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Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: the DiaPROM randomised controlled pilot trial

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ABSTRACT

Objective To pilot test the proposed DiaPROM trial components and address uncertainties associated with conducting a full-scale randomised controlled trial (RCT) to evaluate whether such a trial is feasible.

Design Two-arm pilot RCT.

Participants Adults aged ≥18–39 years, with minimum 1 year type 1 diabetes duration, attending outpatient follow-up. Exclusion criteria were pregnancy, severe cognitive, somatic or psychiatric conditions and impaired vision.

Randomisation and intervention All participants completed electronic Patient-Reported Outcome Measures (PROMs) prior to the annual diabetes consultation. Using computer-generated block-randomisation without blinding, we assigned participants in a 1:1 ratio stratified by sex to receive standard care or an intervention. Physicians reviewed diabetes distress scores (*Problem Areas In Diabetes scale*) and referred individuals with scores ≥30 or single item(s) ≥3 to minimum two diabetes nurse consultations where reported problems were reviewed and discussed.

Outcomes Recruitment and retention rates; participants perceptions about intervention components. Variance and estimated between-group differences in follow-up scores (*Diabetes Distress Scale* (DDS), *WHO 5-Well-being Index*, *Perceived Competence for Diabetes Scale* and *glycaemic control*) and DDS correlation with baseline scores, to assist sample size calculations.

Results We randomised 80 participants to the control or intervention arm (one participant was later excluded). 23/39 intervention arm participants qualified for additional consultations and 17 attended. 67/79 attended the 12-month follow-up (15.2% attrition); 5/17 referred to additional consultations were lost to follow-up (29.4% attrition). Participants reported PROMs as relevant (84.6%) and acceptable (97.4%) but rated the usefulness of consultations as moderate to low. Baseline mean±SD DDS score was 2.1±0.69; DDS SD was 0.71 (95% CI: 0.60 to 0.86) at follow-up; correlation between baseline and follow-up DDS scores was 0.8 (95% CI: 0.7 to 0.9).

Conclusions The pilot trial revealed need for intervention modifications ahead of a full-scale trial to evaluate use of

Strengths and limitations of this study

► This pilot trial systematically addressed procedural uncertainties associated with designing a large-scale randomised controlled trial.

► The pilot trial allowed us to test the feasibility of Patient-Reported Outcome Measures as dialogue support tools in clinical diabetes consultations.

► Well-known, validated tools for measuring the primary and secondary outcomes facilitated comparison with other studies.

► One of the limitations was that we did not specifically predefine retention and attrition criteria for trial progression.

► Logistical challenges concerning cancelled appointments and non-attendance contributed to difficulties implementing the intervention as designed.

PROMs in diabetes consultations. Specifically, participant acceptability and intervention implementation need further investigation.

BACKGROUND

Type 1 diabetes (T1D) is a chronic, auto-immune disease which requires lifelong insulin therapy.[1] Self-management of T1D, the cornerstone of diabetes care, can be described as a 24-hour activity with a constant need to make complex medical decisions and perform challenging diabetes self-management tasks.[2] During emerging and young adulthood, multiple transitions and developmental stressors can trigger additional self-management difficulties.[3] Despite advancements in glucose monitoring, insulin therapy and insulin delivery devices, the burden of living with T1D remains a significant challenge.[4 5] Only 20%–30% of young adults with T1D achieve recommended glycaemic treatment goals.[6–9] Poor general

well-being and emotional distress are known barriers for self-management, and performing behavioural adjustments necessary to promote effective self-management can be challenging.[10] In addition, individual efforts to achieve beneficial outcomes may not produce desired results.[11] Diabetes guidelines recommend routine assessment of psychological, emotional and psychosocial factors that impact personal ability to self-manage, like diabetes distress.[2 12] Nevertheless, recent studies indicate that biomedical outcomes receive disproportionate attention in routine follow-up compared with what people with diabetes find important, such as psychosocial aspects.[13 14]

The construct *diabetes distress* refers to specific negative emotional experiences related to the challenges of living with and managing diabetes and the risk of acute and long-term complications.[10 15 16] Diabetes distress is regarded as an expected reaction first of all impacting on well-being.[17] In T1D studies, regimen distress, fear of hypoglycaemia and complications, feeling overwhelmed and worrying about the future is most commonly reported.[18] Furthermore, diabetes distress is more prevalent among younger than older adults[3] and associated with problematic self-management behaviours related to insulin treatment, glucose monitoring and unsatisfactory glycaemic control.[19–22] Regimen distress appears to drive these associations.[18] However, distress may also occur in individuals who reach recommended treatment goals.[23] Left untreated, mild cases may develop into severe and even chronic distress.[24] In addition, diabetes distress is found to be a risk factor for symptoms of depression.[25] This highlights the importance of addressing diabetes distress in routine diabetes care.[17 26]

