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Complete List of Authors:	Haugstvedt, Anne; Hogskulen pa Vestlandet, Department of Health and Caring Sciences Hernar, Ingvild; Hogskulen pa Vestlandet, Department of Health and Caring Sciences; Univeristy of Bergen, Department of Global Public Health and Primary Care Strandberg, Ragnhild ; Hogskulen pa Vestlandet, Department of Health and Caring Sciences Richards, David; University of Exeter, Medical School Nilsen, Roy; Hogskulen pa Vestlandet, Department of Health and Caring Sciences Tell, Grethe; University of Bergen, Department of Global Public Health and Primary Care Graue, Marit; Hogskulen pa Vestlandet, Department of Health and Caring Sciences
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The use of Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomized controlled trial

Anne Haugstvedt,[1] Ingvild Hernar,[1,2,3] Ragnhild B Strandberg,[1] David Richards,[4] Roy M Nilsen,[1] Grethe S Tell,[2] Marit Graue[1]

[1]Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Bergen, Norway

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

[3]Department of Medicine, Haukeland University Hospital, Bergen, Norway

[4]Institute for Health Research, University of Exeter Medical School, Exeter, UK

Correspondence to: Anne Haugstvedt, Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Post Box 7030, N-5020 Bergen, Norway. Tel: +47 55 58 78 88; Mobile +47 47 82 92 20. E-mail: ahau@hvl.no

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ABSTRACT

Introduction Although diabetes distress is found to be associated with decreased glycaemic control among adults with type 1 diabetes, the psychological and emotional impact of living with the disease is often not recognized and often underreported in diabetes care. Therefore, regular assessment of diabetes distress is recommended. Assessment of diabetes distress using Patient-Reported Outcome Measures (PROMs) in clinical practice has the potential to enhance care for people with diabetes by identifying problems and improving patient-clinician communication. In this study, we aim to develop, test and evaluate the effectiveness of an empowerment-based intervention using PROMs regarding diabetes distress as dialogue support in clinical diabetes consultations among adults with type 1 diabetes.

Methods and analysis As part of the implementation of PROMs in the Norwegian Diabetes Register for Adults, we will utilize PROMs data to improve the quality of clinical diabetes consultations. The study is a randomized controlled trial among adults with type 1 diabetes. We used the Medical Research Council's framework as a guide when developing the study and this protocol describes three of the four phases in this framework: (1) the development phase, (2) the feasibility and piloting phase, and (3) the evaluation phase. Both quantitative and qualitative approaches will be used in the various study phases. In the evaluation phase, the effect of the study intervention will be analysed with linear regression and mixed models.

Ethics and dissemination Ethical approval has been obtained from the Western Norway Regional Committee for Medical and Health Research Ethics for the feasibility study (2016/2200/REC west) and the pilot and randomized controlled trial evaluation study (2017/1506/REC west). Trial registration number ClinicalTrials.gov ID: NCT03471104

Keywords Type 1 diabetes, Diabetes distress, Patient-Reported Outcome Measures (PROMs), Complex intervention

Strengths and limitations of the study

- This is a comprehensive study with the potential to provide new knowledge about the use of Patient-Reported Outcome Measures (PROMs) as dialogue support in clinical diabetes consultations to reduce diabetes distress among patients with type 1 diabetes.
- The use of the Medical Research Council's framework as a guide for the development and evaluation of this randomized controlled trial is a strength because appropriate methodological and practical choices can be made in all phases of the study.
- A key challenge includes possible contamination of the control group although the completed PROMs will not be available in the medical records of the participants in the control group.

INTRODUCTION

The management of type 1 diabetes (T1D) is complex and people living with the condition need to make numerous daily choices related to their medical treatment.[1, 2] They need to monitor their blood glucose and administer insulin several times each day. The burden of living with T1D remains a challenge despite new insulin types and advances in insulin delivery and glucose monitoring technologies.[3] Many Norwegian adults with T1D do not achieve the recommended treatment goals for glycaemic control.[4, 5] This poor goal attainment might be due to inappropriate choice of insulin regimen for the individual, but research has also shown psychological and emotional aspects are important barriers to satisfactory diabetes self-management.[6]

The psychological and emotional impact of living with diabetes is often unrecognized and/or underreported in diabetes care.[7, 8] Diabetes distress, which reflects the emotional response to the burden, worries, anxieties, frustrations and stressors associated with managing diabetes in everyday life,[9, 10] is found to be associated with decreased glycaemic control.[11, 12] Therefore, the International Diabetes Federation recommends regular assessment of diabetes distress.[13] Such assessment is considered feasible and beneficial to promote the recognition of psychological and emotional issues that affect diabetes self-management.[9, 14]

Patient-Reported Outcome Measures (PROMs) involves asking people to complete questionnaires concerning the impact of their condition and its treatment on their health.[15] The integration of PROMs in clinical practice has the potential to improve care for people with diabetes and other chronic diseases by screening for and identifying problems, monitoring progress over time, improving patient-clinician communication and enabling

patients to become more involved in managing their own health.[16] The present study is part of the implementation of PROMs in the Norwegian Diabetes Register for Adults (NDR-A).

Aim

The overarching aim of the Diabetes Patient-Reported Outcome Measures (DiaPROM) trial is to develop, test and evaluate the effectiveness of a structured empowerment-based intervention using PROMs regarding diabetes distress as dialogue support in clinical diabetes consultations among adults with T1D. The primary hypothesis is that the intervention will reduce diabetes distress. A secondary hypothesis is that the intervention will improve overall well-being, perceived competence for diabetes management, glycaemic control, and satisfaction with diabetes follow-up.

METHODS AND ANALYSIS

Study design and study overview

The study is designed as a multidisciplinary randomized controlled intervention trial (RCT) and will consist of several interacting components and a number of behaviours required by those receiving and delivering the intervention. Therefore, we used the Medical Research Council's framework (MRC framework) as a guide when developing the study.[17, 18] The framework describes four important phases in the development, evaluation and implementation of a new intervention initiative: (1) the development phase, (2) the feasibility and piloting phase, (3) the evaluation phase and (4) the implementation phase (figure 1). In this protocol, we will present the study gradually according to the first three phases. The first two phases are the preparatory phases and phase 3 comprises the full-powered RCT. An overview of the phases is presented in Table 1.

Table 1. Overview of the study phases in the DiaPROM trial

Phase	Aims	Methods	Participants
Phase 1: Development	To perform a literature review and meet with health service users to identify relevant PROMs, develop a method for answering PROMs and develop an intervention following PROM scores of concern	Systematic literature searches related to the use of PROMs in interventions, and consultations with several health service users, both individual and in groups	3 persons with type 1 diabetes (individually), and 3 persons with diabetes (in a group)
Phase 2: Feasibility and piloting			
2a: Feasibility study	To feasibility test the technical and practical procedures for collecting PROMs on a touch screen computer, and evaluate the participants' perceived understanding, relevance and number of questions	Qualitative approach (field notes), and quantitative approach (analyse questionnaire data on perceived understanding, relevance and number of questions)	At least 60 patients with type 1 diabetes ≥40 years
2b: Pilot study	To test all the components of the upcoming full-powered RCT	RCT design with outcome measures at baseline and after 1 year. Audiotaping of nurse consultations and qualitative interviews with participants and health care personnel	80 (40 + 40) patients with type 1 diabetes (18–40 years), 6–8 nurse consultations, 15–20 participants and 8–10 physicians and nurses
Phase 3: Evaluation	To evaluate the effectiveness of a structured empowerment-based intervention with the use of PROMs as dialogue support in clinical diabetes consultations	RCT design with outcome measures at baseline, after 1 year and after 2 years. A qualitative approach will be considered based on experiences from the pilot study	A power analysis indicated a need for 77 participants (included 20% dropouts) in each group, but the pilot study will inform the final sample size calculation

We used the SPIRIT checklist (http://www.spirit-statement.org/wp-content/uploads/2013/01/SPIRIT-Checklist-download-8Jan13.pdf) to make sure that all important and recommended items are addressed in the study protocol.

Phase 1: development of the study

The initial development of the DiaPROM trial took place during 2016 and 2017. The essential tasks in the development phase were to determine (1) which PROMs to include, (2) how patients should complete the PROMs, and (3) which intervention should follow PROMs scores of special concern.

Literature review

We performed systematic literature searches to identify published articles on the use of PROMs in clinical diabetes intervention studies. Regarding the use of PROMs in clinical practice, we identified a multi-centre study across eight countries that had tested the feasibility and impact of a procedure for implementing PROMs in routine diabetes care.[14,19] This computer-assisted "Monitoring of Individual Needs in Diabetes" procedure aimed to improve recognition and management of the psychological needs of patients with diabetes in routine care. Regular assessment of psychological needs was implemented as part of the annual review in diabetes clinics. The assessment included diabetes distress measured by the Problem Areas in Diabetes (PAID) scale. Several other studies have reported PAID as an appropriate instrument for use in clinical diabetes consultations. This instrument may contribute to improved communication by making the dialogue between health care providers and patients more therapeutic and goal oriented.[20-25] The PAID scale has been translated into several languages, including Norwegian.[26]

Patient and public involvement

A crucial question when considering which PROMs to include was what adult people with T1D perceived as the most important and relevant aspects to emphasize in diabetes follow-up. Thus, we consulted several groups of health service users. The health service users indicated that the 20 statements in PAID were relevant to a life with diabetes. In addition, they experienced the burden of completing PAID and the study's evaluation measures as acceptable for the participants. To include the voice of the health service users throughout the study, two people with diabetes are included in the project group. They will contribute in all phases of the study. Furthermore, we will invite additional people with diabetes to share their views on the various phases of the study. Involving health service users at different levels

(from consultation to contribution) is important to provide insight into patients' perspectives and useful in terms of shaping the research processes.[27]

Intervention PROMs

Based on the literature review and input from the health service users, we chose the PAID scale as the tool for dialogue support in the study intervention. The scale was developed to gain insight into the breadth of emotional responses to living with diabetes and consists of 20 statements regarding diabetes distress (e.g. "feeling constantly concerned about food and eating", "worrying about low blood sugar reactions").[28-30] The scores are on a 5-point Likert scale from 0 (not a problem) to 4 (serious problem). An item score of 3 (somewhat serious problem) or 4 (serious problem) indicates moderate to serious diabetes distress related to the specific item. Scale scores are transformed to a 0-100 scale, with higher scores indicating greater distress.

Completing PROMs

The literature describes various methods for administration of PROMs such as paper-based self-administration at home or in the clinic, interviews by telephone or personal meetings, computer-assisted self-administration in the clinic or mail- or web-based administration from patients' homes.[16] In our study, we decided on computer-assisted administration on a touch screen computer in the outpatient clinic. Using this method has advantages, such as efficient and simultaneous data entry and minor privacy challenges.

The study intervention

Based on the literature review and input from the health service users, we developed the study intervention that we aim to evaluate in phase 3. The starting point for the intervention is when participants complete the PAID scale and physicians download the scores into the participants' medical record as part of the annual consultation (figure 2).

Further, physicians will review and discuss the PAID scores briefly with participants. Participants with one or more single PAID item(s) score of 3 or 4 (somewhat serious or serious problem), or PAID total score ≥30, will be referred to additional diabetes nurse consultations. Participants with lower scores will receive regular follow-up according to usual clinical protocols.

