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The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and HbA1c ≥ 64 mmol/mol – a group-based randomized controlled trial

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Complete List of Authors:	Mohn, Jannike; Hogskolen i Bergen, Centre for Evidence-Based Practice Graue, Marit; Bergen Univ Coll Assmus, Jõrg; Haukeland Universitetssjukehus Zoffmann, Vibeke; University Hospital of Copenhagen Thordarson, Hrafnkell; Haukeland Universitetssjukehus Peyrot, Mark; Loyola University Maryland Rokne, Berit; Universitetet i Bergen Det medisinsk-odontologiske fakultet
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The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and $HbA_{1c} \geq 64$ mmol/mol – a group-based randomized controlled trial

Running head:

Effect of a behavioral intervention among adults with poorly regulated Type 1 DM

Jannike Mohn, RN./Master of Health Science [1*2 5]

M. Graue, RN./PhD[1 6]

J. Assmus, PhD[3]

V. Zoffmann, RN./PhD[4]

H. Thordarson, MD.[5]

M. Peyrot, PhD [1 7]

B. Rokne, RN./PhD [2 8]

[1]*Bergen University College, Centre for Evidence-Based Practice, Norway*

[2]*University of Bergen, Department of Global Public Health and Primary Care, Norway*

[3]*Haukeland University Hospital, Centre for Clinical Research, Norway*

[4]*Research Unit Women's and Children's Health, The Juliane Marie Centre, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark*

[5]*Haukeland University Hospital, Dept. of Medicine, Section of Endocrinology, Norway*

[6]*Haukeland University Hospital, Dept. of Pediatrics, Norway*

[7]*Department of Sociology, Loyola University Maryland, Baltimore, MD, USA*

[8]*Haukeland University Hospital, Dept. for Research and Development, Norway*

*Corresponding author:

Jannike Mohn

E-mail: jmo@hib.no or jmoh@helse-bergen.no

Mailing address: Bergen University College, Centre for evidencebased practice,

P.O box 7030,

N-5063 Bergen, Norway

Phone: + 47 55 58 75 00 or Mobile +47 91 71 91 54

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Abstract

Objectives: To examine the impact of Guided Self-Determination (GSD) applied in group training (GSD-GT) in poorly controlled Type 1 diabetes mellitus (DM) hypothesizing GSD-GT was superior to 'care as usual' in improving HbA_{1c} and psychological functioning.

Setting: An out-patient clinic at a university hospital in Western Norway.

Participants: 178 adults (all Caucasian) aged 18-55 (mean age 36.7 ±10.7, 62% women) with Type 1 DM for at least one year and $HbA_{1c} \geq 64$ mmol/mol (8.0%) were randomly assigned to participate in either GSD-GT (n = 90) or a control group (n = 88). Among participants allocated to the GSD-GT 48 completed the study, whereas 83 in the CG. Exclusion criteria were severe co-morbidity, major psychiatric disorder, cognitive deficiency/language barriers and pregnancy.

Intervention: Intervention group met 7 times for 2 hours over 14 weeks to promote patient autonomy and intrinsic motivation using reflection sheets and advanced professional communication in accordance with the GSD methodology.

Primary and secondary outcome measures: The primary outcome was 9-month post-intervention HbA_{1c}; secondary outcomes were self-monitored blood glucose (SMBG) frequency, self-reported diabetes competence (PCDS), autonomy support by health-care providers (HCCQ), autonomous versus controlled diabetes motivation (TSRQ), diabetes distress (PAID and DDS), self-esteem (RSES) and psychological well-being (WHO-5 scale).

Results: With 95% confidence intervals (CI) GSD-GT did not have effect on HbA_{1c} (B -0.18, CI (-0.48, 0.12), p=0.234). GSD-GT improved autonomy-motivated behaviour (B 0.51, CI (0.25, 0.77), p<0.001), diabetes distress (PAID, B -6.96, CI (-11.40, -2.52), p=0.002; total

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DDS, B -5.15, CI (-9.34, -0.96), *p*=0.016; DDS Emotional burden, B -7.19, CI (-13.20, -1.19) *p*=0.019) and self-esteem (B 1.43, CI (0.34, 2.52), *p*=0.011).

Conclusions: Although this behavioral intervention exhibited feasibility challenges and did not improve medical outcomes, psychological outcomes improved, especially reduced diabetes distress.

Trial registration: Clinical Trials.gov with identification number NCT 01317459.

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Article summary:

Strengths and limitations of this study

- This study evaluated the effect of a person-centered behavioral intervention among adults with Type 1 DM, scarcely evaluated in the literature compared to educational programmes among persons with Type 2 DM
- Targeting persons with poorly regulated Type 1 DM is a challenge because long-standing poor glycaemic control appears to be a complex and heterogenous phenomenon
- The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems, and attrition from the GSD-GT program

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Introduction

Diabetes is considered a demanding condition requiring complex self-management tasks for the individual. Effective self-management is a prerequisite for preventing long-term complications and the immediate risk of hypoglycaemia. Researchers underscore that diabetes self-management education is an ongoing process rather than a one-time event [1]. American Diabetes Association (ADA) National Standards for Diabetes Self-management Education and Support hold that self-management does not stop when a person with diabetes leaves the educator's office [2]. Consequently, motivation is a key concept, and one based on respect for the individual's autonomy is essential as it is connected with success in reaching and maintaining goals [3]. Therefore, the challenge for health-care professionals (HCPs) is to implement an autonomy supportive approach instead of one based on control or disclaimed responsibility [4]. Considerable barriers to such an approach exist [5] and personal problems in living with the illness might remain unclarified and unresolved [6]. This can contribute to the 37-56% of people with Type 1 DM who are living with blood sugar above target levels [7] and at increased risk of late complications together with poor quality of life [8]. The ADA states that diabetes care is often suboptimal. Lacking are collaborative, multidisciplinary teams well suited to provide appropriate self-management education among persons with diabetes [9].

While many trials have evaluated the effect of diabetes education programs in Type 2 DM [10], there is still a paucity of trials evaluating evidence-based self-management programmes promoting empowerment in adults with Type 1 DM [11]. Among persons with Type 1 DM the DAFNE (Dose Adjustment for Normal Eating) education programme showed significant improvements in HbA_{1c} in the early stage of the trial [12] but more modest longer-term improvements [13]. In an uncontrolled evaluation of the DTTP (Diabetes Teaching and

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Treatment Programme) persons with moderately controlled Type 1 DM improved their HbA_{1c} and treatment satisfaction [14].

Guided Self-Determination (GSD) is a theory- and evidence-based problem-solving method to overcome barriers to collaborative care. It is based on life skills theory, dynamic judgement-building and theories about behaviour change. GSD promotes patient autonomy, participation, skills building and intrinsic motivation. The method is applicable in group training or individual care for a variety of conditions. In a recent study GSD improved physical well-being in women surgically treated for gynaecological cancer [15]. For persons with Type 1 DM the GSD methodology has demonstrated some success. The first randomized controlled trial among adults showed significant improvement in glycaemic control and life-skills [16]. In later studies GSD proved to be either borderline effective or not effective concerning glycaemic control among younger adults/adolescents; however, it reduced diabetes distress and lack of motivation and improved diabetes competence among young adult women [17, 18]. In addition, a case report on a young woman showed considerable reduction in HbA_{1c} after a GSD intervention [19]. Thus, GSD seems worthy of further research. This randomized intervention study seeks to test whether GSD is superior to 'care as usual' (CU) in improving glycaemic control and psychological functioning.

PATIENTS AND METHODS

Design

This study was a prospective, randomized trial with two treatment groups. Participants were recruited from an out-patient setting at a university hospital in Western Norway. The hospital's population is ethnically homogeneous, and includes both urban and rural populations. To test the effect of GSD persons with Type 1 DM and suboptimal metabolic control were invited to participate in an educational group treatment intervention (GSD

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Group-Training, GSD-GT) or care as usual control group, (CG). The Regional Committee for Medical and Health Research Ethics approved the study (approval number 2010/1325), and gave access to the age, gender and HbA_{1c} of non-responders. Participants gave written informed consent.

Recruitment

From February 2011 to March 2013 all persons with Type 1 DM attending consultations at the university hospital (n=561) were assessed for eligibility according to the inclusion criteria (Fig. 1).

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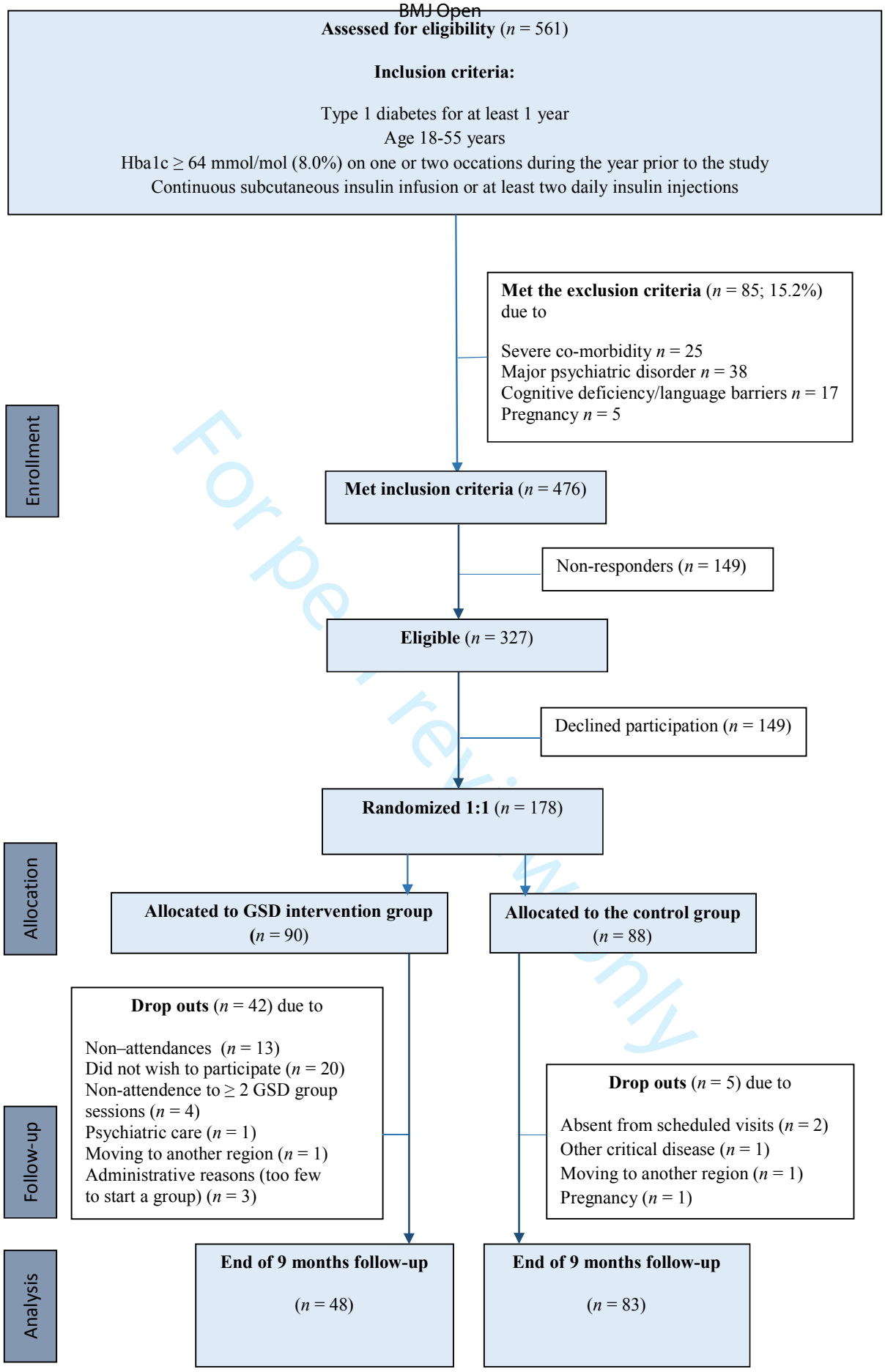

Fig 1. *Study flow diagram*

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After identifying 476 people who met study criteria a request was sent by post 1-3 weeks in advance of their next clinical consultation, inviting them to take part in the study. To those who neither responded to the request nor attended at the clinic appointment an additional letter was sent. If still no response nor attendance at the clinic, they were classified as non-responders (n = 149). Another 149 persons actively declined participation. Their response was given when they were at the clinic, or by telephone if they were unable to meet for their scheduled appointment. Those willing to participate were consented when they were at the clinic (n = 178). The participation rate in the study was 37.4% (178 of the 476 who met inclusion criteria). Participants received no monetary incentives. All sessions were free of charge.

Randomization

The randomization occurred externally and was stratified in computer-generated sequences unknown to the investigators. Blinding was considered impossible due to the nature of the intervention and was not attempted. Participants were randomized to either the usual care CG (*n* = 88; M/W: *n* = 40/48) or GSD-GT (*n* = 90; M/W: *n* = 26/64). The groups consisted of a minimum of two and a maximum of seven participants. Each GSD training group was balanced according to sex and age, preferably an equal number of men and women in each group and age ranging ± 6 years.

In the CG and GSD-GT conditions five and forty-two participants were lost to follow-up, respectively; thus 131 participants (74%) completed the trial. The reasons for drop-out in both study groups, and the total flow of participants through each stage of the trial is depicted in Fig. 1.

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Intervention

The GSD intervention was based on a technique by which the HCPs encourage people with diabetes to reflect on different problem areas concerning their daily lives with diabetes and develop autonomous motivation for life style changes. The technique was partly built on semi-structured work sheets filled in before and between each appointment, making the people with diabetes prepared with enhanced self-insight and ability to talk about personal difficulties. The perceived obstacles and barriers were responded to by HCPs with specific communication skills who conducted each consultation consistent with the GSD methodology [16]. Intervention-group participants met 7 times for 2 hour sessions over 14 weeks. Two GSD-trained diabetes specialist nurses supervised each session. Nurses were given 1 hour per week group-based feedback to secure fidelity to the protocol. No GSD-GT participants received additional treatment during the intervention period, except two participants who needed one extra consultation because of technical problems with their insulin pumps.

The control group received traditional out-patient consultations, 'care as usual', consisting of individual counseling by nurses, physicians or dieticians, with measurements of HbA_{1c} and advice on how to improve glycaemic control. No control-group participants met with GSD-trained nurses during the intervention period.

Assessments

Participant characteristics were assessed at baseline. Primary and secondary outcome measurements were performed at baseline and 9 months after the last session of group intervention (GSD-GT) or 9 months after inclusion (CG).