Patient-reported outcome measures (PROMs) are self-report questionnaires measuring patients' subjective appraisal of a condition, treatment or other health-related outcomes.[27] In clinical consultations, PROMs can be used to increase attention to individual needs, values and preferences. By using PROMs regularly, healthcare providers can screen for self-reported health outcomes, track progress over time and enhance communication with patients.[27–30] Prior to implementation in clinical care settings, studies are needed to evaluate the feasibility, acceptability and effect of using PROMs in routine consultations. We used the Medical Research Council's (MRC) framework for developing and evaluating complex interventions for guidance.[31 32] Accordingly, we developed the Diabetes Patient-Reported Outcome Measures (DiaPROM) trial (ClinicalTrials.gov ID: NCT03471104). The overarching aim was to develop, test and evaluate a structured empowerment-based intervention using PROMs regarding diabetes distress as dialogue support in diabetes consultations among adults with T1D.[33] Furthermore, we hypothesise that the DiaPROM intervention will reduce diabetes distress and improve overall well-being, perceived competence for diabetes management and glycaemic control. First, we conducted a feasibility study to test the technical and practical feasibility and acceptability of capturing PROMs on a touchscreen computer in an outpatient clinic.[34] Then, we conducted the present pilot trial to test all the components of an upcoming fully powered randomised controlled trial (RCT), to determine if such a trial is feasible and appropriate. Here we report the results of the pilot trial using the Consolidated Standards of Reporting Trials 2010 statement: extension to randomised pilot and feasibility trials.[35] Findings from qualitative work undertaken alongside the pilot trial are reported elsewhere.[36 37]

METHODS

Aim
To pilot test the proposed DiaPROM trial components and address uncertainties associated with conducting a full-scale RCT in order to evaluate whether the trial methods and the intervention are feasible. The pilot trial objectives were thus to:

1. Evaluate the recruitment procedures, randomisation procedure and attrition rates.
2. Evaluate the acceptability, appropriateness and implementation of the intervention components.
3. Estimate variance and between-group differences in participant outcomes (diabetes distress; general well-being; perceived diabetes competence and glycaemic control) following intervention or standard care, and correlation between participants' diabetes distress scores at baseline and 12 months, in order to assist future sample size calculations.

Design
The study was designed as a single-centre two-arm pilot RCT.

Setting and participants
In Norway, people with T1D are followed up at hospital clinics. We conducted the pilot trial at a university hospital endocrinology outpatient clinic where approximately 80% of the patients with diabetes have T1D. Eligible participants aged ≥18–39 years with T1D duration for at least 1 year were identified using the clinic's attendance list. We sent invitation letters with consent forms by mail 10–14 days prior to the patients' annual diabetes consultations. Informed by pilot trial sample size guidance and the diabetes distress proportions documented in our feasibility study,[34 38] we aimed to recruit 80 participants, 40 in each arm. Using information from the electronic patient records (EPR), we applied the following exclusion criteria: ongoing pregnancy, severe cognitive deficiency, severe somatic comorbidity (eg, end-stage renal disease, severe heart failure, severe cancer), major psychiatric diagnosis (eg, severe depression or bipolar disorder, schizophrenia) and/or impaired vision.

Pilot trial intervention
We have described the intervention in detail in our protocol paper.[33] Briefly, DIPS, eHealth systems supplier to Norwegian hospitals, developed the technical application

for capturing and transferring electronic PROMs to the diabetes-specific EPR.[39] We asked all participants to arrive 15 min early to complete PROMs on a stationary touch-screen computer located in the outpatient clinic's waiting area prior to two annual diabetes consultations (baseline and 12 months). While completing PROMs, participants received an individual four-character code which was used to download the PROMs to the EPR. The length of the annual consultations was increased from 30 to 45 min. Furthermore, we used the 20-item *Problem Areas In Diabetes (PAID)* scale to assess diabetes distress.[40–42] PAID items are rated on a 5-point Likert-like scale (0, 'not a problem' to 4, 'serious problem'), and an overall diabetes distress score of 0–100 is calculated, with higher scores indicating greater distress. A score ≥40 suggests serious diabetes distress.[10 41] The PAID is widely used, and the Norwegian version is available in the diabetes-specific EPR.[43]

We developed a manual to guide the physicians to download PROMs and review and discuss PAID scores with intervention arm participants, and to identify moderate and serious distress, specifically PAID total score ≥30 or at least one item scored 3 or 4. Next, the physicians were to offer individuals with such scores a minimum of two 30-min diabetes specialist nurse consultations; the first within 4 weeks after randomisation and the second within a further 3 months. We also developed a communication manual where we guided the nurses to review baseline PAID and discuss reported problem areas with the participants using person-centred, empowerment-based communication skills; 'asking open questions', 'active listening', 'responding', 'summing up' and 'agreeing on goals and actions to take'. In addition, we requested the nurses to record problem areas discussed, goals, action strategies and plans in the EPR. In the second consultations, we asked the nurses and participants to discuss the problem areas, goals and actions and to decide whether to continue with consultations (optional number) until the next annual physician consultation. Intervention arm participants with lower PAID scores received follow-up according to standard clinical protocols after the brief review of their PAID scores with the physicians. Control arm participants, whose scores were inaccessible to the clinicians in the EPR, received 'care as usual'.

