Using Patient-Reported Outcome Measures (PROMs) in clinical diabetes consultations

Feasibility testing and piloting the DiaPROM trial among adults with type 1 diabetes

Ingvild Hernar

Thesis for the degree of Philosophiae Doctor (PhD)
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Scientific environment

The PhD candidate was granted admission to the Department of Global Public Health and Primary Care (IGS), Faculty of Medicine, at the University of Bergen (UiB). While the Department of Health and Caring Sciences, Faculty of Health and Social Sciences, at Western Norway University of Applied Sciences (Høgskulen på Vestlandet; HVL) funded the PhD scholarship and provided a work environment at Campus Kronstad in Bergen.

Professor Marit Graue (HVL) has been the PhD candidate's main supervisor, and Professor Grethe S. Tell (UiB), Associate Professor Anne Haugstvedt (HVL) and Associate Professor Ragnhild B. Strandberg (HVL) have been co-supervisors. In addition, Professor Roy M. Nilsen (HVL) and Associate Professor Beate-Christin H. Kolltveit (HVL) have been key resource persons within statistics and qualitative research methods, respectively. Professor David A. Richards at HVL and University of Exeter (UK) and Professor Árún K. Sigurðardóttir at the University of Akureyri, Iceland, have been important international collaborators.

The PhD candidate has been affiliated with the Research Group for Best Practice Research in Diabetes and other Chronic Conditions (DiaBEST) at HVL, the Research Group for Lifestyle Epidemiology at UiB, and the Research Group for Phenomenological Studies in Health Sciences at UiB. The candidate also attended the Research School in Public Health and Primary Health Care at UiB, the PhD candidate forum at HVL, and the Baltic Sea Region Network in Personalised Health Care's PhD summer school.

The studies that form this thesis have been part of the project «The use of Patient-Reported Outcome Measures to promote quality of diabetes care" (DiaPROM), consisting of two subprojects. In subproject 1, the aim has been to implement Patient-Reported Outcome Measures (PROMs) in the National Diabetes Register for Adults (NDR-A). While in subproject 2, we aimed to test an intervention using PROMs in clinical diabetes consultations. The DiaPROM project is a collaboration between

HVL, UiB, the NDR-A, the Norwegian Diabetes Association, the Department of Internal Medicine, Endocrinology Unit, and the Centre for Patient-Reported Outcomes Data at Haukeland University Hospital, led by Associate Professor Anne Haugstvedt (HVL).

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Bergen, 15 April 2021
Ingvild Hernar

Abstract

Background The demands of type 1 diabetes (T1D) may constitute a great burden for people living with the disease. Diabetes distress reflects a range of emotional experiences, such as worry, guilt, and fear, potentially impairing self-management and glycaemic control. Serious diabetes distress is reported by 20-40% of adults with T1D. Consequently, regular assessment in clinical care is recommended. Using Patient-Reported Outcome Measures (PROMs) to assess diabetes distress is considered useful as tools to improve screening and communication between clinicians and people with T1D. Therefore, we developed the Diabetes Patient-Reported Outcome Measure (DiaPROM) trial, an empowerment-based intervention using the Problem Areas in Diabetes (PAID) scale to assess diabetes distress and as a dialogue tool in adult T1D consultations.

Aims The overall aim of the studies conducted as part of this thesis was to feasibility and pilot test the DiaPROM trial, thereby investigate uncertainties associated with running a full-scale randomised controlled trial (RCT). The specific aims were as follows:

1. To examine the feasibility and acceptability of capturing PROMs electronically on a touchscreen computer in clinical diabetes practice (Paper I).
2. To develop a study protocol for the DiaPROM pilot trial (Paper II).
3. 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 (Paper III).
4. To explore young adults' experiences with outpatient follow-up appointments, completing electronic PROMs and using the PAID scale during the DiaPROM pilot trial (Paper IV).

Materials and methods Three studies designed to complement each other: a feasibility study, a pilot trial and a qualitative study, were conducted at the endocrinology outpatient clinic at Haukeland University Hospital, Bergen. Eligible participants were adults with T1D and a minimum of one year diabetes duration. In

the feasibility study, we invited adults ≥ 40 years to avoid including potential candidates for the upcoming pilot trial, in which we recruited younger adults aged 18-39 years. In the qualitative study, we invited pilot trial participants after they had attended the 12-month follow-up visit.

The *feasibility study* had a cross-sectional design (Paper I). The participants completed a set of electronic PROMs on a touchscreen computer at the outpatient clinic. The set contained five validated PROMs (42 items; covering diabetes distress, emotional wellbeing, perceived diabetes competence, hypoglycaemia awareness and health-related quality of life), three glucose variability items and two items concerning current glucose monitoring. Participants also completed a paper questionnaire regarding their perceptions about the PROMs. In addition, we monitored the touchscreen computer's technical performance, observed the participants' actions and collected data on the time needed to complete the PROMs, and we also recorded any missing items.

The *pilot trial* was a two-arm RCT with baseline and 12-month data collection points (Papers II & III). All participant completed electronic PROMs before two annual check-ups. We used computer-generated block-randomisation without blinding to assign participants in a 1:1 ratio, stratified by sex, to receive the intervention or standard care. All intervention arm participants' PAID scores were reviewed by and discussed with a physician, and participants with PAID scores ≥30 or items scored ≥3 were offered additional follow-up. During a minimum of two diabetes specialist nurse consultations guided by an empowerment-based communication manual, reported problem areas were further discussed. Our primary outcome measure was the Diabetes Distress Scale (DDS), secondary outcome measures were the WHO 5-Well-being Index, the Perceived Competence for Diabetes Scale and glycaemic control measured by HbA1c. The pilot trial outcomes were recruitment and retention rates, estimation of variance, between-group differences of follow-up scores and correlations of DDS scores to assist sample size calculations and, finally, participants' perceptions about the intervention components.

In the *qualitative study*, we performed semi-structured individual telephone interviews of pilot trial participants, asking about their experiences with diabetes follow-up and participation in the pilot trial (Paper IV). We analysed the data using Braun & Clarke's thematic analysis.

Results In the *feasibility study*, we recruited 69 participants (50.7% men; median age 51.0 years; median diabetes duration 26.0 years). The median time for completing the electronic PROMs was 8 minutes and 19 seconds, and the average completion rate was 81.4%. Overall, the touchscreen computer functioned well, and the participants found the PROMs understandable and relevant and acceptable for annual completion.

In the *pilot trial*, we randomised 80 participants (mean age 27.2 years; mean diabetes duration 13.7 years) to the control or intervention arm (one participant was later excluded); 23 of 39 intervention arm participants qualified for additional consultations and 17 of these were referred. At 12 months, 67 participants attended the follow-up (15.2% attrition); thereof, 5 (29.4%) of the 17 referred to additional nurse consultations were lost to follow-up. Participants found the PROMs relevant and acceptable but rated the additional nurse consultations' usefulness as moderate. Furthermore, using results from the primary outcome measure, the DDS, we estimated that at least 107 participants would be required per arm in a fully powered, single-site RCT.

In the *qualitative study*, we interviewed 19 participants (age 22-39 years; diabetes duration 5-32 years): 8 from the control arm and 11 from the intervention arm. The analyses generated three themes, each with two *subthemes*: (1) Follow-up with limitations; *Marginal dialogue about everyday challenges* and *Value of supportive relationships and continuity* indicated that the participants experienced the previous follow-up as challenging and insufficient. (2) New insights and raised awareness; *More life-oriented insights* and *Moving out of the comfort zone* suggested mostly positive experiences with completing the PAID and using the scores in the dialogue. (3) Addressing problem areas with an open mind; *Need for elaboration* and

Preparedness for dialogue indicated that further exploration of the PAID scores and openness were essential.

Conclusions The studies' findings highlight the value of combining quantitative and qualitative methods in feasibility and pilot testing to uncover factors that may impede effective interventions in clinical practice. Capturing electronic PROMs was technically feasible and accepted by the participants. Although they found it somewhat uncomfortable and challenging to disclose their diabetes-related problem areas, addressing diabetes distress as part of the consultations was considered highly relevant and important for future diabetes follow-up. Using the PAID helped the healthcare providers see beyond biomedical outcomes, which promoted patient empowerment and person-centred care and facilitated improved patient-provider relationships.

