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Guided self-determination intervention versus attention control for people with type 2 diabetes in outpatient clinics: a protocol for a randomised clinical trial

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ABSTRACT

Introduction In the management of type 2 diabetes, autonomy-supporting interventions may be a prerequisite to achieving more long-term improvement. Preliminary evidence has shown that the guided self-determination (GSD) method might have an effect on haemoglobin A1c and diabetes distress in people with type 1 diabetes. Previous trials were at risk of uncertainty. Thus, the objective is to investigate the benefits and harms of a GSD intervention versus an attention control group intervention in adults with type 2 diabetes.

Methods and analysis This trial protocol is guided by the The Standard Protocol Items: Recommendations for International Trials Statement. We describe the protocol for a pragmatic randomised, dual-centre, parallel-group, superiority clinical trial testing a GSD intervention versus an attention control for people with type 2 diabetes in outpatient clinics. The participants (n=224) will be recruited from two diverse regions of Denmark. The experimental stepped-care intervention will consist of three to five GSD sessions lasting up to 1 hour with a trained GSD facilitator. The sessions will be conducted face to face, by video conference or over the telephone. The attention controls will receive three to five sessions lasting up to an hour with a communication-trained healthcare professional provided face to-face, by video conference, or over the telephone. Participants will be included if they have type 2 diabetes,>18 years old, are not pregnant. Participants will be assessed before randomisation, at 5-month, and 12-month follow-up, the latter being the primary. The primary outcome is diabetes distress. Secondary outcomes are quality of life, depressive symptoms and non-serious adverse events. Exploratory outcomes are haemoglobin A1c, motivation and serious adverse events. Data will be collected using REDCap and analysed using Stata V.16.

Ethics and dissemination The trial will be conducted in compliance with the protocol, the Helsinki Declaration in its latest form, International Harmonisation of Good Clinical Practice guidelines and the applicable regulatory requirement(s). The trial has been approved by the Danish Data Protection Agency (P-2020-864). The Ethics Committee of the Capital Region of Denmark reviewed the trial protocol, but exempted the trial protocol from full review (H-20003638). The results of the trial will be presented at the outpatient clinics treating people with type 2 diabetes, at national and international conferences as well as to associations for people with diabetes and their relatives.

Trial registration number ClinicalTrials.gov identifier: NCT04601311.

Strengths and limitations of this study

► We conducted a systematic review before initiating the trial to justify the rationale for the trial.
► To decrease the risk of a 'Hawthorne effect' and other biases an attention control group was included.
► The trial is designed as a pragmatic trial with few inclusion and exclusion criteria, which may increase the generalisability of the results to clinical practice.
► We conducted power calculations for all secondary outcomes.
► The trial is only a two-centre trial, planning to include a limited population of about 224 participants.

INTRODUCTION

Diabetes affects 425 million people worldwide, and of these, type 2 diabetes accounts for 90%.[1] The prevalence and incidence of type 2 diabetes in particular is rapidly rising.[1] Type 2 diabetes is caused by a genetic disposition in combination with a sedentary lifestyle and overweight.[2] With age being the largest risk factor, the number of people living with type 2 diabetes and various combinations of comorbidities is also increasing.[1 3]

Complications of type 2 diabetes include macrovascular complications such as ischaemic stroke or coronary heart disease.[2 4] Microvascular complications comprise retinopathy, neuropathy and nephropathy.[4] Up to one-third of people with type 2 diabetes have developed one or more complications of type 2 diabetes at the time of diagnosis.[5]

Type 2 diabetes management aims to prevent or reduce complications of diabetes. An appropriate management plan should consider the person's age, cognitive abilities, literacy, social and financial situation, cultural factors, diabetes complications and comorbidities, and health priorities including preferences of care.[6] Performing recommended self-care behaviours is challenging, particularly for populations with other chronic diseases.[7] People with type 2 diabetes stratified for outpatient clinics have a high degree of comorbidity in addition to adverse psychosocial outcomes such as diabetes distress and depressive symptoms.[8 9] Inadequate diabetes self-management is associated with worse psychosocial outcomes.[10]

Diabetes self-management depends on the individual's motivation and autonomy. Autonomy will underpin the planned intervention because satisfactory diabetes self-management is easier to accomplish and maintain if the individual's motivation is autonomous—meaning that the individual strives for goals they genuinely believe in.[11]