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Primary outcome measure

The primary endpoint was glycaemic control (HbA_{1c}) which was assessed in connection with a regularly scheduled visit at the hospital. The blood samples were analysed using high-performance liquid chromatography (DCA Vantage/Siemens, DCA 2000 and DCA 2000+/Bayer), assays standardized and calibrated against the IFCC – (International Federation of Clinical Chemists) standards [20].

Secondary outcome measures

All participants reported the number of self-monitored blood glucose measurements (SMBGs) completed in the past two weeks in the following categories: seven or more measurements per day, one to six measurements per day, and less than daily measurements. Participants also completed seven self-report instruments assessing aspects of psychological functioning consistent with the theoretical framework of GSD.

The *Problem Areas In Diabetes scale* (PAID) measures negative emotions related to living with diabetes (range = 0-100 scale); higher scores represent greater distress [21].

The *Diabetes Distress scale* (DDS) measures the level of diabetes distress with an overall score and 4 subscales: emotional burden, regimen-related, interpersonal-related and medical care-related distress (range = 1-6); higher scores represent greater distress [22].

The *Perceived Competence for Diabetes Scale* (PCDS) assesses the degree to which persons with diabetes feel they can manage the every-day aspects of diabetes care (range = 1-7); higher scores represent greater perceived competence [23].

The *Rosenberg Self-Esteem Scale* (RSES) measures one's overall self-esteem (range = 1-4); higher scores represent better self-esteem [24].

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The *World Health Organization five-item* (*WHO-5) Well-Being Index* measures emotional well-being (range = 0-100); higher scores represent better emotional well-being [25].

The *Health Care Climate Questionnaire* (HCCQ) assesses patients' perceptions of the degree to which health-care providers are supportive of autonomy rather than controlling (range = 1-7); higher scores represent greater perceived support for autonomy [26].

The *Treatment Self-regulation Questionnaire* (TSRQ) assesses the diabetes self-care practices and whether this behavior is self-motivated (autonomous/internal) or controlled (external) [27]. A relative autonomy index (TSRQ Relative Autonomy Index) was also calculated.

The PCDS, the HCCQ and the TSRQ were translated into Norwegian and back-translated into English by professional translators, in accordance with the WHO guidelines [28].

Statistical analysis

Mann-Whitney U tests and χ^2 tests were used to assess randomization efficacy by testing for differences in baseline measures. To assess differential attrition members of GSD-GT who completed the study were compared to those who did not.

We fitted a regression model for each outcome at 9 months to investigate the difference between intervention and control groups both unadjusted and adjusted for baseline outcome. To take into account possible bias introduced by the high attrition rate in the intervention group we additionally adjusted for variables showing unbalanced attrition. We used a linear regression model for all outcomes except SMBG where a multinomial logistic model was used. We used a linear regression model to test whether change in SMBG mediated change in HbA_{1c} and whether psychological effects were mediated by increased autonomy.

There were no intermediate assessments of most outcomes; only HbA_{1c} was assessed for those who did not complete the study. Therefore, per-protocol analysis was performed on all

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outcomes except $HbA_{1c,}$ where an intention-to-treat analysis was performed.

For data analyses, the statistical software program SPSS Statistics (version 22, Chicago, IL, USA 26 (SPSS Inc.) was used. Significance level was set to 0.05. Missing values were handled by pairwise exclusion.

RESULTS

Baseline charachteristics

The mean age of all subjects in the study sample was 36.7 years (±10.7), the median disease duration was 19 years (range = 1-46), 13.5% were unemployed, 96.6% were white and 31.5% had diabetes-related complications. A comparison of the baseline characteristics between the groups (without taking the attrition rate into account) suggests that the randomization was successful for all parameters except sex, in that we found a significant difference in the number of women assigned to the study groups (M/W in the GSD-GT: n = 26/64 (29/71%) versus M/W in the CG: n = 37/46 (45/55%), p = 0.022) (results not shown). Baseline characterstics of the sample are presented in Table 1.

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Table 1 Baseline characteristics of Control group versus GSD Intervention group (N=173)

	A. Control group (Completers) n=83	B. GSD Intervention group B1 Follow-up n=48	B. GSD Intervention group B2 Lost to Follow-up n=42	A vs B1 *P*	B1 vs B2 *P*
Participants characteristics					
Sex, women [1 2]	46 (55.4)	35 (72.9)	29 (69.0)	.047	.686
Age, years [3 4]	37.2 (10.9)	36.9 (9.4)	36.3 (11.6)	.860	.916
Living alone, yes [1 2]	17 (20.5)	5 (10.4)	6 (14.3)	.138	.576
Education University, yes [1 2]	30 (36.1)	23 (47.9)	10 (23.8)	.186	.018
Employed [1 2]					
- Fulltime	54 (65.1)	34 (70.8)	28 (66.7)	.485	.464
- Part-time	16 (19.3)	10 (20.8)	7 (16.7)		
- Not working	13 (15.7)	4 (8.3)	7 (16.7)		
Diabetes duration, years [3 4]	20.6 (11.2)	18.5 (10.6)	18.0 (11.0)	.310	.694
Long-term complications, yes [1 2]	29 (34.9)	11 (22.9)	15 (35.7)	.150	.181
Treatm.regimen, Insulin Pump, yes [1 2]	37 (44.6)	16 (33.3)	20 (47.6)	.206	.168
Severe hypoglycemia, yes [1 2]	35 (42.7)	24 (50.0)	13 (31.7)	.419	.081
BMI [3 4]	26.0 (4.1)	25.0 (3.6)	25.8 (4.0)	.145	.333
Outcomes					
$HbA_{1c,}$ mmol/mol [3 4]	78 (12.7)	76 (10.4)	81 (11.7)		
$HbA_{1c,}$ % [3 4]	9.3 (1.2)	9.1 (1.0)	9.5 (1.1)	.320	.018
SMBG [5 1 2]					

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- >=7 times per day	8 (9.6)	8 (16.7)	5 (11.9)	.439	.627
- 1-6 times per day	51 (61.4)	29 (60.4)	24 (57.1)		
- < every day	24 (28.9)	11 (22.9)	13 (31.0)		
PAID [6 3 4]	35.3 (18.7)	36.8 (19.3)	41.6 (24.4)	.696	.355
DDS [7 3 4] (sumscore)	31.9 (16.7)	33.1 (16.4)	37.3 (20.9)	.643	.340
DDS Emotional burden [3 4]	36.0 (22.5)	36.9 (25.6)	42.3 (26.0)	.985	.297
DDS Physician distress [3 4]	17.7 (19.9)	18.1 (18.2)	19.7 (23.1)	.826	.990
DDS Regimen distress [3 4]	45.8 (23.7)	44.7 (21.8)	53.9 (25.4)	.816	.036
DDS Interpersonal distress [3 4]	21.0 (20.1)	26.1 (19.3)	24.9 (23.2)	.101	.577
PCDS [8 3 4]	4.5 (1.6)	4.4 (1.4)	3.9 (1.6)	.734	.088
RSES [9 3 4]	19.6 (5.5)	19.5 (5.4)	19.0 (6.2)	.876	.624
WHO5 [10 3 4]	57.6 (18.6)	60.9 (19.8)	57.1 (20.5)	.338	.468
HCCQ [11 3 4]	5.1 (1.4)	4.9 (1.6)	4.8 (1.6)	.595	.923
TSRQ Autonomy [12 3 4]	5.2 (1.1)	5.4 (1.0)	4.9 (1.3)	.754	.088
TSRQ Control [13 3 4]	3.2 (1.3)	3.5 (1.2)	3.1 (1.2)	.073	.061
TSRQ RAI [14 3 4]	2.0 (1.3)	1.8 (1.5)	1.8 (1.7)	.339	.588

[1]N (%), [2]Chi-square (x^2), [3]Mean (SD), [4]Mann-Whitney,

[5]Self-Monitoring Blood Glucose, [6]Problem Areas in Diabetes scale, [7]Diabetes Distress Scale, [8]Perceived Competence in Diabetes Scale, [9]Rosenberg Self-Esteem Scale, [10]WHO(5)Well-being Index, [11]Health Care Climate Questionnaire, [12]Treatment Self-Regulation Questionnaire, Autonomous motivation, [13]Treatment Self-Regulation Questionnaire, Controlled motivation, [14]Treatment Self-Regulation Questionnaire, Relative Autonomy Index

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Due to the considerable number of drop-outs in GSD-GT, participants were stratified into Follow-up and Lost to Follow-up. There was a statistically significant difference at baseline between CG and GSD-GT Follow-up regarding sex ($p = 0.047$). The remaining baseline characterstics did not differ significantly between these groups. The analysis of attrition showed that GSD-GT Lost to Follow-up participants had poorer baseline glycemic control than GSD-GT Follow-up participants. Similarly, there were significantly fewer persons with education at a university level in the GSD-GT Lost to Follow-up and they scored higher on diabetes distress (DDS, Subscale 3, Regimen distress) than persons in the GSD-GT Follow-up group. There were no statistically significant differences regarding the remaining baseline characteristics between these groups.

Among participants allocated to the CG there were no statistically significant baseline differences between those who fulfilled the trial ($n = 83$) and those who were lost to follow-up ($n = 5$, data not shown).

Primary outcome

As seen in Table 2, HbA_{1c} declined significantly within both groups ($p<0.001$) from baseline to the 9 month follow-up, with no significant difference between the groups.

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Table 2 Outcomes in control group and Guided-Self-Determination (GSD) intervention group (N=131)

	Within group change[1]						Between groups change[2 3]					
	Control group Mean (SD)			GSD group Mean (SD)			Model 1			Model 2		
	Baseline (n = 83)	9 months (n = 83)	p-value	Baseline (n = 48)	9 months (n = 48)	p-value	Effect size[4]	B (95% CI)	p-value	Effect size[4]	B (95% CI)	p-value
Primary Outcome												
HbA_{1c} % [5]	9.3 (1.2)	8.9 (1.3)	<0.001	9.1 (1.0)	8.5 (1.1)	<0.001	0.005	-0.15 (-0.45, 0.15)	.316	0.007	-0.18 (-0.48, 0.12)	.234
HbA_{1c} mmol/mol	78 (12.7)	74 (14.1)		76 (10.4)	70 (11.7)							
Secondary outcomes Medical												
PCDS[6]	4.5 (1.6)	4.7 (1.5)	.305	4.4 (1.4)	4.7 (1.6)	.071	0.003	0.25 (-0.18, 0.67)	.247	0.003	0.26 (-0.17, 0.70)	.229
HCCQ[7]	5.1 (1.4)	5.0 (1.4)	.618	4.9 (1.6)	5.0 (1.6)	.802	0.000	0.04 (-0.46, 0.54)	.873	0.000	0.03 (-0.48, 0.54)	.904
Type of motivation												
TSRQ[8] Autonomy	5.2 (1.1)	5.1 (1.1)	.085	5.4 (1.0)	5.6 (0.9)	.060	0.067	0.53 (0.28, 0.79)	< .001	0.061	0.51 (0.25, 0.77)	< .001
TSRQ Control	3.2 (1.3)	3.1 (1.3)	.532	3.5 (1.2)	3.3 (1.1)	.072	0.000	0.13 (-0.13, 0.40)	.321	0.000	0.16 (-0.11, 0.43)	.237

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TSRQ Index	2.0 (1.3)	1.9 (1.2)	.364	1.8 (1.5)	2.3 (1.3)	.014	0.047	0.40 (0.06, 0.73)	.020	0.038	0.35 (0.01, 0.69)	.045
Psychological												
PAID[9]	35.3 (18.7)	34.2 (19.6)	.488	36.8 (19.3)	29.8 (18.9)	.002	0.038	-6.66 (-11.03, -2.29)	.003	0.043	-6.96 (-11.40, -2.52)	.002
DDS[10] overall	31.9 (16.7)	30.4 (17.5)	.323	33.1 (16.4)	27.9 (16.8)	.012	0.022	-4.45 (-8.62, -0.27)	.037	0.033	-5.15 (-9.34, -0.96)	.016
DDS Emotional burden	36.0 (22.5)	35.7 (24.4)	.995	36.9 (25.6)	35.7 (24.4)	.019	0.035	-6.92 (-12.82, -1.01)	.022	0.042	-7.19 (-13.20, -1.19)	.019
DDS Physician distress	17.7 (19.9)	17.8 (19.0)	.864	18.1 (18.2)	19.3 (19.7)	.337	0.001	1.14 (-4.38, 6.66)	.684	0.000	-0.41 (-5.80, 4.98)	.880
DDS Regimen distress	45.8 (23.7)	40.2 (22.1)	.005	44.7 (21.8)	36.8 (22.8)	.001	0.015	-4.96 (-10.55, 0.64)	.082	0.018	-5.38 (-11.07, 0.32)	.064
DDS Interpersonal distress	21.0 (20.1)	22.2 (21.6)	.455	26.1 (19.3)	22.8 (22.3)	.383	0.005	-2.20 (-8.26, 3.87)	.475	0.005	-2.24 (-8.40, 3.91)	.472
RSES[11]	19.6 (5.5)	18.9 (5.5)	.027	19.5 (5.4)	20.2 (4.8)	.267	0.041	1.30 (0.22, 2.38)	.018	0.048	1.43 (0.34, 2.52)	.011
WHO5[12]	57.6 (18.6)	56.3 (21.4)	.129	60.9 (19.8)	60.6 (17.4)	.960	0.010	3.58 (-2.24, 9.40)	.226	0.019	4.97 (-0.80, 10.75)	.091

[1]All within group change values referred as t-tests
[2] Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3]Regression coefficient from linear regression
[4] Partial η^2
[5] Within group- or between group change equal for HbA_{1c} in per cent or mmol/mol

[6]Perceived Competence in Diabetes Scale, [7]Health Care Climate Questionnaire, [8]Treatment Self-Regulation Questionnaire, [9]Problem Areas in Diabetes scale, [10]Diabetes Distress Scale, [11]Rosenberg Self-Esteem Scale, [12]WHO (5) Well-being Index

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Secondary outcomes

The results for all secondary outcome measures are presented in Table 2, except SMBG (Table 3). Secondary outcomes are clustered into a) medical measures, b) type of motivation and c) psychological measures.

a) Medical measures:

The proportion of SMBG seven times per day or more increased significantly within both groups from baseline to the 9 month follow-up. There was no significant difference between groups in change at the 9-month follow-up. The change of HbA_{1c} was not mediated by the change of SMBG (p=0.728, data not shown). Self-perceived diabetes competence (PCDS) and autonomy support from health care professionals (HCCQ) showed no significant change, neither within nor between groups.

b) Type of motivation:

The TSRQ Relative Autonomy Index showed a significant improvement within the GSD-GT group ($p = 0.014$), and a significant difference between groups in change (B = 0.35, $p = 0.045$). This finding was due primarily to a significant improvement in TSRQ Autonomy for GSD-GT relative to CG (B = 0.51, $p < 0.001$). TSRQ Control remained unchanged within both groups, with no significant difference between groups.

c) Psychological measures:

Participants in the GSD-GT group exhibited a significant reduction in diabetes-related distress relative to the CG as measured by the PAID, the DDS overall score and the DDS Emotional burden subscale (B = -6.96, $p = 0.002$; B = -5.15, $p = 0.016$ and B = -7.19, $p = 0.019$, respectively). In addition, a reduction in DDS Regimen distress was reported within the GSD-GT group as well as the CG; the difference in group improvement did not reach significance. The GSD-GT group showed an increase in self-esteem (RSES) relative to the CG (B = 1.43, p

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= 0.011); the CG experienced a decrease in self-esteem (p = 0.027). The level of overall well-being (WHO-5) showed no significant change, neither within nor between the study groups. Neither PAID, DDS Total nor RSES were significantly mediated by TSRQ Autonomy ($p>0.070$, data not shown).