However, we decided not to proceed directly to a full-scale evaluation trial. This decision was based on findings indicating attrition, fidelity issues related to implementation and low acceptance or over-inclusion of cases, suggesting that the intervention requires additional development. Consequently, before commencing a full-scale RCT, the intervention requires modifications and additional development and possibly further feasibility and acceptability testing, focusing on inclusion criteria, intervention flexibility and healthcare provider training, specifically using the PAID in the patient-provider interaction.

List of Publications

Paper I. Hernar I, Graue M, Richards D, Strandberg RB, Nilsen RM, Tell GS, Haugstvedt A. Electronic capturing of patient-reported outcome measures on a touchscreen computer in clinical diabetes practice (the DiaPROM trial): a feasibility study. Pilot Feasibility Studies. 2019;5(1):29. doi: 10.1186/s40814-019-0419-4.

Paper II. Haugstvedt A, Hernar I, Strandberg RB, Richards DA, Nilsen RM, Tell GS, Graue M. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomised controlled trial pilot study. BMJ Open. 2019;9(1):e024008. doi: 10.1136/bmjopen-2018-024008.

Paper III. Hernar I, Graue M, Richards DA, Strandberg RB, Nilsen RM, Rekdal M, Løvaas KF, Madsen TV, Tell GS, Haugstvedt A. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: the DiaPROM randomised controlled pilot trial. BMJ Open. 2021;11(4):e042353. doi: 10.1136/bmjopen-2020-042353

Paper IV. Hernar I, Graue M, Strandberg RB, Lie SS, Sigurdardottir AK, Richards DA, Kolltveit BH, Haugstvedt A. Young adults with type 1 diabetes and their experiences with diabetes follow-up and participation in the DiaPROM pilot trial: A qualitative study. Diabet Med. 2021;00:e14535. doi:10.1111/dme.14535.

Abbreviations

CGM - Continuous Glucose Monitoring

CI - Confidence Interval

CSII - Continuous Subcutaneous Insulin Infusion

DCCT - Diabetes Control and Complications Trial

DDS - Diabetes Distress Scale

DiaBEST - Best Practice Research in Diabetes and other Chronic Conditions

DiaPROM - Diabetes Patient-Reported Outcome Measures

EDIC - Epidemiology of Diabetes Interventions and Complications

EPR(s) - Electronic Patient Record(s)

FGM - Flash Glucose Monitoring

HbA_{1c} - Haemoglobin A_{1c}

HVL - Western Norway University of Applied Sciences (Høgskulen på Vestlandet)

IGS - Department of Global Public Health and Primary Care

ISOQOL - International Society for Quality of Life Research

MDI - Multiple Daily Injections

MRC - Medical Research Council

NDR-A - Norwegian Diabetes Register for Adults

PAID - Problem Areas in Diabetes scale

PCDS - Perceived Competence for Diabetes Scale

PREMs - Patient-Reported Experience Measures

PRO(s) - Patient-Reported Outcome(s)

PROM(s) - Patient-Reported Outcome Measure(s)

SD - Standard Deviation

SMBG - Self-Monitoring Blood Glucose

T1D - Type 1 diabetes

T2D - Type 2 diabetes

UiB - University of Bergen

WHO-5 - World Health Organisation 5-item well-being scale

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3. Paper-based questionnaire, baseline pilot trial (Paper III).
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5. Interview guide, qualitative study (Paper IV).
6. Physicians' study manual, baseline pilot trial (Paper III).
7. Nurses' study manual and communication guide, pilot trial (Paper III.)
8. Physicians' study manual, 12-month follow-up pilot trial (Paper III).
9. Regional Ethics Committee Approval, feasibility study.
10. Regional Ethics Committee Approval, pilot trial and qualitative study.
11. Written information and consent form, feasibility study.
12. Written information and consent form, pilot trial and qualitative study.

1. Introduction

Diabetes mellitus is a cluster of chronic endocrine diseases characterised by persistently elevated blood glucose (1). Diabetes is typically classified into broad etiologic groups to reflect the clinical heterogeneity: type 1 diabetes (T1D), latent autoimmune diabetes in adults, type 2 diabetes (T2D), gestational diabetes, specific types of diabetes due to genetic defects or diseases of the exocrine pancreas and medically or chemically induced diabetes (2). The International Diabetes Federation estimates that 463 million adults (20-79 years) presently live with diabetes and that 1.1 million children and adolescents (0-19 years) have T1D, with an estimated 128,900 new cases per year (3). Diabetes thus poses a significant public health challenge. Because the focus of this thesis is on adults with T1D, the review of the literature is restricted to this group.

1.1 Type 1 diabetes

T1D is caused by destruction of the insulin-producing β-cells in the Langerhans islets in the pancreas, and people with T1D, therefore, require lifelong exogenous insulin therapy (4). The pathogenesis of T1D is not fully understood. An estimated 70-90% of cases are presumably caused by an autoimmune response, whilst the remaining cases are considered idiopathic. Environmental agents most likely trigger the β-cell destruction in genetically predisposed people, typically developing over months or years without the individual noticing any symptoms (4, 5). T1D may be diagnosed at any age but most commonly during childhood and adolescence (4, 6). Boys and men are slightly more affected compared to girls and women (1.5:1 ratio). Studies also suggest seasonal variation with more cases diagnosed in colder months (4, 7). At T1D onset, classic symptoms are polyuria, polydipsia and weight loss due to hyperglycaemia effects and, in some cases, ketoacidosis (7). Standardised laboratory methods for measuring glycaemia levels through plasma glucose or Haemoglobin A_{1c} (HbA_{1c}) are used as diagnostic tools (8, 9). Current diagnostic criteria are either fasting plasma glucose levels ≥7.0 mmol/L, non-fasting plasma glucose levels ≥11.1 mmol/L or HbA_{1c} ≥48 mmol/mol (6.5%). Two abnormal tests are required for

diagnosis unless the patient has random plasma glucose levels ≥11.1 mmol/L and hyperglycaemia symptoms.

Internationally, T1D incidence and prevalence vary considerably between countries and underlying mechanisms for this variation is unknown (4, 10). Over decades, an increased incidence was observed (11), which later seemed to level off in some countries (4). To date, the exact diabetes prevalence and incidence in Norway is unclear, apart from T1D in children and adolescents. The Norwegian Childhood Diabetes Registry's annual report for 2019 reports an incidence of 37.7 per 100,000 person-years for the age group 0-14 years (12). The Norwegian Diabetes Register for Adults' (NDR-A, 76.1% coverage for hospital outpatient clinics) 2019 estimate was 9.2 new cases of T1D per 100,000 person-years in adults >18 years (61% aged 18-39 years) (13). Data from the national prescription database and regional population-based health studies combined with diagnosis codes from primary and specialist care suggests that approximately 23,000 Norwegians have T1D (14).

When Banting & Best introduced insulin replacement therapy in 1922, the lives of people with T1D changed dramatically as the disease was transformed from fatal to chronic (15). Later, long-term survival resulted in the discovery of microvascular and macrovascular diabetes complications (16). The specific complications were retinopathy, nephropathy and neuropathy, causing blindness, kidney failure and amputations, and cardiovascular diseases, causing myocardial infarctions, angina and strokes. However, the aetiology of diabetes complications and whether they were glucose-dependent or not was debated for years. In 1986, the Oslo study reported preventive effects of long term (2 years) near normoglycaemia on the progression of microvascular complications in a sample of 45 people with T1D (17). In 1993, this finding was corroborated by the Diabetes Control and Complications Trial (DCCT), which had followed 1441 people with T1D over 6.5 years (18). The DCCT demonstrated that intensive insulin therapy (at least three insulin injections per day) compared to conventional therapy of the time (one or two daily insulin injections) led to improved glycaemic control; however, with a 3-fold increased risk of hypoglycaemia. Twenty years later, the combined results from the DCCT with its

longitudinal Epidemiology of Diabetes Interventions and Complications (EDIC) follow-up study demonstrated that achieving near-to-normal glycaemia as safely as possible reduced microvascular and macrovascular diabetes complications (19). These results have played an important role in T1D treatment as the insulin replacement therapy evolved from taking fixed doses to a more complex regimen with dose adjustments. Together with other treatment innovations, this has led to markedly improved long-term health for people with T1D.