Thus, autonomy-supporting interventions and intrinsic motivation may be crucial factors in achieving real-life patient engagement and more long-term improvement through shared decision-making and collaborative goal setting.[12 13] A method designed to promote autonomy and intrinsic motivation in people with diabetes is the guided self-determination (GSD) method—an empowerment-based method recognised as a life-skills approach[14] clinically applicable in person within diabetes–provider relationships.[15–19] In the GSD approach, the person with diabetes has the primary role of preparing for consultations at home, by filling in reflection sheets, which enables the person to clarify and prioritise what is important to change, thus becoming able to express their thoughts in communication with the healthcare professionals. Subsequently, they may improve clinical outcomes[19–21] through the following pathways[15–17]: increased perceived autonomy support from the healthcare professionals, increased perceived competence in managing diabetes, decreased diabetes-related distress and ultimately improved glycaemic control.[18 19]

We previously conducted a systematic review and meta-analysis to investigate the evidence of psychosocial interventions on diabetes distress, HbA1c, depression and health-related quality of life in people with type 2 diabetes.[22] We found small effects of psychosocial interventions on diabetes distress and depressive symptoms, but the risk of bias and heterogeneity of included trials were high and the certainty of the evidence was very low to moderate.[22] To investigate autonomy-supportive interventions specifically, we searched the Cochrane Database of Systematic Reviews and PubMed using the search terms: type 2 diabetes, theory-based interventions, GSD, self-determination theory, illness integration theory and person-centred approaches in different combinations. From the searches, we identified only five randomised clinical trials investigating the effect of GSD in people with type 1 diabetes.[19 21 23 24] The trial results showed statistically significant improvements in glycaemic control,[19] diabetes

distress[21] and diabetes competences.[19 21] We identified no systematic reviews assessing the effects of GSD. Thus, we also conducted a systematic review investigating the effect of GSD or self-determination theory-based interventions versus standard care in people with diabetes.[25] However, all identified randomised clinical trials were at high risk of bias and the certainty of the evidence was low, which might entail that the previous trials overestimated the beneficial effects of GSD.[26] Furthermore, none of the trials described adverse events.

We here describe our new randomised clinical trial going to assess GSD versus attention control for people with type 2 diabetes. Our choice of the attention control group is based on the most recent international recommendations on type 2 diabetes management.[3] Additionally, we provide up to five contacts with a research assistant trained in supportive communication techniques to the participants in the control group. The inclusion of an attention control group is meant to alleviate expectation bias and reduce attrition[27] as well as the effects of the Hawthorne effect.[28]

OBJECTIVES
The primary objective is to assess if GSD intervention versus attention control in people with type 2 diabetes:
► Reduces diabetes distress with at least six points on the Problem Areas in Diabetes (PAID) Scale.[29]

The secondary objectives are to assess if GSD intervention versus attention control for people with type 2 diabetes:
► Reduces depressive symptoms and anxiety with at least three points on the Hospital Anxiety and Depression Scale (HADS).[30 31]
► Improves physical and mental quality of life with at least six points on the SF-36 Scale.[32 33]
► Reduces adverse events with at least five points on the Negative Effects Questionnaire 20-items (NEQ-20).[34 35]

Furthermore, the exploratory objectives are to assess if GSD intervention versus attention control in adults with type 2 diabetes:
► Improves serum HbA1c.
► Motivation measured by the Treatment Self-Regulation Questionnaire (TSRQ).
► Reduces the proportion of participants with one or more serious adverse events in the intervention period according to the International Harmonisation of Good Clinical Practice (ICH-GCP) definition.[36]