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Table 3 Outcomes for Self-Monitoring Blood Glucose (SMBG) in control group and Guided Self-Determination (GSD) intervention group (N=131)

	Within group change[1]						Between groups change[2 3]			
	Control group n (%)			GSD group n (%)			Model 1		Model 2	
	Baseline (*n* = 83)	9 months (*n* = 82)	*p*-value	Baseline (*n* = 48)	9 months (*n* = 47)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
SMBG										
>=7 times per day	8 (9.6%)	54 (65.9%)	<0.001	8 (16.7%)	34 (72.3%)	<0.001	1.02 (0.35, 2.95)	0.971	0.92 (0.31, 2.74)	0.887
1-6 times per day	51 (61.4%)	10 (12.2%)		29 (60.4%)	8 (17.0%)		1		1	
< daily	24 (28.9%)	18 (22.0%)		11 (22.9%)	5 (10.6%)		3.38 (0.65, 17.58)	0.148	3.12 (0.57, 16.97)	0.189

[1]All within group change values referred as Chi-square (x^2)
[2]Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3]Odds ratio from Multinomial Logistic regression

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Discussion

Contrary to the study hypothesis, a group-based GSD programme among persons with suboptimally regulated Type 1 DM did not improve the medical outcomes (glycaemic control, frequency of SMBG, perceived competence for diabetes management, perception of healthcare professionals being supportive of patient autonomy). The hypothesis regarding improvement of psychological functioning was partly confirmed, with improvement in the level of autonomy-motivated behaviour, psychological distress and self-esteem, but not the level of overall well-being.

Long-standing poor glycaemic control appears to be a complex and heterogenous phenomenon [29] and several educational programs have been evaluated for their effectiveness for improving glycaemic control [13, 30, 31]. Some researchers indicate that evaluation studies need to better understand the complexity of variance in HbA1c [32]. The present study revealed a substantial decrease in HbA_{1c} in both groups, with no difference between groups. It is likely that the change in CG HbA_{1c} was driven by the 'observer effect,' i.e., that individuals modify or improve their behavior in response to their awareness of being observed [33]. As an additional quality of metabolic control follow-up data on mild or severe hypoglycaemia could have been evaluated, but was not assessed.

The GSD-GT intervention demonstrated a significant improvement in diabetes distress. There were no between-group differences in diabetes distress at baseline among those completing the study. Although the GSD-GT study group consisted of persons with many life resources (being young, well-educated and employed) participants still had a rather substantial level of self-reported diabetes distress (43% scoring ≥40 on the PAID scale) at baseline, comparable to previous research [17]. Our results confirm that although a behavioral intervention may not improve medical outcomes among persons with persistently poor glycaemic control, psychological outcomes may improve. This raises the possibility that if interventions resulting

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in behaviour change also reduce diabetes distress, the gains in diabetes self-management might be sustained over the long term, as argued by Zagarins [34].

One of the key elements of GSD is to support persons with diabetes to clarify and express their unique difficulties and barriers to healthy coping. This is done by mobilizing their own potential for change in interactions with autonomy supportive HCPs and by utilizing semi-structured reflection sheets. Instead of being instructed by HCPs, the core principle in GSD is individualized goal setting, a treatment strategy comparable to other behavioral interventions [11]. In a cross-sectional study HCPs being autonomy supportive was associated with the perceived level of diabetes distress mediated through the perceived level of diabetes competence [35]. In the current study, and incongruent with prior research on the GSD approach [16, 17], there was no change in HCP autonomy support (HCCQ) and level of diabetes competence (PCDS). However, GSD increased autonomous motivation (TSRQ Autonomy) and reduced diabetes distress. In terms of patient outcomes, improvement of autonomous motivation for change is hypothesized to be the key mechanism; autonomy support from HCPs is merely one strategy for activating that mechanism. Although the mediation analysis in the current study did not confirm that increasing autonomy mediates mental health benefits (PAID, DDS Total and RSES), the individual's use of reflection sheets may play a more important role in GSD. This interpretation is consistent with a recently published qualitative paper evaluating how a GSD approach could bring about a dramatic change in a young woman' s perception of her diabetes [19].

The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems, and attrition from the GSD-GT program. A pre-study power calculation expecting 25% drop-out and a difference of 0.6% change in HbA1c (SD 1.3) between groups yielded a power 0.80 with 218 participants. As this premise was violated, the interpretation of

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the results is challenging. It remains to a certain extent unclear whether the nonsignificant results are attributable to insufficient power, attrition or the effect of the intervention. Consistent with previous studies, targeting distressed persons with diabetes [36] seems to be difficult because those with the greatest need for psychological support are most likely to drop out of the psychological intervention. Conversely, those who completed the study had lower levels of diabetes distress and HbA_{1c} at baseline, reflecting less need for improvement of competence to manage the every-day aspects of their diabetes care. Perhaps future research on behavioral interventions, especially GSD, should assess patient interest in making changes prior to randomization so that study participants are appropriate for the intervention.

In the present study, the failure to achieve the primary study goal could possibly be explained by incongruence between the research focus on medical outcomes and participants' possibly prioritizing aspects of life other than clinical improvements. Consequently, it is important to assess individual goals in future research using personalized approaches to improving outcomes. In line with the DAWN2 study, there are still unmet needs of people with diabetes and those who care for them, and promotion of innovative efforts to improve self-management and life skills performance should be facilitated [37]. Efforts to manage emotional distress have been suggested as an integral part of diabetes care [38]. Improving psychosocial outcomes requires a shift away from a purely medical model to a person-centered model with greater emphasis on psychosocial aspects. Barnard and colleagues have advocated a holistic model of diabetes care aiming at enhanced diabetes self-management and improved outcomes by considering intrinsic thoughts, as well as the environment and therapy regimen [39].

The present study exemplifies a complex behavioral intervention with feasibility challenges and does not confirm improvements in HbA_{1c} and other medical outcomes. However, autonomous motivation improved and might be one mechanism for reducing diabetes distress.

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a. Contributorship statement:

JM, MG, BR, VZ and HT contributed to conception and design of the study. JM collected the data. JM, JA and MP gave substantial contribution to the analysis and interpretation of data. JM wrote the first draft of this manuscript and MG, BR, and MP gave substantial contributions to the interpretation of data and revised the manuscript critically. VZ and HT gave substantial contributions to the intellectual content of the manuscript and revised the manuscript critically. All authors read and contributed to the final draft of the paper.

b. **Competing interests:**

Conflict of interests: Author MP declared the following potential conflict of interest: Consulting fees from Astra Zeneca, Calibra, Lilly, and Novo Nordisk; advisory panel of GlaxcoSmithCline, Lilly, and Novo Nordisk; research grants from Novo Nordisk; Speaker for Novo Nordisk. The remaining authors declare that they have no conflict of interest.

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d. **Data sharing statement:**

No additional data available

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	—
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	—
Sample size	7a	How sample size was determined	22
	7b	When applicable, explanation of any interim analyses and stopping guidelines	—
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	—

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		assessing outcomes) and how	1
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12-13-14-15-16
	13b	For each group, losses and exclusions after randomisation, together with reasons	13-15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	9
	14b	Why the trial ended or was stopped	—
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	TABLE 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	15
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	TABLE 2+3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	—
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	—
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	22-23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22-23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21-23
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	attached file
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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BMJ Open

The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and HbA1c ≥ 64 mmol/mol – a group-based randomized controlled trial

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Secondary Subject Heading:	Patient-centred medicine, Communication
Keywords:	General diabetes < DIABETES & ENDOCRINOLOGY, self-management, diabetes distress, educational method, psychological functioning, HbA1c

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The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and $HbA_{1c} \geq 64$ mmol/mol – a group-based randomized controlled trial

Running head:

Effect of a behavioral intervention among adults with Type 1 DM and chronically elevated HbA_{1c}

Jannike Mohn, RN./Master of Health Science [1*2 5]

M. Graue, RN./PhD[1 6]

J. Assmus, PhD[3]

V. Zoffmann, RN./PhD[4]

H. Thordarson, MD.[5]

M. Peyrot, PhD [1 7]

B. Rokne, RN./PhD [2 8]

[1]*Western Norway University of Applied Sciences, Centre for Evidence-Based Practice, Norway*

[2]*University of Bergen, Department of Global Public Health and Primary Care, Norway*

[3]*Haukeland University Hospital, Centre for Clinical Research, Norway*

[4]*Research Unit Women's and Children's Health, The Juliane Marie Centre, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark*

[5]*Haukeland University Hospital, Dept. of Medicine, Section of Endocrinology, Norway*

[6]*Haukeland University Hospital, Dept. of Pediatrics, Norway*

[7]*Department of Sociology, Loyola University Maryland, Baltimore, MD, USA*

[8]*Haukeland University Hospital, Dept. for Research and Development, Norway*

*Corresponding author:

Jannike Mohn

E-mail: jmo@hvl.no or jmoh@helse-bergen.no

Mailing address: Western Norway University of Applied Sciences, Centre for Evidence-Based practice,

P.O box 7030,

N-5063 Bergen, Norway

Phone: + 47 55 58 75 00 or Mobile +47 91 71 91 54

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Abstract

Objectives: To examine the impact of Guided Self-Determination (GSD) applied in group training (GSD-GT) in people with chronically elevated HbA_{1c} and Type 1 diabetes mellitus (DM) hypothesizing GSD-GT was superior to 'care as usual' in improving HbA_{1c} and psychological functioning.

Setting: An out-patient clinic at a university hospital in Western Norway.

Participants: 178 adults (all Caucasian) aged 18-55 (mean age 36.7 ±10.7, 62% women) with Type 1 DM for at least one year and $HbA_{1c} \geq 64$ mmol/mol (8.0%) were randomly assigned to participate in either GSD-GT or a control group. Exclusion criteria were severe co-morbidity, major psychiatric disorder, cognitive deficiency/language barriers and pregnancy.

Intervention: Intervention group met 7 times for 2 hours over 14 weeks to promote patient autonomy and intrinsic motivation using reflection sheets and advanced professional communication in accordance with the GSD methodology.

Primary and secondary outcome measures: The primary outcome was 9-month post-intervention HbA_{1c}; secondary outcomes were self-monitored blood glucose (SMBG) frequency, self-reported diabetes competence (PCDS), autonomy support by health-care providers (HCCQ), autonomous versus controlled diabetes motivation (TSRQ), diabetes distress (PAID and DDS), self-esteem (RSES) and psychological well-being (WHO-5 scale).

Results: Among participants allocated to the GSD-GT (n = 90) 48 completed the study, whereas 83 completed in the CG (n = 88). With 95% confidence intervals (CI) GSD-GT did not have effect on HbA_{1c} (B -0.18, CI (-0.48, 0.12), p=0.234). GSD-GT improved autonomy-motivated behaviour (B 0.51, CI (0.25, 0.77), p<0.001), diabetes distress (PAID, B -6.96, CI (-11.40, -2.52), p=0.002; total DDS, B -5.15, CI (-9.34, -0.96), p=0.016; DDS Emotional

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burden, B -7.19, CI (-13.20, -1.19) p=0.019) and self-esteem (B 1.43, CI (0.34, 2.52), p=0.011).

Conclusions: Results from this behavioral intervention must be interpreted cautiously because of recruitment and attrition problems. Medical outcomes did not improve. Psychological outcomes improved, especially reduced diabetes distress.

Trial registration: Clinical Trials.gov with identification number NCT 01317459.

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Article summary:

Strengths and limitations of this study

- This study evaluated the effect of a person-centered behavioral intervention among adults with Type 1 DM, scarcely evaluated in the literature compared to educational programmes among persons with Type 2 DM
- Targeting persons with Type 1 DM and chronically elevated HbA_{1c} is a challenge because long-standing poor glycaemic control appears to be a complex and heterogenous phenomenon
- The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems, and attrition from the GSD-GT program

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Introduction

Diabetes is considered a demanding condition requiring complex self-management tasks for the individual. Effective self-management is a prerequisite for preventing long-term complications and the immediate risk of hypoglycaemia. Researchers underscore that diabetes self-management education is an ongoing process rather than a one-time event [1]. American Diabetes Association (ADA) National Standards for Diabetes Self-management Education and Support hold that self-management does not stop when a person with diabetes leaves the educator's office [2]. Consequently, motivation is a key concept, and one based on respect for the individual's autonomy is essential as it is connected with success in reaching and maintaining goals [3]. Therefore, the challenge for health-care professionals (HCPs) is to implement an autonomy supportive approach instead of one based on control or disclaimed responsibility [4]. Considerable barriers to such an approach exist [5] and personal problems in living with the illness might remain unclarified and unresolved [6]. This can contribute to the 37-56% of people with Type 1 DM who are living with blood sugar above target levels [7] and at increased risk of late complications together with poor quality of life [8]. The ADA states that diabetes care is often suboptimal. Lacking are collaborative, multidisciplinary teams well suited to provide appropriate self-management education among persons with diabetes [9].

One of the first structured diabetes treatment and education programmes for Type 1 DM was developed between 1980 and 1990 [10]. While many trials have evaluated the effect of diabetes education programs in Type 2 DM , there is still a paucity of trials evaluating evidence-based self-management programmes promoting empowerment in adults with Type 1 DM [11]. Among persons with Type 1 DM the DAFNE (Dose Adjustment for Normal Eating) education programme showed significant improvements in HbA_{1c} in the early stage of the trial [12] but more modest longer-term improvements [13]. A self-management-oriented

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education programme (PRIMAS) showed effect on glycemic control and reduced diabetes distress at six months follow-up compared with an established education programme in a multi-centre trial [14]. In an uncontrolled evaluation of the DTTP (Diabetes Teaching and Treatment Programme) persons with moderately controlled Type 1 DM improved their HbA_{1c} and treatment satisfaction [15].