Outcomes
Recruitment
We recorded the number of individuals invited, number of people attending consultations and number of people who consented to participate in the pilot trial. At baseline, we observed if eligible participants started the PROM sessions by themselves and provided a friendly reminder or assistance to those who did not. At 12 months, we performed similar observations and guidance.

Sample characteristics
Sociodemographic and diabetes-related information was gathered from the participants' EPR: age, sex, ethnic origin, diabetes duration, diabetes long-term complications, comorbidities, body mass index, glyco-sylated haemoglobin (Haemoglobin A_{1c} (HbA_{1c})) level, number of self-reported symptomatic hypoglycaemic events in the previous month, history of hypoglycaemia requiring assistance and hospitalisation due to ketoac-idosis and insulin injection device. We also obtained self-report data on current type of glucose monitoring device, daily glucose measurement count, first language, educational level, cohabitation status and work affilia-tion. In addition, we received ethical approval to record age, sex and HbA_{1c} of eligible participants who declined participation.

Primary outcome measure
To avoid using the same questionnaire for diabetes distress assessment as an element of the intervention and as an outcome measure, we chose the *Diabetes Distress Scale (DDS)* as our primary outcome.[43] The 17-item DDS measures diabetes-specific problems rated on a 6-point Likert-like scale (1, 'no problem' to 6, 'serious problem').[44] The scale yields an overall diabetes distress score and four subscales: emotional burden (five items; eg, 'Feeling that diabetes controls my life'), physician-related distress (four items; eg, 'Feeling that my doctor doesn't take my concerns seri-ously enough'), regimen-related distress (five items; eg, 'Feeling that I am not testing my blood sugars frequently enough') and diabetes-related interpersonal distress (three items; eg, 'Feeling that friends or family are not supportive enough of self-care efforts'). Item scores are averaged to form a total and subscale scores from 1 to 6, with higher values indicating greater distress.[45] Scores are then categorised as little or no distress (<2.0), moderate distress (2.0–2.9) and high distress (≥3.0). Moderate and high distress is considered clinically relevant.[45]

Secondary outcomes measures
We used the *WHO 5-Well-being Index (WHO-5)* 5-item measure of current general well-being.[46] Items are scored on a 6-point Likert-like scale (0, 'at no time' to 5, 'all the time'). A 0–100 score is calculated and scores <50 suggest impaired well-being, while ≤28 indicate likely depres-sion.[46 47] A 10-point change is considered clinically rele-vant.[46] The measure is reported to be psychometrically sound, acceptable and suitable for diabetes outpatient settings.[48–50] The 4-item *Perceived Competence for Diabetes Scale (PCDS)* assesses the degree to which people with diabetes feel they can manage daily aspects of diabetes care (1, 'strongly disagree' to 7, 'strongly agree').[51] Item scores are averaged to form a score. Finally, we obtained information about glycaemic control from routinely performed blood samples measuring HbA_{1c} (mmol/mol) recorded in the EPR.

Experiences with the pilot trial intervention
After each annual consultation, participants were asked to complete a paper questionnaire, which included the DDS (primary outcome measure) and questions about experiences with and perceptions about the pilot trial

components. We asked all participants PROMs acceptability questions (five response options from 'not at all' to 'very large degree'): relevance, number of items and willingness for annual completion. In addition, we asked about preferred completion method (electronic or paper). Intervention arm participants were also asked about PAID use and consultation usefulness. Finally, we reviewed the nurses' EPR notes for intervention arm participants referred to additional follow-up, to evaluate intervention consultation fidelity (per-protocol).

Randomisation

We randomised participants in a 1:1 ratio to an intervention or control arm using computer-generated block-randomisation at the patient level, developed and administered by DIPS.[39] The computerised allocation took place when the physicians downloaded PROMs to the EPR. Group allocation information appeared on the computer screen, and the physicians told the participants. Furthermore, we stratified by sex to ensure equal numbers (20) of male and female participants in each arm. Due to the nature of the intervention, blinding of group allocation to participants, healthcare providers and research personnel was not possible.

Analyses

All analyses were carried out using Stata SE 16 for Windows.[52] At each timepoint, we estimated means, SD and 95% CI of SDs of outcome measures for both groups. To examine within and between-group variation of paired differences in outcome measures from baseline to 12-month follow-up, we estimated means and SDs, and means and 95% CIs, respectively. Using Spearman's correlation coefficient, we estimated correlation with 95% CI between participants' primary outcome measure scores at baseline and 12 months. The primary outcome measure SD, 95% CI of SD and correlation coefficient was used to assist in full trial sample size calculations. In all analyses, we computed missing items using person-mean substitution if at least 50% of the items per scale were completed.[53 54]

Patient and public involvement

In the protocol paper,[33] we have provided a detailed description of health service user involvement based on the *Guidance for Reporting Involvement of Patients and the Public 2 (GRIPP2) short form.*[55]