METHODS AND DESIGN
Design
The trial is designed as a pragmatic, investigator-initiated, dual-centre, randomised, parallel-group, assessor-blinded, superiority clinical trial of persons with type 2 diabetes. Participants (n=224) will be recruited from the Department of Endocrinology, the University Hospital of Copenhagen—Rigshospitalet, The Capital Region of
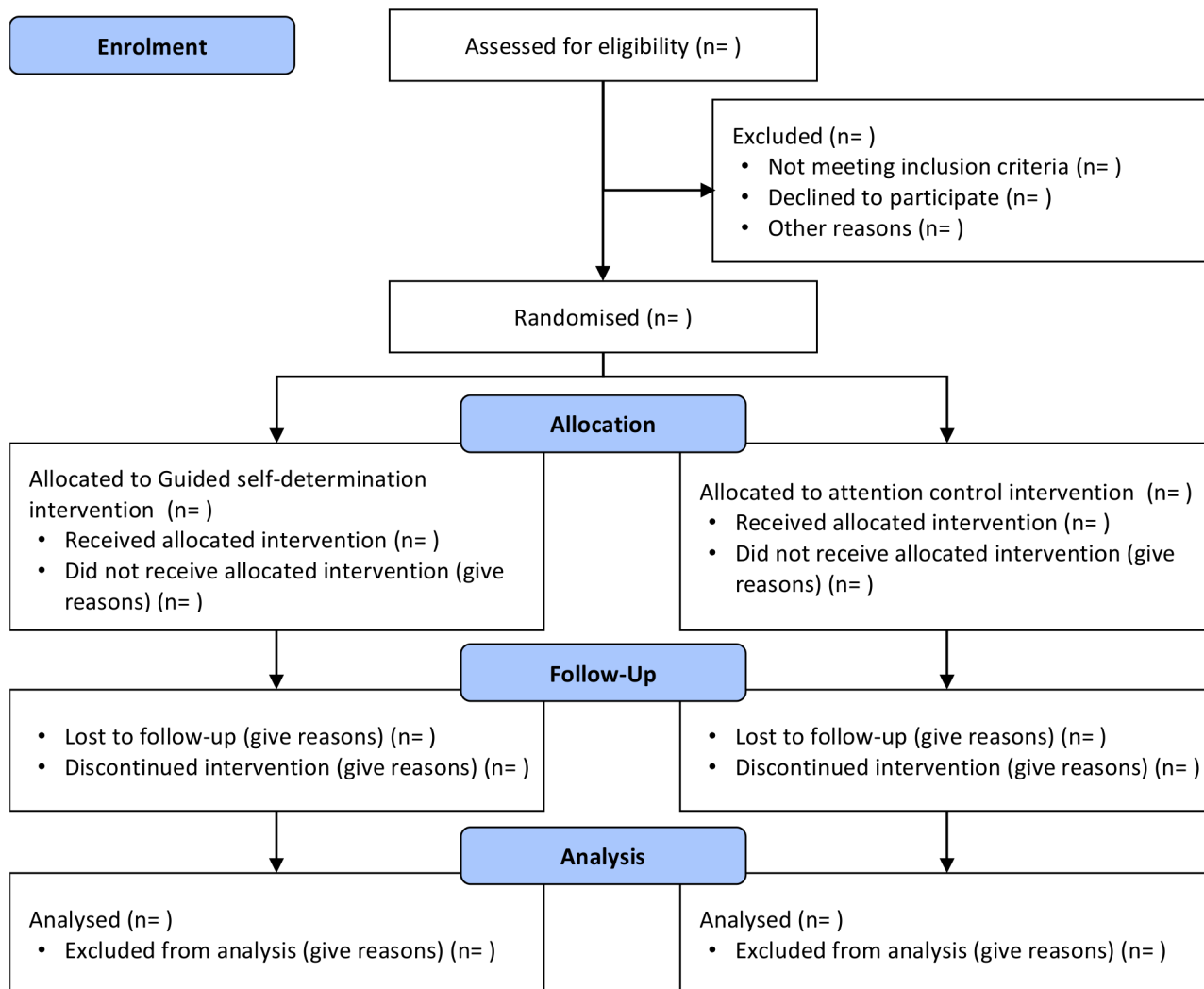
Figure 1 Flowchart of the trial.

Denmark and Steno Diabetes Center Odense, Odense University Hospital, The Southern Region of Denmark. We adhere to the The Standard Protocol Items: Recommendations for International Trials Statement regarding conduct[37] and the Consolidated Standards of Reporting Trials Statement extension for non-pharmacologic treatment interventions regarding reporting of this trial.[38 39] Initially, the planned start date was 15 August 2020, but the start was delayed due Denmark's first wave of COVID-19. Consequently, the first participant was randomised on 11 November 2020. The second wave of COVID-19 (from December 2020 to March 2021) meant further delay for the trial. The last date of follow-up for the last participant is expected to be in June 2023. Data analysis and publication of results are expected to be carried out from July to December 2023. Flowchart of the trial figure 1: the flowchart (n=224) will be filled in at the end of the trial. As part of this trial, we also plan for a nested qualitative study to elaborate on the mechanism of action in people with type 2 diabetes as well as the online versus face-to-face preferences and barriers.

Patient and public involvement
The development of the GSD method is based on a comprehensive involvement of people with diabetes.[15–17] The results of the trial will be presented to the participants and their relatives and associations for people with diabetes in Denmark and abroad, such as the Danish Association of Diabetes and Diabetes UK.