1.1.1 Treatment of type 1 diabetes

The overarching goal for all treatment is for people with diabetes to live their lives in full, in principal unrestricted lives, and prevent acute and long-term complications of the disease and its treatment (9). Worldwide, the most commonly recommended glycaemic target for non-pregnant adults with T1D is currently HbA_{1c} of 53 mmol/mol (7%) (3). Other important measures to maintain adequate treatment in everyday life are blood or interstitial glucose levels. In adults without long-term complications or additional health challenges, the glucose target range is specified as 3.9-10.0 mmol/L while minimising time in hypoglycaemia (<3.9 mmol/L) and hyperglycaemia (>10.0 mmol/L) and trying to completely avoid glucose <3.0 mmol/L and >13.9 mmol/L (20). In addition, blood pressure, weight/BMI, lipids and albuminuria are important markers and measures targeted in treatment and follow-up as these are involved with the development of complications (9). However, treatment targets should always be individualised, weighing the benefits of intensified treatment against the risk of frequent or severe hypoglycaemia episodes, which can seriously impact the quality of life (9).

International and national publications suggest that only 20-30% of adults with T1D reach the recommended HbA_{1c} targets (<53 mmol/mol or <7.0%) (13, 21-23). Furthermore, higher HbA_{1c} levels are associated with younger age among adults (22-25). In a Norwegian study of adolescents and young adults with T1D, approximately 10% of those aged 14-24 achieved target HbA_{1c} (25). In the age group 25-30 years, this varied between 13% and 22%. According to the NDR's 2019 annual report, 14% of adults (≥ 18 years) with T1D had HbA_{1c} >75 mmol/mol (9.0%) (13). Another

study using NDR-A data found that high educational levels, not living alone, and higher frequencies of glucose monitoring and symptomatic hypoglycaemia were associated with lower HbA_{1c} levels (23).

Glucose monitoring

HbA_{1c} alone is insufficient to direct T1D therapy, which also involves frequent glucose level monitoring to inform and direct insulin dosage (26). The options are Self-Monitoring Blood Glucose (SMBG), Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM). SMBG measures capillary blood using fingerpricks and glucose meters (26). CGM systems measure interstitial glucose levels using a subcutaneously injected sensor connected to a transmitter which communicates glucose values to a receiver (20, 27, 28). Therefore, CGMs allows for direct observation of glycaemic excursions and daily glucose profiles that provide an overview of glucose variability over time, especially beneficial for people who experience frequent or severe hypoglycaemic episodes and/or have developed hypoglycaemia unawareness. FGM functions as a hybrid between SMBG and CGM and is the latest developed method for measuring interstitial glucose levels (29). Users scan a subcutaneously injected sensor by passing a reader over it to get glucose readings.

Insulin replacement therapy

Today's insulin therapy recommendations for people with T1D are largely based on the DCCT and EDIC studies (18, 19). The goal is to resemble the physiological insulin profile of a non-diabetic pancreas through administering insulin by Multiple Daily Injections (MDI) using insulin pens or Continuous Subcutaneous Insulin Infusion (CSII) via an insulin pump (26, 30). Basal insulin is administered to maintain a near fasting normoglycaemic state by suppressing hepatic glucose production and delivered by injecting long-acting insulin once or twice daily by pen or continuous infusion of rapid-acting insulin via a pump. In comparison, bolus insulin refers to rapid-acting insulin administered via pen or pump to decrease postprandial glucose excursions by covering the extra need for insulin after meals are absorbed (26). Boluses are ideally not fixed doses but adjusted to match the

physiologic insulin requirement, which depends on carbohydrate intake, current and previous glucose levels, taken and/or planned physical activity and the individual's general state (27).

Pens are used by approximately 60% of insulin users worldwide, although variations exist between countries and age groups (31). Reusable or prefilled insulin pens are usually offered to adults with T1D at diagnosis. While in paediatric clinics, CSII is more often the first choice (27). Several pumps can receive CGM data. Some also allow the CGM data to address hypo- and hyperglycaemia by automatically adjusting basal insulin delivery (sensor-augmented pumps). In 2019, 79% of Norwegian children and adolescents with T1D used CSII, while 74% used CGMs (12). Corresponding figures for adults were 34% and 46%, respectively (13).

Technological breakthroughs frequently occur; for example, hybrid artificial pancreases (closed-loop systems), 'Do-it-yourself' artificial pancreas systems and implantable insulin pumps are being developed and tested, although not yet commonly used (32). In addition, new insulin formulas are also under development. Nevertheless, people with T1D still carry an increased risk of developing complications. Achieving and maintaining glucose levels necessary to prevent complications requires that people with T1D acquire, implement and maintain complex self-management skills (33). In the care for people with chronic diseases, it is important to recognise that their everyday lives are lived despite illness, symptoms or disabilities (34).

1.2 Self-management

Being diagnosed with a chronic disease usually means that the individual has to attain considerable knowledge about the disease and its treatment, integrate new routines, lifestyles or behaviours and learn how to cope with major changes in everyday life (35). Further, people are expected to maintain these often complex and demanding behavioural and practical everyday efforts and make decisions that affect diseases management without advice from healthcare providers (34). Knowledge is an

essential element of disease management; however, increased knowledge alone is not enough. The concept self-management refers to *"the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to affect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life. Thus, a dynamic and continuous process of self-regulation is established"* (35, p. 178). However, acquiring and sustaining self-management is challenging and dependent on self-efficacy and resilience and acquiring the needed knowledge (34).

1.2.1 Diabetes self-management

Diabetes self-management can be described as the continuous efforts to lead a 'normal' life by balancing physical and psychosocial well-being with the treatment regimen (36). Active and sustained self-management is a prerequisite for optimal treatment and a key determinant of treatment outcomes. In addition to practical skills such as insulin delivery and glucose monitoring, as mentioned earlier, self-management also involves a comprehensive understanding of nutritional, hormonal, physical and emotional impacts on glycaemia to match the individual need for insulin (26, 37). Core self-management behaviours critical to T1D treatment, therefore, include glucose monitoring, carbohydrate awareness and/or counting, managing equipment and injection sites, insulin dose adjustments, managing hypo- and hyperglycaemia, handling physical activity and accessing healthcare (37). The complexity of T1D self-management has recently been highlighted in a study that identified 150 self-regulatory behaviours needed for optimal and sustained self-management and 39 barriers and enablers to these behaviours (38).

Diabetes treatment requires the use of technology. Choice of insulin delivery method and glucose monitoring device should ideally be based on individual preference and willingness and ability to take on technical tasks. Irrespective of the insulin delivery method, there are several factors related to injection technique that can affect insulin absorption and thereby the effect, such as needle length, rotation of injection sites and lipodystrophy (31, 39). Nevertheless, the MDI and CSII regimens support a flexible

lifestyle with fewer restrictions than simpler insulin regimes with fewer injections (40). Achieving near-normoglycaemia without increasing hypoglycaemic events is possible using MDI and CSII (41). However, potential CSII advantages include more precise insulin delivery and the possibility to adjust basal insulin levels, which can be particularly effective if target HbA_{1c} is not achieved, for example, due to escalations of hypoglycaemia or hypoglycaemia unawareness (41, 42). Improved blood glucose variability also contributes to greater lifestyle flexibility and higher treatment satisfaction (41, 43). However, in cases of technical malfunction or user errors, the lack of circulating long-acting insulin means that hypoinsulinaemia is imminent. In addition, CGM can contribute to reduced HbA_{1c} and hypoglycaemia, increased time in range and improved treatment satisfaction in people with T1D (44). However, CSII and CGM equipment is typically worn on the body, which can serve as a constant reminder and make the disease visible. Further, all devices used to optimise clinical outcomes require active, knowledgeable users who interpret the data and act appropriately (26).