RESULTS
Recruitment, randomisation, sample characteristics, and retention

Between 15 January and 7 May 2018, we assessed 149 patients with T1D for eligibility and randomised 80 participants, 40 (50%) to each trial arm (figure 1). The randomisation procedure yielded two groups with equal distribution of men and women. Baseline characteristics for the total sample and trial arms are presented in

table 1. Compared with the included participants, the 22 who declined had longer diabetes duration (13.7±7.0 years (95% CI: 12.2 to 15.3) vs 18.6±10.2 years (95% CI: 14.1 to 23.1)), while there were no differences in gender distribution, age or HbA$_{1c}$ level. Furthermore, 24/40 (60.0%) intervention arm participants qualified for additional nurse follow-up (figure 1). One participant was later excluded due to newly discovered language problems. In total, 17/23 (73.9%) were referred and attended 1–5 consultations (mean±SD 2.2±1.1); 12/17 (70.6%) attended the per-protocol minimum. After reviewing the nurses' EPR notes, we registered that 28/38 consultations were performed according to the protocol, while 10/38 focused on other aspects than diabetes distress assessed by the PAID. Therefore, a mean of 1.65 (0–2) intervention consultations was conducted, and 9/17 received per-protocol follow-up of minimum two sessions. The 12-month follow-up was performed from 5 December 2018 to 17 June 2019. Twelve participants were lost to follow-up (overall attrition rate 15.2%; intervention arm: 8 (20.5%); control arm: 4 (10%)), but none withdrew consent (figure 1). Furthermore, 5/17 referred to additional nurse consultations were lost to follow-up (attrition rate 29.4%).

Acceptability, appropriateness and implementation of the intervention components

At baseline, 21/79 (26.6%) participants located the touchscreen computer without guidance, 43 (54.4%) confirmed they had read the written study information. At 12 months, five participants completed PROMs on paper; four because of a defective touchscreen and one asked for a telephone consultation. Of the remaining 62 participants, we had to remind 30 (48.4%) to complete PROMs. Furthermore, 2/17 participants referred to additional nurse follow-up delayed the first consultation for 4–6 months. The remaining 15/17 were offered the first consultation within 27.0±4.8 (19–35) days after randomisation. However, due to five participants postponing at least once, the consultations were conducted after 42.5±27.7 (22–123) days. The second appointments (n=15) were offered after 85.5±30.6 (20–133) days and attended by 12 participants after 100.8±35.3 (20–153) days.

Total WHO-5, PAID and PCDS completeness was 99.4% at baseline and 99.2% at 12 months. When asked about preferred method for completing PROMs in the future, two (2.6%) individuals chose paper-completion, whereas 42 (54.5%) opted for in-clinic computerised PROMs and 33 (42.9%) favoured home-based web-completion (online supplemental figure 1). Seventy-five (97.4%) reported that number of items were acceptable to a large or very large degree, 72 (92.3%) found the items relevant and 66 (84.6%) were willing to complete PROMs annually (online supplemental figure 1).

Among intervention arm participants, 23/39 (59.0%) and 13/31 (41.9%) reported PAID items scored ≥3 and/or a total score ≥30 (moderate to high distress) at baseline and follow-up, respectively (online supplemental table 1).

