between baseline and follow-up was considered a clinically relevant between-group change.

Secondary outcomes were SBP, HbA_{1c}, lipid profile, self-management behaviour, medication adherence, health status, diabetes-related quality of life, and cost-effectiveness. SBP, HbA_{1c}, fasting glucose and lipid profiles were retrieved from electronic medical records at baseline and after 2.5-year follow-up (all values between 3 months before baseline and 3 months after 2.5-year follow-up) by independent assessors. Participants completed a set of questionnaires at home, at both baseline and after 2.5 years of follow-up, in order to assess self-management behaviour, medication adherence, health status and quality of life.

Self-management was assessed by the Summary of Diabetes Self-Care Activities (SDSCA) validated questionnaire (10 items, score range 1–7, higher scores indicating better self-management) [16] and medication adherence by the validated five-item Medication Adherence Rating Scale (MARS-5; score range 1–5, higher scores indicating closer adherence) [17]. Health status was assessed with the validated five-item EuroQol health questionnaire (EQ-5D; score range –0.594 to 1.00, higher scores indicating better experienced health status), the EuroQol visual analogue scale health questionnaire (EQ-VAS; one item, score range 0–100, higher scores indicating better health status) [18] and the 36-item short-form health survey (SF-36; two general domains: physical health and mental health, score range 0–100, higher scores indicating better health status) [19]. Diabetes-related quality of life was assessed with the validated Audit of Diabetes-Dependent Quality-of-Life (ADDQoL) questionnaire (19 items, weighted impact score range –9 to 9, with negative scores indicating a negative impact and positive scores a positive impact of diabetes on an individual's quality of life) [20].

The planned cost-effectiveness analysis has previously been explained in detail [14], and included a plan to determine the incremental cost-effectiveness ratio. Costs of the BGI programme and diabetes-related healthcare resource use during the whole study period were also included in the cost calculation.

Statistical analyses

The BGI programme has previously been reported to result in a significant BMI difference of 0.77 kg/m^2 in individuals with screen-detected Type 2 diabetes [11]. For the present study, we calculated that a minimum sample size of 88 (44 per group) would be required to achieve 80% power to detect this difference in a design with repeated (n=6) BMI measurements (usual diabetes care includes weight measurement every 3 months), with a standard deviation of 1.7 kg/m^2 (for each group), and an α value of 0.05. Because of an expected drop-out rate of 20%, we needed to include a total of 106 participants. We performed an intention-to-treat analysis (all participants, including those who discontinued the intervention, were analysed in the group to which they were originally randomized). Descriptive statistics were used to analyse baseline characteristics. Categorical variables are reported as counts and percentages; continuous variables as means with SD values for normally distributed data, or medians with interquartile ranges for non-normally distributed data. Changes were evaluated with analysis of covariance, adjusted for baseline values. The differential changes of the two groups were subtracted to assess between-group effects. As disease control data were missing for only one participant per group it was not necessary to impute data. With regard to the self-reported outcome measures, the percentage of missing data was too large to allow multiple imputation. A P value <0.05 was taken to indicate statistical significance. IBM SPSS statistics version 21 was used for the statistical analysis.

Results

In total, 1590 individuals were informed about the ELDES study, of whom 1471 declined participation or did not respond. During pre-selection, 11 people were excluded as a result of high scores on anxiety and/or depression; no individuals completely free of problems relevant to self-management were identified. People excluded during pre-selection were significantly younger and their median HbA_{1c} was significantly higher [59 mmol/mol (7.5%) vs 48 mmol/mol (6.5%)] than those who participated (Appendix S1).

The remaining 108 participants were randomized: 56 to the intervention group (BGI) and 52 to the control group. During follow-up, one participant died before completing the 2.5-year period and one participant moved to another general practice (Fig. 2). Both groups were well matched overall. By chance, the control group had a larger percentage of participants who were male, married, and/or employed. Furthermore, there were some differences between groups in the prevalence of diabetes-related complications. BMI was similar in the two groups at baseline (intervention group: 29.6±4.9 kg/m^2; control group: 30.1±4.5 kg/m^2; Table 1).