Trial sites and personnel
Both trial sites are specialised in type 2 diabetes with high complexity (ie, high degree of comorbidity and/or complications); thus, participants recruited for this trial are likely to have type 2 diabetes and one or more complications and/or comorbidities.

Registered nurses will be recruited for training and certification in the GSD method. The nurses undergoing training will be certified in the GSD method after a 32-hour structured and supervised training course. Subsequently, the nurses will be required to document their ability to use the reflection sheets and communication skills in two supervised courses with people with diabetes. After the courses, they will be required to fill in a self-assessment

form, which is discussed with Vibeke Zoffmann to finalise their individual certification as GSD facilitators. During the training period, models from the three grounded theories will be used as fidelity assessment tools.

Selection of participants

All people with diabetes referred to, or followed at the participating clinical trial sites (Department of Endocrinology, University Hospital of Copenhagen—Rigshospitalet and Steno Diabetes Center Odense, Odense University Hospital) are considered for participation and will be eligible, if they comply with the inclusion and exclusion criteria indicated below.

Inclusion criteria
► Being 18 years of age or older.
► Having been diagnosed with type 2 diabetes for three or less months according to the International Classification System of Diseases (ICD-11.2–11.9)
► Having signed informed consent.

Exclusion criteria
► Pregnancy; women who are premenopausal will be asked if they are pregnant or are planning pregnancy prior to inclusion.
► Prior participation in GSD course(s) for the past two years.
► Lack of signed informed consent.

Screening and informed consent

Potentially eligible participants will be approached and screened for eligibility by clinical staff (nurses/dieticians/physicians) at the outpatient clinics. Study nurses at each site will screen record to identify potentially eligible participants.

If eligible, detailed written patient information will be provided in person or by email and supplemented by verbal information. This information is only provided by the GSD certified nurses or the investigators. The clinical personnel will provide the information on the trial in an undisturbed room at the clinic. It will be stressed that the eligible person with diabetes will have the opportunity of bringing a third party (eg, a relative or friend). Eligible persons will be given at least 2 days to reflect before deciding to participate and will sign informed consent prior to inclusion and collection of any data. Due to our pragmatic design with few inclusion and exclusion criteria, no prior testing of participants' eligibility will be necessary.

Baseline assessments

We will collect the following data: sex, age, marital status, duration of diagnosis, employment, educational level, diabetes treatment, medications, number of comorbidities (complications of diabetes and other comorbidities). Data on diabetes-related comorbidities are retinopathy, nephropathy and neuropathy. Other comorbidities are defined as psychiatric comorbidities (depression, anxiety, schizophrenia, bipolar disorder) and medical comorbidities (cardiovascular disease, cancer, musculoskeletal disease, liver disease, apoplexy, abuse diagnoses). Baseline information will be collected from participants' records.

Randomisation

Participants will be centrally randomised at a 1:1 ratio using a web-based system developed by The Copenhagen Trial Unit. The allocation will be computer-generated through permuted blocks of varying sizes and concealed to the investigators. The certified GSD nurses will enrol the participants and assign the interventions. The randomisation will be stratified according to (1) centre and (2) sex, the latter due to a better effect on HbA1c and diabetes distress in women than men.[21]

Experimental intervention

The GSD is a theory-based and evidence-based problem-solving method to overcome barriers to collaborative care. It is a life-skills approach[14] that strives at promoting autonomous motivation, empowerment and self-determination. Its focus areas are life-illness integration,[16] relational potential for change and shared decision-making.[15 17] These concepts are integrated into worksheets which are essential to the practical application of the method. The GSD method entails advanced professional communication skills such as active listening, mirroring and values-clarifying responses to facilitate autonomous reflection in the people with diabetes focusing on diabetes management issues perceived as challenging.[15]

Experienced diabetes nurses certified in the GSD method provide the experimental intervention as a stepped-care intervention to each participant individually. Before randomisation, both the intervention and the control group will be supported in formulating one personal value-clarifying goal: 'One thing I want to achieve in my life with diabetes within a year is [….]'.

Within the first 4 months after randomisation, the participant will receive two to five need-based sessions with the GSD facilitator that will be conducted face to face, by video or over the telephone. The number of conversations will be decided by the participant–facilitator dyad during the second session based on the participant's perceived need. Facilitators will be unaware of the participant's level of diabetes distress, depression and anxiety scores. The stepped-care intervention will be provided as a digital version, an analogue GSD (in paper) or a mixed version as preferred by the participant.