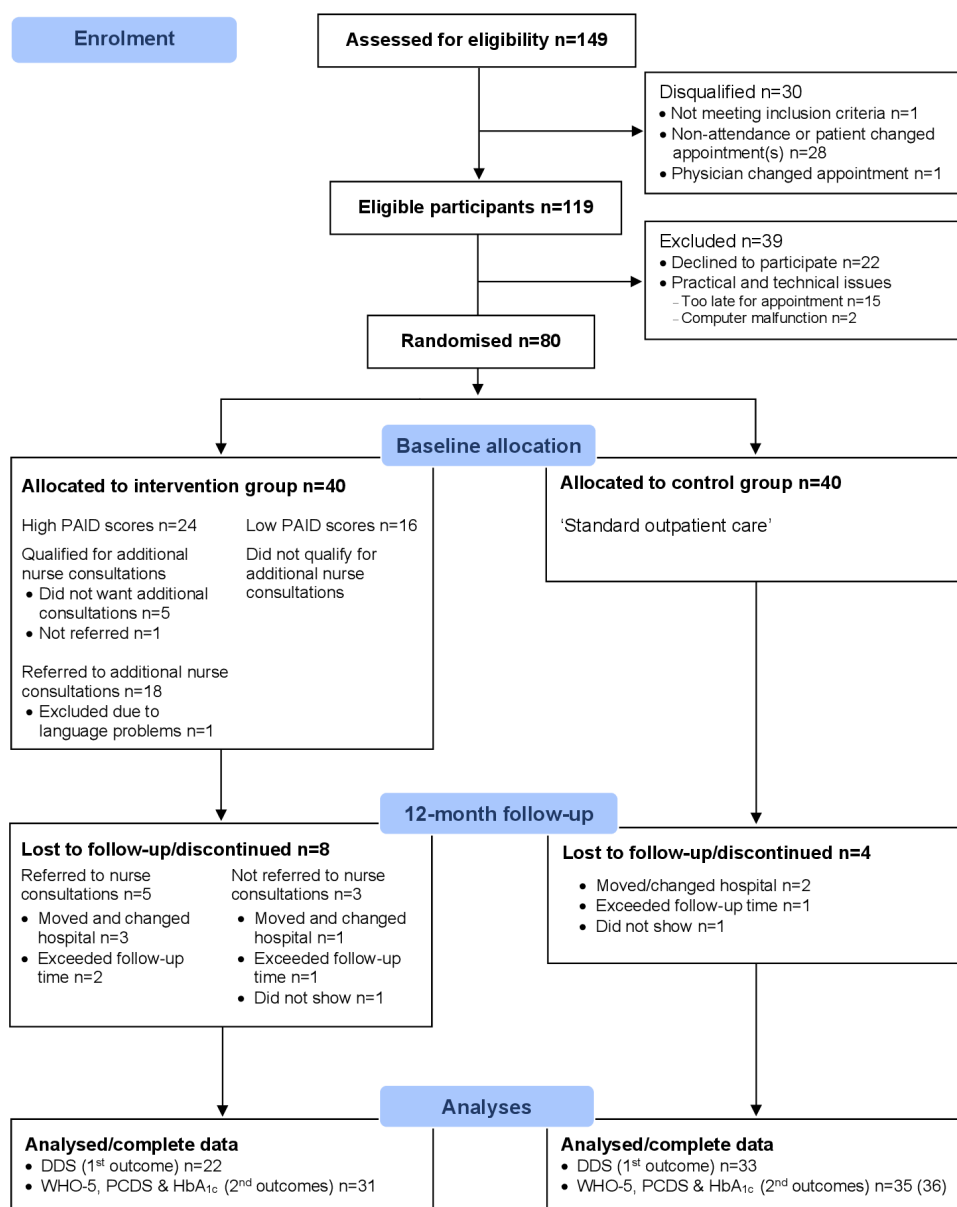## DiaPROM Pilot Trial CONSORT 2010 Flow Diagram

Figure 1 The DiaPROM pilot trial's consolidated standards of reporting trials flow diagram.
(CONSORT, Consolidated Standards of Reporting Trials; DiaPROM, Diabetes Patient-Reported Outcome Measures; DDS, Diabetes Distress Scale; PAID, Problem Areas In Diabetes; PCDS, Perceived Competence for Diabetes Scale.)

The control arm participants' corresponding proportions were 19/40 (47.5%) and 20/36 (55.6%). Thirty (76.9%) intervention group participants reported that the PAID results were discussed at baseline, of which 15 (38.5%) found it useful to a large or very large degree and 10 (25.6%) to some degree. At 12 months, 20/24 (83.3%) reported that PAID was discussed and 11 (45.8%) found it useful to a large or very large degree. Only 10/17 referred to additional follow-up completed all items about PAID use; five found the discussions useful; four reported to have benefitted to a large degree, whereas three had not benefitted at all. In total, 17/53 (32.1%) participants stated that completing PROMs had to some degree led to discussions related to diabetes-related challenges

which would not otherwise have been discussed (similar in both trial arms). Furthermore, 14 (26.4%) reported that completing PROMs had been a positive experience, while 24/53 (45.2%) found it somewhat positive (similar in both trial arms).

Outcome measures

In total, 67/79 (84.8%) participants responded to all DDS items at baseline and 58/67 (86.6%) at 12 months (online supplemental table 2). Mean scores and SDs of the outcome measures at baseline and follow-up for each trial arm are reported in tables 2 and 3. At follow-up, the sample's SD of DDS score was 0.71 (95% CI: 0.60 to 0.86) (table 2). From baseline to follow-up, we observed a

Table 1 Baseline sociodemographic and clinical characteristics of the DiaPROM pilot trial participants with type 1 diabetes aged 18–40 years (n=79)