Despite technological innovations, many people with T1D struggle to achieve optimal glycaemic control, especially young adults (21-23, 25). The young adult phase ranges from about 19 to 40 years of age (45). The transition from adolescence to adulthood can be challenging in its own right, and adding T1D brings a unique set of challenges (46). As young people with T1D adapt to new adult roles and seek normalcy, they are also assuming responsibility and taking charge over their diabetes management (47) or being diagnosed and starting their life with diabetes. Paradoxically, reaching recommended glucose targets increases the risk of hypoglycaemic events (18), partly due to insulin delivery limitations. Not surprisingly, poor glycaemic control is linked to suboptimal self-management behaviours (23, 48). Studies also report less self-management engagement in emerging and younger adults (23, 24, 49). However, self-management inattentiveness is not necessarily a product of negligence but may be a consequence of competing priorities momentarily transcending the individual's perceived importance of diabetes management (50). Poor glycaemic control and self-management are complex

phenomena that appear to be affected by biomedical and psychosocial factors, separately and in interaction (51).

Self-management is ultimately the person's responsibility, maybe supported by a partner, family or friends. Diabetes self-management is particularly challenging because individual efforts to achieve beneficial outcomes may not necessarily produce positive results (52). In everyday life, acute diabetes complications such as severe hypoglycaemia and hyperglycaemia, or ketoacidosis, are possibly the most immediate threats because these complications can lead to permanent illness or even death. The dilemma of striving for glycaemic control without hypoglycaemic events disrupting daily routines can potentially affect emotional well-being and diabetes-related psychosocial aspects and lead to some deliberately raising their glucose levels (51). Overall, technological innovations have improved and will continue to contribute to diabetes care quality improvements; however, we have yet to alleviate the daily burden for those living with T1D (53). Emotional influences are potential drivers for sustained self-management, highlighting the importance of clinicians being attentive to and addressing the emotional aspects of living with T1D (38).

1.3 Emotional burden of diabetes

Due to the nature of the disease, people with T1D never get 'time off', which constitutes a great burden for the individual. Although far from everyone develops long-term complications, fear of vision loss, kidney failure and nerve damage can cause concern and negatively impact the person's perceived quality of life. Population-based studies and reviews have demonstrated that the well-being of many people with T1D is impaired through reduced health-related quality of life (54), experiencing anxiety or depression symptoms (55, 56), eating disorders and insulin restriction (55, 57), fear of hypoglycaemia (58) and diabetes distress (59).

1.3.1 Diabetes distress

Introduced in the mid-1990s, the construct *diabetes distress* (also known as diabetes-specific distress or diabetes-related distress) reflects the emotional impact of living

with and self-managing diabetes (60-63). The construct is operationalised to include a range of emotional experiences such as feeling overwhelmed or frustrated by self-management demands and diabetes-related stressors, as well as feelings of guilt, burden, worry, sadness and fear, and dissatisfaction with interpersonal relations and support from significant others and/or healthcare providers (64, 65).

Diabetes distress is content-related and an expected response to the demands of diabetes that impact on well-being (61). Furthermore, diabetes distress is an affective state, not a trait, which may vary significantly by distress source and over time (66). In addition, mild distress cases may develop into severe, chronic distress if left untreated (67). Diabetes distress is not considered psychopathology and is distinct from depression (61); however, a risk factor for the incidence and persistence of depression (68). Furthermore, diabetes distress and depression can exist separately or co-occur, suggesting a bidirectional relationship (69).

About 20-40% of people with T1D experience elevated or severe diabetes distress (59, 70). Regimen distress, fear of hypoglycaemia and complications, feeling overwhelmed and burned out and worrying about the future is most commonly reported (59, 71). One in four people with diabetes reports elevated levels of diabetes distress likely to impact clinical outcomes (72). Cross-sectional and longitudinal studies have investigated associations between diabetes distress and various demographic, clinical and social aspects. Diabetes distress is reported to be more prevalent among younger than older adults (73), which is possibly linked with shorter diabetes duration (70) and specific age-related challenges (73). Furthermore, women typically report higher distress levels than men (72, 74-76). There are also reports of associations between diabetes distress and problematic self-management behaviours related to insulin treatment and glucose monitoring (73, 77, 78) and between diabetes distress and unsatisfactory glycaemic control (73-81). These associations appear to be driven by regimen distress (75, 79, 81, 82). Moreover, lack of social network or low social support is associated with higher distress levels (70, 74).

The causal impact of diabetes distress on self-management behaviour and glycaemic control is not properly understood (62). Bidirectional relationships are likely since distress may influence glycaemic control indirectly via its impact on self-management or vice versa. Diabetes distress related to self-management problems and/or poor glycaemic control may lead to feelings of guilt, worries and fears (62, 71). Further, diabetes non-acceptance and fear of hypoglycaemia can cause less optimal treatment behaviour and poor glycaemic control. However, individuals that reach recommended treatment goals for glycaemic control are not exempt from experiencing diabetes distress (71).

1.3.2 Monitoring diabetes distress

Since diabetes distress is content-related, different interventions are required for different distress sources (e.g. worry about the future, concern about not performing enough glucose tests and fear of hypoglycaemia) (61). The "Monitoring of Individual Needs in Diabetes" study suggested that intervening on diabetes distress could be as straightforward as screening and discussing scores and outcomes in routine clinical appointments (83, 84). The authors claim that clinicians may be able to distinguish whether an individual is likely experiencing diabetes distress or symptoms of depression by addressing content and severity and thereby taking the appropriate actions according to their findings. A systematic review of intervention studies assessing diabetes distress in T1D found that numerous studies have measured diabetes distress but that few interventions have specifically targeted it (59). Further, the review identified a lack of interventions targeting elevated diabetes distress in younger adults. The authors listed goal-setting, problem-solving, reflection, supportive listening and addressing emotional challenges as aspects that seemingly offered greater reductions in diabetes distress but also in HbA_{1c} (59).

Routine monitoring of emotional well-being among people with diabetes was first recommended in 1994 (85). Since then, several diabetes guidelines and position statements have done the same (3, 86-89); however, regular assessment is still not the rule (90). In addition, renowned researchers in the field suggest that all people with diabetes may benefit from a routine follow-up where diabetes distress is

acknowledged as an expected part of diabetes (60, 61). Especially young adults who are undergoing a particularly vulnerable phase, which warrants further focus on diabetes distress and self-management issues (73). Others have suggested that addressing diabetes distress alongside biomedical measures may improve patient-provider collaboration (91).

1.4 Diabetes follow-up in the healthcare services

People with T1D need skills and confidence to manage their treatment regimen in daily life. Also, they need lifelong healthcare services, but their follow-up requirements vary according to life events and transitional phases (92-94). According to US estimates, people with diabetes spend less than 1% of their lifetime with healthcare providers (or 1.5 twenty-minute consultations per year) (95). Besides providing a range of biomedical services and interventions, healthcare providers have a crucial role in care delivery and providing informed expert support and structured self-management training (40). Furthermore, patient-provider relationships influence psychological and somatic treatment outcomes and are therefore of utmost importance (96, 97). Long-term support by competent healthcare providers responsive to individuals' needs is recommended since self-management training does not necessarily result in immediate adoption and maintenance of skills or behaviour changes (98), which poses challenges for the services and makes testing new intervention initiatives more challenging for researchers.

1.4.1 Routine follow-up

The Norwegian diabetes guideline recommends that people with T1D are offered interdisciplinary follow-up by specialist healthcare services (hospital outpatient clinics or private specialist care) (9). This follow-up should be tailored to the individual's needs, with at least one consultation per year. The hospitals' diabetes teams involved in outpatient care typically consist of physicians (with or without specialisation in endocrinology or internal medicine), nurses and diabetes specialist nurses. Several clinics also receive support from clinical nutritionists, podiatrists, social workers, and other physician specialities such as ophthalmologists,

nephrologists, cardiologists and neurologists. To date, most Norwegian diabetes outpatient clinics do not employ psychologists or psychiatrists.