The GSD intervention will require participants to complete 13 reflection sheets in a predefined order as preparation for five individual sessions scheduled every second week (figure 2). The sheets will be handwritten or digitally written on pages hosted at the Danish national health portal, Sundhed.dk. Additionally, a set of five sheets on motivation for evidence-based glucose control will be used in an analogue format. It will be possible to share and discuss the digital pages completed on the Sundhed.dk's platform face to face, over phone, or by

Overview of sessions

Information, written consent, HbA1c and baseline questionnaires.

Personal goal stated by answering the unfinished sentence:

One thing I want to achieve in my life with diabetes within a year is…

Randomisation

Analogue, digital, telephone GSD   Analogue, digital, telephone attention control

Session 0 face-to-face	**Session 0 face-to-face**
Intervention group	**Attention control group**
Invitation to collaboration is reviewed	Introduction to phone
Choice of digital, analogue or combined GSD	contact person
Provision of reflection sheets/SDK pages for meeting 1	Personal goal registered in
Meeting 1 and 2 are scheduled	Redcap
Session 1 (2 weeks after)	**Visit 1 (2 weeks after)**
Your body - what you feel, what you see	Follow-up on personal goal
Symptoms in everyday life with diabetes	
Important events and periods	
What is currently challenging or difficult?	
Unfinished sentences (1-2 / 2)	
Make a drawing or write some words	
Session 2 (4 weeks after)	**Session 2 (4 weeks after)**
Relatives or companion's unfinished sentences (when needed)	Follow-up on personal goal
Your week	
Your everyday life and plans to change your lifestyle	
For and against	
Room for diabetes in my life	
TIMEOUT	
Patient's & nurse's lists are updated	
Agreement on problem/challenge to focus on	
Session 3 (6 weeks after)	**Session 3 (6 weeks after)**
Dynamic judgment building	Follow-up on personal goal
Your observations	
Your thoughts	
Your goals and intentions	
Your actions	
Problem solving for now and in the future	
Session 4 (8 weeks after)	**Session 4 (8 weeks after)**
Making the long-term test (HbA1c) my friend	Follow-up on personal goal
Blood glucose measurements and my reasons for measuring	
My ideal blood sugar values	
What can be gained by lowering HbA1c?	
What can I gain from my ideal HbA1c goal?	
OBS only analogue reflection sheets available for visit 4	
Session 5 (10 weeks after)	**Session 5 (10 weeks after)**
Your outcome in one sentence	Follow-up on personal goal
Changes you are still working on	
Topics you want to talk to others about	
Schedule next appointment at the outpatient clinic	**Schedule next appointment at the outpatient**
with relevant HCPs and collaborators	**clinic with relevant HCPs and collaborators**

Short version:
Meetings 1-2-4-5
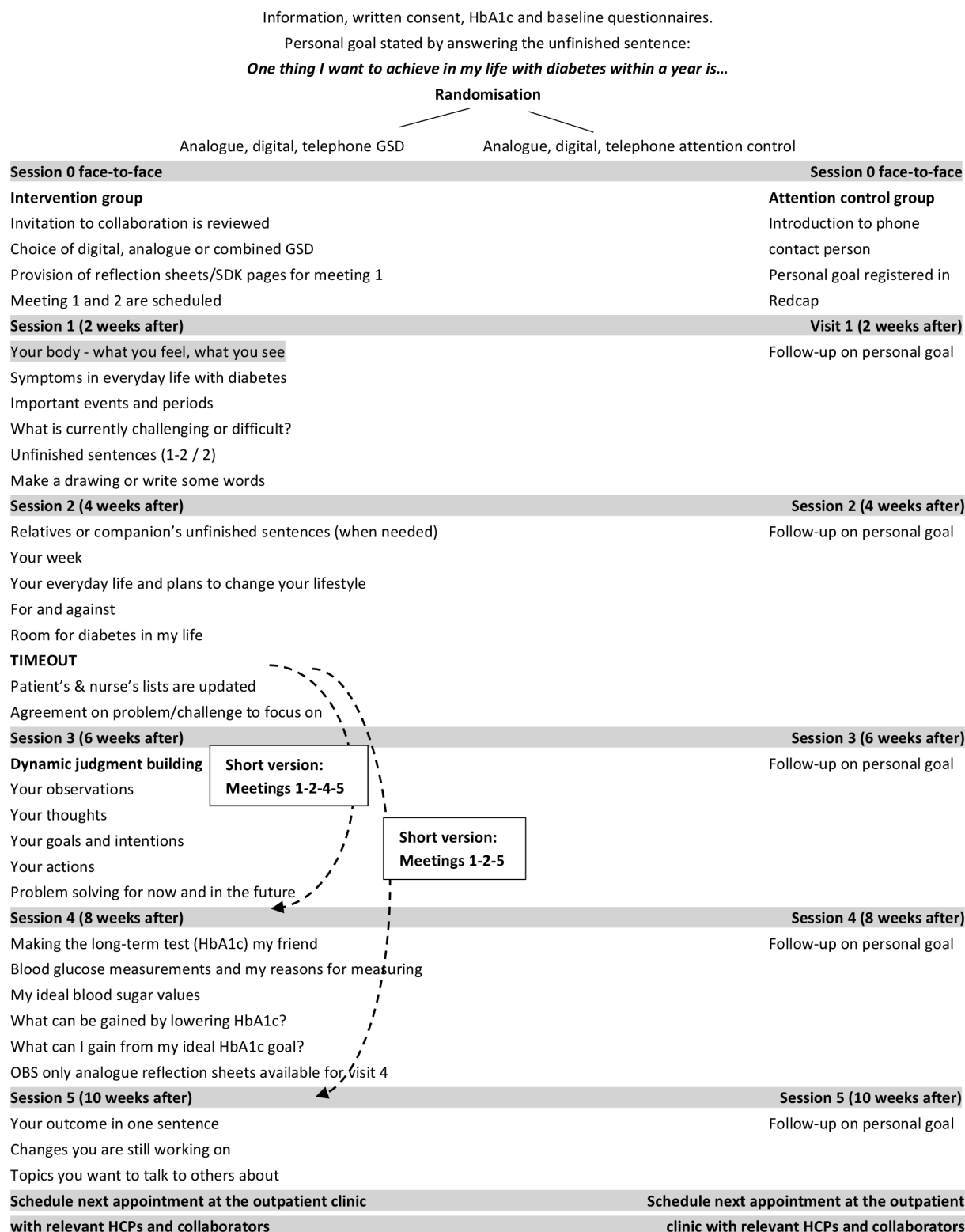
Short version:
Meetings 1-2-5