The nurse follow-up for those with PAID scores of concern will consist of at least two consultations. The first will take place within 4 weeks after the annual consultation and inclusion in the trial, and the second within 3 months after the first. After the second nurse consultation, the nurse and the participant will agree on any further follow-up until the next annual consultation with the physician. The diabetes nurses' review of PAID scores in conversation with participants will follow a communication manual based on key elements from empowerment theory and self-determination theory, such as empathetic communication and autonomy support.[31-33] The communication skills highlighted in the manual involve "active listening", "asking open questions", "responding", "summing up" and "agreeing on goals and actions to take". For further work with the participants problem areas, goals and actions to take will be written on a separate form. Finally, 12 months after inclusion, the participants will complete the PAID again before the annual consultation with the physician.

Evaluation measures

The measurements used to measure the effect of the evaluation study (phase 3) were also chosen on the basis of the literature review and considerations in the development phase. Diabetes distress, measured by the Diabetes Distress Scale (DDS), has been chosen as the primary outcome in the study. The DDS contains 17 items and 4 subscales: emotional burden (5 items), physician-related distress (4 items), regimen distress (5 items) and diabetes-related interpersonal distress (3 items).[34] The scores are on a 6-point Likert scale from 1 (not a

problem) to 6 (serious problem) with a mean total or subscale score from 1 to 6.[35] As secondary outcomes, the World Health Organization's 5-item well-being index (WHO-5)[36-38] and the Perceived Competence for Diabetes Scale (PCDS)[39-41] are included for evaluation of overall well-being and perceived diabetes competence, respectively.

The participants will complete both the PAID and the evaluation PROMs before the annual consultation, and some standard questions about satisfaction with follow-up in health care will be completed after the same consultation.

Phase 2a: feasibility study

A feasibility study started in 2017 with the aims of (1) examining the technical and practical feasibility of collecting PROMs on a touch screen computer in the outpatient clinic, and (2) evaluating the participants' perceived understanding, the number and relevance of items, and the acceptability of completing PROMs annually. The participants in the feasibility study were adults with T1D aged ≥40 years from Haukeland University Hospital in western Norway.

Data collection and outcomes

The data collection has been completed. Regarding the first aim, field observations provided data on the technical and practical procedures related to the completion of PROMs on the touch screen computer. Informal conversations with participants and health care personnel about their experiences also took place. Regarding perceived understanding, relevance and number of items, and acceptability of completing PROMs annually, we included a paper-based questionnaire with questions adapted for this study.

Data analysis

The data analysis is ongoing and will be completed in 2018. The field notes from the observations and informal conversations will be grouped by themes explaining the main content of the notes. The perceived understanding, the number and relevance of items and acceptability have been analysed descriptively. As additional analyses, we have estimated the proportion of participants meeting the inclusion criteria, the proportion of eligible patients showing up at the clinic and the proportion completing the PROMs. These estimates will give important information on recruitment of participants for the upcoming pilot and evaluation study.

Preliminary results

Almost 20% of 137 invited patients did not show up at the clinic (change of appointments, sick, no reason given). Further, most of the invited participants did not go directly to the computer on arrival at the clinic as instructed on the information sheet. Thus, we need to develop clearer information and procedures for the pilot study to avoid loss of potential participants among those invited. Sixty-nine individuals participated in the study and 83% of them reported that, to a high or a very high degree, they would be positive about an annual completion of PROMs. Further analyses of the results from the feasibility study are ongoing, and we plan to publish these in a separate article.

Phase 2b: pilot study

A pilot study will be conducted to test the feasibility of all the components of the forthcoming full-powered RCT; thus, the pilot will be designed as a randomized controlled trial in the same way as the evaluation study (phase 3). The aims of the pilot study are to:

1. evaluate the recruitment and the number of dropouts during the intervention;
2. evaluate the performance of the randomization procedure;

3. evaluate if the PAID scores qualifying for referral to nurse consultations seem suitable;
4. evaluate the variance in participants' outcome measurements and the estimated between-group differences and their 95% confidence intervals (CI);
5. evaluate if the intervention consultations are suitable and conducted in accordance with the given procedure; and
6. explore the patients' and health care personnel's experiences with the use of PAID as dialogue support in clinical diabetes consultations.

Participants

In accordance with recommendations for pilot RCTs of interventions,[42] we will include 80 participants: 40 in the intervention group and 40 in the control group. The participants should have T1D for at least 1 year and aged ≥18 to <40 years. The same inclusion and exclusion criteria as described for the evaluation study will be applied. At inclusion, we will test the computer-based randomization procedure described for the evaluation study. The participants allocated to the intervention group will receive the described intervention with all its components. Thus, the pilot study will last for a year.

Data collection and outcomes

All participants (both intervention and control groups) will complete the study PROMs (before the annual consultation) and a paper-based questionnaire about their experience and satisfaction with the diabetes follow-up (after the consultation) at baseline and after 12 months (at the end of the intervention). Regarding data entry of these data, range checks for data values will be performed. We will document all types of contacts between the participants and the diabetes outpatient clinic for all participants throughout the study period. The outcome measures will be identical to the outcome measures described for the evaluation study.

To test if the extra consultations by diabetes nurses are carried out in accordance with the procedure described for the intervention, a random selection of consultations (6–8) will be audiotaped. For this audiotaping, we will obtain additional consent from the patients and from the nurses. Qualitative in-depth interviews with 15–20 participants and 8–10 health care personnel (physicians and nurses) will be conducted after the intervention regarding their experiences with the intervention and the use of PAID as dialogue support in clinical consultations.

Data analysis

In accordance with the aims of the pilot study, the recruitment of participants, the number of dropouts during the intervention, the performance of the randomization procedure, and the participants' PAID scores will be analysed descriptively. To evaluate the variance in the outcome measures and the estimated between-group differences, we will estimate the mean, SD and CI of the DDS and the other evaluation measurements before and after the intervention period for both the intervention and control groups. To evaluate whether the intervention consultations were suitable and conducted in accordance with the given procedures, we will transcribe the audiotaped consultations and analyse them using thematic analysis.[43] The interviews to evaluate the patients' and health care personnel's experiences with the use of PAID in the clinical consultations will also be transcribed and analysed with thematic analysis.

Phase 3: the evaluation study (the RCT)

The primary aim of the full-powered study is to evaluate the effectiveness of the structured empowerment-based intervention with the use of PROMs as dialogue support in clinical diabetes consultations in accordance with the overarching aim of the DiaPROM trial.

Our procedures may be modified on the basis of data collected from the feasibility and pilot studies.

Participants and eligibility criteria

As in the pilot study, participants will be adults with T1D for at least 1 year aged from ≥18 to <40 years recruited from two university hospitals in western Norway. Pregnant women, patients with severe somatic or psychiatric co-morbidities and people unable to read and complete questionnaires on the computer because of language, reading, or cognitive problems will be excluded. Eligible participants will receive information and consent forms by regular mail before the annual diabetes consultation at the clinic. The information form include information about volunteerism and the possibility to withdraw from the study at any time point without consequences.

Sample size calculations

Preliminary power calculations have been performed based on a power of 80% and a significance level of 5% to detect the minimal clinically important difference (MCID) in DDS scores between the intervention group and the control group after the intervention. The MCID is set to 0.4 for DDS scores from 1 to 6. A review of health-related quality of life instruments by Normann *et al.*[44] found that the MCID estimates often appear to be half an SD. Previous Norwegian data from Strandberg *et al.*[11] indicated a mean score (SD) of 2.0 (0.8) for the DDS, yielding half SD of approximately 0.4. This is consistent with Fisher *et al.*[35] who indicated 0.4 as a clinically meaningful difference in DDS, which was also half SD in that study. The power calculations based on these data indicate that 64 participants in each group will be sufficient to detect a treatment difference after the intervention. To account for dropout (20%), we will include at least 77 participants in each group. However, we will

update the power calculations after the pilot study has been conducted to take post-intervention between-group estimates (means and SDs) into account.

Randomization procedure and allocation concealment

We will use computer-generated block randomization at the patient level to ensure equal numbers of participants in the intervention and control groups. Further, we will stratify for gender to secure equal numbers of men and women in each group. When participants complete the PROMs on the touch screen computer, they will receive an individual four-character code. When the physician downloads the PROMs data using the code, a concealed computerized allocation will take place. Information about which group the person is allocated will appear on the computer screen and the physician will inform the participant immediately. Thus, neither the participants nor the health care providers can be blinded.

The intervention

Participants allocated to the intervention group will receive the intervention described in the development section (p. 8). The intervention will last for a year; from one annual consultation to the next. For most patients the annual consultations normally constitute "care as usual". All participants will receive their usual care. The intervention will constitute an additional care.

The control group

The control group will receive "care as usual" which does not include a structured focus on psychological and emotional diabetes distress. All participants complete the PROMs scores before an annual consultation. The randomization take place afterwards. However, for the participants allocated to the control group, the scores will not be accessible in the electronic patient records until the study is completed.

Data collection and outcomes

Participants will complete the primary and secondary outcome measures at baseline, at 12 months (after the intervention) and at 24 months follow-up. For subgroup analyses, we will perform a computerized retrieval of the following variables from the participants' electronic patient records: sex, age, ethnicity, body mass index, diabetes duration, HbA_{1c}, insulin regimen, insulin doses, severe hypoglycaemic episodes needing assistance in the past year, hospitalizations, co-morbidities and diabetes late complications.

Data analysis

To assess both short- and long-term effects of the intervention, we will collect one pre-intervention measure and two post-intervention (after 1 and 2 years) measures for both the intervention and control group. All analyses will be on an intention-to-treat basis, and we will compare intervention and control groups for each follow-up time using linear mixed effects models with DDS as the primary outcome measure. All models will define intervention, time and intervention-by-time interaction as fixed effects (all categorical), whereas a random intercept will be specified to account for correlated observations of the same individual (an exchangeable correlation structure assumed). To obtain *p* values or 95% CI for difference in DDS means between the comparison groups at different time points, we will perform a post-hoc test for pairwise comparison accounting for multiple testing. To test whether the predicted DDS means change differently over time, we will use the likelihood ratio test by comparing the log-likelihood between models with and without the intervention-by-time interaction. In linear mixed effects models, all available DDS measures for an individual will be used for estimation even though certain measures may be missing on follow-up for that individual. The model will produce unbiased estimates provided the data are missing at random. As this is a

block-randomized trial, we will assume that the comparison groups are similar in all aspects except the treatment.

Qualitative approach

In addition to the quantitative evaluation of the study effect, we will explore the patients' and health care personnel's experiences of the intervention's effectiveness and appropriateness. However, data and analyses from the qualitative approaches in the pilot study will be considered before deciding on the final strategy and procedures for the qualitative approach in the evaluation study.

ETHICS AND DISSEMINATION

The Norwegian Regional Committee for Medical and Health Research Ethics has approved the feasibility study (2016/2200/REK west) and the pilot and evaluation study (2017/1506/REK west). Haukeland University Hospital, Bergen, Norway is the responsible research institution (trial sponsor) where the study data will be stored on a secure research server. In order to protect confidentiality, names of the potential and enrolled participants will be stored separate from the other study data. Only the principle investigator and a few members of the project group have access to the study data. If important protocol modifications happen, this will be communicated to the ethic committee and ClinicalTrials.gov. Further information and contact data can be obtained from ClinicalTrials.gov, registration number NCT03471104.