Clinic non-attendance is a significant worldwide problem associated with younger age and subsequent suboptimal outcomes (99). Reasons for non-attendance are diverse, but lack of patient-provider relationships and perceived follow-up benefits have been identified as important barriers for regular attendance (100).

1.4.2 Empowerment-based follow-up

Most adults with T1D wish to engage with healthcare providers and discuss their self-management and emotional challenges during follow-up (50, 93, 101-103). However, studies report that adult healthcare services focus more on glucose levels and other biomedical measures than the adults' total life situation (47, 101, 104, 105). In a Norwegian study about the transition from paediatric to adult T1D care, young adults reported being less satisfied with adult care (105). The participants described a follow-up characterised by routine and biomedical checklists that were less personal with less focus on the psychosocial aspects than they had been accustomed to in paediatric care. Hence, holistic, person-centred approaches adapted to individual needs for follow-up are called for, in addition to more time and more frequent visits. Especially among young adults, individual life priorities may lead to diabetes management and follow-up not being a top priority (46, 50).

Patient empowerment is acknowledged as a core value in achieving high-quality, person-centred healthcare (106). Empowerment is multidimensional and distinct interpretations of the concept have resulted in different definitions (107). Overall, empowerment-based approaches seek to strengthen peoples' general abilities and is, therefore, considered health-enhancing. Also, empowerment involves shifting the patient-provider relationship's power dynamics away from paternalism and towards collaboration (108). Since diabetes affects all aspects of a person's life, self-managing the disease requires the ability to make informed choices and decisions about treatment and self-care actions. Consequently, the philosophy of empowerment was proposed as relevant for diabetes care around thirty years ago (108, 109). This

thesis is based on a definition of the empowerment process as *"the discovery and development of one's inherent capacity to be responsible for one's own life […] people are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions and sufficient experience to evaluate the effectiveness of their decisions"* (109, p. 38).

The empowerment approach is described as collaborative, motivational and tailored to support patients in developing goals for managing their disease and making appropriate self-management decisions affecting their everyday lives (110, 111). Patient empowerment is seen as a process to achieve (or regain) control where the healthcare providers facilitate and offer information and knowledge to assist the patients in making informed decisions. For guiding patient-provider relationships, empowerment is acknowledged as an alternative to the paternalistic compliance-oriented approach (107). However, the success of empowerment seems contingent on person-centredness and patient-provider communication quality (112).

According to systematic reviews, empowerment-based interventions for people with diabetes can improve health status, including biomedical, psychosocial and self-management outcomes (113, 114). Hence, empowering people with T1D is valuable; nevertheless, it depends on providers implementing a person-centred approach, acknowledging the patients' main concern and experiences (107). Core elements and outcomes of empowerment-based interventions include identifying problems or concerns, goal setting and action planning, self-management, communication, problem-solving and reflection on changes (107, 115).

1.4.3 Patient-Reported Outcome Measures

A Patient-Reported Outcome (PRO) is defined as *"a measurement of any aspect of a patient's health that comes directly from the patient without interpretation of the patient's response"* (116, p. 101). Currently, PROs are considered essential in the movement towards empowerment-based and person-centred systems for structuring, monitoring and delivering healthcare (117, 118). PROs can be captured by Patient-Reported Outcome Measures (PROMs), typically self-report questionnaires, that

assess various health-related constructs (119). PROMs were originally developed for research purposes and to obtain self-reports regarding issues and information that could not be assessed objectively by an observer or researcher (120). Integrating PROMs in clinical practice has the potential to improve care for people with diabetes by identifying patients' problems and preferences through systematic screening, improving patient-provider communication, promoting self-management, facilitating shared decision making, monitoring progress over time and tailoring follow-up (117, 119, 121, 122). In an overview of systematic reviews reporting on PROM use in routine cancer care, PROMs were found to improve pain management, symptom detection and patient-provider communication, in addition to increasing patient involvement and the use of supportive care (123). However, the authors highlight that healthcare services must be adequately resourced to respond to the patients' needs.

Capturing PROMs electronically

PROMs can be administered on paper, web-based systems or electronic devices. Systematic reviews and meta-analyses report that administrating PROMs on paper or electronic interfaces produce equivalent data (124-127). Electronic capturing also has clear benefits that can produce higher quality data by reducing missing and unusable data, such as only allowing one response option per item and not permitting continuation before all items are completed (128-130). Electronically captured PROMs can be transferred to or integrated into the electronic patient records (EPR), which involves less administrative burden and responsibility and reduces potential errors in secondary data entry (128, 129). Electronic completion is typically preferred by patients and researchers over paper-based methods and might also be less time consuming or faster (127, 130, 131).

1.4.4 Patient-provider communication

Although essential in recognising individual needs, the psychological and emotional impact of living with diabetes has been largely unrecognised and greatly underreported by clinicians (132, 133). For healthcare providers to engage the patient as an active partner in the clinical setting, they must know the person behind the patient and establish a partnership (134). The first step is listening to the person's

narrative. Using PROMs for screening purposes and as dialogue tools can enhance patient-provider communication and support patients to disclose or express their symptoms, worries or challenges (135, 136).

When collected for use in clinical care, PROMs should be accompanied by a review and discussion of scores to elaborate on identified issues (121, 136, 137). Providers can use communication techniques to assist and support patients in the empowerment process (138, 139). Based on a positive atmosphere where providers demonstrate an interest in the patient, communication techniques entails asking attentive questions and using active listening, allowing patients to express emotions and take the necessary time, offering emotional and autonomy support and individualised information and advice, encouraging the patients to set goals and participate in decision-making and finally asking them to evaluate their efforts (107, 139). Empathy-based communication seems likely to catalyst improved self-management, further facilitating changes that lead to increased well-being (97).

1.5 Rationale for the thesis

Integrating assessment of diabetes distress using PROMs and empowerment-based communication techniques as dialogue tools can improve care for people with diabetes and enable them to become more involved in self-management. Hence, there is a rationale for collecting and using PROMs in clinical diabetes practice to support individual patients' care (119, 140). Regular assessment of diabetes distress is recommended to promote the recognition of psychological and emotional challenges that affect diabetes self-management (60, 61). Previous studies have shown that using PROMs to monitor diabetes distress followed by a discussion of outcomes is feasible and beneficial in terms of improving well-being in adults with diabetes (83, 84, 141). To our knowledge, there has not been a systematic evaluation in Norwegian diabetes care services. Thus, before implementing PROMs and empowerment-based communication techniques as dialogue tools in clinical consultations, research is needed to evaluate their feasibility, acceptability and effect.

2. Aims

The overarching aim of the Diabetes Patient-Reported Outcome Measures (DiaPROM) trial is to develop, test and evaluate an empowerment-based intervention using the patient-reported Problem Areas in Diabetes (PAID) scale as a dialogue tool in outpatient consultations among young adults with T1D. We propose that the intervention will reduce diabetes distress and improve overall emotional well-being, perceived competence in diabetes management and glycaemic control.

The overall aim of the studies conducted as part of this thesis was to feasibility and pilot test the DiaPROM trial, thereby investigate uncertainties associated with running a full-scale randomised controlled trial (RCT). The specific aims were as follows:

1. To examine the feasibility and acceptability of capturing PROMs electronically on a touchscreen computer in clinical diabetes practice (Paper I).
2. To develop a study protocol for the DiaPROM pilot trial (Paper II).
3. 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 (Paper III).
4. To explore young adults' experiences with outpatient follow-up appointments, completing electronic PROMs and using the PAID scale during the DiaPROM pilot trial (Paper IV).

3. Materials and methods

3.1 Study designs

The DiaPROM trial's overarching design is a complex intervention that consists of several interacting components and a number of behaviours required by those receiving and delivering it (142). Our work was guided by the Medical Research Council's (MRC) framework for developing and evaluating complex interventions in health (142, 143), which describes a stepwise approach for developing, feasibility and pilot testing, evaluating and implementing an intervention (Figure 1).