Figure 2 Overview of sessions. GSD, guided self-determination. HCP, healthcare professional

a secure video function called 'Hi Doctor'. Participants opting for a digital session will be able to access Sundhed.dk through a link provided by the certified GSD facilitator and complete the reflection sheets as preparation for the session.

Each session will have a standard duration of up to 1 hour. Participants will have the opportunity to bring a relative or a friend to the second section. The relative or friend will also have completed a reflection sheet as preparation. An overview of visits and the reflection sheets are

presented in figure 2. Reasons for a short version 1-2-4-5 and a short version 1-2-5 are low complexity and consequently reduced needs, respectively. The total number of reflection sheets filled in by the participants will be recorded in REDCap to document adherence to the offered intervention.

Control intervention

The participants in the control group will receive an attention control intervention that will include the following components: (1) before randomisation, the attention control group is supported in formulating one personal value-clarifying goal: 'One thing I want to achieve in my life with diabetes within a year is […]'; (2) the participant's personal goal will be registered by a communication-trained healthcare professional (the communication applied by the communication-trained healthcare professional will be advanced as she will have communication skills as a certified counsellor); (3) the communication-trained healthcare professional will follow-up the goal by contacting the participants in the control group 2 weeks and 1 month after randomisation to hear how they are doing with the goal, and if they wish to continue with three more sessions provided face-to-face, by video, or over telephone. The decision on three more session will be needs-defined. These needs-defined sessions will be scheduled concurrently with the sessions in the experimental group, namely 6 weeks, 8 weeks and 10 weeks after randomisation; and (4) all sessions will last up to 1 hour. The relatively short intervention has been qualitatively evaluated[40] and aims at being applicable in clinical practice in a population with a high degree of comorbidity. An overview of contacts in the attention control group is presented in figure 2.

Cointerventions

Both groups will receive standard treatments, including a 20 min visit to their primary care physician every 5–6 months. Both groups will receive follow-up questionnaires electronically at 5-month and 12-month follow-up. Facilitators and investigators will be alerted if participants do not respond to the questionnaires and the two subsequent reminders, after which the participant will be contacted by phone.

Concomitant interventions

Participants will continue with their usual antidiabetic medication regime during the trial and follow-up periods and they will be asked about their current treatment at each session also through follow-up contacts. Any initiation or discontinuation of medication (including antidiabetics) will be recorded.

Outcomes

For an overview of all outcomes and their corresponding time of assessment, see table 1.