	All	Groups	
	n=79	Intervention, n=39	Control, n=40
Gender, women	40 (50.6)	20 (50.6)	20 (50.0)
Age, years	27.2±5.0	27.1±4.7	27.3±5.3
European origin	79 (100.0)	39 (100.0)	40 (100.0)
Norwegian first language	74 (93.7)	36 (92.3)	38 (95.0)
Living alone	17 (21.5)	4 (10.3)	13 (32.5)
University/college education	37 (46.8)	21 (53.9)	16 (40.0)
Work affiliation			
Full-time work	36 (45.6)	18 (46.2)	18 (45.0)
Part-time work	5 (6.3)	0 (0.0)	5 (12.5)
Student	25 (31.7)	15 (38.5)	10 (25.0)
Other	13 (16.4)	6 (15.3)	7 (17.5)
Diabetes duration, years	13.7±7.0	13.6±6.4	13.9±7.6
Long-term complication(s)	16 (20.3)	4 (10.3)	12 (30.0)
Retinopathy*	15 (19.0)	4 (10.3)	11 (27.5)
Nephropathy	1 (1.3)	0 (0.0)	1 (2.5)
Comorbidities/other autoimmune diseases			
Thyroid disease	5 (6.3)	2 (5.1)	3 (7.5)
Coeliac disease	8 (10.1)	4 (10.2)	4 (10.0)
HbA_{1c} (mmol/mol)†	65.4±14.5	64.8±13.2	66.0±15.8
HbA_{1c} (%)	8.1±1.3	8.1±1.2	8.2±1.4
HbA_{1c} ≤53 mmol/mol (≤7.0%)‡	15 (19.0)	7 (18.0)	8 (20.0)
Body Mass Index (kg/m^2)	24.6±5.6	24.2±7.1	25.0±3.6
Symptomatic hypos last month	9.8±10.5	11.4±12.6	8.1±7.5
Severe hypoglycaemic event ever§	34 (43.0)	18 (46.1)	16 (40.0)
Ketoacidosis (ever hospitalised)	17 (21.5)	7 (17.9)	10 (25.0)
Insulin pump	38 (48.1)	20 (51.3)	18 (45.0)
Continuous glucose monitoring (CGM)	22 (27.9)	11 (28.2)	11 (27.5)
Self-blood glucose monitoring (SBGM)	53 (67.1)	27 (69.2)	26 (65.0)
Flash glucose monitoring (FGM)	2 (2.5)	1 (2.5)	1 (2.5)
Daily SBGM/FGM¶	47 (85.5)	25 (89.3)	22 (81.5)
Weekly count SBGM/FGM	32.8±22.9	39.4±25.3	26.7±18.9

Data are shown as n (%) (of patients with valid values) or mean±SD.
*Any degree of retinopathy
†Haemoglobin A_{1c}.
‡HbA_{1c} target achieved.
§At least one severe hypoglycaemic event with need of assistance (yes).
¶Total n based on participants using SBGM or FGM.
DiaPROM, Diabetes Patient-Reported Outcome Measures.

reduction in DDS overall score by an average of 0.25 (SD: 0.42) in the intervention arm but no apparent reduction in the control arm (0.00, SD: 0.47). The intervention arm's DDS subscale scores were all improved (−0.14 to −0.39, SDs: 0.66 to 0.86), while the control arm's changes in subscales scores ranged from −0.07 to 0.09 (SDs: 0.54 to 0.82). For other outcome variables (WHO-5, PCDS and HbA_{1c}), only small changes were seen (table 3). The correlation coefficient between baseline and follow-up DDS scores was 0.8 (95% CI: 0.7 to 0.9) (online supplemental table 3).

In addition, 18/33 (54.5%) and 11/26 (42.3%) intervention arm participants reported moderate to high distress measured by the DDS overall score at baseline

Table 2 Primary outcome measures at baseline and 12-month follow-up with variability and between-group differences—the DiaPROM pilot trial

Outcome measure	Participants	Baseline				12 months				Change from baseline to 12 months			Between-group difference¶	
		n	Mean	SD	95% CI*	n	Mean	SD	95% CI*	n	Mean	SD	Mean	95% CI†
Primary outcome														
DDS‡ overall score	All	72	2.1	0.69	0.59 to 0,82	60	2.0	0.71	0.60 to 0.86	55	−0.10	0.46	−0.25	−0.49 to 0.00
	Intervention	33	2.1	0.69	0.55 to 0.91	26	1.8	0.57	0.45 to 0.79	22	−0.25	0.42		
	Control	39	2.1	0.71	0.58 to 0.91	34	2.1	0.79	0.64 to 1.04	33	0.00	0.47		
Emotional burden§	All	72	2.5	1.05	0.90 to 1.25	60	2.4	1.03	0.87 to 1.26	55	−0.08	0.76	−0.39	−0.82 to 0.05
	Intervention	33	2.5	1.06	0.85 to 1.40	26	2.3	0.97	0.76 to 1.34	22	−0.32	0.86		
	Control	39	2.4	1.05	0.85 to 1.35	34	2.4	1.09	0.88 to 1.43	33	0.07	0.64		
Physician-related distress§	All	72	1.5	0.74	0.64 to 0.88	60	1.4	0.67	0.57 to 0.82	55	−0.10	0.70	−0.07	−0.45 to 0.31
	Intervention	33	1.6	0.89	0.71 to 1.17	26	1.4	0.64	0.50 to 0.89	22	−0.14	0.66		
	Control	39	1.5	0.59	0.48 to 0.76	34	1.4	0.71	0.57 to 0.93	33	−0.07	0.73		
Regimen-related distress§	All	72	2.4	0.89	0.76 to 1.06	60	2.2	0.88	0.75 to 1.07	55	−0.13	0.76	−0.19	−0.59 to 0.21
	Intervention	33	2.4	0.91	0.73 to 1.20	26	2.1	0.66	0.52 to 0.91	22	−0.24	0.66		
	Control	39	2.4	0.87	0.71 to 1.12	34	2.3	1.01	0.81 to 1.33	33	−0.05	0.82		
Interpersonal distress§	All	73	1.8	0.83	0.71 to 0.99	60	1.7	0.91	0.77 to 1.10	56	−0.11	0.67	−0.48	−0.85 to −0.11
	Intervention	34	1.8	0.77	0.62 to 1.02	26	1.5	0.54	0.42 to 0.75	23	−0.39	0.75		
	Control	39	1.8	0.90	0.74 to 1.15	34	1.9	1.09	0.88 to 1.43	33	0.09	0.54		

*95% CIs around the SD

†95% CIs around the mean between-group differences.