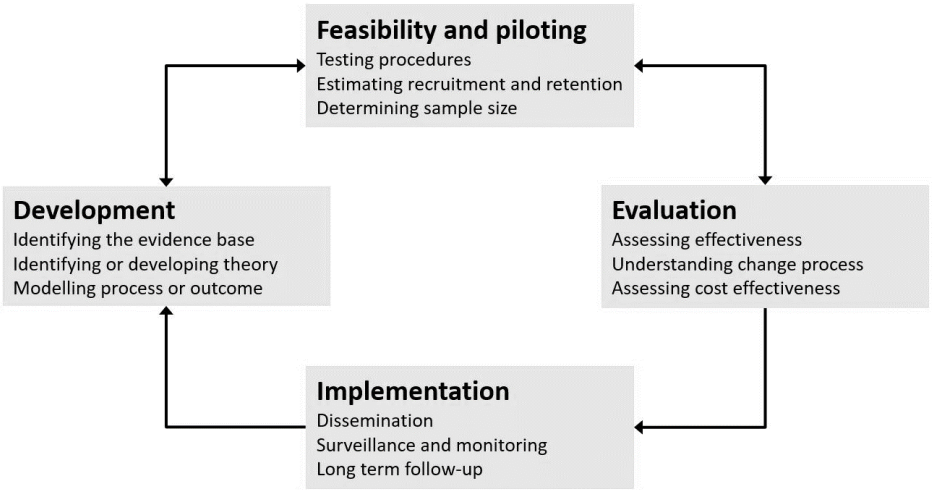

Figure 1. *Phases and key components of developing, testing, evaluating, and implementing a complex intervention (based on a figure in Craig (142)).*

This thesis consists of studies from the feasibility and pilot phase of a complex intervention. While the terms *feasibility* and *piloting* have previously been used interchangeably, we have applied Eldridge et al.'s framework for defining such studies (144). Here, feasibility is considered an overarching concept involving all studies in preparation for the main evaluation trial. Thus, all pilot studies are feasibility studies, but not all feasibility studies are pilot studies. Specifically, feasibility studies address and test specific intervention components, procedures or

parameters important for conducting a full-scale trial (144). In comparison, pilot trials assess the feasibility of an entire set of procedures for a full-scale evaluation trial but on a smaller scale (and without testing hypotheses about the intervention's efficacy) (144).

Using different methodological approaches is considered appropriate in the feasibility and piloting phase of an intervention initiative (145, 146). Addressing uncertainties about an intervention by collecting quantitative and qualitative data may provide a more comprehensive assessment of feasibility and acceptability than applying solely quantitative measures (145, 146). Therefore, we designed quantitative and qualitative studies intended to complement each other (Table 1). First, we conducted a feasibility study with cross-sectional data (paper I). The subsequent pilot trial was designed as a two-arm RCT with baseline and 12-month data collection points (papers II & III). Finally, we undertook a qualitative study where a sample of the pilot trial participants was interviewed (paper IV).

***Table 1**. Overview of the study designs and samples.*

	Feasibility study	**Pilot trial protocol**	**Pilot trial**	**Qualitative study**
Paper	I	II	III	IV
Design	Cross-sectional study		Two-arm RCT	Qualitative interview study
Sample	N=69 adults with type 1 diabetes aged ≥40		N=79 adults with type 1 diabetes aged ≥18-<40 - Intervention arm n=39 - Control arm n=40	N=19 recruited from the pilot RCT - Intervention arm n=11 - Control arm n=8

Moreover, in paper II, we outlined interviewing the healthcare providers engaged in the pilot trial. The study has been conducted (147), and although it is not part of the thesis, the results are considered in the general discussion.

3.2 Study setting and recruitment

The DiaPROM feasibility study and the pilot trial took place at the endocrinology outpatient clinic at Haukeland University Hospital, Bergen, where about 1500 adults

with T1D received follow-up during 2017-2019 (13, 148, 149). According to the NDR-A, 39% of the clinic's T1D population used insulin pump therapy, and 43% had a continuous glucose monitoring device in 2019 (13). These numbers are, respectively, 5% above and 3% below the national average. The clinic employs endocrinologists, physicians specialising in endocrinology (or other internal medicine specialities), diabetes nurse specialists and health service secretaries.

Recruitment for both the feasibility study and the pilot trial was performed by identifying eligible participants from the endocrinology outpatient clinic's planned consultations. One to two weeks prior to the consultations, invitation letters with consent forms were sent by postal mail to eligible participants. A project group member was present in the clinic to assist participants and clinicians. In the qualitative study, we recruited pilot trial participants who had attended their 12-month follow-up visit by contacting them by mail 3-7 days after this visit.

3.3 Study participants

In all three studies, eligible participants were adults with T1D and a minimum one-year diabetes duration. We applied the following exclusion criteria obtained from the EPR: pregnancy, cognitive deficiency (e.g., Down's syndrome, Alzheimer), severe medical 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 the burden of completing PROMs and addressing the responses might be too challenging for these groups of patients. Also, information about language or vision indicating that the person could not complete the electronic PROMs was applied as exclusion criteria.

The sampling for the feasibility study and the pilot trial was consecutive. In the feasibility study, we invited adults ≥40 years to avoid including potential participants for the upcoming pilot trial, where we invited younger adults aged 18-39 years. In the pilot trial, we used computerised concealed allocation to randomise the participants in a 1:1 ratio to the intervention or control arm; 40 (50%) in each. Further, we stratified

by sex and used blocking to ensure equal numbers (20) of men and women in each arm. While in the qualitative study, we purposefully invited pilot trial participants who had attended and completed the 12-month follow-up.

3.4 User involvement

In health service research, the term *user involvement* refers to including and engaging service users as collaborators in the research process, for example, patients, informal carers, the public, healthcare providers and policymakers (150). The users' unique perspective adds complementary insights to those of the researchers. Therefore, involving service users is found to improve research relevance, appropriateness and quality (151). In the DiaPROM project's development phase, we invited a group of service users to collaborate in developing the intervention. The group was recruited from the Diabetes Association and consisted of people with lived experience of T1D and parents to people with T1D. Two of the service users were included in the DiaPROM project group, both previously experienced with user involvement in research. Overall, the users contributed to the research agenda and design, the intervention's content, data analyses and dissemination (152, 153). Specifically, we consulted the group before choosing diabetes distress as the intervention's focus. Further, the users provided input and opinions on the PROMs, the electronic collection of PROMs and the intervention's communication techniques. Moreover, in the qualitative studies, one user was included as a co-researcher contributing to study designs, preparing the interview guides, data analyses and writing the papers.

3.5 Data collection

3.5.1 Sociodemographic and clinical diabetes-related data

The following sociodemographic and clinical diabetes-related data were collected from the participants' electronic patient records (EPR); age, sex, ethnic origin, diabetes duration, diabetes long-term complications, comorbidities, body mass index, HbA_{1c} level, symptomatic hypoglycaemic events the previous month, history of hypoglycaemic events requiring assistance, history of hospitalisation due to

ketoacidosis and insulin injection device. In addition, we collected self-reported electronic data from the touchscreen computer on the use of glucose monitoring device and glucose measurement frequencies. Finally, we obtained information concerning first language, educational level, cohabitation status and work affiliation, in addition to the acceptability of completing PROMs electronically on a touchscreen computer from a paper-based questionnaire.

3.5.2 Self-report questionnaires

The electronic self-report questionnaire completed by participants in both the feasibility study and the pilot trial contained 47 items in total (Appendix 1); five validated PROMs (42 items), three glucose variability items developed for the studies and two items concerning current glucose monitoring device and glucose measurement count (daily/weekly), as these variables were not available in the EPR at the time.

In Table 2, details about the validated PROMs and the glucose variability items are provided. Briefly, we used the Problem Areas in Diabetes (PAID) scale to identify and assess diabetes distress (64, 154, 155). The World Health Organisation 5-item Well-being Index (WHO-5) was included as a measure of overall emotional well-being (156, 157). We used the Perceived Competence for Diabetes Scale (PCDS) to map self-perceived ability for diabetes self-management (158, 159). Further, we included the 'Gold scale' to assess hypoglycaemia awareness (160) and the RAND-12 Health Status Inventory (RAND-12) to map health-related quality of life (161, 162). In addition, we developed three items asking the participants to assess their self-perceived occurrence of hyperglycaemia, hypoglycaemia and fluctuating glucose levels over the latest couple of weeks.