Completing the PROMs may activate latent psychological or psychosocial problems and negative feelings. To care for any participants in the control group reporting worryingly high levels of distress, the research team will continuously review the reported distress levels

and discuss with the physicians the possible need for more intensive care or referral to psychological or psychiatric follow-up for those reporting worryingly levels of distress.

We will present the findings of the study phases at national and international conferences and submit manuscripts to peer-reviewed journals and popular science journals. We will also publish the findings in popular science journals, public newspapers and journals for relevant user groups.

DISCUSSION

In this multi-phase study, we have used relevant literature and input from health service users in selecting PAID to focus on diabetes distress as a component of the intervention. Schmitt *et al.*[25] emphasize the necessity of a justified choice of measurement and recommend the use of the PAID when the clinical or scientific purpose is to assess a variety of emotional concerns related to living with diabetes. Carlsen *et al.*[45] found that the use of PAID could benefit patients but emphasized the need for follow-up studies to evaluate whether the PAID should be implemented in routine diabetes care.

The choice of PAID as the intervention tool and the DDS as the primary evaluation tool is in accordance with previous research. Both instruments have previously shown satisfactory psychometric properties to map individual levels of diabetes distress, but it has been claimed that the PAID has some advantages for use in clinical practice and the DDS might have some advantages for use in clinical trials, because it also contributes to identifying sub-domains of distress.[11, 25]

Strengths and limitations

The use of the MRC framework is a strength in the development of this study, because it includes several complex and interacting components that need to be considered and tested before conducting a full-scale randomized controlled trial.

We have included primarily disease-specific evaluation measures, but also one generic PROM (WHO-5). Disease-specific PROMs are used to capture information that is most pertinent to particular patient groups, but they might miss domains affecting the patient that are unrelated to their disease.[16, 46] Generic instruments may capture broad dimensions of health and allow for comparisons between populations but might not be sensitive to changes in disease-specific health domains over time or in relation to interventions.[15]

The fact that the control group in the study will also complete the PAID and the evaluation PROMs before the annual diabetes consultation, and that the same physicians meet participants from both the intervention and the control groups might lead to intervention contamination challenges. This might be a challenge although the scores will not be accessible in the electronic patient records of participants in the control group. The pilot study will provide important information about the extent of this challenge and will be considered before the sample size calculation for the evaluation study.

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Contributors

AH, IH, RBS, RMN, GST, DR and MG contributed to the design of the study. AH drafted the manuscript for the study protocol. All authors contributed to editing the final manuscript.

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Competing interests

None declared.

Patient consent

Obtained.

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Figure 1. Key elements in the Medical Research Council's guidance for developing, evaluating and implementing complex interventions (MRC framework). Reproduced from Craig *et al.*[17] with permission.

Figure 2. The study intervention in the DiaPROM trial.

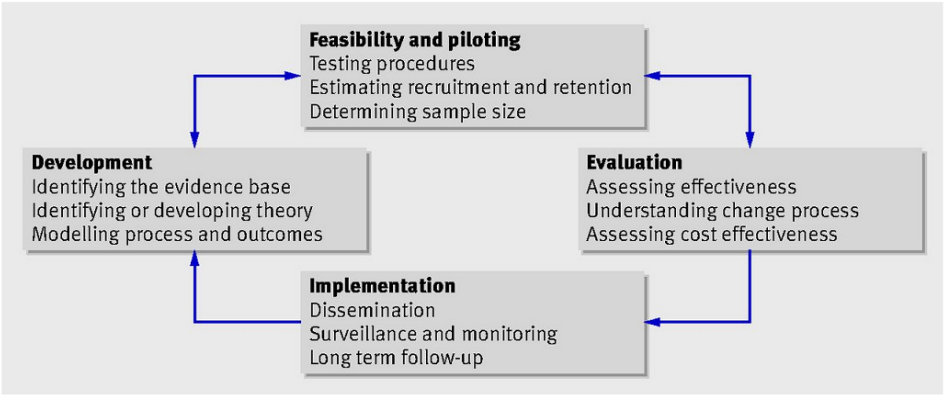

Figure 1

Figure 1

92x49mm (300 x 300 DPI)

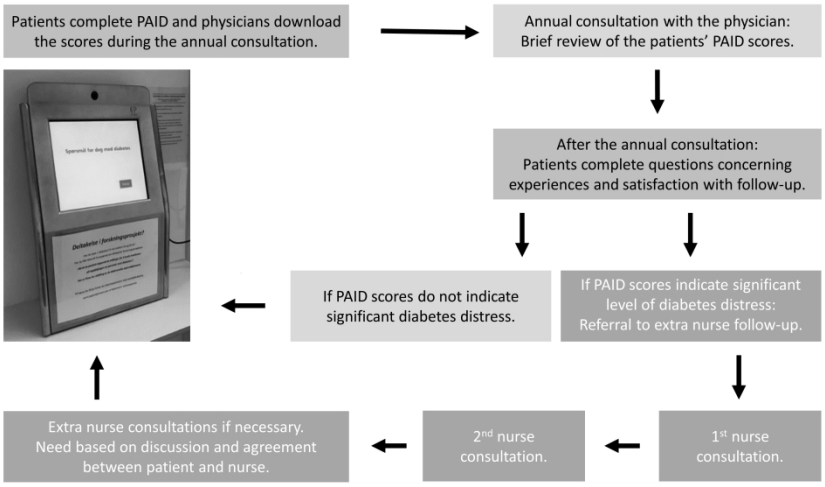

Figure 2 The intervention

Figure 2

338x190mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Answer (DiaPROM trial)
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	The title identify design, population, the intervention (use of PROMs) and trial acronym.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Trial registration number is included (p. 2 and 17).
	2b	All items from the World Health Organization Trial Registration Data Set	All items have been checked and relevant items are included in the protocol.
Protocol version	3	Date and version identifier	Version 10.05.2018
Funding	4	Sources and types of financial, material, and other support	Funding statement is included in the paper (p. 19).
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Included
	5b	Name and contact information for the trial sponsor	Name of trial sponsor is included (p.17).
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Included (page 17, 19 and 20).
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Included in the introduction section (p. 4) and aim section (p. 5) .

	6b	Explanation for choice of comparators	Described (p. 15)
Objectives	7	Specific objectives or hypotheses	An overarching aim and study hypotheses are described in the aim section (p. 5)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Described in the method section (starts on p. 5)
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study setting for feasibility-, pilot- and evaluation studies and participants are described in the method section (starts on p. 5) and in Table 1 (p. 6)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Described in the method section (starts on p. 5).
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Described in the method section (starts on p. 5).
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Described in the method section (p. 14)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Described in the method section (p. 15)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Primary and secondary outcomes, analyses of data from each phases of the study, time point for collecting outcome measures and explanations for clinical relevance is included in the method section (starts on p. 5).

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Described in the method section (starts on p. 5). A figure describing the steps in the intervention is also included.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	The rationale for number of participants is described in the method section for the feasibility-, pilot – and evaluation study (starts on p. 5). The sample size calculation for the evaluation study is presented (p. 14)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	How the feasibility- and pilot study will inform the evaluation study regarding the procedures for among others the participant enrolment is described (p. 13).
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Included in the method section (p. 14).
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Described in the method section (p. 14)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Described in the method section (p. 14)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Described in the method section (p. 15).
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	The study is not blinded for the participants and the health care providers as stated (p. 15).
Methods: Data collection, management, and analysis			

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Plans for assessments are described in the method section (starts at p. 5). The study evaluation measures are described (p. 9). References to the included instruments are given.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Described in the analysis section (p. 16)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data storage is described (p. 17). Data entry is described (p. 8, 12 and 16).
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistical analysis plans for each study phase are included (p. 11, 13 and 16)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Described (p. 16).
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Included in the data analysis section (p. 16)
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	None planned.

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	None planned.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Included in the Ethics and dissemination section (p. 17).
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not planned.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Included (p.2 and 17).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Described in the Ethics and dissemination section (p. 17).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	The procedures is described in the method section (starts at p. 4)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Described in the Ethics and dissemination section (p. 17).
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Included (p. 19)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Described in the Ethics and dissemination section (p. 17).
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Described in the Ethics and dissemination section (p. 17).
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not available in English.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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The use of Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomized controlled trial pilot study.

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The use of Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomized controlled trial pilot study.

Anne Haugstvedt,[1] Ingvild Hernar,[1,2,3] Ragnhild B Strandberg,[1] David Richards,[4] Roy M Nilsen,[1] Grethe S Tell,[2] Marit Graue[1]

[1]Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Bergen, Norway

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

[3]Department of Medicine, Haukeland University Hospital, Bergen, Norway

[4]Institute for Health Research, University of Exeter Medical School, Exeter, UK

Correspondence to: Anne Haugstvedt, Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Post Box 7030, N-5020 Bergen, Norway. Tel: +47 55 58 78 88; Mobile +47 47 82 92 20. E-mail: ahau@hvl.no

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ABSTRACT

Introduction Although diabetes distress is found to be associated with decreased glycaemic control among adults with type 1 diabetes, the psychological and emotional impact of living with the condition is often not recognized and often underreported in diabetes care. Therefore, regular assessment of diabetes distress is recommended. Assessment of diabetes distress using Patient-Reported Outcome Measures (PROMs) in clinical practice has the potential to enhance care for people with diabetes by identifying problems and improving patient-clinician communication. In this study protocol, we describe a pilot randomized controlled trial (RCT) aiming to test the feasibility of all components of an empowerment-based intervention using PROMs as dialogue support in clinical diabetes consultations, and to address the uncertainties associated with running a fully powered evaluation study.

Methods and analysis We will undertake a two arm pilot RCT of an intervention utilising the Problem Areas In Diabetes scale (PAID) in clinical diabetes consultations in order to conclude whether a fully powered trial is appropriate and/or feasible. The study will also include qualitative in-depth interviews with participants and health care personnel. Our objectives are to: 1) evaluate the recruitment procedures and attrition rates; 2) evaluate the performance of the randomization procedure; 3) evaluate the participants' mean scores on the outcome measures before and after the intervention; 4) evaluate if the intervention consultations are acceptable and feasible; and 5) explore patients' and health care personnel's experiences with the use of PAID as dialogue support in clinical diabetes consultations. The quantitative data analysis includes descriptive statistics (frequencies, percentages, means, SD and CI). For the qualitative data, we will perform thematic analysis.

Ethics and dissemination Ethical approval has been obtained from the Western Norway Regional Committee for Medical and Health Research Ethics (2017/1506/REC west). The trial is registered in ClinicalTrials.gov (ID: NCT03471104).