Guided Self-Determination (GSD) is a theory- and evidence-based problem-solving method to overcome barriers to collaborative care. It is based on life skills theory, dynamic judgement-building and theories about behaviour change. GSD promotes patient autonomy, participation, skills building and intrinsic motivation [16] The method is applicable in group training or individual care for a variety of conditions. In a recent study GSD improved physical well-being in women surgically treated for gynaecological cancer [17]. For persons with Type 1 DM the GSD methodology has demonstrated some success. The first randomized controlled trial among adults showed significant improvement in glycaemic control and life-skills [18]. In later studies GSD proved to be either borderline effective or not effective concerning glycaemic control among younger adults/adolescents; however, it reduced diabetes distress and lack of motivation and improved diabetes competence among young adult women [19, 20]. In addition, a case report on a young woman showed considerable reduction in HbA_{1c} after a GSD intervention [21]. Thus, GSD seems worthy of further research. This randomized intervention study seeks to test whether GSD is superior to 'care as usual' (CU) in improving glycaemic control and psychological functioning.

PATIENTS AND METHODS

Design

This study was a prospective, randomized trial with two treatment groups. Participants were recruited from an out-patient setting at a university hospital in Western Norway. The

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hospital's population is ethnically homogeneous, and includes both urban and rural populations. To test the effect of GSD persons with Type 1 DM and suboptimal metabolic control were invited to participate in an educational group treatment intervention (GSD Group-Training, GSD-GT) or care as usual control group, (CG). The Regional Committee for Medical and Health Research Ethics approved the study (approval number 2010/1325), and gave access to the age, gender and HbA_{1c} of non-responders. Participants gave written informed consent.

Recruitment

From March 2011 to March 2013 all persons with Type 1 DM attending consultations at the university hospital (n=561) were assessed for eligibility according to the inclusion criteria (Fig. 1). Further details on inclusion and exclusion criteria are outlined elsewhere [22]. A pre-study power calculation for a t-test assuming a 0.05 significance level and a power of 0.8 expecting 25% drop-out and a difference of 0.6% change in HbA_{1c} (SD 1.3) between groups led to 218 participants needed to include. Expected change in HbA_{1c} was based on clinical relevance.

After identifying 476 people who met study criteria a request was sent by post 1-3 weeks in advance of their next clinical consultation, inviting them to take part in the study. To those who neither responded to the request nor attended at the clinic appointment an additional letter was sent. If still no response nor attendance at the clinic, they were classified as non-responders (n = 149). Another 149 persons actively declined participation. Their response was given when they were at the clinic, or by telephone if they were unable to meet for their scheduled appointment. Those willing to participate were consented when they were at the clinic (n = 178). The participation rate in the study was 37.4% (178 of the 476 who met

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inclusion criteria). Participants received no monetary incentives. All sessions were free of charge.

Randomization

The randomization occurred externally and was stratified in computer-generated sequences unknown to the investigators. Blinding was considered impossible due to the nature of the intervention and was not attempted. Participants were randomized to either the usual care CG (n = 88; M/W: n = 40/48) or GSD-GT (n = 90; M/W: n = 26/64). The groups consisted of a minimum of two and a maximum of seven participants. Each GSD training group was balanced according to sex and age, preferably an equal number of men and women in each group and age ranging ± 6 years.

In the CG and GSD-GT conditions five and forty-two participants were lost to follow-up, respectively; thus 131 participants (74%) completed the trial. The reasons for drop-out in both study groups, and the total flow of participants through each stage of the trial is depicted in Fig. 1.

Intervention

The GSD intervention was based on a technique by which the HCPs encourage people with diabetes to reflect on different problem areas concerning their daily lives with diabetes and develop autonomous motivation for life style changes. The technique was partly built on semi-structured work sheets filled in before and between each appointment, making the people with diabetes prepared with enhanced self-insight and ability to talk about personal difficulties. The perceived obstacles and barriers were responded to by HCPs with specific communication skills who conducted each consultation consistent with the GSD methodology [18]. Intervention-group participants met 7 times for 2 hour sessions over 14 weeks. Two GSD-trained diabetes specialist nurses supervised each session. Nurses were given 1 hour per

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week group-based feedback to secure fidelity to the protocol. No GSD-GT participants received additional treatment during the intervention period, except two participants who needed one extra consultation because of technical problems with their insulin pumps.

The control group received traditional out-patient consultations, 'care as usual', consisting of individual counseling by nurses, physicians or dieticians, with measurements of HbA_{1c} and advice on how to improve glycaemic control. No control-group participants met with GSD-trained nurses during the intervention period.

Assessments

Participant characteristics were assessed at baseline. Primary and secondary outcome measurements were performed at baseline and 9 months after the last session of group intervention (GSD-GT) or 9 months after inclusion (CG). Due to individual differences in days/weeks from point of randomization to start of intervention group, a clear post intervention standardization on the time of the follow-up assessment was difficult to obtain between the groups.

Primary outcome measure

The primary endpoint was glycaemic control (HbA_{1c}) which was assessed in connection with a regularly scheduled visit at the hospital. The blood samples were analysed using high-performance liquid chromatography (DCA Vantage/Siemens, DCA 2000 and DCA 2000+/Bayer), assays standardized and calibrated against the IFCC – (International Federation of Clinical Chemists) standards [23].

Secondary outcome measures

All participants reported the number of self-monitored blood glucose measurements (SMBGs) completed in the past two weeks in the following categories: seven or more measurements per

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day, one to six measurements per day, and less than daily measurements. Participants also completed seven self-report instruments assessing aspects of psychological functioning consistent with the theoretical framework of GSD.

The *Problem Areas In Diabetes scale* (PAID) measures negative emotions related to living with diabetes (range = 0-100 scale); higher scores represent greater distress [24].

The *Diabetes Distress scale* (DDS) measures the level of diabetes distress with an overall score and 4 subscales: emotional burden, regimen-related, interpersonal-related and medical care-related distress (range = 1-6); higher scores represent greater distress [25].

The *Perceived Competence for Diabetes Scale* (PCDS) assesses the degree to which persons with diabetes feel they can manage the every-day aspects of diabetes care (range = 1-7); higher scores represent greater perceived competence [26].

The *Rosenberg Self-Esteem Scale* (RSES) measures one's overall self-esteem (range = 1-4); higher scores represent better self-esteem [27].

The *World Health Organization five-item* (*WHO-5) Well-Being Index* measures emotional well-being (range = 0-100); higher scores represent better emotional well-being [28].

The *Health Care Climate Questionnaire* (HCCQ) assesses patients' perceptions of the degree to which health-care providers are supportive of autonomy rather than controlling (range = 1-7); higher scores represent greater perceived support for autonomy [29].

The *Treatment Self-regulation Questionnaire* (TSRQ) assesses the diabetes self-care practices and whether this behavior is self-motivated (autonomous/internal) or controlled (external) [30]. A relative autonomy index (TSRQ Relative Autonomy Index) was also calculated.

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The PCDS, the HCCQ and the TSRQ were translated into Norwegian and back-translated into English by professional translators, in accordance with the WHO guidelines [31].

Statistical analysis

Mann-Whitney U tests and χ^2 tests were used to assess randomization efficacy by testing for differences in baseline measures. To assess differential attrition members of GSD-GT who completed the study were compared to those who did not.

We fitted a regression model for each outcome at 9 months to investigate the difference between intervention and control groups both unadjusted and adjusted for baseline outcome. To take into account possible bias introduced by the high attrition rate in the intervention group we additionally adjusted for variables showing unbalanced attrition. We used a linear regression model for all outcomes except SMBG where a multinomial logistic model was used. We used a linear regression model to test whether change in SMBG mediated change in HbA_{1c} and whether psychological effects were mediated by increased autonomy.

There were no intermediate assessments of most outcomes; only HbA_{1c} was assessed for those who did not complete the study. Therefore, per-protocol and intention-to-treat analyses were identical for all outcomes except $HbA_{1c,}$ where intention-to-treat analysis was selected as the more conservative choice.

For data analyses, the statistical software program SPSS Statistics (version 22, Chicago, IL, USA 26 (SPSS Inc.) was used. Significance level was set to 0.05. Missing values were handled by pairwise exclusion.

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RESULTS

Baseline characteristics

The mean age of all subjects in the study sample was 36.7 years (±10.7), the median disease duration was 19 years (range = 1-46), 13.5% were unemployed, 96.6% were white and 31.5% had diabetes-related complications. A comparison of the baseline characteristics between the groups (without taking the attrition rate into account) suggests that the randomization was successful for all parameters except sex, in that we found a significant difference in the number of women assigned to the study groups (M/W in the GSD-GT: n = 26/64 (29/71%) versus M/W in the CG: n = 37/46 (45/55%), p = 0.022) (results not shown). Baseline characteristics of the sample are presented in Table 1.

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Table 1 Baseline characteristics of Control group versus GSD Intervention group (N=173)

	A. Control group (Completers)	B. GSD Intervention group		A vs B1	B1 vs B2
	n=83	B1 Follow-up n=48	B2 Lost to Follow-up n=42	*P*	*P*
Participants characteristics					
Sex, women [1 2]	46 (55.4)	35 (72.9)	29 (69.0)	.047	.686
Age, years [3 4]	37.2 (10.9)	36.9 (9.4)	36.3 (11.6)	.860	.916
Living alone, yes [1 2]	17 (20.5)	5 (10.4)	6 (14.3)	.138	.576
Education University, yes [1 2]	30 (36.1)	23 (47.9)	10 (23.8)	.186	.018
Employed [1 2]					
- Fulltime	54 (65.1)	34 (70.8)	28 (66.7)	.485	.464
- Part-time	16 (19.3)	10 (20.8)	7 (16.7)		
- Not working	13 (15.7)	4 (8.3)	7 (16.7)		
Diabetes duration, years [3 4]	20.6 (11.2)	18.5 (10.6)	18.0 (11.0)	.310	.694
Long-term complications, yes [1 2]	29 (34.9)	11 (22.9)	15 (35.7)	.150	.181
Treatm.regimen, Insulin Pump, yes [1 2]	37 (44.6)	16 (33.3)	20 (47.6)	.206	.168
Severe hypoglycemia, yes [1 2]	35 (42.7)	24 (50.0)	13 (31.7)	.419	.081
BMI [3 4]	26.0 (4.1)	25.0 (3.6)	25.8 (4.0)	.145	.333
Outcomes					
$HbA_{1c,}$ mmol/mol [3 4]	78 (12.7)	76 (10.4)	81 (11.7)		
$HbA_{1c,}$ % [3 4]	9.3 (1.2)	9.1 (1.0)	9.5 (1.1)	.320	.018
SMBG [5 1 2]					

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- >=7 times per day	8 (9.6)	8 (16.7)	5 (11.9)	.439	.627
- 1-6 times per day	51 (61.4)	29 (60.4)	24 (57.1)		
- < every day	24 (28.9)	11 (22.9)	13 (31.0)		
PAID [6 3 4]	35.3 (18.7)	36.8 (19.3)	41.6 (24.4)	.696	.355
DDS [7 3 4] (sumscore)	31.9 (16.7)	33.1 (16.4)	37.3 (20.9)	.643	.340
DDS Emotional burden [3 4]	36.0 (22.5)	36.9 (25.6)	42.3 (26.0)	.985	.297
DDS Physician distress [3 4]	17.7 (19.9)	18.1 (18.2)	19.7 (23.1)	.826	.990
DDS Regimen distress [3 4]	45.8 (23.7)	44.7 (21.8)	53.9 (25.4)	.816	.036
DDS Interpersonal distress [3 4]	21.0 (20.1)	26.1 (19.3)	24.9 (23.2)	.101	.577
PCDS [8 3 4]	4.5 (1.6)	4.4 (1.4)	3.9 (1.6)	.734	.088
RSES [9 3 4]	19.6 (5.5)	19.5 (5.4)	19.0 (6.2)	.876	.624
WHO5 [10 3 4]	57.6 (18.6)	60.9 (19.8)	57.1 (20.5)	.338	.468
HCCQ [11 3 4]	5.1 (1.4)	4.9 (1.6)	4.8 (1.6)	.595	.923
TSRQ Autonomy [12 3 4]	5.2 (1.1)	5.4 (1.0)	4.9 (1.3)	.754	.088
TSRQ Control [13 3 4]	3.2 (1.3)	3.5 (1.2)	3.1 (1.2)	.073	.061
TSRQ RAI [14 3 4]	2.0 (1.3)	1.8 (1.5)	1.8 (1.7)	.339	.588

[1]N (%), [2]Chi-square (x^2), [3]Mean (SD), [4]Mann-Whitney,

[5]Self-Monitoring Blood Glucose, [6]Problem Areas in Diabetes scale, [7]Diabetes Distress Scale, [8]Perceived Competence in Diabetes Scale, [9]Rosenberg Self-Esteem Scale, [10]WHO(5)Well-being Index, [11]Health Care Climate Questionnaire, [12]Treatment Self-Regulation Questionnaire, Autonomous motivation, [13]Treatment Self-Regulation Questionnaire, Controlled motivation, [14]Treatment Self-Regulation Questionnaire, Relative Autonomy Index

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Due to the considerable number of drop-outs in GSD-GT, participants were stratified into Follow-up and Lost to Follow-up. There was a statistically significant difference at baseline between CG and GSD-GT Follow-up regarding sex ($p = 0.047$). The remaining baseline characteristics did not differ significantly between these groups. The analysis of attrition showed that GSD-GT Lost to Follow-up participants had poorer baseline glycemic control than GSD-GT Follow-up participants. Similarly, there were significantly fewer persons with education at a university level in the GSD-GT Lost to Follow-up and they scored higher on diabetes distress (DDS, Subscale 3, Regimen distress) than persons in the GSD-GT Follow-up group. There were no statistically significant differences regarding the remaining baseline characteristics between these groups.

Among participants allocated to the CG there were no statistically significant baseline differences between those who fulfilled the trial ($n = 83$) and those who were lost to follow-up ($n = 5$, data not shown).

Primary outcome

As seen in Table 2, HbA_{1c} declined significantly within both groups ($p<0.001$) from baseline to the 9 month follow-up, with no significant difference between the groups.