BMI and weight decreased in both groups without a significant intervention effect (P=0.57). Glycaemic control, total cholesterol, HDL cholesterol, triglyceride levels and SBP were on target at baseline and remained stable over time in both groups, without significant between-group effects. LDL cholesterol values were good at baseline (BGI group: 2.6±0.9 mmol/l; control group: 2.4±0.8 mmol/l) and levels remained stable in the BGI group, but decreased significantly in the control group (2.2±0.7 mmol/l), resulting in a

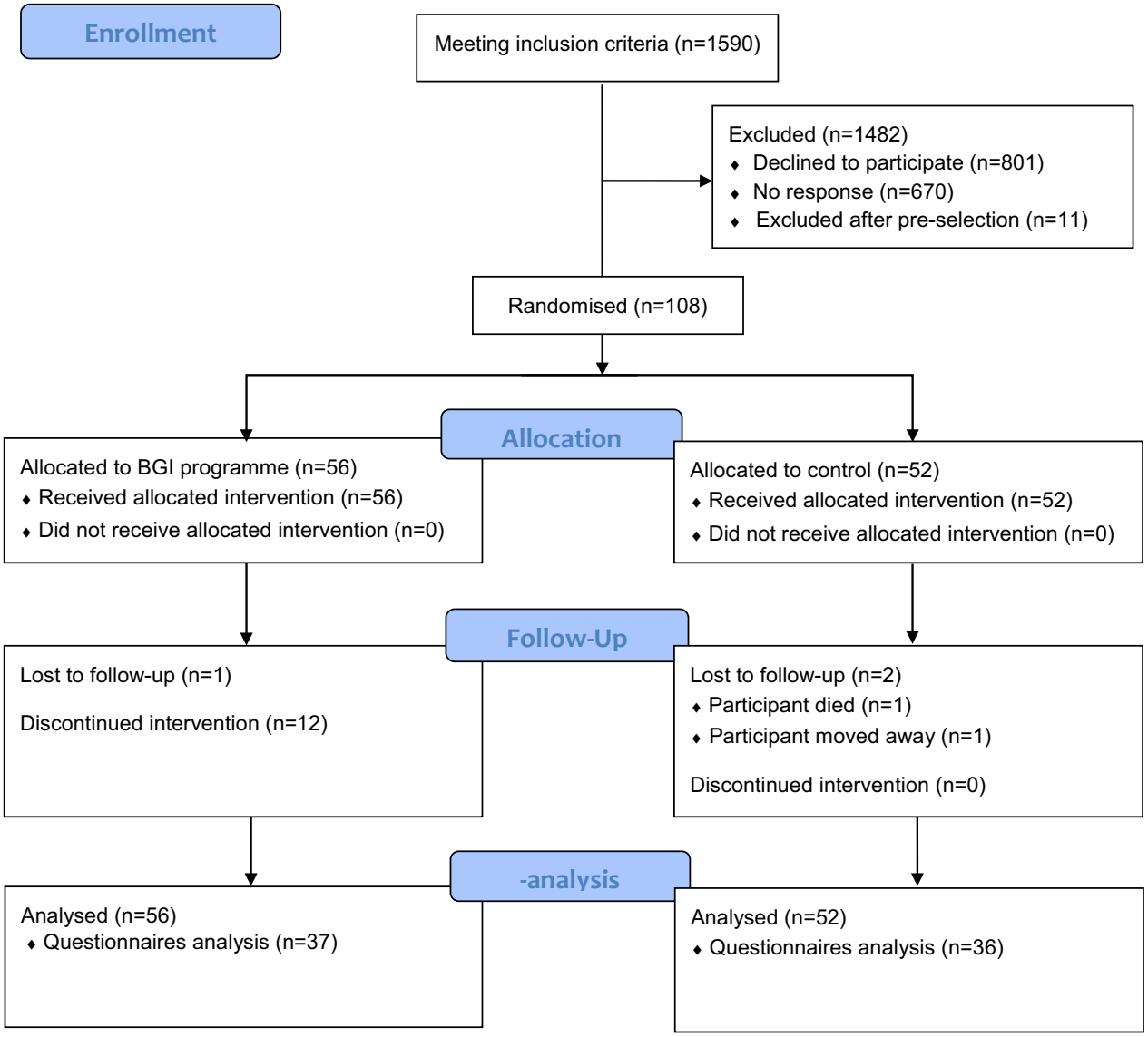

FIGURE 2 CONSORT 2010 flow diagram.

significant between-group effect in favour of the control group (P=0.01; Table 2).