Keywords Type 1 diabetes, Diabetes distress, Patient-Reported Outcome Measures (PROMs), Complex intervention

Strengths and limitations of the study

- This is a study with the potential to provide new knowledge about the use of Patient-Reported Outcome Measures (PROMs) as dialogue support in clinical diabetes consultations among patients with type 1 diabetes.
- The use of the Medical Research Council's framework as a guide for the development of study intervention initiatives like this is a strength because the feasibility and uncertainties related to a fully-powered RCT can be illuminated before a resource intensive fully powered RCT is conducted.
- A key challenge includes possible contamination of the control group although the completed PROMs will not be available in the electronic patient records (EPR) of the participants in the control group.

INTRODUCTION

The management of type 1 diabetes (T1D) is complex and people living with the condition need to make numerous daily choices related to their medical treatment.[1, 2] They need to monitor their blood glucose and administer insulin several times each day. The burden of living with T1D remains a challenge despite new insulin types and advances in insulin delivery and glucose monitoring technologies.[3] Many Norwegian adults with T1D do not achieve the recommended treatment goals for glycaemic control.[4, 5] This poor goal attainment might be due to inappropriate choice of insulin regimen for the individual, but research has also shown psychological and emotional aspects are important barriers to satisfactory diabetes self-management.[6]

The psychological and emotional impact of living with diabetes is often unrecognized and/or underreported in diabetes care.[7, 8] Diabetes distress, which reflects the emotional response to the burden, worries, anxieties, frustrations and stressors associated with managing diabetes in everyday life,[9, 10] is found to be associated with decreased glycaemic control.[11, 12] Therefore, regular assessment of diabetes distress is recommended.[13] Such assessment is considered feasible and beneficial to promote the recognition of psychological and emotional issues that affect diabetes self-management.[9, 14]

Collecting Patient-Reported Outcome Measures (PROMs) involves asking people to complete questionnaires concerning the impact of their condition and its treatment on their health.[15] The integration of PROMs in clinical practice has the potential to improve care for people with diabetes and other chronic conditions by screening for and identifying problems, monitoring progress over time, improving patient-clinician communication and enabling people to become more involved in managing their own health.[16] Therefore, the

overarching aim of the Diabetes Patient-Reported Outcome Measures trial (DiaPROM trial) is to develop, test and evaluate the effectiveness of a structured empowerment-based intervention using PROMs regarding diabetes distress as dialogue support in clinical diabetes consultations among adults with T1D. Our proposition is that the DiaPROM intervention initiative will reduce diabetes distress and further improve overall well-being, improve perceived competence for diabetes management and improve glycaemic control. Based on experiences, we also believe that improved focus on the psychological and emotional burden of the disease will improve satisfaction with diabetes follow-up. This paper describes the protocol for a pilot randomized controlled trial (RCT) to test the feasibility of and uncertainties associated with a fully powered evaluation study.

The development of the DiaPROM trial

The DiaPROM trial is part of the implementation of PROMs in the Norwegian Diabetes Register for Adults (NDR-A). We wanted to design a study to test a method for utilizing the PROMs data in clinical diabetes practice. The study is multidisciplinary and consists of several interacting components and a number of behaviours required by those receiving and delivering the intervention. Thus, we consider the study as a complex intervention with a need to develop and test the various components gradually before conducting a fully powered RCT. As guidance in this process, we used the Medical Research Council's framework (MRC framework) for the evaluation of complex interventions.[17, 18] The framework describes four important phases in the development, evaluation and implementation of a new intervention initiative: (1) the development phase, (2) the feasibility and piloting phase, (3) the evaluation phase and (4) the implementation phase (figure 1).

The development of the DiaPROM trial took place during 2016 and 2017. Initially, the essential tasks were to determine which PROMs to include and how patients should complete the PROMs.

PROMs to include

We reviewed the literature to identify published articles on the use of PROMs as dialogue support in clinical diabetes practice. We wanted to identify the most common used PROMs to measure diabetes distress. We recognized that studies have primarily used PROMs to evaluate interventions' effects; relatively few publications have reported on the use of PROMs in clinical diabetes care. We did identify, however, a multi-centre study across eight countries that had tested the feasibility and impact of a procedure for implementing PROMs in routine diabetes care.[14, 19] This computer-assisted "Monitoring of Individual Needs in Diabetes" procedure aimed to improve recognition and management of the psychological needs of patients with diabetes in routine care. Regular assessment of psychological needs was implemented as part of the annual review in diabetes clinics. The assessment included diabetes distress measured by the Problem Areas in Diabetes (PAID) scale. Accordingly, Schmitt *et al.*[20] emphasize the necessity of a justified choice of measurement and recommend the use of the PAID when the clinical purpose is to bear in mind a variety of emotional concerns related to living with diabetes. Some other studies have reported PAID as an appropriate instrument for use in clinical diabetes consultations, as well.[21-25] The scale may contribute to improved communication by making the dialogue between health care providers and patients more therapeutic and goal oriented.

Patient and public involvement

Involving health service users throughout all phases of a study is important to provide insight into patients' perspectives and ensure that the research focuses on issues relevant for the health service users and the public.[26, 27] Patient and public involvement (PPI) is also useful in terms of shaping the research processes.[26] In this study, we used the GRIPP2 short form as guidance for including and reporting PPI.[27] To include the voice of the health service users throughout the study, two people with diabetes have been included in the DiaPROM project group, both experienced with PPI and research. They will contribute to all phases of the study. Furthermore, we have included additional people with diabetes to share their views on the various phases of the study, recruited mainly from national and local diabetes associations.

A crucial question when we considered which PROMs to include in the study, was what adult people with T1D perceived as the most important and relevant aspects to emphasize in diabetes follow-up. Thus, in parallel with the literature review, we consulted the health service users. In addition to the health service users in the project group, we met the leader of the Norwegian Diabetes Association and a group of four representatives from the local diabetes association (two with T1D and two parents of children with T1D where one had type 2 diabetes herself). First, we used open question to the health service users to determine which topics they perceived as important and relevant to include in a set of PROMs. After an open discussion, we asked them to review several generic instruments (e.g. World Health Organization's 5-item well-being index (WHO-5), RAND-12 Health Status Inventory (RAND-12), Patient Activation Measure (PAM)) and diabetes-specific instruments (e.g. PAID, Diabetes Distress Scale (DDS), Perceived Competence for Diabetes Scale (PCDS)). The user representatives considered the advantages and shortcomings of using the 20

statements in PAID as dialogue support in the intervention. They found the instrument relevant and suitable to be used in the intervention.

The PAID

Based on the literature review and in accordance with the input from the health service users, we chose the PAID scale for use in the study intervention. The participants' PAID scores will constitute the basis for the dialogue in the clinical consultations. The scale was developed to gain insight into the breadth of emotional responses to living with diabetes, and consists of 20 statements regarding diabetes distress (e.g. "feeling constantly concerned about food and eating", "worrying about low blood sugar reactions").[28-30] The scores are on a 5-point Likert scale from 0 (not a problem) to 4 (serious problem). An item score of 3 (somewhat serious problem) or 4 (serious problem) indicates moderate to serious diabetes distress related to the specific item. Scale scores are transformed to a 0-100 scale, with higher scores indicating greater distress, and a PAID total score >40 suggests serious diabetes-related distress. To identify both moderate and serious distress, we defined scores of concern as PAID total scores ≥30 or single item scores of 3 or 4. The scale has been translated into several languages, including Norwegian.[31]

Method for completing PROMs

The literature describes various methods for administration of PROMs such as paper-based self-administration at home or in the clinic, interviews by telephone or personal meetings, computer-assisted self-administration in the clinic or mail- or web-based administration from patients' homes.[16] In our study, we decided on computer-assisted administration on a touchscreen computer in the outpatient clinic. Using this method has advantages, such as efficient and simultaneous data entry and minor privacy challenges.

Feasibility study

We conducted a feasibility study in 2017 to examine the technical and practical feasibility of collecting PROMs on a touchscreen computer in the outpatient clinic, and evaluate the participants' perceived understanding and relevance of the items in the PAID and the included outcome measures. We also evaluated the acceptability of completing PROMs annually. Field observations and comments from the participants provided data on the technical and practical procedures. Sixty-nine individuals with T1D ≥40 years participated in the study and 83% of them reported that, to a high or a very high degree, they would be positive about an annual completion of PROMs. However, almost 20% of 137 invited patients did not show up at the clinic (change of appointments, sick, no reason given), and most of the invited ones did not go directly to the computer on arrival at the clinic as instructed in the information sheet. Thus, we developed clearer information and procedures for the pilot study to avoid loss of potential participants among those invited. Further analyses of the results from the feasibility study are ongoing, and we plan to publish these in a separate article.

Aim

The purpose of the pilot RCT reported here is to test the feasibility of the proposed DiaPROM trial components and address the uncertainties associated with running a fully powered RCT, in order to conclude whether such a trial is appropriate and/or feasible. Our objectives are to:

1. evaluate the recruitment procedures and attrition rates;
2. evaluate the performance of the randomization procedure;
3. evaluate the participants' mean scores on the outcome measures before and after the intervention;

4. evaluate if the intervention consultations are acceptable and feasible; and
5. explore patients' and health care personnel's experiences with the use of PAID as dialogue support in clinical diabetes consultations.

METHODS AND ANALYSIS

We will undertake a two arm pilot RCT with embedded qualitative study on participants' and health care providers' views of the DiaPROM intervention initiative. We report our protocol here using the SPIRIT checklist (http://www.spirit-statement.org/wp-content/uploads/2013/01/SPIRIT-Checklist-download-8Jan13.pdf).

Participants and eligibility criteria

As recommended for pilot RCTs,[32] we will include 80 participants: 40 in the intervention group and 40 controls. Participants will have T1D for at least 1 year and be aged ≥18 to <40 years. We will exclude people who are unable to read or complete the PROMs on the touchscreen computer. Furthermore, we will exclude pregnant woman, patients with known and recorded cognitive deficiency (e.g. Down's syndrome, Alzheimer), severe somatic comorbidity (e.g. end stage renal disease, severe heart failure, severe cancer), and/or a major psychiatric diagnosis (e.g. severe depression, bipolar disorder, schizophrenia) as diabetes distress is often neither ethical nor possible to discuss with these group of patients. Eligible participants will receive information and consent forms by regular mail before their annual diabetes consultation at the clinic. The information form will include information about the possibility to withdraw from the study at any time point without consequences.

Randomization procedure and allocation concealment

We will randomize eligible and consenting participants, using computer-generated block randomization at the patient level, stratified for gender, immediately after the participants have completed both the PAID and the self-reported outcome measures. When participants complete the measures on the touchscreen computer in the outpatient clinic, they will receive an individual four-character code. When the physician downloads the PROMs data using the code, a concealed computerized allocation will take place. Information about which group the person is allocated to will appear on the computer screen and the physician will inform the participant immediately. It is not possible to blind either participants or health care providers.

Trial intervention

After participants have completed the PAID scale, physicians download the scores into the participants' electronic patient record (EPR) as part of the annual consultation (figure 2). Physicians then review and discuss the PAID scores briefly with participants. Participants with one or more single PAID item(s) score of 3 or 4 (somewhat serious or serious problem), or PAID total score ≥30, will be referred to additional diabetes nurse consultations. Participants with lower scores will receive regular follow-up according to usual clinical protocols.