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Table 2 Outcomes in control group and Guided-Self-Determination (GSD) intervention group (N=131)

	Within group change[1]						Between groups change[2 3]					
	Control group Mean (SD)			GSD group Mean (SD)			Model 1			Model 2		
	Baseline (n = 83)	9 months (n = 83)	p-value	Baseline (n = 48)	9 months (n = 48)	p-value	Effect size[4]	B[5] (95% CI)	p-value	Effect size[4]	B[5] (95% CI)	p-value
Primary Outcome												
HbA_{1c} % [6]	9.3 (1.2)	8.9 (1.3)	<0.001	9.1 (1.0)	8.5 (1.1)	<0.001	0.005	-0.15 (-0.45, 0.15)	.316	0.007	-0.18 (-0.48, 0.12)	.234
HbA_{1c} mmol/mol	78 (12.7)	74 (14.1)		76 (10.4)	70 (11.7)							
Secondary outcomes Medical												
PCDS[7]	4.5 (1.6)	4.7 (1.5)	.305	4.4 (1.4)	4.7 (1.6)	.071	0.003	0.25 (-0.18, 0.67)	.247	0.003	0.26 (-0.17, 0.70)	.229
HCCQ[8]	5.1 (1.4)	5.0 (1.4)	.618	4.9 (1.6)	5.0 (1.6)	.802	0.000	0.04 (-0.46, 0.54)	.873	0.000	0.03 (-0.48, 0.54)	.904
Type of motivation												
TSRQ[9] Autonomy	5.2 (1.1)	5.1 (1.1)	.085	5.4 (1.0)	5.6 (0.9)	.060	0.067	0.53 (0.28, 0.79)	< .001	0.061	0.51 (0.25, 0.77)	< .001
TSRQ Control	3.2 (1.3)	3.1 (1.3)	.532	3.5 (1.2)	3.3 (1.1)	.072	0.000	0.13 (-0.13, 0.40)	.321	0.000	0.16 (-0.11, 0.43)	.237

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TSRQ Index	2.0 (1.3)	1.9 (1.2)	.364	1.8 (1.5)	2.3 (1.3)	.014	0.047	0.40 (0.06, 0.73)	.020	0.038	0.35 (0.01, 0.69)	.045
Psychological												
PAID[10]	35.3 (18.7)	34.2 (19.6)	.488	36.8 (19.3)	29.8 (18.9)	.002	0.038	-6.66 (-11.03, -2.29)	.003	0.043	-6.96 (-11.40, -2.52)	.002
DDS[11] overall	31.9 (16.7)	30.4 (17.5)	.323	33.1 (16.4)	27.9 (16.8)	.012	0.022	-4.45 (-8.62, -0.27)	.037	0.033	-5.15 (-9.34, -0.96)	.016
DDS Emotional burden	36.0 (22.5)	35.7 (24.4)	.995	36.9 (25.6)	35.7 (24.4)	.019	0.035	-6.92 (-12.82, -1.01)	.022	0.042	-7.19 (-13.20, -1.19)	.019
DDS Physician distress	17.7 (19.9)	17.8 (19.0)	.864	18.1 (18.2)	19.3 (19.7)	.337	0.001	1.14 (-4.38, 6.66)	.684	0.000	-0.41 (-5.80, 4.98)	.880
DDS Regimen distress	45.8 (23.7)	40.2 (22.1)	.005	44.7 (21.8)	36.8 (22.8)	.001	0.015	-4.96 (-10.55, 0.64)	.082	0.018	-5.38 (-11.07, 0.32)	.064
DDS Interpersonal distress	21.0 (20.1)	22.2 (21.6)	.455	26.1 (19.3)	22.8 (22.3)	.383	0.005	-2.20 (-8.26, 3.87)	.475	0.005	-2.24 (-8.40, 3.91)	.472
RSES[12]	19.6 (5.5)	18.9 (5.5)	.027	19.5 (5.4)	20.2 (4.8)	.267	0.041	1.30 (0.22, 2.38)	.018	0.048	1.43 (0.34, 2.52)	.011
WHO5[13]	57.6 (18.6)	56.3 (21.4)	.129	60.9 (19.8)	60.6 (17.4)	.960	0.010	3.58 (-2.24, 9.40)	.226	0.019	4.97 (-0.80, 10.75)	.091

[1]All within group change values referred as t-tests
[2] Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3]Regression coefficient from linear regression
[4] Partial η^2
[5] B = unstandardized coefficients
[6] Within group- or between group change equal for HbA_{1c} in per cent or mmol/mol

[7]Perceived Competence in Diabetes Scale, [8]Health Care Climate Questionnaire, [9]Treatment Self-Regulation Questionnaire, [10]Problem Areas in Diabetes scale, [11]Diabetes Distress Scale, [12]Rosenberg Self-Esteem Scale, [13]WHO (5) Well-being Index

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Secondary outcomes

The results for all secondary outcome measures are presented in Table 2, except SMBG (Table 3). Secondary outcomes are clustered into a) medical measures, b) type of motivation and c) psychological measures.

a) Medical measures:

The proportion of SMBG seven times per day or more increased significantly within both groups from baseline to the 9 month follow-up. There was no significant difference between groups in change at the 9-month follow-up. The change of HbA_{1c} was not mediated by the change of SMBG (p=0.728, data not shown). Self-perceived diabetes competence (PCDS) and autonomy support from health care professionals (HCCQ) showed no significant change, neither within nor between groups.

b) Type of motivation:

The TSRQ Relative Autonomy Index showed a significant improvement within the GSD-GT group ($p = 0.014$), and a significant difference between groups in change (B = 0.35, $p = 0.045$). This finding was due primarily to a significant improvement in TSRQ Autonomy for GSD-GT relative to CG (B = 0.51, $p < 0.001$). TSRQ Control remained unchanged within both groups, with no significant difference between groups.

c) Psychological measures:

Participants in the GSD-GT group exhibited a significant reduction in diabetes-related distress relative to the CG as measured by the PAID, the DDS overall score and the DDS Emotional burden subscale (B = -6.96, $p = 0.002$; B = -5.15, $p = 0.016$ and B = -7.19, $p = 0.019$, respectively). In addition, a reduction in DDS Regimen distress was reported within the GSD-GT group as well as the CG; the difference in group improvement did not reach significance. The GSD-GT group showed an increase in self-esteem (RSES) relative to the CG (B = 1.43, p

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= 0.011); the CG experienced a decrease in self-esteem (p = 0.027). The level of overall well-being (WHO-5) showed no significant change, neither within nor between the study groups. Neither PAID, DDS Total nor RSES were significantly mediated by TSRQ Autonomy ($p>0.070$, data not shown).

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Table 3 Outcomes for Self-Monitoring Blood Glucose (SMBG) in control group and Guided Self-Determination (GSD) intervention group (N=131)

	Within group change[1]						Between groups change[2 3]			
	Control group n (%)			GSD group n (%)			Model 1		Model 2	
	Baseline (*n* = 83)	9 months (*n* = 82)	*p*-value	Baseline (*n* = 48)	9 months (*n* = 47)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
SMBG										
>=7 times per day	8 (9.6%)	54 (65.9%)	<0.001	8 (16.7%)	34 (72.3%)	<0.001	1.02 (0.35, 2.95)	0.971	0.92 (0.31, 2.74)	0.887
1-6 times per day	51 (61.4%)	10 (12.2%)		29 (60.4%)	8 (17.0%)		1		1	
< daily	24 (28.9%)	18 (22.0%)		11 (22.9%)	5 (10.6%)		3.38 (0.65, 17.58)	0.148	3.12 (0.57, 16.97)	0.189

[1]All within group change values referred as Chi-square (x^2)
[2]Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3]Odds ratio from Multinomial Logistic regression

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DISCUSSION

Statement of the principal findings and possible explanations

Contrary to the study hypothesis, a group-based GSD programme among persons with Type 1 DM and chronically elevated HbA_{1c} did not improve the medical outcomes (glycaemic control, frequency of SMBG, perceived competence for diabetes management, perception of healthcare professionals being supportive of patient autonomy). The hypothesis regarding improvement of psychological functioning was partly confirmed, with improvement in the level of autonomy-motivated behaviour, psychological distress and self-esteem, but not the level of overall well-being.

Long-standing elevated HbA_{1c} appears to be a complex and heterogenous phenomenon [32] and educational programs have been evaluated for their effectiveness for improving glycaemic control [13, 33, 34]. Some researchers indicate that evaluation studies need to better understand the complexity of variance in HbA_{1c} [35]. The present study revealed a substantial decrease in HbA_{1c} in both groups, with no difference between groups. It is likely that the change in CG HbA_{1c} was driven by the 'observer effect,' i.e., that individuals modify or improve their behavior in response to their awareness of being observed [36]. As an additional quality of metabolic control follow-up data on mild or severe hypoglycaemia could have been evaluated, but was not assessed.

Strengths of the study in relation to other studies

Strengths of the study include the random assignment of patients and their heterogeneity. The GSD-GT intervention demonstrated a significant improvement in diabetes distress. There were no between-group differences in diabetes distress at baseline among those completing the study. The GSD-GT study group consisted of persons with a rather substantial level of self-reported diabetes distress (43% scoring ≥40 on the PAID scale) at baseline, comparable

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to previous research [19]. Our results confirm that although a behavioral intervention may not improve medical outcomes among persons with persistently elevated HbA_{1c} psychological outcomes may improve. This raises the possibility that if interventions resulting in behaviour change also reduce diabetes distress, the gains in diabetes self-management might be sustained over the long term, as argued by Zagarins [37].

One of the key elements of GSD is to support persons with diabetes to clarify and express their unique difficulties and barriers to healthy coping. This is done by mobilizing their own potential for change in interactions with autonomy supportive HCPs and by utilizing semi-structured reflection sheets. Instead of being instructed by HCPs, the core principle in GSD is individualized goal setting, a treatment strategy comparable to other behavioral interventions [14]. In a cross-sectional study HCPs being autonomy supportive was associated with the perceived level of diabetes distress mediated through the perceived level of diabetes competence [22]. In the current study, and incongruent with prior research on the GSD approach [18, 19], there was no change in HCP autonomy support (HCCQ) and level of diabetes competence (PCDS). However, GSD increased autonomous motivation (TSRQ Autonomy) and reduced diabetes distress. In terms of patient outcomes, improvement of autonomous motivation for change is hypothesized to be the key mechanism; autonomy support from HCPs is merely one strategy for activating that mechanism. Although the mediation analysis in the current study did not confirm that increasing autonomy mediates mental health benefits (PAID, DDS Total and RSES), the individual's use of reflection sheets may play a more important role in GSD. This interpretation is consistent with a recently published qualitative paper evaluating how a GSD approach could bring about a dramatic change in a young woman' s perception of her diabetes [21].

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Weaknesses of the study and future research

The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems and attrition from the GSD-GT program. As the power calculation premise was violated, the interpretation of the results is challenging. It remains to a certain extent unclear whether the nonsignificant results are attributable to insufficient power, attrition or the effect of the intervention.

Consistent with previous studies, targeting distressed persons with diabetes [38] can be difficult because those with the greatest need for psychological support are most likely to drop out of the psychological intervention. Conversely, those who completed the study had lower levels of diabetes distress and HbA_{1c} at baseline, reflecting less need for improvement of competence to manage the every-day aspects of their diabetes care. Perhaps future research on behavioral interventions, especially GSD, should assess patient interest in making changes prior to randomization so that study participants are appropriate for the intervention.

In the present study, the failure to achieve the primary study goal could possibly be explained by incongruence between the research focus on medical outcomes and participants' possibly prioritizing aspects of life other than clinical improvements. Consequently, it is important to assess individual goals in future research using personalized approaches to improving outcomes. In line with the DAWN2 study, there are still unmet needs of people with diabetes and those who care for them, and promotion of innovative efforts to improve self-management and life skills performance should be facilitated [39]. Efforts to manage emotional distress have been suggested as an integral part of diabetes care [40]. Improving psychosocial outcomes requires a shift away from a purely medical model to a person-centered model with greater emphasis on psychosocial aspects. Barnard and colleagues have advocated a holistic model of diabetes care aiming at enhanced diabetes self-management and

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improved outcomes by considering intrinsic thoughts, as well as the environment and therapy regimen [41].

Implications for clinicians

The present study exemplifies a complex behavioral intervention with feasibility challenges and does not confirm improvements in HbA_{1c} and other medical outcomes. However, autonomous motivation improved and might be one mechanism for reducing diabetes distress.

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Figure legend:

Fig. 1. *Study flow diagram*

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a. Contributorship statement:

JM, MG, BR, VZ and HT contributed to conception and design of the study. JM collected the data. JM, JA and MP gave substantial contribution to the analysis and interpretation of data. JM wrote the first draft of this manuscript and MG, BR, and MP gave substantial contributions to the interpretation of data and revised the manuscript critically. VZ and HT gave substantial contributions to the intellectual content of the manuscript and revised the manuscript critically. All authors read and contributed to the final draft of the paper.

b. **Competing interests:**

Conflict of interests: Author MP declared the following potential conflict of interest: Consulting fees from Astra Zeneca, Calibra, Lilly, and Novo Nordisk; advisory panel of GlaxcoSmithCline, Lilly, and Novo Nordisk; research grants from Novo Nordisk; Speaker for Novo Nordisk. The remaining authors declare that they have no conflict of interest.