Self-management activities did not change significantly between groups over the course of 2.5 years (Table 2). Health status measured with three questionnaires (EQ5D, EQ-VAS, SF-36) was already good at baseline and remained stable over time, with no between-group effects. In both groups the highest SF-36 scores were found for mental health. Participants experienced few negative effects of their diabetes on their quality of life and this did not change significantly over time between groups (Table 2).

We opted not to perform a formal cost-effectiveness analysis because no effect was found on clinical outcomes, and healthcare costs were comparable between groups. Both groups only differed with respect to the number of e-consultations (n=106 in the BGI group vs n=36 in the control group) and in receiving the BGI programme (Table 3). A large proportion of the healthcare costs in both groups were attributable to the 3-monthly check-ups and an annual review by the general practitioner (n=379 in the BGI group vs n=213 in the control group), which is in accordance with the guidelines from the Dutch College of General Practitioners. Healthcare costs for diabetes complications were assumed to be comparable (Table 1). It is difficult to give an indication of differences in healthcare costs between groups because, in the Netherlands, all the aforementioned consultations are included in an annual lump sum that a general practitioner receives for each individual who receives diabetes care from the diabetes team in his/her general practice, with the exclusion of the costs for prescribed medications. The latter are partly paid by the individuals themselves and partly by the health insurance companies directly to the pharmacists.

Discussion

This study examined the long-term effects of the BGI self-management programme on cardiovascular risk factors, self-management and quality of life in pre-selected individuals with Type 2 diabetes of up to 5 years' duration. In contrast to the original BGI study, the present study found no evidence for an intervention effect on BMI. In line with our previous study, we found a nonsignificant effect with regard to glycaemic control. For LDL cholesterol, a between-group effect was found in favour of the control group, although follow-up levels in both groups were within the normal range. Owing to the use of pre-selection criteria, participants

Table 1 Baseline characteristics of study participants

	N	BGI (n=56)	N	Control (n=52)
Age, years	56	62.9 ± 8.3	52	61.7 ± 7.4
Sex, male	56	27 (48.2)	52	33 (63.5)
Education level	56		52	
Low		16 (28.6)		18 (34.6)
Intermediate		20 (35.7)		17 (32.7)
High		20 (35.7)		17 (32.7)
Marital status, married	55	36 (65.5)	51	40 (78.4)
Paid employment, employed	54	16 (29.6)	51	21 (41.2)
Smoking status	56		52	
Current		4 (7.1)		6 (11.5)
Former		31 (55.4)		22 (42.3)
Never		21 (37.5)		24 (46.2)
BMI, kg/m^2	55	29.6 ± 4.9	52	30.1 ± 4.6
Weight, kg	55	88.2 ± 16.2	52	87.8 ± 15.4
SBP, mmHg	55	132 ± 13.2	52	133 ± 14.5
Venous fasting glucose, mmol/l	55	7.4 (6.8–8.7)	52	7.5 (6.8–8.5)
HbA_{1c}, mmol/mol	55	47 (44 – 53)	52	49 (45 – 54)
HbA_{1c}, %	55	6.5 (6.2–7.0)	52	6.6 (6.3–7.1)
Lipid profile				
Total cholesterol, mmol/l	49	4.6 ± 0.9	47	4.1 ± 0.9
LDL cholesterol, mmol/l	55	2.6 ± 0.9	52	2.4 ± 0.8
HDL cholesterol, mmol/l	49	1.3 ± 0.3	47	1.2 ± 0.4
Triglycerides, mmol/l	55	1.6 (1.2–2.1)	52	1.6 (1.2–2.1)
Complications				
Myocardial infarction	55	1 (1.8)	52	6 (11.5)
Other chronic ischaemic heart disease	55	1 (1.8)	52	1 (1.9)
Stroke	55	2 (3.6)	52	–
Transient ischaemic attack	55	1 (1.8)	52	–
Intermittent claudication	54	–	52	2 (3.8)
Nephropathy (eGFR <60 ml/min/1.73m^2)	55	5 (9.3)	52	3 (5.8)
Retinopathy	55	–	52	–
Neuropathy	55	4 (7.3)	52	3 (5.8)

SBP, systolic blood pressure.
Data are n (%), means ± SD, or medians (interquartile range).