Additional nurse follow-up will consist of at least two consultations. The first will take place within four weeks after randomization, and the second within a further three months. After the second nurse consultation, the nurse and the participant will agree any further follow-up until the next annual consultation with the physician. Diabetes nurses will review PAID scores and discuss the reported problem areas and distress with participants by

following a communication manual based on key elements from empowerment theory and self-determination theory, such as empathetic communication and autonomy support.[33-35] These communication skills involve "active listening", "asking open questions", "responding", "summing up" and "agreeing on goals and actions to take". Nurses will record their work on participants' problem areas, goals and actions. The intervention will last for a maximum of one year, until the next annual consultation.

Control procedure

The control group will receive "care as usual" which does not include a structured focus on psychological and emotional diabetes distress. For most patients the annual consultation normally constitute "care as usual". Although all participants will complete the PAID before randomization, for control participants the scores will not be accessible to clinicians in the EPR until the study is completed. For ethical reasons, we will not prevent physicians discussing psychological or emotional issues with participants in the control group if participants specifically raise such an issue. Unlike participants in the intervention group, such discussions will not be structured with reference to PAID data. We will identify to what extent such discussions have taken place by reviewing participants' EPR.

Training of health care personnel

Before the study commences, we will have a one-hour meeting with the participating physicians, and they will be trained in how to download the PAID scores into the EPR and how to briefly discuss the scores in the annual consultations. Further, they will get both oral information and written instructions regarding the interpretation of the PAID scores including instructions on the criteria for referral of participants to extra follow-up by the diabetes nurses. Nurses will get both oral and written information and a 2 x 1 hour training in how to

interpret scores and discuss the reported problem areas, how to follow the communication manual in the consultations, and how to agree upon goals and actions to take with the participants.

Data collection and outcome measures

All participants (both intervention and control groups) will complete the outcome measures electronically before the annual consultation at baseline and after 12 months. After the annual consultation, the participants will complete a paper-based questionnaire about their experience and satisfaction with the diabetes follow-up. We will evaluate the recruitment procedures and attrition rates by observing and monitoring number of eligible participants invited, number of invited people declining participation, number of people who attended the clinic, number of intervention participants attended the nurse consultations, and number of consultations conducted. We will also observe and document the technical performance of the randomization procedure. Finally, we will document all types of contacts between participants and the diabetes outpatient clinic for all participants throughout the study period.

To describe the study sample and evaluate the technical procedure of data retrieval from EPR, we will perform a computerized retrieval of the following variables from the participants' EPR: sex, age, ethnicity, body mass index, diabetes duration, HbA_{1c} (secondary outcome), insulin regimen, insulin doses, severe hypoglycaemic episodes needing assistance in the past year, hospitalizations, co-morbidities and diabetes late complications.

The outcome measures to evaluate the effect of the intervention in the evaluation phase of the study (phase 3), were chosen based on a literature review and considerations among the researchers and the health service users. We decided upon the DDS as primary outcome. DDS measures diabetes distress and contains 17 items and 4 subscales: emotional

burden (5 items), physician-related distress (4 items), regimen distress (5 items) and diabetes-related interpersonal distress (3 items).[36] The scores are on a 6-point Likert scale from 1 (not a problem) to 6 (serious problem) with mean total or subscale score from 1 to 6.[37] Total or subscale scores >3 are defined as high levels of distress. The DDS has previously shown satisfactory psychometric properties to map diabetes distress, and might have advantages for use as outcome measure in clinical trials because it contributes to identify sub-domains of distress.[11, 20, 31] To measure the secondary outcomes, overall well-being and perceived diabetes competence, we have included the WHO-5[38-40] and the PCDS.[41-43] We will use HbA1c as the target for glycaemic control.

We will invite all participants from the intervention group and all health care personnel (physicians and diabetes nurses) participating in the intervention group to individual in-depth interviews to collect qualitative data on their experiences with the intervention, including the use of PAID as dialogue support in clinical consultations. This will provide a sample of about 15-20 participants and 10-15 health care personnel. All interviews will be conducted at the outpatient clinic, and will be audio recorded after obtaining consent from participants.

Data analysis

We will use Stata SE 15 for Windows for all statistical analyses,[44] and for data entry range checks for data values will be performed. We will report the recruitment of participants and the number of trial dropouts descriptively (frequencies and percentages). Further, we will report the means, SD and CI of the DDS and the other outcome measurements before and after the intervention period for both the intervention and control groups. As the study is a pilot and the sample size is small, we will not perform inferential statistics and analyze

between group calculations. The participants' PAID scores will be analysed descriptively (mean, SD), as well.

We will transcribe verbatim and analyse participants' and health care personnel's experiences with the intervention, by using thematic analysis.[45] Thematic analysis is a flexible qualitative method without any specific theoretical foundation and consists of six steps: 1) transcribing, reading and re-reading, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming the themes, and 6) producing the report.

ETHICS AND DISSEMINATION

The Norwegian Regional Committee for Medical and Health Research Ethics has approved the study (2017/1506/REK west). Haukeland University Hospital, Bergen, Norway is the responsible research institution (trial sponsor) where the study data will be stored on a secure research server. In order to protect confidentiality, names of the potential and enrolled participants will be stored separate from the other study data. Only the principle investigator and other clearly identified members of the project group have access to the study data. If important protocol modifications happen, this will be communicated to the ethic committee and ClinicalTrials.gov. Further information can be obtained from ClinicalTrials.gov, registration number NCT03471104.

Completing the PROMs may activate latent psychological or psychosocial problems and negative feelings. To care for any participants in the control group reporting worryingly high levels of distress (e.g. above cut points for severe levels of distress measured by PAID and/or DDS), the research team will continuously review the reported distress levels. We will discuss potential needs for more intensive care or referral to psychological or psychiatric

follow-up for those reporting worryingly levels of distress with the physicians and diabetes nurses.

We will present the findings of the study phases at national and international conferences and submit manuscripts to peer-reviewed journals and popular science journals. Further, we will also publish the findings in popular science journals, public newspapers and journals for relevant user groups. One of the health service users will participate in the writing and publication process.

DISCUSSION

In the pilot RCT study described in this protocol, we aim to test the feasibility of, and address the clinical and methodological uncertainties associated with running a fully powered RCT testing the effect of an intervention incorporating the use of PAID to decrease diabetes distress among people with T1D. The study will provide knowledge on the use of PAID in clinical diabetes practice, although the purpose primarily is to prepare the ground for the design and conduct of a full powered RCT.

Diabetes distress has been shown to be a barrier for satisfactory glycaemic control, [11, 12] and a more structured focus on diabetes distress, may have the potential to improve long-term health for people with T1D by reducing the distress and improving glycaemic control. A previous literature review by Carlsen *et al.*[46] found that the use of PAID could benefit patients but emphasized the need for follow-up studies to evaluate whether the PAID should be implemented in routine diabetes care to enhance a more structured focus on diabetes distress. The choice of utilizing PAID as dialogue support in the intervention and the DDS as the primary outcome measure is in accordance with previous research. Both instruments have previously shown satisfactory psychometric properties to map individual

levels of diabetes distress, but it has been claimed that the PAID has advantages for use in clinical practice and that the DDS have advantages for use in clinical trials, because it also contributes to identifying sub-domains of distress.[11, 20, 31]

Strengths and limitations

The use of the MRC framework is a strength in the development of this study, because it includes several complex and interacting components that need to be considered and tested with the purpose to reveal uncertainties before conducting a fully powered RCT. In addition, the use of the GRIPP2 short form to guide the PPI throughout all phases of the development of the intervention initiative is considered a strength. The health service users included in the project have influenced among others the choice of PROMs, the choice of the theoretical foundation for the intervention, and the discussions related to the qualitative component of the study.

We have included primarily disease-specific outcome measures, but also one generic PROM (WHO-5). Disease-specific PROMs are used to capture information that is most pertinent to particular patient groups, but they might miss domains affecting the patient that are unrelated to their disease.[16, 47] Generic instruments may capture broad dimensions of health and allow for comparisons between populations but might not be sensitive to changes in disease-specific health domains over time or in relation to interventions.[15]

The fact that the control group in the study will also complete the PAID and the evaluation PROMs before the annual diabetes consultation, and that the same physicians meet participants from both the intervention and the control groups might lead to intervention contamination challenges. This might be a challenge although the scores will not be accessible in the electronic patient records of participants in the control group.

Acknowledgements

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Contributors

AH and MG applied for funding of the trial. AH, IH, MG and RBS designed the study with involvement of GST, DR and RMN. AH wrote the first draft of the study protocol. All other authors have edited and critically reviewed the manuscript, and all authors read and approved the final version.

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Competing interests

None declared.

Patient consent

There is no patient data included in this report.

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Figure 1. Key elements in the Medical Research Council's guidance for developing, evaluating and implementing complex interventions (MRC framework). Reproduced from Craig *et al.*[17] with permission.

Figure 2. The study intervention in the DiaPROM trial.

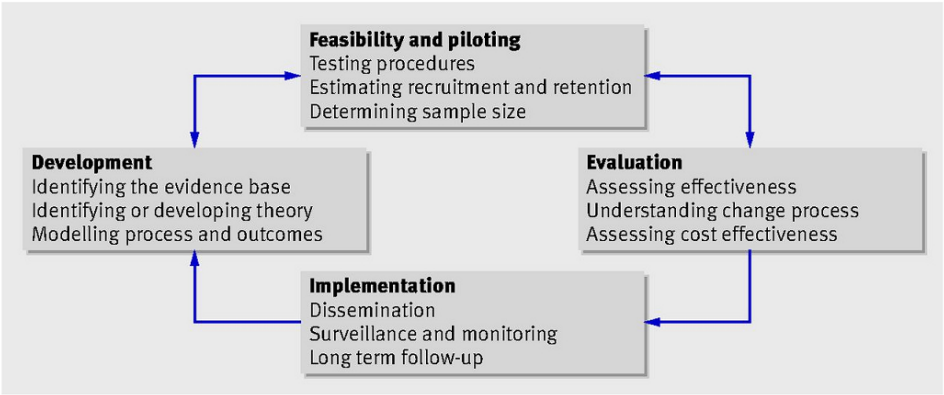

Figure 1

Figure 1

92x49mm (300 x 300 DPI)

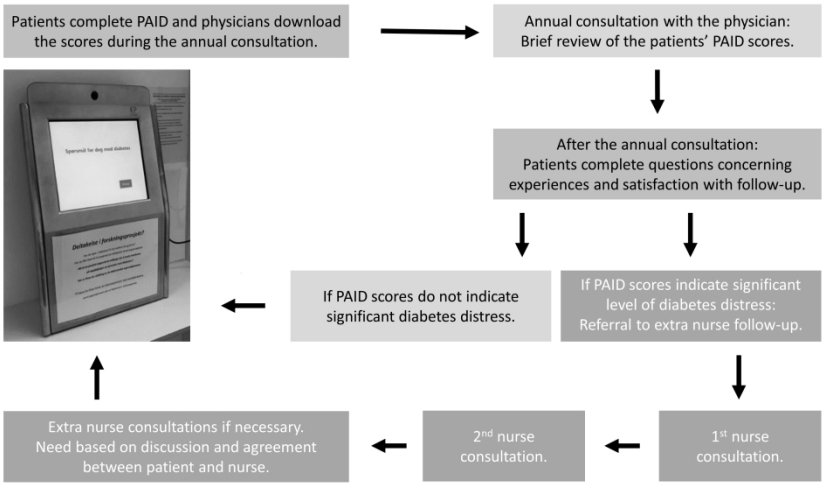

Figure 2 The intervention

Figure 2

338x190mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Answer (DiaPROM trial)
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	The title identify design, population, the intervention (use of PROMs) and trial acronym.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Trial registration number is included (p. 2 and 15).
	2b	All items from the World Health Organization Trial Registration Data Set	All items have been checked and relevant items are included in the protocol.
Protocol version	3	Date and version identifier	Version 25.10.2018
Funding	4	Sources and types of financial, material, and other support	Funding statement is included in the paper (p. 18).
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Included
	5b	Name and contact information for the trial sponsor	Name of trial sponsor is included (p.18).
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Included (page 15 and 18).
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Described in the introduction section (p. 4-5) and aim section (p. 9-10) .