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d. **Data sharing statement:**

No additional data available

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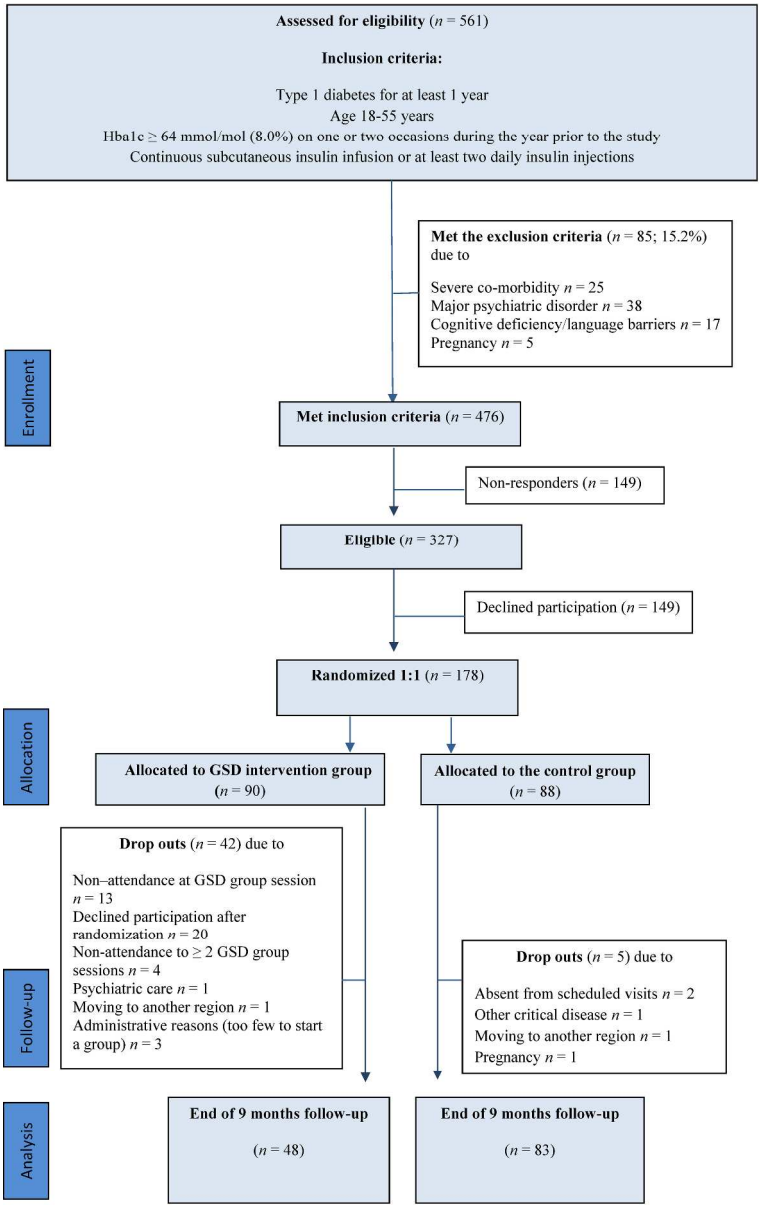

Fig. 1. Study flow diagram

268x427mm (300 x 300 DPI)

BMJ Open

The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and HbA1c ≥ 64 mmol/mol – a group-based randomized controlled trial

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The effect of Guided Self-Determination on self-management in persons with Type 1 diabetes mellitus and $HbA_{1c} \geq 64$ mmol/mol – a group-based randomized controlled trial

Running head:

Effect of a behavioral intervention among adults with Type 1 DM and chronically elevated HbA_{1c}

Jannike Mohn, RN./Master of Health Science [1*2 5]

M. Graue, RN./PhD[1 6]

J. Assmus, PhD[3]

V. Zoffmann, RN./PhD[4]

H. Thordarson, MD.[5]

M. Peyrot, PhD [1 7]

B. Rokne, RN./PhD [2 8]

[1]*Western Norway University of Applied Sciences, Centre for Evidence-Based Practice, Norway*

[2]*University of Bergen, Department of Global Public Health and Primary Care, Norway*

[3]*Haukeland University Hospital, Centre for Clinical Research, Norway*

[4]*Research Unit Women's and Children's Health, The Juliane Marie Centre, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark*

[5]*Haukeland University Hospital, Dept. of Medicine, Section of Endocrinology, Norway*

[6]*Haukeland University Hospital, Dept. of Pediatrics, Norway*

[7]*Department of Sociology, Loyola University Maryland, Baltimore, MD, USA*

[8]*Haukeland University Hospital, Dept. for Research and Development, Norway*

*Corresponding author:

Jannike Mohn

E-mail: jmo@hvl.no or jmoh@helse-bergen.no

Mailing address: Western Norway University of Applied Sciences, Centre for Evidence-Based practice,

P.O box 7030, N-5063 Bergen, Norway

Phone: + 47 55 58 75 00 or Mobile +47 91 71 91 54

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Abstract

Objectives: To determine whether the impact of Guided Self-Determination (GSD) applied in group training (GSD-GT) in people with chronically elevated HbA_{1c} and Type 1 diabetes mellitus (DM) was superior to 'care as usual' in improving HbA_{1c} and psychological functioning.

Setting: An out-patient clinic at a university hospital in Western Norway.

Participants: 178 adults (all Caucasian) aged 18-55 (mean age 36.7 ±10.7, 62% women) with Type 1 DM for at least one year and $HbA_{1c} \geq 64$ mmol/mol (8.0%) were randomly assigned to participate in either GSD-GT or a control group. Exclusion criteria were severe co-morbidity, major psychiatric disorder, cognitive deficiency/language barriers and pregnancy.

Intervention: Intervention group met 7 times for 2 hours over 14 weeks to promote patient autonomy and intrinsic motivation using reflection sheets and advanced professional communication in accordance with the GSD methodology.

Primary and secondary outcome measures: The primary outcome was HbA_{1c} and secondary outcomes (all outcomes 9 months post-intervention) were self-monitored blood glucose (SMBG) frequency, self-reported diabetes competence (PCDS), autonomy support by health-care providers (HCCQ), autonomous versus controlled diabetes motivation (TSRQ), diabetes distress (PAID and DDS), self-esteem (RSES) and psychological well-being (WHO-5 scale).

Results: Among participants allocated to the GSD-GT (n = 90) 48 completed the study, whereas 83 completed in the CG (n = 88). With 95% confidence intervals (CI) GSD-GT did not have effect on HbA_{1c} (B -0.18, CI (-0.48, 0.12), p=0.234). GSD-GT improved autonomy-motivated behaviour (B 0.51, CI (0.25, 0.77), p<0.001), diabetes distress (PAID, B -6.96, CI (-11.40, -2.52), p=0.002; total DDS, B -5.15, CI (-9.34, -0.96), p=0.016; DDS Emotional

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burden, B -7.19, CI (-13.20, -1.19) p=0.019) and self-esteem (B 1.43, CI (0.34, 2.52), p=0.011).

Conclusions: Results from this behavioral intervention must be interpreted cautiously because of recruitment and attrition problems. Medical outcomes did not improve. Psychological outcomes improved, especially reduced diabetes distress.

Trial registration: Clinical Trials.gov with identification number NCT 01317459.

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Article summary

Strengths and limitations of this study

- This study evaluated the effect of a person-centered behavioral intervention among adults with Type 1 DM, scarcely evaluated in the literature compared to educational programmes among persons with Type 2 DM
- Targeting persons with Type 1 DM and chronically elevated HbA_{1c} is a challenge because long-standing poor glycaemic control appears to be a complex and heterogenous phenomenon
- The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems, and attrition from the GSD-GT program

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Introduction

Diabetes is considered a demanding condition requiring complex self-management tasks for the individual. Effective self-management is a prerequisite for preventing long-term complications and the immediate risk of hypoglycaemia. Researchers underscore that diabetes self-management education is an ongoing process rather than a one-time event [1]. American Diabetes Association (ADA) National Standards for Diabetes Self-Management Education and Support hold that self-management does not stop when a person with diabetes leaves the educator's office [2]. Consequently, motivation is a key concept, and one based on respect for the individual's autonomy is essential as it is connected with success in reaching and maintaining goals [3]. Therefore, the challenge for health-care professionals (HCPs) is to implement an autonomy supportive approach instead of one based on control or disclaimed responsibility [4]. Considerable barriers to such an approach exist [5] and personal problems in living with the illness might remain unclarified and unresolved [6]. This can contribute to the 37-56% of people with Type 1 DM who are living with blood sugar above target levels [7] and at increased risk of late complications together with poor quality of life [8]. The ADA states that diabetes care is often suboptimal; lacking are collaborative, multidisciplinary teams well suited to provide appropriate self-management education among persons with diabetes [9].

One of the first structured diabetes treatment and education programmes for Type 1 DM was developed between 1980 and 1990 [10]. While many trials have evaluated the effect of diabetes education programs in Type 2 DM, there is still a paucity of trials evaluating evidence-based self-management programmes promoting empowerment in adults with Type 1 DM [11]. Among persons with Type 1 DM the DAFNE (Dose Adjustment for Normal Eating) education programme showed significant improvements in HbA_{1c} in the early stage of the trial [12] but more modest longer-term improvements [13]. A self-management-oriented

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education programme (PRIMAS) showed effect on glycaemic control and reduced diabetes distress at six months follow-up compared with an established education programme in a multi-centre trial [14]. In an uncontrolled evaluation of the DTTP (Diabetes Teaching and Treatment Programme) persons with moderately controlled Type 1 DM improved their HbA_{1c} and treatment satisfaction [15].

Guided Self-Determination (GSD) is a theory- and evidence-based problem-solving method to overcome barriers to collaborative care. It is based on life skills theory, dynamic judgement-building and theories about behaviour change. GSD promotes patient autonomy, participation, skills building and intrinsic motivation [16]. The method is applicable in group training (GSD-GT) or individual care for a variety of conditions. In a recent study, GSD improved physical well-being in women surgically treated for gynaecological cancer [17]. For persons with Type 1 DM the GSD methodology has demonstrated some success. The first randomized controlled trial among adults showed significant improvement in glycaemic control and life-skills [18]. In later studies GSD proved to be either borderline effective or not effective concerning glycaemic control among younger adults/adolescents; however, it reduced diabetes distress and lack of motivation and improved diabetes competence among young adult women [19, 20]. In addition, a case report on a young woman showed considerable reduction in HbA_{1c} after a GSD intervention [21]. In conclusion, GSD seems worthy of further research for several reasons. First, patient involvement and person-centered care are highly appreciated and recommended, but difficult to implement as part of clinical care [22]. Second, GSD is one of few interventions which clinicians are able to facilitate in routine clinical care after rather short training. Third, persons with diabetes have a primary role in GSD, spending their time at home clarifying what is important for them to change and becoming able to express their thoughts in communication with HCPs. Consequently, efficiency of patient-provider communication increases without extra use of HCP resources.

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Last, GSD has the potential for improvement of HbA_{1c}, as well as increased self-determination and decrease of diabetes-related burden [18]. This randomized intervention study tests whether GSD-GT is superior to 'care as usual' (CU) in improving glycaemic control and psychological functioning among adults with suboptimally regulated Type 1 DM.

PATIENTS AND METHODS

Design

This study was a prospective, randomized trial with a control group and a treatment group. Participants were recruited from an out-patient setting at a university hospital in Western Norway. The hospital's population is ethnically homogeneous, and includes both urban and rural populations. To test the effect of GSD persons with Type 1 DM and suboptimal metabolic control were invited to participate in an educational group treatment intervention (GSD-GT) or care as usual control group, (CG). The Regional Committee for Medical and Health Research Ethics approved the study (approval number 2010/1325), and gave access to the age, gender and HbA_{1c} of non-responders. Participants gave written informed consent.

Recruitment

From March 2011 to March 2013 all persons with Type 1 DM attending consultations at the university hospital (n=561) were assessed for eligibility according to the inclusion criteria (Fig. 1). Further details on inclusion and exclusion criteria are outlined elsewhere [23]. A pre-study power calculation for a t-test assuming a 0.05 significance level and a power of 0.8 expecting 25% drop-out and a difference of 0.6% change in HbA_{1c} (SD 1.3) between groups led to 218 participants needed to include. Expected change in HbA_{1c} was based on clinical relevance.

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After identifying 476 people who met study criteria a request was sent by post 1-3 weeks in advance of their next clinical consultation, inviting them to take part in the study. To those who neither responded to the request nor attended at the clinic appointment an additional letter was sent. If still no response nor attendance at the clinic, they were classified as non-responders (n = 149). Another 149 persons actively declined participation. Their response was given when they were at the clinic, or by telephone if they were unable to meet for their scheduled appointment. Those willing to participate were consented when they were at the clinic (n = 178). The participation rate in the study was 37.4% (178 of the 476 who met inclusion criteria). Participants received no monetary incentives. All sessions were free of charge.

Randomization

The randomization occurred externally and was stratified in computer-generated sequences unknown to the investigators. Blinding was considered impossible due to the nature of the intervention and was not attempted. Participants were randomized to either the usual care CG (n = 88; M/W: n = 40/48) or GSD-GT (n = 90; M/W: n = 26/64). The groups consisted of a minimum of two and a maximum of seven participants. Each GSD training group was balanced according to sex and age, preferably an equal number of men and women in each group and age ranging ± 6 years.

In the CG and GSD-GT conditions five and forty-two participants were lost to follow-up, respectively; thus 131 participants (74%) completed the trial. The reasons for drop-out in both study groups, and the total flow of participants through each stage of the trial is depicted in Fig. 1.

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Intervention

The GSD intervention was based on a technique by which the HCPs encourage people with diabetes to reflect on different problem areas concerning their daily lives with diabetes and develop autonomous motivation for life style changes. The technique was partly built on semi-structured work sheets filled in before and between each appointment, making the people with diabetes prepared with enhanced self-insight and ability to talk about personal difficulties. The perceived obstacles and barriers were responded to by HCPs with specific communication skills who conducted each consultation consistent with the GSD methodology [18]. Intervention-group participants met 7 times for 2 hour sessions over 14 weeks. Two GSD-trained diabetes specialist nurses supervised each session. Nurses were given 1 hour per week group-based feedback to secure fidelity to the protocol. No GSD-GT participants received additional treatment during the intervention period, except two participants who needed one extra consultation because of technical problems with their insulin pumps.

The control group received traditional out-patient consultations, 'care as usual', consisting of individual counseling by nurses, physicians or dieticians, with measurements of HbA_{1c} and advice on how to improve glycaemic control. No control-group participants met with GSD-trained nurses during the intervention period.

Assessments

Participant characteristics were assessed at baseline. Primary and secondary outcome measurements were planned to be performed at baseline and 9 months after the last session of group intervention (GSD-GT) or 9 months after inclusion (CG). Because of the need to get enough participants to start group sessions there was a large variation in time from randomization to start of intervention in the IG (Mean=4.9 months, SD=3.6). There was also some variation in time from baseline to follow-up in the CG (Mean=10.9 months, SD=2.4)

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and time from last session to follow-up in the IG (Mean 9.3 months, SD=1.0) because many participants needed several reminders before they handed in the follow-up questionnaire.

Primary outcome measure

The primary endpoint was glycaemic control (HbA_{1c}) which was assessed in connection with a regularly scheduled visit at the hospital. The blood samples were analysed using high-performance liquid chromatography (DCA Vantage/Siemens, DCA 2000 and DCA 2000+/Bayer), assays standardized and calibrated against the IFCC – (International Federation of Clinical Chemists) standards [24].

Secondary outcome measures

All participants reported the number of self-monitored blood glucose measurements (SMBGs) completed in the past two weeks in the following six categories: 'seven or more measurements per day', 'four to six measurements per day', 'one to three measurements per day', 'less than every day', 'less than every week' and 'no monitoring last 14 days'. Due to small size of some categories we chose to collapse into the following three categories: 'seven or more measurements per day', 'one to six measurements per day', and 'less than daily measurements'. Participants also completed seven self-report instruments assessing aspects of psychological functioning consistent with the theoretical framework of GSD.