‡Diabetes Distress Scale mean score (1–6).

§Diabetes Distress Scale subscale mean scores (1–6).

¶Differences between intervention and control arm.

DDS, Diabetes Distress Scale; DiaPROM, Diabetes Patient-Reported Outcome Measures.

Table 3 Secondary outcome measures at baseline and 12-month follow-up with variability and between-group differences—the DiaPROM pilot trial

Outcome measure	Participants	Baseline				12months				Change from baseline to 12months			Between-group difference**	
		n	Mean	SD	95% CI*	n	Mean	SD	95% CI*	n	Mean	SD	Mean	95% CI†
Secondary outcomes														
WHO-5‡ score	All	79	62.4	17.4	15.0 to 20.6	67	62.8	16.2	13.8 to 19.5	67	0.75	16.3	−0.55	−8.7 to 7.6
	Intervention	39	63.4	19.9	16.3 to 25.6	31	64.0	16.4	13.1 to 21.9	31	0.45	17.6		
	Control	40	61.4	14.8	12.1 to 19.0	36	61.8	16.1	13.1 to 21.0	36	1.00	15.3		
PCDS§ score	All	79	5.1	1.3	1.1 to 1.5	66	5.3	1.3	1.1 to 1.6	66	0.05	0.99	0.36	−0.1 to 0.9
	Intervention	39	5.0	1.4	1.1 to 1.8	31	5.4	1.3	1.0 to 1.7	31	0.24	1.18		
	Control	40	5.3	1.1	0.9 to 1.4	35	5.2	1.3	1.1 to 1.7	35	−0.12	0.78		
HbA$_{1c}$ value¶	All	79	65.4	14.5	12.5 to 17.2	66	62.8	14.6	12.5 to 17.6	66	−1.10	11.2	1.48	−4.1 to 7.0
	Intervention	39	64.8	13.2	10.8 to 17.0	31	61.8	15.1	12.1 to 20.2	31	−0.32	11.4		
	Control	40	66.0	15.8	12.9 to 20.3	35	63.8	14.4	11.6 to 18.9	35	−1.80	11.1		

*95% CIs around the SD.
†95% CIs around the mean between-group differences.
‡World Health Organisation five-item well-being index (0–100).
§Perceived Competence for Diabetes Scale (1–7).
¶Haemoglobin A$_{1c}$ (mmol/mol).
**Differences between intervention and control arm.
DiaPROM, Diabetes Patient-Reported Outcome Measures.

and follow-up, respectively (online supplemental table 4). Corresponding proportions for control arm participants were 15/39 (38.5%) and 17/34 (50.0%). Regarding DDS subscales, the percentage of participants reporting moderate to high emotional burden and regimen-related distress was persistent at ~60%, across groups and timepoints.

DISCUSSION

In this randomised controlled pilot trial, we found that it was feasible to recruit and randomise young adults with T1D attending routine diabetes consultations to a trial using PAID and communication techniques as dialogue support tools. The participants were positive towards completing PROMs. Furthermore, we were able to retain 67/79 (84.8%) participants at 12 months. However, we identified implementation challenges related to the intervention consultations, and 5/17 (29.4%) participants referred to additional consultations were lost to follow-up at 12 months.

Strengths and limitations

The pilot trial's key strengths were that it systematically addressed uncertainties associated with designing a large-scale RCT. Moreover, well-known, validated tools for measuring primary and secondary outcomes allowed for comparison with other studies. The results inform technical and practical issues of conducting a full-scale trial. Similar to our feasibility study,[34] findings suggest that completing electronic PROMs was generally accepted and technically feasible. We were able to recruit and randomise 80 participants over 15 weeks. However, one fundamental limitation was that the 12-month follow-up lasted nearly twice as long (28 weeks), mainly caused by cancelled appointments, non-attendance and loss to follow-up. Another limitation was not having predefined criteria for retention and attrition progression rates. However, this is not yet common.[56] Furthermore, complete follow-up was not achieved, and attrition differed by trial arm: 10% in the control arm, 20% in the intervention arm and 29% among those who were referred to additional follow-up. Systematic differences between completers and drop-outs may have introduced attrition bias.[57] However, clinic non-attendance is not uncommon among young adults with T1D and has been linked to difficulties communicating with the services, conflicting schedules, low perceived value of attendance and challenges with developing relationships.[58 59] The retention, implementation and acceptability issues are further explored in qualitative interviews. In summary, these issues will impact power calculations by increasing the target sample needed, in addition to affecting intervention implementation and the duration of a full-scale RCT.