	6b	Explanation for choice of comparators	Described (p. 11-12)
Objectives	7	Specific objectives or hypotheses	An overarching aim of the DiaPROM trial are described (p. 5), and the aim of the present pilot RCT are described in the aim section (p. 9-10)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Described in the methods section (starts on p. 10)
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study setting and participants for the pilot study are described in the methods section (starts on p. 10).
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Described in the methods section (starts on p. 10).
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Described in the methods section (starts on p. 10).
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Described in the methods section (p. 13) and in the ethic section (p. 15-16).
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Described in the methods section (p. 10-13)

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Primary and secondary outcomes for the forthcoming fully powered RCT are described (p. 5). The objectives for the present pilot RCT are described (p. 9-10), and the analyses of data (p. 14-15), time point for collecting outcome measures (p. 13-14), and explanations for clinical relevance of the DiaPROM trial (p. 4-5 and 16), as well.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Described in the methods section (starts on p. 10). A figure describing the steps in the intervention is also included.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	The rationale for number of participants is described in the methods section (p. 10).
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Not relevant for a pilot study
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Included in the methods section (p. 11).
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Described in the methods section (p. 11)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Described in the methods section (p. 11)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Described in the methods section (p. 11).

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	The study is not blinded for the participants and the health care providers as stated (p. 11).
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Plans for assessments and included measures are described in the methods section (p. 13-14). References to the included instruments are given.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	The relevant information for a pilot RCT is described in the methods section (p. 10-14)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data storage is described (p. 15). Data entry is described (p. 14). Reference to where details of data management procedures can be found is described (p. 2 and 15)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistical analysis plans for both quantitative and qualitative data are included (p. 14-15)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A for a pilot study.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A for a pilot study.
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	None planned.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	None planned.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Included in the ethics and dissemination section (p. 15-16).
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not planned.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Included (p.2 and 16).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Described in the ethics and dissemination section (p. 15-16).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Described in the method section (starts on p. 10)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Described in the ethics and dissemination section (p. 15-16).

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Included (p. 18)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Described in the ethics and dissemination section (p. 15-16).
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Described in the ethics and dissemination section (p. 15-16).
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not available in English.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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The use of Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomized controlled trial pilot study.

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The use of Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomized controlled trial pilot study.

Anne Haugstvedt,[1] Ingvild Hernar,[1,2,3] Ragnhild B Strandberg,[1] David Richards,[4] Roy M Nilsen,[1] Grethe S Tell,[2] Marit Graue[1]

[1]Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Bergen, Norway

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

[3]Department of Medicine, Haukeland University Hospital, Bergen, Norway

[4]Institute for Health Research, University of Exeter Medical School, Exeter, UK

Correspondence to: Anne Haugstvedt, Department of Health and Caring Sciences, Western Norway University of Applied Sciences, Post Box 7030, N-5020 Bergen, Norway. Tel: +47 55 58 78 88; Mobile +47 47 82 92 20. E-mail: ahau@hvl.no

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ABSTRACT

Introduction Although diabetes distress is found to be associated with decreased glycaemic control among adults with type 1 diabetes, the psychological and emotional impact of living with the condition is often not recognized and often underreported in diabetes care. Therefore, regular assessment of diabetes distress is recommended. Assessment of diabetes distress using Patient-Reported Outcome Measures (PROMs) in clinical practice has the potential to enhance care for people with diabetes by identifying problems and improving patient-clinician communication. In this study protocol, we describe a pilot randomized controlled trial (RCT) aiming to test the feasibility of all components of an empowerment-based intervention using PROMs as dialogue support in clinical diabetes consultations, and to address the uncertainties associated with running a fully powered evaluation study.

Methods and analysis We will undertake a two arm pilot RCT of an intervention utilizing the Problem Areas In Diabetes scale (PAID) in clinical diabetes consultations in order to conclude whether a fully powered trial is appropriate and/or feasible. The study will also include qualitative in-depth interviews with participants and health care providers. Our objectives are to: 1) evaluate the recruitment procedures and attrition rates; 2) evaluate the performance of the randomization procedure; 3) evaluate the participants' mean scores on the outcome measures before and after the intervention; 4) evaluate if the intervention consultations are acceptable and feasible; and 5) explore patients' and health care providers experiences with the use of PAID as dialogue support and empowerment-based communication skills in clinical diabetes consultations.The quantitative data analysis includes descriptive statistics (frequencies, percentages, means, SD and CI). For the qualitative data, we will perform thematic analysis.

Ethics and dissemination Ethical approval has been obtained from the Western Norway Regional Committee for Medical and Health Research Ethics (2017/1506/REC west). The trial is registered in ClinicalTrials.gov (ID: NCT03471104).

Keywords Type 1 diabetes, Diabetes distress, Patient-Reported Outcome Measures (PROMs), Complex intervention

Strengths and limitations of the study

- This is a study with the potential to provide new knowledge about the use of Patient-Reported Outcome Measures (PROMs) as dialogue support in clinical diabetes consultations among patients with type 1 diabetes.
- The use of the Medical Research Council's framework as a guide for the development of study intervention initiatives like this is a strength because the feasibility and uncertainties related to a fully-powered RCT can be illuminated before a resource intensive fully powered RCT is conducted.
- A key challenge includes possible contamination of the control group although the completed PROMs will not be available in the electronic patient records (EPR) of the participants in the control group.

INTRODUCTION

The management of type 1 diabetes (T1D) is complex and people living with the condition need to make numerous daily choices related to their medical treatment.[1, 2] They need to monitor their blood glucose and administer insulin several times each day. The burden of living with T1D remains a challenge despite new insulin types and advances in insulin delivery and glucose monitoring technologies.[3] Many Norwegian adults with T1D do not achieve the recommended treatment goals for glycaemic control.[4, 5] This poor goal attainment might be due to inappropriate choice of insulin regimen for the individual, but research has also shown psychological and emotional aspects are important barriers to satisfactory diabetes self-management.[6]

The psychological and emotional impact of living with diabetes is often unrecognized and/or underreported in diabetes care.[7, 8] Diabetes distress, which reflects the emotional response to the burden, worries, anxieties, frustrations and stressors associated with managing diabetes in everyday life,[9, 10] is found to be associated with decreased glycaemic control.[11, 12] Therefore, regular assessment of diabetes distress is recommended.[13] Such assessment is considered feasible and beneficial to promote the recognition of psychological and emotional issues that affect diabetes self-management.[9, 14]

Collecting Patient-Reported Outcome Measures (PROMs) involves asking people to complete questionnaires concerning the impact of their condition and its treatment on their health.[15] The integration of PROMs in clinical practice has the potential to improve care for people with diabetes and other chronic conditions by screening for and identifying problems, monitoring progress over time, improving patient-clinician communication and enabling people to become more involved in managing their own health.[16, 17] However, using

PROMs in itself may not affect health outcomes. The collection of PROMs should be accompanied by a discussion of results to elaborate on any problems identified by the assessment.[14, 17] Previous research has shown that the use of PROMs to monitor diabetes psychological distress and general wellbeing followed by a discussion of outcomes improves psychological wellbeing in both adults and youth with diabetes.[14, 18, 19] In the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) MIND study,[14] the skills used in discussions of PROMs data regarding diabetes distress and wellbeing were based on empowerment theory and patient-centred communication. Empowerment in nursing and health care is defined as a motivational approach and process using specific counselling and communication techniques to assist patients in making health-promoting behaviour changes.[20] The approach is patient-centred with the health care providers facilitating and providing information and knowledge to assist the patients in taking informed decisions. The desired outcomes in the empowerment process are control and self-determination. A systematic review by Chen & Li [21] states that interventions aiming to empower people with chronic illnesses are able to improve health status, improve outcome indicators of psychological and social aspects, and improve self-management. The authors of the DAWN MIND study suggest further research on process evaluations to explore the role of empowerment- and patient-centred skills such as active listening, use of open-ended questions, and promoting active patient participation in the decision making process.[14]

The overarching aim of the Diabetes Patient-Reported Outcome Measures trial (DiaPROM trial) is to develop, test and evaluate a structured empowerment-based intervention using PROMs regarding diabetes distress as dialogue support in clinical diabetes consultations among adults with T1D. Our proposition is that the DiaPROM intervention initiative will reduce diabetes distress and further improve overall wellbeing, improve perceived competence for diabetes management and improve glycaemic control. Based on

experiences and research,[14, 18, 19] we also believe that improved focus on the psychological and emotional burden of the disease will improve satisfaction with diabetes follow-up. This paper describes the protocol for a pilot randomized controlled trial (RCT) to test the feasibility of and uncertainties associated with a fully powered evaluation study.

The development of the DiaPROM trial

The DiaPROM trial is part of the implementation of PROMs in the Norwegian Diabetes Register for Adults (NDR-A). We wanted to design a study to test a method for utilizing the PROMs data in clinical diabetes practice. The study is multidisciplinary and consists of several interacting components and a number of behaviours required by those receiving and delivering the intervention. Thus, we consider the study as a complex intervention with a need to develop and test the various components gradually before conducting a fully powered RCT. As guidance in this process, we used the Medical Research Council's framework (MRC framework) for the evaluation of complex interventions.[22, 23] The framework describes four important phases in the development, evaluation and implementation of a new intervention initiative: (1) the development phase, (2) the feasibility and piloting phase, (3) the evaluation phase and (4) the implementation phase (figure 1).

The development of the DiaPROM trial took place during 2016 and 2017. Initially, the essential tasks were to determine which PROMs to include and how patients should complete the PROMs.

PROMs to include

We reviewed the literature to identify published articles on the use of PROMs as dialogue support in clinical diabetes practice. We wanted to identify the most common used PROMs to measure diabetes distress. We recognized that studies have primarily used PROMs

to evaluate interventions' effects; relatively few publications have reported on the use of PROMs in clinical diabetes care. We did identify, however, the DAWN MIND study that tested the feasibility and impact of the computer-assisted "Monitoring of Individual Needs in Diabetes" procedure aimed to improve recognition and management of the psychological needs of patients with diabetes by implementing PROMs in routine diabetes care.[14, 24] Regular assessment of psychological needs was implemented as part of the annual review in diabetes clinics across eight countries. The assessment included among others diabetes distress measured by the Problem Areas in Diabetes (PAID) scale. Accordingly, Schmitt *et al.*[25] emphasize the necessity of a justified choice of measurement and recommend the use of the PAID when the clinical purpose is to bear in mind a variety of emotional concerns related to living with diabetes. Some other studies have reported PAID as an appropriate instrument for use in clinical diabetes consultations, as well.[26-30] The scale may contribute to improved communication by making the dialogue between health care providers and patients more therapeutic and goal oriented.