Table 2 Effectiveness of the BGI programme on biomedical outcomes, self-management, health status and quality of life

	N	BGI group		N	Control group		Between-group effect	
		Baseline	2.5-year follow-up		Baseline	2.5-year follow-up	Adjusted mean difference	P
BMI, kg/m^2	55	29.6 (4.9)	29.2 (4.8)	51	30.1 (4.5)	29.6 (4.5)	−0.41	0.57
Weight, kg	55	88.2 (16.2)	86.6 (16.1)	51	87.7 (15.4)	86.7 (14.1)	0.13	0.91
SBP, mmHg	55	132 (13)	135 (17)	51	133 (14)	135 (15)	0.90	0.75
Fasting glucose, mmol/l	55	7.4 (6.8–8.7)	7.9 (7.0–8.8)	51	7.3 (6.7–8.1)	7.5 (6.8–8.5)	0.00†	0.94
HbA_{1c}, mmol/mol	55	47 (44 - 53)	49 (45–54)	51	49 (45–54)	50 (46–54)	0.01†	0.67
HbA_{1c}, %	55	6.5 (6.2–7.0)	6.6 (6.3–7.1)	51	6.6 (6.3–7.1)	6.7 (6.3–7.1)	0.01†	0.67
Total cholesterol, mmol/l	49	4.6 (0.9)	4.3 (0.9)	48	4.1 (0.9)	4.3 (0.8)	0.02	0.88
LDL cholesterol mmol/l	54	2.6 (0.9)	2.5 (0.9)	50	2.4 (0.8)	2.3 (0.7)	−0.24	0.01
HDL cholesterol, mmol/l	49	1.3 (0.3)	1.2 (0.3)	48	1.2 (0.4)	1.2 (0.4)	−0.02	0.59
Triglycerides, mmol/l	55	1.6 (1.2–2.1)	1.4 (1.0–2.0)	51	1.6 (1.2–2.1)	1.8 (1.1–2.4)	−0.21†	0.29
Self-management	27			30				
Diet general		4.9 (1.7)	4.2 (1.4)		3.7 (2.0)	4.1 (1.7)	0.14	0.70
Diet specific		5.2 (1.1)	5.3 (1.2)		4.8 (1.3)	5.1 (1.0)	0.26	0.34
Diet vegetables		4.1 (1.8)	4.4 (1.9)		3.7 (1.9)	4.2 (1.7)	0.20	0.59
Diet fats		6.2 (1.1)	6.3 (1.3)		5.9 (1.7)	6.0 (1.2)	0.29	0.40
Exercise		2.8 (2.0)	3.6 (1.9)		3.5 (1.8)	3.2 (1.6)	0.43	0.29
Glycaemic control		0.4 (1.3)	0.7 (1.5)		0.4 (1.2)	0.5 (1.3)	0.17	0.56
Foot care		0.4 (0.9)	1.1 (2.0)		1.4 (2.1)	0.8 (1.5)	0.31	0.40
Medication adherence	32	4.9 (0.2)	4.7 (0.5)	30	4.9 (0.1)	4.9 (0.1)	−0.18	0.06
Health status, EQ-VAS score	34	75.4 (10.5)	73.4 (18.0)	34	75.2 (13.8)	74.9 (15.3)	−1.00	0.79
EQ5D	34	0.8 (0.2)	0.8 (0.3)	34	0.8 (0.1)	0.7 (0.3)	0.08	0.15
Quality of Life, SF-36 score	37			36				
Physical health		71.2 (20.3)	75.3 (18.3)		72.6 (21.8)	73.8 (21.0)	2.71	0.50
Mental health		82.0 (12.4)	80.0 (14.1)		78.5 917.3)	77.9 (17.4)	1.46	0.67
Diabetes Quality of Life	34	−0.9 (1.0)	−0.7 (0.9)	32	−1.0 (1.0)	−1.0 (1.1)	0.24	0.24

EQ5D, five-item EuroQol health questionnaire; EQ-VAS, EuroQol visual analogue scale health questionnaire; SBP, systolic blood pressure; SF-36, 36-item short-form health survey.
Data are means ± SD, or medians (interquartile range).
†Log transformation.

Table 3 Type and number of diabetes-related consultations over the course of 2.5 years in both study groups

Type of consultation	BGI group (*n*=38)	Control group (*n* =34)
Routine monitoring visits	379	213
Extra consultations < 20 min	29	18
Extra consultations >30 min	26	15
Telephone consultations	56	52
E-consultations	106	36
Interdisciplinary consultations	16	11

showed room for improvement in self-management, but no significant intervention effects were found. Health status and diabetes-related quality of life were already good at baseline and remained stable after 2.5 years.