Generalisability and transferability to other settings and populations may be limited due to our use of electronic technologies for completing PROMs, our choice of only including young adults with T1D, and that the Norwegian health insurance system differs from other countries. Finally, although PAID scores were not accessible in the control arm participants' EPRs, we cannot rule out contamination. Since all participants completed PROMs in the same manner, control arm participants' consultations may have been influenced by individual responses and thoughts about the questionnaires. Moreover, consulting styles within a service probably differs between clinicians. For ethical reasons, we could not instruct the physicians to avoid discussing diabetes distress in the control arm if participants requested it.

Implications and future research

Using current pilot trial data and a conservative DDS SD estimate to calculate the minimal clinically important difference (0.5× SD),[60] and assuming that SD (0.71) is equal for each trial arm in a full-scale, single-site RCT, we estimate at least 107 participants will be required per arm to provide 90% power based on a two-sided 5% significance level. The calculation was based on the formula of a two-sample t-test for difference post-intervention and allowed for 25% attrition.

Since 10% of the participants did not complete the paper-based measures, and there was considerably more missing DDS items than other PROM items, we will strive for capturing all future data electronically. Furthermore, only a minority of participants approached the touchscreen computer by themselves. Therefore, we will continue with in-clinic guidance and e-mail or SMS reminders to support data collection. A web-based PROMs platform, recently available in Norway, will possibly enable more complete data collections in future studies. Moreover, we observed that 36 (45.6%) participants had not read the study information prior to coming to the clinic but still consented. The drop-out rates and other findings suggest that consultations were not considered useful, adequate or appropriate by the participants. This could in part be explained by protocol inflexibility and/or the waiting time between PROMs completion and additional consultations. In addition, we may not have provided sufficient detailed information about the nature of the intervention components, especially the additional follow-up. Also, this key intervention component may not have fitted the participants' personal beliefs, preferences, capabilities and/or life circumstances.[61] We may also have underestimated the contribution of the baseline review of scores and discussions between intervention arm participants and physicians. Furthermore, our criteria for offering additional follow-up may have led to overinclusion of cases but we must also consider barriers to clinic attendance and dissatisfaction with the follow-up.[14 58] Another aspect which requires consideration, is that simply answering questions for assessment purposes, such as PROMs, may affect research participants by stimulating new thinking about problem areas or behaviours, which then may lead to action-taking.[62] This question-behaviour effect makes it even more difficult to evaluate complex interventions.

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Diabetes distress scores were similar to previous studies.[20] [21] [63] Approximately half of the participants reported moderate to serious distress, which supports statements that diabetes distress is common and worthy of individual attention in diabetes care.[4] [12] [15] Although the pilot trial was not powered for inferential statements, the observed between-group differences in DDS scores suggest promising effects of assessing and addressing diabetes distress. Compared with lack of assessment and follow-up, education-based or emotion-focused interventions targeting diabetes distress in adults with T1D have been found clinically effective.[24] [64] [65] In the pilot trial, we focused on real-life clinical consultations. Hence, the clinicians meet individuals with different needs which may entail applying either education-based or emotion-focused interventions or both, depending on individual diabetes distress foci, discussions with each individual and clinical experience. Personalising diabetes care by addressing diabetes distress systematically, may increase healthcare providers' attentiveness towards the individual experiences of living with diabetes.

Implementation fidelity and difficulties in delivering the intervention as designed appeared challenging for the clinic. One aspect was providing the consultations within the specified timeframe. Recommendations of 2-week to 1-month intervals between consultations[23] [66] may be difficult to achieve within regular working hours unless telephone or digital communication are used.[67] The observed lack of intervention fidelity, for example, not reviewing the PAID during annual consultations, may be partly explained by low sense of project ownership from the clinicians. This highlights the importance of organisational incentives, management facilitation of new intervention initiatives and possibly cultural aspects in this setting. Our efforts to encourage intervention fidelity by providing information, developing manuals and arranging meetings and training for the clinicians may not have been sufficient. Consequently, we must seek to further identify key contextual, organisational and behavioural factors and mechanisms of impact. The pilot trial results show that we must involve health service users and clinicians in further development of the intervention and undertake more feasibility work with process evaluations to inform the design of a full-scale trial.[68]

CONCLUSIONS

Results from this randomised controlled pilot trial show that it is feasible to recruit and randomise young adults with T1D attending an outpatient clinic to a study using electronically captured PROMs to assess diabetes distress. However, the intervention was not provided as planned. Low perceived usefulness and high attrition rate among intervention arm participants also suggest low acceptability or overinclusion. The pilot trial revealed problems with design and deliverability and highlighted the need for several intervention modifications before initiating a full-scale evaluation of using electronic PROMs in diabetes consultations.

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