Patient and public involvement

Involving health service users throughout all phases of a study is important to provide insight into patients' perspectives and ensure that the research focuses on issues relevant for the health service users and the public.[31, 32] Patient and public involvement (PPI) is also useful in terms of shaping the research processes.[31] In this study, we used the GRIPP2 short form as guidance for including and reporting PPI.[32] To include the voice of the health service users throughout the study, two people with diabetes have been included in the DiaPROM project group, both experienced with PPI and research. They will contribute to all phases of the study. Furthermore, we have included additional people with diabetes to share

their views on the various phases of the study, recruited mainly from national and local diabetes associations.

A crucial question when we considered which PROMs to include in the study, was what adult people with T1D perceived as the most important and relevant aspects to emphasize in diabetes follow-up. Thus, in parallel with the literature review, we consulted the health service users. In addition to the health service users in the project group, we met the leader of the Norwegian Diabetes Association and a group of four representatives from the local diabetes association (two with T1D and two parents of children with T1D where one had type 2 diabetes herself). First, we used open question to the health service users to determine which topics they perceived as important and relevant to include in a set of PROMs. After an open discussion, we asked them to review several generic instruments (e.g. World Health Organization's 5-item wellbeing index (WHO-5), RAND-12 Health Status Inventory (RAND-12), Patient Activation Measure (PAM)) and diabetes-specific instruments (e.g. PAID, Diabetes Distress Scale (DDS), Perceived Competence for Diabetes Scale (PCDS)). The user representatives considered the advantages and shortcomings of using the 20 statements in PAID as dialogue support in the intervention. They found the instrument relevant and suitable to be used in the intervention.

The PAID

Based on the literature review and in accordance with the input from the health service users, we chose the PAID scale for use in the study intervention. The participants' PAID scores will constitute the basis for the dialogue in the clinical consultations. The scale was developed to gain insight into the breadth of emotional responses to living with diabetes, and consists of 20 statements regarding diabetes distress (e.g. "feeling constantly concerned about food and eating", "worrying about low blood sugar reactions").[33-35] The scores are on a 5-

point Likert scale from 0 (not a problem) to 4 (serious problem). An item score of 3 (somewhat serious problem) or 4 (serious problem) indicates moderate to serious diabetes distress related to the specific item. Scale scores are transformed to a 0-100 scale, with higher scores indicating greater distress, and a PAID total score >40 suggests serious diabetes-related distress. To identify both moderate and serious distress, we defined scores of concern as PAID total scores ≥30 or single item scores of 3 or 4. The scale has been translated into several languages, including Norwegian.[36]

Method for completing PROMs

The literature describes various methods for administration of PROMs such as paper-based self-administration at home or in the clinic, interviews by telephone or personal meetings, computer-assisted self-administration in the clinic or mail- or web-based administration from patients' homes.[16, 17] Electronic PROMs collection is preferred since the patients' responses can be transferred to the electronic patient records without scanning paper forms or punching data.[17] In our study, we decided on computer-assisted administration on a touchscreen computer in the outpatient clinic. Using this method has advantages, such as efficient and simultaneous data entry and minor privacy challenges.

Feasibility study

We conducted a feasibility study in 2017 to examine the technical and practical feasibility of collecting PROMs on a touchscreen computer in the outpatient clinic, and evaluate the participants' perceived understanding and relevance of the items in the PAID and the included outcome measures. We also evaluated the acceptability of completing PROMs annually. Field observations and comments from the participants provided data on the technical and practical procedures. Sixty-nine individuals with T1D ≥40 years participated in

the study and 83% of them reported that, to a high or a very high degree, they would be positive about an annual completion of PROMs. However, almost 20% of 137 invited patients did not show up at the clinic (change of appointments, sick, no reason given), and most of the invited ones did not go directly to the computer on arrival at the clinic as instructed in the information sheet. Thus, we developed clearer information and procedures for the pilot study to avoid loss of potential participants among those invited. Further analyses of the results from the feasibility study are ongoing, and we plan to publish these in a separate article.

Aim

The purpose of the pilot RCT reported here is to test the feasibility of the proposed DiaPROM trial components and address the uncertainties associated with running a fully powered RCT, in order to conclude whether such a trial is appropriate and/or feasible. Our objectives are to:

1. evaluate the recruitment procedures and attrition rates;
2. evaluate the performance of the randomization procedure;
3. evaluate the participants' mean scores on the outcome measures before and after the intervention;
4. evaluate if the intervention consultations are acceptable and feasible; and
5. explore patients' and health care providers' experiences with the use of PAID as dialogue support and empowerment-based communication skills in clinical diabetes consultations.

METHODS AND ANALYSIS

We will undertake a two arm pilot RCT with embedded qualitative study on participants' and health care providers' views of the DiaPROM intervention initiative. We

report our protocol here using the SPIRIT checklist (http://www.spirit-statement.org/wp-content/uploads/2013/01/SPIRIT-Checklist-download-8Jan13.pdf).

Participants and eligibility criteria

As recommended for pilot RCTs,[37] we will include 80 participants: 40 in the intervention group and 40 controls. Participants will have T1D for at least 1 year and be aged ≥18 to <40 years. We will exclude people who are unable to read or complete the PROMs on the touchscreen computer. Furthermore, we will exclude pregnant woman, patients with known and recorded cognitive deficiency (e.g. Down's syndrome, Alzheimer), severe somatic comorbidity (e.g. end stage renal disease, severe heart failure, severe cancer), and/or a major psychiatric diagnosis (e.g. severe depression or bipolar disorder, schizophrenia) as diabetes distress is often neither ethical nor possible to discuss with these group of patients. Eligible participants will receive information and consent forms by regular mail before their annual diabetes consultation at the clinic. The information form will include information about the possibility to withdraw from the study at any time point without consequences.

Randomization procedure and allocation concealment

We will randomize eligible and consenting participants, using computer-generated block randomization at the patient level, stratified for gender, immediately after the participants have completed both the PAID and the self-reported outcome measures. When participants complete the measures on the touchscreen computer in the outpatient clinic, they will receive an individual four-character code. When the physician downloads the PROMs data using the code, a concealed computerized allocation will take place. Information about which group the person is allocated to will appear on the computer screen and the physician

will inform the participant immediately. It is not possible to blind either participants or health care providers.

Trial intervention

After participants have completed the PAID scale, physicians download the scores into the participants' electronic patient record (EPR) as part of the annual consultation (figure 2). Physicians then review and discuss the PAID scores briefly with participants. Participants with one or more single PAID item(s) score of 3 or 4 (somewhat serious or serious problem), or PAID total score ≥30, will be referred to additional diabetes nurse consultations. Participants with lower scores will receive regular follow-up according to usual clinical protocols.

Additional nurse follow-up will consist of at least two consultations. The first will take place within four weeks after randomization, and the second within a further three months. After the second nurse consultation, the nurse and the participant will agree any further follow-up until the next annual consultation with the physician. Diabetes nurses will review PAID scores and discuss the reported problem areas and distress with participants by following a communication manual based on key elements from empowerment theory and self-determination theory, such as empathetic communication and autonomy support.[38-40] These communication skills involve "active listening", "asking open questions", "responding", "summing up" and "agreeing on goals and actions to take". Nurses will record their work on participants' problem areas, goals and actions. The intervention will last for a maximum of one year, until the next annual consultation.

Control procedure

The control group will receive "care as usual" which does not include a structured focus on psychological and emotional diabetes distress. For most patients the annual consultation normally constitute "care as usual". Although all participants will complete the PAID before randomization, for control participants the scores will not be accessible to clinicians in the EPR until the study is completed. For ethical reasons, we will not prevent physicians discussing psychological or emotional issues with participants in the control group if participants specifically raise such an issue. Unlike participants in the intervention group, such discussions will not be structured with reference to PAID data. We will identify to what extent such discussions have taken place by reviewing participants' EPR.

Training of health care providers

Before the study commences, we will have a one-hour meeting with the participating physicians, and they will be trained in how to download the PAID scores into the EPR and how to briefly discuss the scores in the annual consultations. Further, they will get both oral information and written instructions regarding the interpretation of the PAID scores including instructions on the criteria for referral of participants to extra follow-up by the diabetes nurses. Nurses will get both oral and written information and a 2 x 1 hour training in how to interpret scores and discuss the reported problem areas, how to follow the communication manual in the consultations, and how to agree upon goals and actions to take with the participants.

Data collection and outcome measures

All participants (both intervention and control groups) will complete the outcome measures electronically before the annual consultation at baseline and after 12 months. After

the annual consultation, the participants will complete a paper-based questionnaire about their experience and satisfaction with the diabetes follow-up. We will evaluate the recruitment procedures and attrition rates by observing and monitoring number of eligible participants invited, number of invited people declining participation, number of people who attended the clinic, number of intervention participants attended the nurse consultations, and number of consultations conducted. We will also observe and document the technical performance of the randomization procedure. Finally, we will document all types of contacts between participants and the diabetes outpatient clinic for all participants throughout the study period.

To describe the study sample and evaluate the technical procedure of data retrieval from EPR, we will perform a computerized retrieval of the following variables from the participants' EPR: sex, age, ethnicity, body mass index, diabetes duration, HbA_{1c} (secondary outcome), insulin regimen, insulin doses, severe hypoglycaemic episodes needing assistance in the past year, hospitalizations, co-morbidities and diabetes late complications.

The outcome measures to evaluate the effect of the intervention in the evaluation phase of the study (phase 3), were chosen based on a literature review and considerations among the researchers and the health service users. We decided upon the DDS as primary outcome. DDS measures diabetes distress and contains 17 items and 4 subscales: emotional burden (5 items), physician-related distress (4 items), regimen distress (5 items) and diabetes-related interpersonal distress (3 items).[41] The scores are on a 6-point Likert scale from 1 (not a problem) to 6 (serious problem) with mean total or subscale score from 1 to 6.[42] Total or subscale scores >3 are defined as high levels of distress. The DDS has previously shown satisfactory psychometric properties to map diabetes distress, and might have advantages for use as outcome measure in clinical trials because it contributes to identify sub-domains of distress.[11, 25, 36] To measure the secondary outcomes, overall wellbeing and

perceived diabetes competence, we have included the WHO-5[43-45] and the PCDS.[46-48] We will use HbA1c as the target for glycaemic control.

We will invite all participants from the intervention group and all health care providers (physicians and diabetes nurses) participating in the intervention group to individual in-depth interviews to collect qualitative data on their experiences with the intervention, including the use of PAID as dialogue support in clinical consultations. This will provide a sample of about 15-20 participants and 10-15 health care providers. All interviews will be conducted at the outpatient clinic, and will be audio recorded after obtaining consent from participants.