These unexpected results can be explained in several ways. One explanation is that the BGI programme is effective in recently diagnosed participants who lack a diabetes self-management education, but not when participants have already received guidance in diabetes self-management. Another possibility is that the BGI programme is effective in people with poorly controlled diabetes (as in the original BGI study), but not in those with well-controlled disease (ELDES). Alternatively, BGI might be ineffective over the long term, irrespective of group selection criteria. Another possibility is that provision of education, a key element of self-management support, via BGI would be most effective during specific periods in the course of the disease, for example, when treatment needs to be intensified or when complications occur. Finally, study design effects may have played a role, and we cannot rule out a Hawthorne effect of participation in a randomized controlled trial or effects related to pragmatic trials, such as the way the nurse educators presented the course. We did not assess the latter aspect in a formal fidelity evaluation; however, the present study reflects a real-life situation in which an educational programme has been offered by thoroughly trained practice nurses.

Our findings with regard to the ineffectiveness of the BGI programme in reducing BMI over the long term are in line with previous research, including a systematic review [1,7,21,22]. With regard to weight, our results were similar to a systematic review, which found a small reduction (–1.9%) in favour of the self-management programme [1]. An investigation of the Look Ahead programme, however, did report a significant weight reduction after 4 years (of –6.15% of initial weight), although no long-term results for BMI were reported [23]. These differences in impact on

weight might be attributable to differences in the effectiveness of self-management education, such as the BGI programme, compared with a lifestyle intervention such as the Look Ahead programme. A lifestyle intervention focuses on the adoption of a healthy lifestyle. A self-management education programme not only focuses on healthy behaviour, but also provides essential knowledge, abilities and skills to self-manage the changes in symptoms inherent to a progressive disease and to cope with the psychosocial consequences of a chronic disease. The Look Ahead programme may have placed greater emphasis on weight reduction, whereas, in the BGI programme, weight was only one of several aspects in a broader programme.

Our nonsignificant HbA_{1c} findings are in line with the 2.5-year follow-up findings from another Dutch lifestyle programme [21], the 3-year follow-up findings of the DESMOND study [7] and those of a meta-analysis that included four studies with a follow-up of between 12 and 18 months [HbA_{1c} mean difference of –0.1% (95% CI –0.3 to 0.1)] [22]. This is in contrast to three systematic reviews and the Look Ahead programme that showed a significant decrease in HbA_{1c} in favour of the self-management/lifestyle group, with mean differences ranging from –0.27 to –0.87%, the effect being smaller after longer follow-up [23–26]. The lack of change in the present study might be partly attributable to excellent baseline values. While other studies found a small decrease in SBP after a follow-up of between 12 months and 4 years [7,22,23], we found no difference in change for SBP and significant decrease in LDL cholesterol in the control group, for which we have no explanation.

Unlike the present study, most other studies did not assess long-term patient-reported outcome measures after a diabetes self-management programme. The 3-year follow-up results from the DESMOND study are comparable to those of the present study, with, again, no effect on quality of life being found [7].

The present theory-based study, with a relatively long follow-up of 2.5 years, took place in a routine clinical setting with ongoing primary care disease management during the study, supporting the applicability of the intervention. The use of pre-selection should have increased the efficacy of the intervention; however, all participants randomized to the intervention group were asked to invest significant time and effort, which might explain an inclusion rate of only 7.5% (although this was also partly attributable to the recruitment procedure via invitation by letter, rather than a personal invitation). Generalizability is therefore questionable. However, one could also argue that such a low inclusion rate underpins the statement that 'one size does not fit all', even if pre-selection is taken into account.

In conclusion, the present study indicates that the BGI programme had no distinct long-term effects on clinical variables, self-management behaviour or quality of life in pre-selected individuals diagnosed with Type 2 diabetes of between 3 months' and 5 years' duration, and with excellent cardiometabolic control on average. The challenge when designing a self-management educational programme for people with diabetes will be customization to suit patient needs and accommodation of specific phases over the course of the disease. One possibility would be to develop an educational programme with individual modules that patients can then select.

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Competing interests

None declared.

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The datasets and/or analyses used in the present study will be made available by the corresponding author on reasonable request.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1 Baseline characteristics of included participants versus participants excluded during pre-selection.