Primary outcome

▶ Diabetes distress at 12-month follow-up assessed by the validated 20-item scale of diabetes-related distress burden, PAID.[29 41] The sum of items ranging from 0 (not a problem) to 4 (a serious problem) will be transformed into a 0 to 100 sum score by multiplying by 1.25. A score ≥30 will indicate high diabetes distress.[29] PAID will be measured at baseline and at 5-month and

Table 1	Outcomes and timepoints			
	Enrolment	**Allocation (baseline)**	**Follow-up**	
Timepoint	-t1	0	5 months	12 months
Guided self-determination				
Attention control				
Cointerventions				
Assessments: socio-demographic factors (at baseline only), diabetes-related comorbidities, psychiatric comorbidities and medical comorbidities	X	X		
Problem Areas in Diabetes		X	X	X
SF-36, Hospital Anxiety and Depression Scale, Treatment Self-Regulation Questionnaire, Negative Effects Questionnaire 20-items		X		X
Serum HbA1c		X		X
Severe hypoglycaemia				X
Diabetes medication at 5-month and 12-month follow-up change in diabetes medication		X	X	X

12-month follow-up, with 12 months as the primary follow-up timepoint.

Secondary outcomes

► Depressive symptoms assessed by the HADS[30 31] with 14 questions ranging from 0 to 3 divided into two subscales for depression and anxiety. In this trial, we will apply the cut-off points for the total scale, as recommended in populations with minor comorbid psychiatric disorders.[42] Scores>13 indicate moderate depression and >19 indicate a major depressive disorder. HADS will be measured at 12-month follow-up.[42 43]

► Generic quality of life assessed by SF-36, V.1.0, consisting of 36-items divided into a physical and mental domain with eight subscales: general health, physical functioning, social functioning, mental health, physical role, emotional role, bodily pain and vitality. We will assess the physical and mental scale at 12-month follow-up.[32 33]

► Adverse events[36] in the intervention period assessed by the NEQ-20 consisting of 20-items on a 5-point Likert scale assessed at 12 month follow-up.[34 35]

Exploratory outcomes

► Serum HbA1c concentration will be assessed from the participants' records at 12-months ±2-week follow-up.

► Type of motivation (autonomous/external), controlled (external) or resigned (amotivated) regarding diabetes self-care practices will be assessed by the TSRQ.[44] The TSRQ consists of 21 items divided into three subscales: (1) autonomous (eight items); (2) controlled behaviour (nine items); and (3) amotivated (four items). TSRQ will be measured at 12-month follow-up.

► Proportion of participants with one or more serious adverse events in the intervention period, defined according to the International Harmonisation of Good Clinical Practice definition, as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalisation or the prolonging of existing hospitalisation, and resulted in persistent or significant disability or jeopardised the patient.[36]

Blinding

Participants and treatment providers will not be blinded to the allocated trial intervention. The treatment providers will not be involved in the analyses. All other medical personnel will be blinded to the notes in the participant's electronic records. Outcome assessors and external statisticians at The Copenhagen Trial Unit will be blinded to the participants' randomisation status. The statistical analyses will be conducted with the intervention groups coded as X and Y. After conducting the statistical analyses under code, the steering committee will write two abstracts while the blinding is intact—one assuming that the experimental intervention group is X and the control

intervention group is Y, and one assuming the opposite. After this, the code will be broken.[45 46]

Participants' discontinuation and withdrawal

Participants will be able to withdraw consent from participation in the trial at any time without reason and consequences for future treatment at the clinics. One of the investigators will contact the participant and ask which aspects of the trial they wish to withdraw from: (1) the trial intervention or control group; (2) the follow-up assessments; and/or (3) use of already collected data. Only if a participant wishes to fully withdraw from the abovementioned points, the data will not be used in the analyses. In all of the abovementioned cases, the trial investigators will encourage them to continue with the follow-up assessments.

Discontinuation of a participant at the choice of the investigators will happen if:
1. The participant gets pregnant during the intervention period, or
2. The participant experiences intolerable adverse reactions.

In all of the abovementioned cases, the trial investigators will encourage them to continue with the follow-up assessments. A Data Monitoring Commiittee is not required in non-pharmacological diabetes self-management interventions,[36] but the trial management committee will monitor recruitment, treatment and attrition rates and any concerns related to the trial.

Data management

Data collection will be conducted by the certified facilitors using tablets and electronic case report form developed in the data collection management system REDCap. All self-reported questionnaires will be collected from REDCap. An overview of outcomes measures and data collection timepoints can be found in table 1.