Data analysis

We will use Stata SE 15 for Windows for all statistical analyses,[49] and for data entry range checks for data values will be performed. We will report the recruitment of participants and the number of trial dropouts descriptively (frequencies and percentages). Further, we will report the means, SD and CI of the DDS and the other outcome measurements before and after the intervention period for both the intervention and control groups. As the study is a pilot and the sample size is small, we will not perform inferential statistics and analyze between group calculations. The participants' PAID scores will be analyzed descriptively (mean, SD), as well.

We will transcribe verbatim and analyse participants' and health care providers' experiences with the intervention, by using thematic analysis.[50] Thematic analysis is a flexible qualitative method without any specific theoretical foundation and consists of six steps: 1) transcribing, reading and re-reading, 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming the themes, and 6) producing the report.

ETHICS AND DISSEMINATION

The Norwegian Regional Committee for Medical and Health Research Ethics has approved the study (2017/1506/REK west). Haukeland University Hospital, Bergen, Norway is the responsible research institution (trial sponsor) where the study data will be stored on a secure research server. In order to protect confidentiality, names of the potential and enrolled participants will be stored separate from the other study data. Only the principle investigator and other clearly identified members of the project group have access to the study data. If important protocol modifications happen, this will be communicated to the ethic committee and ClinicalTrials.gov. Further information can be obtained from ClinicalTrials.gov, registration number NCT03471104.

Completing the PROMs may activate latent psychological or psychosocial problems and negative feelings. To care for any participants in the control group reporting worryingly high levels of distress (e.g. above cut points for severe levels of distress measured by PAID and/or DDS), the research team will continuously review the reported distress levels. We will discuss potential needs for more intensive care or referral to psychological or psychiatric follow-up for those reporting worryingly levels of distress with the physicians and diabetes nurses.

We will present the findings of the study phases at national and international conferences and submit manuscripts to peer-reviewed journals and popular science journals. Further, we will also publish the findings in popular science journals, public newspapers and journals for relevant user groups. One of the health service users will participate in the writing and publication process.

DISCUSSION

In the pilot RCT study described in this protocol, we aim to test the feasibility of, and address the clinical and methodological uncertainties associated with running a fully powered RCT testing the effect of an intervention incorporating the use of PAID to decrease diabetes distress among people with T1D. The study will provide knowledge on the use of PAID in clinical diabetes practice, although the purpose primarily is to prepare the ground for the design and conduct of a full powered RCT. In addition, the qualitative evaluation will provide important knowledge on the specific empowerment-based communication skills used to discuss PAID scores of concern in the clinical consultations. In an upcoming fully powered evaluation study (phase 3) we plan to test the effect of the entire intervention package including both the use of PAID and the empowerment-based follow-up. A major limitation of such an effect study is the lack of information on how specific parts of the intervention may affect the results.

Diabetes distress has been shown to be a barrier for satisfactory glycaemic control, [11, 12] and a more structured focus on diabetes distress, may have the potential to improve long-term health for people with T1D by reducing the distress and improving glycaemic control. A previous literature review by Carlsen *et al.*[51] found that the use of PAID could benefit patients but emphasized the need for follow-up studies to evaluate whether the PAID should be implemented in routine diabetes care to enhance a more structured focus on diabetes distress.

The choice of utilizing PAID as dialogue support in the intervention and the DDS as the primary outcome measure is in accordance with previous research. Both instruments have previously shown satisfactory psychometric properties to map individual levels of diabetes

distress, but it has been claimed that the PAID has advantages for use in clinical practice and that the DDS have advantages for use in clinical trials, because it also contributes to identifying sub-domains of distress.[11, 25, 36] However, there will be an overlap between the intervention measure (PAID) and the primary outcome measure (DDS) in this study. Using PAID in the intervention may prime the participants' responses to the DDS, but the inclusion of WHO-5 and the PCDS as additional outcomes may compensate for the overlap between PAID and DDS. Previous research has shown links between diabetes distress measured by PAID, and wellbeing and perceived competence. Snoek *et al*.[14] indicated an overlap between predictors for diabetes distress and general wellbeing measured by WHO-5, and Mohn *et al.*[48] showed an association between greater diabetes distress and lower perceived competence for diabetes self-management measured by PCDS.

Strengths and limitations

The use of the MRC framework is a strength in the development of this study, because it includes several complex and interacting components that need to be considered and tested with the purpose to reveal uncertainties before conducting a fully powered RCT. In addition, the use of the GRIPP2 short form to guide the PPI throughout all phases of the development of the intervention initiative is considered a strength. The health service users included in the project have influenced among others the choice of PROMs, the choice of the theoretical foundation for the intervention, and the discussions related to the qualitative component of the study.

We have included primarily disease-specific outcome measures, but also one generic PROM (WHO-5). Disease-specific PROMs are used to capture information that is most pertinent to particular patient groups, but they might miss domains affecting the patient that are unrelated to their disease.[16, 52] Generic instruments may capture broad dimensions of

health and allow for comparisons between populations but might not be sensitive to changes in disease-specific health domains over time or in relation to interventions.[15]

The fact that the control group in the study will also complete the PAID and the evaluation PROMs before the annual diabetes consultation, and that the same physicians meet participants from both the intervention and the control groups might lead to intervention contamination challenges. This might be a challenge although the scores will not be accessible in the electronic patient records of participants in the control group.

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Contributors

AH and MG applied for funding of the trial. AH, IH, MG and RBS designed the study with involvement of GST, DR and RMN. AH wrote the first draft of the study protocol. All other authors have edited and critically reviewed the manuscript, and all authors read and approved the final version.

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Competing interests

None declared.

Patient consent

There is no patient data included in this report.

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Figure 1. Key elements in the Medical Research Council's guidance for developing, evaluating and implementing complex interventions (MRC framework). Reproduced from Craig *et al.*[17] with permission.

Figure 2. The study intervention in the DiaPROM trial.

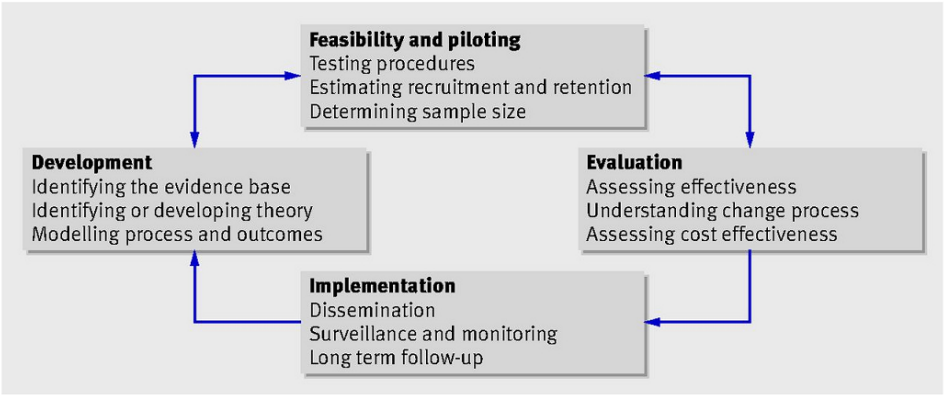

Figure 1

Figure 1

92x49mm (300 x 300 DPI)

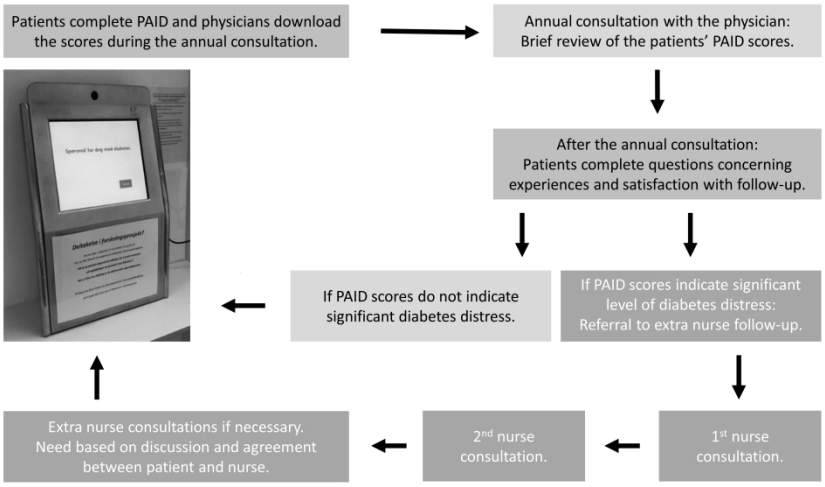

Figure 2 The intervention

Figure 2

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Section/item	Item No	Description	Answer (DiaPROM trial)
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	The title identify design, population, the intervention (use of PROMs) and trial acronym.
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Trial registration number is included (p. 2 and 15).
	2b	All items from the World Health Organization Trial Registration Data Set	All items have been checked and relevant items are included in the protocol.
Protocol version	3	Date and version identifier	Version 25.10.2018
Funding	4	Sources and types of financial, material, and other support	Funding statement is included in the paper (p. 18).
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Included
	5b	Name and contact information for the trial sponsor	Name of trial sponsor is included (p.18).
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Included (page 15 and 18).
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Described in the introduction section (p. 4-5) and aim section (p. 9-10) .

	6b	Explanation for choice of comparators	Described (p. 11-12)
Objectives	7	Specific objectives or hypotheses	An overarching aim of the DiaPROM trial are described (p. 5), and the aim of the present pilot RCT are described in the aim section (p. 9-10)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Described in the methods section (starts on p. 10)
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Study setting and participants for the pilot study are described in the methods section (starts on p. 10).
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Described in the methods section (starts on p. 10).
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Described in the methods section (starts on p. 10).
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Described in the methods section (p. 13) and in the ethic section (p. 15-16).
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Described in the methods section (p. 10-13)

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Primary and secondary outcomes for the forthcoming fully powered RCT are described (p. 5). The objectives for the present pilot RCT are described (p. 9-10), and the analyses of data (p. 14-15), time point for collecting outcome measures (p. 13-14), and explanations for clinical relevance of the DiaPROM trial (p. 4-5 and 16), as well.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Described in the methods section (starts on p. 10). A figure describing the steps in the intervention is also included.
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	The rationale for number of participants is described in the methods section (p. 10).
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Not relevant for a pilot study
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Included in the methods section (p. 11).
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Described in the methods section (p. 11)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Described in the methods section (p. 11)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Described in the methods section (p. 11).

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	The study is not blinded for the participants and the health care providers as stated (p. 11).
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Plans for assessments and included measures are described in the methods section (p. 13-14). References to the included instruments are given.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	The relevant information for a pilot RCT is described in the methods section (p. 10-14)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data storage is described (p. 15). Data entry is described (p. 14). Reference to where details of data management procedures can be found is described (p. 2 and 15)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Statistical analysis plans for both quantitative and qualitative data are included (p. 14-15)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A for a pilot study.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A for a pilot study.
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	None planned.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	None planned.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Included in the ethics and dissemination section (p. 15-16).
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not planned.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Included (p.2 and 16).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Described in the ethics and dissemination section (p. 15-16).
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Described in the method section (starts on p. 10)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Described in the ethics and dissemination section (p. 15-16).

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Included (p. 18)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Described in the ethics and dissemination section (p. 15-16).
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Described in the ethics and dissemination section (p. 15-16).
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not available in English.
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.