Pilot trial participants also completed the Diabetes Distress Scale (DDS) on paper at baseline and 12-month (Appendices 3 & 4). The DDS yields an overall diabetes distress score and four subscales (Table 2): emotional burden (5 items), physician-related distress (4 items), regimen-related distress (5 items) and diabetes-related interpersonal distress (3 items) (163, 164).

We asked all feasibility study and pilot trial participants (baseline and 12 months) to complete a paper-based questionnaire after completing the electronic PROM and the consultations (Appendices 2, 3 & 4). The item wording and response alternatives were based on the Norwegian Institute of Public Health's user experience questionnaires (165). Specifically, we asked about first language, educational level, marital/cohabitation status and work affiliation. In addition, we asked them about the relevance of the PROMs, acceptance of the number of items, the preferred method for completing PROMs and willingness for annual completion. Pilot trial participants were also asked about the consultations with physicians and nurses, specifically if and how the PAID was used during the consultations, and if they found the conversations with the clinicians acceptable and useful (Appendices 3 & 4).

Table 2. *Overview of PROMs collected during the DiaPROM feasibility and pilot phase (in order of completion).*

Title	Abbrev.	Construct	Items	Scales	Score	Interpretation	
WHO-5 Well-being index[3]	WHO-5	General emotional well-being	5	6-point scale. [0] never to [5] all of the time. 0-100 score is obtained by multiplying the sum score (0-25) by 4.	0-100	≤50 <28	Indication of suboptimal well-being and further testing is recommended. Likely depression.
Problem Areas in Diabetes scale	PAID	Diabetes distress	20	5-point scale. [0] no problem to [4] serious problem. 0-100 score is obtained multiplying the sum score (0-80) by 1.25.	0-100 Item score	 ≥40 ≥3	Higher scores indicate more distress. Serious diabetes distress. Source of distress.
Perceived Competence in Diabetes Scale[3]	PCDS	Perceived diabetes competence	4	7-point scale. [1] strongly disagree to [7] strongly agree. Scores are summated and divided by 4 to form a mean score.	1-7	-	Higher scores indicate better perceived competence.
Gold Scale[1]	Gold	Awareness of hypoglycaemia	1	Visual analogue scale of 1 to 7. [1] always aware to [7] never aware. Item score.	1-7	≥4	Higher scores indicate lower awareness of hypoglycaemia. Impaired awareness.
High/Low/Varied glucose levels[1,#]	-	Perceived glucose variability	3	Visual analogue scale of 1 to 7. [1] not at all to [7] most of the time. Item scores.	1-7	-	Lower scores indicate better perceived control over blood glucose fluctuations.
RAND-12 Health Status Inventory[1]	RAND-12	Health-related quality of life	12	Response options differ. The physical health component (PHC) and the mental health component (MHC) has 6 items each.	0-100 PHC & MHC	>50 40-49 30-39 <30	Indicates person is likely to be well. Indicates mild disability. Indicates moderate disability. Indicates severe disability.
Diabetes Distress Scale[2]	DDS	Diabetes distress	17	6-point scale. [1] no problem to [6] very serious problem. Scores are summated and divided by 17 to form a mean total score.	1-6	<2.0 2.0-2.9 ≥3.0 (≥ 2.0	Little or no distress. Moderate distress. Serious diabetes distress. Clinically meaningful distress.)

[1] Scores not reported in the papers. [2] The pilot trial's primary outcome (completed on paper). Yields four subscales: emotional burden, physician-related distress, regimen-related distress, diabetes-related interpersonal distress. [3] Secondary outcomes in the pilot trial. [#] Developed for the feasibility study.

3.5.3 Collecting electronic PROMs

We used a stationary 17″ touchscreen computer for the technical and practical procedures for collecting PROMs. DIPS AS, the leading supplier of eHealth systems to Norwegian hospitals, developed the software application for completing the PROMs, a secure data repository for temporary PROMs data storage and the method for transferring these data to the participants' diabetes-specific hospital records (166). The diabetes-specific record is also the Norwegian Diabetes Register for Adults' electronic tool for collecting register data from outpatient clinics (167). Project funds paid for the computer and the software application.

The computer was located next to the outpatient clinic's waiting area to ensure visibility. The participants were not required to log in. By tapping the screen, they found information concerning the data collection procedure and the measured constructs. Next, the PROM items appeared one at a time (Figure 2). Further details about how the participants completed the PROMs are provided in paper I. In addition to PROM scores, the software registered the minutes and seconds used to complete the PROMs and also the number of completed and missing items.

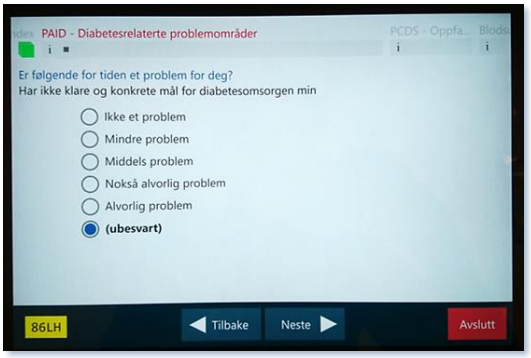

Figure 2. *Example of a PROM item presented on the computer screen.*

3.5.4 Individual interviews

In the qualitative study (paper IV), we used individual interviews. The pilot trial participants were offered either a face-to-face or a telephone interview, and we asked them to suggest the time and place. The semi-structured interview guide was

developed jointly in the author group, which included a service user. We used open-ended questions pertinent to the study's aim (Appendix 5). The guide was piloted in the first two interviews to assess its relevance and usefulness, which led to minor adjustments.

The PhD candidate conducted the interviews, which were audio-recorded. The overall intention was for all participants to openly communicate their views and experiences and the meanings they assigned to them. This was emphasized by conveying that no right or wrong answers existed and striving to conduct the interviews in a non-judgemental manner. First, we invited all participants to share their experiences with previous diabetes outpatient follow-up visits. Next, they were asked about specific pilot trial experiences, i.e., the electronic completion and relevance of the PROMs. The intervention arm participants were also encouraged to share experiences with the physicians' review of the PAID scores and, where relevant, with attending additional diabetes specialist nurse consultations. After the interviews, the interviewer wrote reflection notes. The data were transcribed verbatim within a maximum of three days, also marking pauses and sound utterances. Later, all transcripts were checked against the recordings for accuracy.

3.6 The DiaPROM intervention

The DiaPROM intervention consisted of interacting components, which required several behaviours from its participants and the physicians and diabetes specialist nurses delivering it (Figure 3). At baseline, each participant completed the electronic PROMs (Table 2) on the touchscreen computer prior to his or her annual diabetes consultation. The physician then downloaded the PROMs to the participant's EPR guided by a study manual (Appendix 6), which also described the computerised and random allocation of participants to either an intervention or a control arm. The physician informed the participant about the allocation directly after the PROMs had been downloaded. Then the participant received follow-up according to trial arm allocation, as described below. At 12 months, all participants completed the PROMs again.