The *Problem Areas In Diabetes scale* (PAID) measures negative emotions related to living with diabetes (range = 0-100 scale); higher scores represent greater distress [25].

The *Diabetes Distress Scale* (DDS) measures the level of diabetes distress with an overall score and 4 subscales: emotional burden, regimen-related, interpersonal-related and medical care-related distress. The range is 1-6 for each item. Total score is calculated by transforming the mean score to a 0-100 range. Higher scores represent greater distress [26].

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The *Perceived Competence for Diabetes Scale* (PCDS) assesses the degree to which persons with diabetes feel they can manage the every-day aspects of diabetes care. The range is 1-7 for each item and the mean is used as a total score. Higher scores represent greater perceived competence [27].

The *Rosenberg Self-Esteem Scale* (RSES) measures one's overall self-esteem. The range is 1-4 for each item and total score is calculated as the mean of all items multiplied by 10. Higher scores represent better self-esteem [28].

The *World Health Organization five-item Well-Being Index* (WHO-5) measures emotional well-being. The range for each item is 0-6 and a total score is calculated by transforming the sum to a 0-100 range. Higher scores represent better emotional well-being [29].

The *Health Care Climate Questionnaire* (HCCQ) assesses patients' perceptions of the degree to which health-care providers are supportive of autonomy rather than controlling. The range is 1-7 for each item and total score is calculated as the mean of all items; higher scores represent greater perceived support for autonomy [30].

The *Treatment Self-Regulation Questionnaire* (TSRQ) assesses the diabetes self-care practices and whether this behavior is self-motivated (autonomous/internal) or controlled (external) [31]. Each item ranges from 1-7 and behavior scores are calculated as the mean of items within the internal and external dimensions separately. A relative autonomy index (TSRQ Relative Autonomy Index) was also calculated.

The PCDS, the HCCQ and the TSRQ were translated into Norwegian and back-translated into English by professional translators, in accordance with the WHO guidelines [32].

Statistical analysis

Mann-Whitney U tests and χ^2 tests were used to assess randomization efficacy by testing for

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differences in baseline measures. To assess differential attrition members of GSD-GT who completed the study were compared to those who did not. We fitted a regression model for each outcome at 9 months to investigate the difference between intervention and control groups both unadjusted and adjusted for baseline outcome and sex. To take into account possible bias introduced by the high attrition rate in the intervention group we additionally adjusted for variables showing unbalanced attrition. We used a linear regression model for all outcomes except SMBG where a multinomial logistic model was used. We used a linear regression model to test whether change in SMBG mediated change in HbA_{1c} and whether psychological effects were mediated by increased autonomy.

There were no intermediate assessments of questionnaire data; therefore it was not possible to intention-to-treat analysis for persons who dropped out and per-protocol analyses were thus performed. HbA_{1c} was assessed for those who did not complete the study because it could be obtained from medical records. Therefore, intention-to-treat analysis of HbA_{1c} was performed. Because of the difference in follow-up time between GSD-GT and CG and because of the large variation within each group we also did additional analyses where we estimated the association between change in outcome measures and length of follow-up within each group. Associations were tested using linear regression with change in outcome measure as dependent variable and follow-up time in months as independent variable with adjustment for baseline measurement of the outcome variable. For data analyses, the statistical software program SPSS Statistics (version 22, Chicago, IL, USA 26 (SPSS Inc.) was used. Significance level was set to 0.05. Missing values were handled by pairwise exclusion.

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RESULTS

Baseline characteristics

The mean age of all subjects in the study sample was 36.7 years (±10.7), the median disease duration was 19 years (range = 1-46), 13.5% were unemployed, 96.6% were white and 31.5% had diabetes-related complications. A comparison of the baseline characteristics between the groups (without taking the attrition rate into account) suggests that the randomization was successful for all parameters except sex, in that we found a significant difference in the number of women assigned to the study groups (M/W in the GSD-GT: n = 26/64 (29/71%) versus M/W in the CG: n = 37/46 (45/55%), p = 0.022) (results not shown). Baseline characteristics of the sample are presented in Table 1.

Due to the considerable number of drop-outs in GSD-GT, participants were stratified into Follow-up and Lost to Follow-up to analyse the effects of attrition. The only statistically significant difference at baseline between CG and GSD-GT Follow-up was for sex (p = 0.047). The GSD-GT Lost to Follow-up participants had poorer baseline glycemic control and scored higher on diabetes distress (DDS, Subscale 3, Regimen distress) than GSD-GT Follow-up participants. Similarly, there were significantly fewer persons with education at a university level in the GSD-GT Lost to Follow-up group than in the GSD-GT Follow-up group.

Among participants allocated to the CG there were no statistically significant baseline differences between those who fulfilled the trial (n = 83) and those who were lost to follow-up (n = 5, data not shown).

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Primary outcome

As seen in Table 2, HbA_{1c} declined significantly within both groups ($p<0.001$) from baseline to follow-up, with no significant difference between the groups.

Secondary outcomes

The results for all secondary outcome measures are presented in Table 2, except SMBG (Table 3). Secondary outcomes are clustered into a) medical measures, b) type of motivation and c) psychological measures.

a) Medical measures

The proportion of SMBG seven times per day or more increased significantly within both groups from baseline to follow-up. There was no significant difference between groups in change at follow-up. The change of HbA_{1c} was not mediated by the change of SMBG ($p=0.728$, data not shown). Self-perceived diabetes competence (PCDS) and autonomy support from health care professionals (HCCQ) showed no significant change, neither within nor between groups.

b) Type of motivation

The TSRQ Relative Autonomy Index showed a significant improvement within the GSD-GT group ($p = 0.014$), and a significant difference between groups in change (B = 0.35, $p = 0.045$). This finding was due primarily to a significant improvement in TSRQ Autonomy for GSD-GT relative to CG (B = 0.51, $p < 0.001$). TSRQ Control remained unchanged within both groups, with no significant difference between groups.

c) Psychological measures

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Participants in the GSD-GT group exhibited a significant reduction in diabetes-related distress relative to the CG as measured by the PAID, the DDS overall score and the DDS Emotional burden subscale (B = -6.96, $p = 0.002$; B = -5.15, $p = 0.016$ and B = -7.19, $p = 0.019$, respectively). In addition, a reduction in DDS Regimen distress was reported within the GSD-GT group as well as the CG; the difference in group improvement did not reach significance. The GSD-GT group showed an increase in self-esteem (RSES) relative to the CG (B = 1.43, $p = 0.011$); the CG experienced a decrease in self-esteem ($p = 0.027$). The level of overall well-being (WHO-5) showed no significant change, neither within nor between the study groups. Neither PAID, DDS Total nor RSES were significantly mediated by TSRQ Autonomy ($p>0.070$, data not shown).

Length of follow-up

Results from linear regression analyses for the association between outcome measures and length of follow-up in the intervention group are shown in Table 4. There were no significant associations, i.e the change was not larger for patients with longer follow-up. Corresponding analyses for the control group also showed no significant associations with length of follow-up (results not shown).

DISCUSSION

Statement of the principal findings and possible explanations

Contrary to the study hypothesis, a group-based GSD programme among persons with Type 1 DM and chronically elevated HbA_{1c} did not improve the medical outcomes (glycaemic control, frequency of SMBG, perceived competence for diabetes management, perception of healthcare professionals being supportive of patient autonomy). The hypothesis regarding improvement of psychological functioning was partly confirmed, with improvement in the

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level of autonomy-motivated behaviour, diabetes distress and self-esteem, but not the level of general psychological well-being.

Long-standing elevated HbA_{1c} appears to be a complex and heterogenous phenomenon [33] and educational programs have been evaluated for their effectiveness for improving glycaemic control [13, 34, 35]. Some researchers indicate that evaluation studies need to better understand the complexity of variance in HbA_{1c} [36]. The present study revealed a substantial decrease in HbA_{1c} in both groups, with no difference between groups. It is likely that the change in CG HbA_{1c} was driven by the 'observer effect,' i.e., that individuals modify or improve their behavior in response to their awareness of being observed [37]. Additional measures of quality of metabolic control would have been follow-up data on mild or severe hypoglycaemia, but these were not assessed.

Strengths of the study in relation to other studies

The GSD-GT intervention demonstrated a significant improvement in diabetes distress. There were no between-group differences in diabetes distress at baseline among those completing the study. The GSD-GT study group consisted of persons with a rather substantial level of self-reported diabetes distress (43% scoring ≥40 on the PAID scale) at baseline, comparable to previous research [19]. Our results confirm that although a behavioral intervention may not improve medical outcomes among persons with persistently elevated HbA_{1c} psychological outcomes may improve. This raises the possibility that if interventions resulting in behaviour change also reduce diabetes distress, the gains in diabetes self-management might be sustained over the long term, as argued by Zagarins [38]. One of the key elements of GSD is to support persons with diabetes to clarify and express their unique difficulties and barriers to healthy coping. This is done by mobilizing their own potential for change in interactions with autonomy supportive HCPs and by utilizing semi-structured reflection sheets. Instead of being

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instructed by HCPs, the core principle in GSD is individualized goal setting, a treatment strategy comparable to other behavioral interventions [14]. In a cross-sectional study, HCPs being autonomy supportive was associated with the perceived level of diabetes distress mediated through the perceived level of diabetes competence [23]. In the current study, and incongruent with prior research on the GSD approach [18, 19], there was no change in HCP autonomy support (HCCQ) and level of diabetes competence (PCDS). However, GSD increased autonomous motivation (TSRQ Autonomy) and reduced diabetes distress. In terms of patient outcomes, improvement of autonomous motivation for change is hypothesized to be the key mechanism; autonomy support from HCPs is merely one strategy for activating that mechanism. Although the mediation analysis in the current study did not confirm that increasing autonomy mediates mental health benefits (PAID, DDS Total and RSES), the individual's use of reflection sheets may play a more important role in GSD. This interpretation is consistent with a recently published qualitative paper evaluating how a GSD approach could bring about a dramatic change in a young woman' s perception of her diabetes [21].

Weaknesses of the study and future research

The most obvious limitation of this study is that generalizability might be distorted due to recruitment problems and attrition from the GSD-GT program. As the power calculation premise was violated, the interpretation of the results is challenging. It remains to a certain extent unclear whether the results are attributable to insufficient power, differential attrition or the effect of the intervention. However, there was no significant difference in change in HbA_{1c} between GSD-GT participants who completed the study versus those who did not (p-value from t-test 0.71), indicating that it was not the participants with the poorest effect of the intervention that dropped out. Because of lacking follow-up questionnaires we were not able

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to do the same test for psychosocial measurements, but it is reasonable to assume that differences between drop-outs and completers would mirror what we found for HbA1c. Nevertheless, it is worthwhile to consider potential reasons for high rates of attrition in the intervention group. Only four participants dropped out after attending an GSD session, comparable to the two participants in the CG who did not make their follow-up medical visits. Most of the dropouts in the GSD-GT group did not attend a single session (33/39), suggesting some possible interpretations for this post-randomization/pre-participation attrition:
The time from randomization to start of GSD-GT (Mean 4.9 months, SD=3.6) could perhaps discurage individuals who were highly motivated by time of randomization but considered the waiting time to be too long until the GSD-GT started. Another aspect might be that some individuals found the intervention too comprehensive and demanding after more detailed information was given with regard to the pre-intervention work sheets that participants were encouraged to fill in before each group session.

Another limitation is the difference in length of follow-up between the GSD-GT group and the CG. We did however not find any association between the changes in outcomes and length of follow-up in the two groups. Thus, we do not think that the longer follow-up in the GSD-GT group can explain the reported effects of the intervention. In addition, frequency of blood sugar measurement were measured using a rather crude categorization which might cause loss of important information. Using SMBG as a continuous variable would have been optimal as that would have offered a between-group comparison of the absolute number of measurements per day. However, when designing this study we considered the variation in demands of the disease to differ too much from one day to another, making it difficult to give a valid estimate of the number of measurement per day. We thus choose to use a variable with six categories, but had to collapse this into three categories because of few patients in each

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category. We tried different categorizations but did not find any significant intervention effect.

Consistent with previous studies, targeting distressed persons with diabetes [39] can be difficult because those with the greatest need for psychological support are most likely to drop out of the psychological intervention. Conversely, those who completed the study had lower levels of diabetes distress and HbA_{1c} at baseline, reflecting less need for improvement of competence to manage the every-day aspects of their diabetes care. Perhaps future research on behavioral interventions, especially GSD, should assess patient interest in making changes prior to randomization so that study participants are appropriate for the intervention.

In the present study, the failure to achieve the primary study goal could possibly be explained by incongruence between the research focus on medical outcomes and participants' possibly prioritizing aspects of life other than clinical improvements. Consequently, it is important to assess individual goals in future research using personalized approaches to improving outcomes. In line with the DAWN2 study, there are still unmet needs of people with diabetes and those who care for them, and promotion of innovative efforts to improve self-management and life skills performance should be facilitated [40]. Efforts to manage emotional distress have been suggested as an integral part of diabetes care [41]. Improving psychosocial outcomes requires a shift away from a purely medical model to a person-centered model with greater emphasis on psychosocial aspects. Barnard and colleagues have advocated a holistic model of diabetes care aiming at enhanced diabetes self-management and improved outcomes by considering intrinsic thoughts, as well as the environment and therapy regimen [42].

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Implications for clinicians

The present study exemplifies a complex behavioral intervention with feasibility challenges and does not confirm improvements in HbA_{1c} and other medical outcomes. However, autonomous motivation improved and might be one mechanism for reducing diabetes distress.