Sample size

The sample size was determined by a predicted difference in the primary outcome measure, PAID, between the experimental and control group. We could not identify any previous studies quantising the minimal important difference of PAID. Informed by the estimated mean and SD from the trials included in our systematic review[25] (results not yet published), we pragmatically chose six PAID points as the minimal important difference. It must be noted that the minimal important difference should preferably be based on low risk of bias trials, as high risk of bias trials may overestimate the effect.[26] Unfortunately, it was only possible to identify trials at high risk of bias in our systematic review.[25] In another review conducted by our research group,[22] we did, however, identify trials at low risk of bias investigating the effect of psychosocial interventions (not GSD). We found that estimates from these trials at low risk of bias[47] roughly corresponded to the minimal important difference and SDs chosen for our sample size calculation. Consistent with these trials that

used PAID as an outcome measure, we expect a SD of 16. With a power of 80% (a beta at 20%) and an α at 5%, two-tailed, a sample size of 112 participants is needed in each intervention group corresponding to a total of 224 participants included in the trial.

Power calculation for the secondary outcomes

Based on previous trials,[32 33] an estimated minimal important difference of six points±SD of 15 on the SF-36 scale, α at 5%, and 112 participants in each intervention group, we achieved a power of 84.9%.

Based on previous trials,[40 48] an estimated minimal important difference of three points±SD of six on the HADS scale, α at 5%, and 112 participants in each intervention group, we achieve a power of 96.3%.

No minimal clinically important difference based on previous trials has been reported when applying the NEQ-20.[34 35] Thus, we pragmatically expect a difference of five points±SD of 13 on the NEQ-20, α at 5% and 112 participants in each group. Hence, we achieved a power of 82.1%.

Statistical methods

All continuous outcomes will be assessed by linear regression and the dichotomous outcomes will be assessed by logistic regression. The primay outcome, PAID will be measured at baseline and at 5-month and 12-month follow-up, with 12 months as the primary follow-up time-point. All secondary and exploratory outcomes will be assessed at baseline and 12-month follow-up. The analyses will be performed on the intention-to-treat and per-protocol basis, respectively, and will be adjusted for the stratification variables: site and sex. We will conduct subgroup analyses on educational level, sex and number of comorbidities.

The five-step procedure developed by Jakobsen *et al*[49] will be applied to assess if the threshold for clinical and statistical significance is crossed. Missing data will be handled according to the recommendations by Jakobsen *et al.*[50] All analyses will be conducted blinded with the experimental and the control group concealed as X and Y. A detailed statistical analysis plan will be published prior to the analysis of trial data.

Ethics and dissemination

The trial will be conducted in compliance with the protocol, the Helsinki Declaration in its latest form,[51] ICH-GCP guidelines,[36] and the applicable regulatory requirement(s). The trial has been approved by the Danish Data Protection Agency (P-2020-864). The Ethics Committee of the Capital Region of Denmark reviewed the trial protocol on two occasions, but exempted the trial protocol from full review (H-20003638) dated 16 January and 18 August 2020.

Dissemination policy

The results of the trial will be presented at the outpatient clinics treating people with type 2 diabetes, at national and international conferences as well as to associations for people with diabetes and their relatives. Negative, positive or neutral results will be published in international peer-reviewed journals. Following international guidelines, we will publish the anonymised individual participant data transparently together with our publication.[52 53]

Perspectives

The trial aims to provide evidence for or against an effect of GSD compared with attention controls in people with type 2 diabetes in an outpatient clinic setting. The GSD method has not yet been tested in this population and may help identify subgroups of people with diabetes for whom GSD may be more or less effective and the most efficient way of delivering it.

This information may potentially increase results' cost-effectiveness and external validity. Likewise, their generalisability might be increased by the trial's pragmatic design including few exclusion criteria.

Furthermore, before planning this protocol, we conducted a systematic review using the Cochrane methodology to synthesise the evidence for the beneficial and harmful effects of GSD or self-determination theory interventions.[25] The systematic review considered both risks of random errors and systematic errors to identify critical gaps in existing trials investigating the GSD method. A potential limitation might be that a high level of literacy may be required to achieve the optimal benefit of the reflection sheets.[54]

Trial status

This is the first version of the trial protocol dated 9 October 2020. The first participant is scheduled for inclusion in November 2020.

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including intervention design. ASM wrote up the protocol with regular supervision from MR, VZ, TT, JL, CG, JCJ and JL. TBS assisted in setting up procedures and data collection at the recruiting sites. BR, TBS and EM read and commented the final manuscript before it was submitted for publication. All authors read and approved the final manuscript.

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