Figure legend:

Fig. 1. *Study flow diagram*

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Table 1 Baseline characteristics of Control group versus GSD Intervention group (N=173)

	A. Control group (Completers)	B. GSD Intervention group		A vs B1	B1 vs B2
	n=83	B1 Follow-up n=48	B2 Lost to Follow-up n=42	*P*	*P*
Participants characteristics					
Sex, women [1 2]	46 (55.4)	35 (72.9)	29 (69.0)	.047	.686
Age, years [3 4]	37.2 (10.9)	36.9 (9.4)	36.3 (11.6)	.860	.916
Living alone, yes [1 2]	17 (20.5)	5 (10.4)	6 (14.3)	.138	.576
Education University, yes [1 2]	30 (36.1)	23 (47.9)	10 (23.8)	.186	.018
Employed [1 2]					
- Fulltime	54 (65.1)	34 (70.8)	28 (66.7)	.485	.464
- Part-time	16 (19.3)	10 (20.8)	7 (16.7)		
- Not working	13 (15.7)	4 (8.3)	7 (16.7)		
Diabetes duration, years [3 4]	20.6 (11.2)	18.5 (10.6)	18.0 (11.0)	.310	.694
Long-term complications, yes [1 2]	29 (34.9)	11 (22.9)	15 (35.7)	.150	.181
Treatm.regimen, Insulin Pump, yes [1 2]	37 (44.6)	16 (33.3)	20 (47.6)	.206	.168
Severe hypoglycemia, yes [1 2]	35 (42.7)	24 (50.0)	13 (31.7)	.419	.081
BMI [3 4]	26.0 (4.1)	25.0 (3.6)	25.8 (4.0)	.145	.333
Outcomes					
$HbA_{1c,}$ mmol/mol [3 4]	78 (12.7)	76 (10.4)	81 (11.7)		
$HbA_{1c,}$ % [3 4]	9.3 (1.2)	9.1 (1.0)	9.5 (1.1)	.320	.018
SMBG [5 1 2]					
- >=7 times per day	8 (9.6)	8 (16.7)	5 (11.9)	.439	.627
- 1-6 times per day	51 (61.4)	29 (60.4)	24 (57.1)		
- < every day	24 (28.9)	11 (22.9)	13 (31.0)		

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PAID [6 3 4]	35.3 (18.7)	36.8 (19.3)	41.6 (24.4)	.696	.355
DDS [7 3 4] (sumscore)	31.9 (16.7)	33.1 (16.4)	37.3 (20.9)	.643	.340
DDS Emotional burden [3 4]	36.0 (22.5)	36.9 (25.6)	42.3 (26.0)	.985	.297
DDS Physician distress [3 4]	17.7 (19.9)	18.1 (18.2)	19.7 (23.1)	.826	.990
DDS Regimen distress [3 4]	45.8 (23.7)	44.7 (21.8)	53.9 (25.4)	.816	.036
DDS Interpersonal distress [3 4]	21.0 (20.1)	26.1 (19.3)	24.9 (23.2)	.101	.577
PCDS [8 3 4]	4.5 (1.6)	4.4 (1.4)	3.9 (1.6)	.734	.088
RSES [9 3 4]	19.6 (5.5)	19.5 (5.4)	19.0 (6.2)	.876	.624
WHO5 [10 3 4]	57.6 (18.6)	60.9 (19.8)	57.1 (20.5)	.338	.468
HCCQ [11 3 4]	5.1 (1.4)	4.9 (1.6)	4.8 (1.6)	.595	.923
TSRQ Autonomy [12 3 4]	5.2 (1.1)	5.4 (1.0)	4.9 (1.3)	.754	.088
TSRQ Control [13 3 4]	3.2 (1.3)	3.5 (1.2)	3.1 (1.2)	.073	.061
TSRQ RAI [14 3 4]	2.0 (1.3)	1.8 (1.5)	1.8 (1.7)	.339	.588

[1]N (%), [2]Chi-square (x^2), [3]Mean (SD), [4]Mann-Whitney,

[5]Self-Monitoring Blood Glucose, [6]Problem Areas in Diabetes scale (range 0-100), [7]Diabetes Distress Scale (range 0-100), [8]Perceived Competence in Diabetes Scale (range 1-7), [9]Rosenberg Self-Esteem Scale (range 10-40), [10]WHO(5)Well-being Index (range 0-100), [11]Health Care Climate Questionnaire (range 1-7), [12]Treatment Self-Regulation Questionnaire, Autonomous motivation (range 1-7), [13]Treatment Self-Regulation Questionnaire, Controlled motivation (range 1-7), [14]Treatment Self-Regulation Questionnaire, Relative Autonomy Index (range 0-6)

Table 2 Outcomes in control group and Guided-Self-Determination (GSD) intervention group (N=131)

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	Within group change[1]						Between groups change[2]					
	Control group Mean (SD)			GSD group Mean (SD)			Model 1			Model 2		
	Baseline (n = 83)	Follow-up (n = 83)	p-value	Baseline (n = 48)	Follow-up (n = 48)	p-value	Effect size[3]	Group Difference[4] (95% CI)	p-value	Effect size[4]	Group Difference[4] (95% CI)	p-value
Primary Outcome												
HbA_{1c} % [5]	9.3 (1.2)	8.9 (1.3)	<0.001	9.1 (1.0)	8.5 (1.1)	<0.001	0.005	-0.15 (-0.45, 0.15)	.316	0.007	-0.18 (-0.48, 0.12)	.234
HbA_{1c} mmol/mol	78 (12.7)	74 (14.1)		76 (10.4)	70 (11.7)							
Secondary outcomes Medical												
PCDS[6]	4.5 (1.6)	4.7 (1.5)	.305	4.4 (1.4)	4.7 (1.6)	.071	0.003	0.25 (-0.18, 0.67)	.247	0.003	0.26 (-0.17, 0.70)	.229
HCCQ[7]	5.1 (1.4)	5.0 (1.4)	.618	4.9 (1.6)	5.0 (1.6)	.802	0.000	0.04 (-0.46, 0.54)	.873	0.000	0.03 (-0.48, 0.54)	.904
Type of motivation												
TSRQ[8] Autonomy	5.2 (1.1)	5.1 (1.1)	.085	5.4 (1.0)	5.6 (0.9)	.060	0.067	0.53 (0.28, 0.79)	< .001	0.061	0.51 (0.25, 0.77)	< .001
TSRQ Control	3.2 (1.3)	3.1 (1.3)	.532	3.5 (1.2)	3.3 (1.1)	.072	0.000	0.13 (-0.13, 0.40)	.321	0.000	0.16 (-0.11, 0.43)	.237
TSRQ Index	2.0 (1.3)	1.9 (1.2)	.364	1.8 (1.5)	2.3 (1.3)	.014	0.047	0.40 (0.06, 0.73)	.020	0.038	0.35 (0.01, 0.69)	.045

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Psychological												
PAID[9]	35.3 (18.7)	34.2 (19.6)	.488	36.8 (19.3)	29.8 (18.9)	.002	0.038	-6.66 (-11.03, -2.29)	.003	0.043	-6.96 (-11.40, -2.52)	.002
DDS[10] overall	31.9 (16.7)	30.4 (17.5)	.323	33.1 (16.4)	27.9 (16.8)	.012	0.022	-4.45 (-8.62, -0.27)	.037	0.033	-5.15 (-9.34, -0.96)	.016
DDS Emotional burden	36.0 (22.5)	35.7 (24.4)	.995	36.9 (25.6)	35.7 (24.4)	.019	0.035	-6.92 (-12.82, -1.01)	.022	0.042	-7.19 (-13.20, -1.19)	.019
DDS Physician distress	17.7 (19.9)	17.8 (19.0)	.864	18.1 (18.2)	19.3 (19.7)	.337	0.001	1.14 (-4.38, 6.66)	.684	0.000	-0.41 (-5.80, 4.98)	.880
DDS Regimen distress	45.8 (23.7)	40.2 (22.1)	.005	44.7 (21.8)	36.8 (22.8)	.001	0.015	-4.96 (-10.55, 0.64)	.082	0.018	-5.38 (-11.07, 0.32)	.064
DDS Interpersonal distress	21.0 (20.1)	22.2 (21.6)	.455	26.1 (19.3)	22.8 (22.3)	.383	0.005	-2.20 (-8.26, 3.87)	.475	0.005	-2.24 (-8.40, 3.91)	.472
RSES[11]	19.6 (5.5)	18.9 (5.5)	.027	19.5 (5.4)	20.2 (4.8)	.267	0.041	1.30 (0.22, 2.38)	.018	0.048	1.43 (0.34, 2.52)	.011
WHO5[12]	57.6 (18.6)	56.3 (21.4)	.129	60.9 (19.8)	60.6 (17.4)	.960	0.010	3.58 (-2.24, 9.40)	.226	0.019	4.97 (-0.80, 10.75)	.091

[1]All within group change values referred as t-tests
[2] Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3] Partial η^2
[4] Unstandardized regression coefficient from linear regression adjusted for covariates, interpreted as difference in group means,.
[5] Within group- or between group change equal for HbA_{1c} in per cent or mmol/mol
[6]Perceived Competence in Diabetes Scale, [7]Health Care Climate Questionnaire, [8]Treatment Self-Regulation Questionnaire, [9]Problem Areas in Diabetes scale, [10]Diabetes Distress Scale, [11]Rosenberg Self-Esteem Scale, [12]WHO (5) Well-being Index

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Table 3 Outcomes for Self-Monitoring Blood Glucose (SMBG) in control group and Guided Self-Determination (GSD) intervention group (N=131)

	Within group change[1]						Between groups change[2 3]			
	Control group n (%)			GSD group n (%)			Model 1		Model 2	
	Baseline (*n* = 83)	Follow-up (*n* = 82)	*p*-value	Baseline (*n* = 48)	Follow-up (*n* = 47)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
SMBG										
>=7 times per day	8 (9.6%)	54 (65.9%)	<0.001	8 (16.7%)	34 (72.3%)	<0.001	1.02 (0.35, 2.95)	0.971	0.92 (0.31, 2.74)	0.887
1-6 times per day	51 (61.4%)	10 (12.2%)		29 (60.4%)	8 (17.0%)		1		1	
< daily	24 (28.9%)	18 (22.0%)		11 (22.9%)	5 (10.6%)		3.38 (0.65, 17.58)	0.148	3.12 (0.57, 16.97)	0.189

[1]All within group change values referred as Chi-square (x^2)
[2]Model 1: Adjusted for baseline value of outcome, Model 2: Adjusted for baseline value of outcome and sex
[3]Odds ratio from Multinomial Logistic regression

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Table 4 Associations between length of follow-up and change in primary outcome and significant secondary outcomes in the Guided-Self-Determination (GSD) intervention group

	n	Time to Follow-up[1] Mean (SD)	Change Mean (SD)	B[2]	*p*-value
$HbA_{1c,}$ %	87	16.1 (5.6)	-0.51 (1.21)	-0.03	.154
PAID[3]	47	17.6 (3.6)	-6.7 (13.8)	-0.2	.764
DDS[4] Overall	47	17.6 (3.6)	-5.4 (14.0)	-0.4	.542
DDS Emotional burden	48	17.6 (3.6)	-7.1 (20.1)	0.1	.945
RSES[5]	47	17.6 (3.6)	0.6 (3.5)	-0.1	.435
TSRQ Autonomy[6]	49	17.6 (3.6)	0.2 (0.9)	0.03	.388

[1]Total follow-up time from date of randomization measured in months, [2]B=unstandardized regression coefficients [3]Problem Areas in Diabetes scale, [4]Diabetes Distress Scale, [5]Rosenberg Self-Esteem Scale, [6]Treatment Self-Regulation Questionnaire, Autonomous motivation

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a. Contributorship statement:

JM, MG, BR, VZ and HT contributed to conception and design of the study. JM collected the data. JM, JA and MP gave substantial contribution to the analysis and interpretation of data. JM wrote the first draft of this manuscript and MG, BR, and MP gave substantial contributions to the interpretation of data and revised the manuscript critically. VZ and HT gave substantial contributions to the intellectual content of the manuscript and revised the manuscript critically. All authors read and contributed to the final draft of the paper.

b. **Competing interests:**

Conflict of interests: Author MP declared the following potential conflict of interest: Consulting fees from Astra Zeneca, Calibra, Lilly, and Novo Nordisk; advisory panel of GlaxcoSmithCline, Lilly, and Novo Nordisk; research grants from Novo Nordisk; Speaker for Novo Nordisk. The remaining authors declare that they have no conflict of interest.

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d. **Data sharing statement:**

No additional data available

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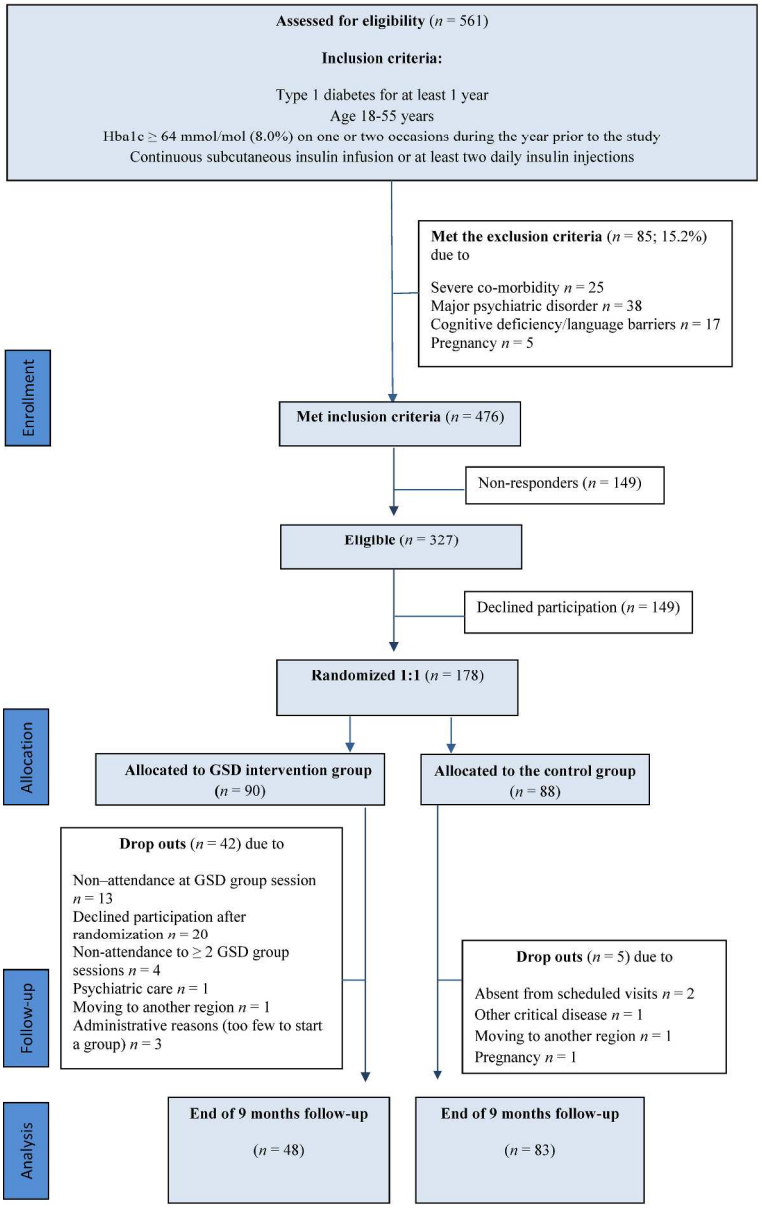

Fig. 1. Study flow diagram

268x427mm (300 x 300 DPI)