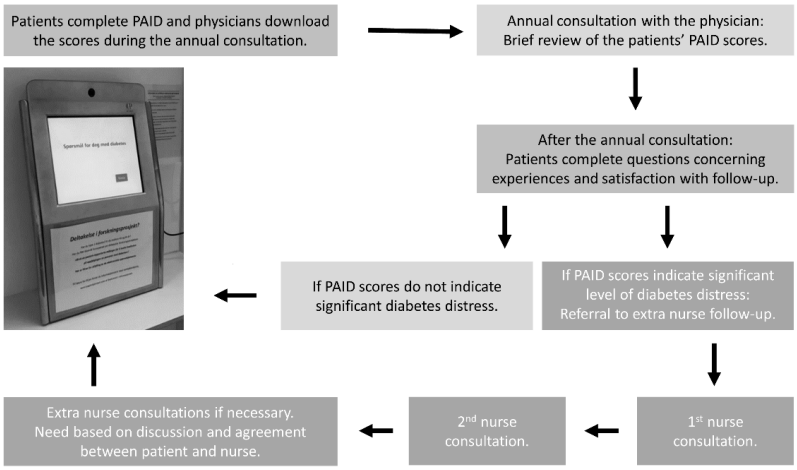

Figure 3. *The intervention flow chart (reprinted from paper II).*

3.6.1 Intervention arm procedures

After the intervention arm participants' PROMs had been downloaded, the physicians proceeded with reviewing the PAID, developed to identify and measure diabetes distress and standardised primarily for adults with T1D (64, 154, 155). The PAID is widely used and translated into multiple languages, including Norwegian (75). The twenty problem areas are rated on a 5-point Likert scale as 0 'not a problem', 1 'minor problem', 2 'moderate problem', 3 'somewhat serious problem' and 4 'serious problem' (Appendix 1). The scale yields an overall diabetes distress score of 0-100 (Table 2), indicating diabetes distress severity (155, 168). A total score ≥40 has been defined as serious diabetes distress (60, 155). Identifying specific sources of distress (e.g., items scored ≥3), also referred to as the 'red flag' approach, can serve as targets for intervention and conversation starters (155, 168).

In the intervention consultations, the PAID served as a tool to identify diabetes distress and a dialogue tool, or starting point, for conversations about diabetes distress (Figure 4). The physicians were instructed to identify total scores ≥30 and items scored ≥3 (marked with red bars in the EPR), which qualified for additional diabetes specialist nurse consultations (Appendix 6). Participants with scores <30 and items <3 were to receive no specific follow-up of their scores but rather usual follow-up.

We also asked the physicians to be attentive to the WHO-5 in case of scores suggesting depression and thus need for specialist follow-up.

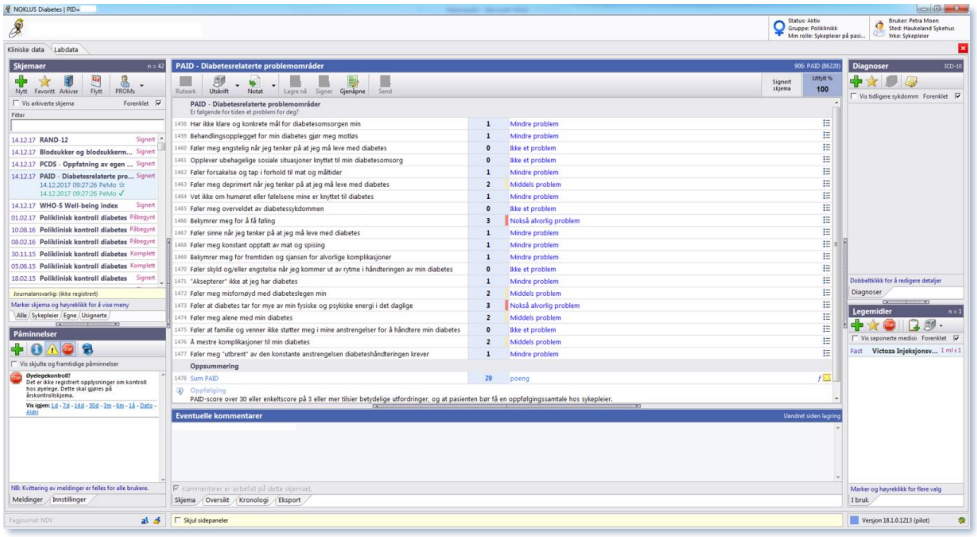

Figure 4. *The PAID scale as presented in the EPR.*

The additional nurse follow-up consisted of a minimum of two consultations (Figure 3). The first consultations were planned to take place within four weeks and the second within another three months. We developed a manual to guide and support the nurses through the consultations (Appendix 7). Step-by-step, the guide described how to use the PAID and the empowerment-based communication principles and techniques as dialogue tools in the consultations. On the manual's backside, we further elucidated the background for the communication principles. The specific techniques were *asking questions*, *listening*, *responding* and *summing up*. We also asked the nurse and participant to formulate and write down goals and actions and plan further follow-up based on the young adult's wishes and needs. At 12 months, we provided the physicians with an adapted manual with information about the PROM downloading procedure and the PAID (and WHO-5) review among intervention arm participants (Appendix 8).

3.6.2 Control arm procedures

For participants allocated to the control arm, the downloaded PROMs and their responses were not visible in the EPR neither at baseline nor at the 12-month visit. Hence, the controls did not receive a review of their scores. Instead, they were offered 'standard outpatient care', typically consisting of individual consultations at the outpatient clinic adapted to their needs (9). However, all people with T1D are supposed to receive at least one consultation per year with a physician (9). This annual consultation is characterised as a structured follow-up of glycaemic control and insulin dosage, assessment of symptoms and risks of microvascular and macrovascular complications and appraisal of treatment targets in cooperation with the patient; in addition, referral to other healthcare specialists if needed. Some also receive diabetes specialist nurse follow-up, typically regarding specific challenges with glycaemic control or self-management issues, or for educational purposes and extra support.

3.6.3 Training the healthcare providers

Before the pilot trial commenced, we arranged two 1-hour meetings with the outpatient clinic's physicians in order to reach all of them. The participating physicians were trained in downloading the PROMs to the EPR (Appendices 6 & 8). They received oral information and written instructions on interpreting the PAID scores and were trained to briefly discuss the PAID scores in the annual consultations. In addition, instructions on the criteria for participants' referral to additional follow-up by the diabetes specialist nurses were provided in the manual (Appendix 6). Before the 12-month follow-up, we repeated the physicians' training.

The diabetes specialist nurses participated in the meetings with the physicians before baseline. Further, they received written information prior to the 2×1 hours of specific training, which entailed interpretation of the PAID scores, discussion of the reported problem areas with the participants, in addition to how to follow the communication manual and agree on goals and actions to take with the participants (Appendix 7). All of the nurses had previously taken part in a group-based guided self-determination RCT (169), where they had completed a competence programme consisting of

multiple training sessions and workshops (170). The guided self-determination trial and the present pilot trial's communication principles, presented in the training and the manual, were based on key empowerment-based elements, such as empathetic communication and autonomy support.

3.6.4 Primary and secondary outcome measures

In the pilot trial, primary and secondary outcomes were measured at baseline and 12 months. The choice of outcome measures to assess the intervention's effect in a full-scale evaluation trial was based on a literature review and consultation with the user group, in addition to considerations within the project group. We decided on diabetes distress measured by the DDS as the primary outcome. Compared to the PAID, we found that the DDS appeared advantageous as an outcome measure due to its distress subscales (75, 171). Further, the scale has been shown to have satisfactory internal reliability and validity (163). The Norwegian version has also demonstrated high internal consistency and test-retest reliability (75).

Further, we decided on overall emotional well-being, perceived diabetes competence and glycaemic control measured by the WHO-5, the PCDS and HbA_{1c} (mmol/mol) as the secondary outcomes. The WHO-5 has been shown to have psychometrically sound properties as an outcome measure and for clinical use among people with diabetes (156, 157). Also, the PCDS has demonstrated good internal reliability and validity and high internal consistency (158, 159, 172).

3.7 Data analyses

3.7.1 Statistical analyses

Statistical analyses were carried out using Stata SE for Windows, versions 15 and 16 (173). For each study, we registered the number of invited participants. In both the feasibility study and the pilot trial, we registered how many attended their appointments, how many were excluded and how many declined to participate. Finally, we calculated the proportion of people who consented. All three study samples' demographic and clinical characteristics were presented using descriptive

statistics. We used frequencies and percentages to describe categorical variables and either medians and minimum-maximum or means and standard deviations (SD) to describe continuous variables.

Before analysing the validated PROMs, we quantified the proportion of missing items and subsequently handled these using person-mean substitution if at least 50 % of the items per scale were completed (174, 175). In both the feasibility study and the pilot trial, we calculated frequencies, percentages and proportions of participants with diabetes distress scores qualifying for additional follow-up. We quantified the self-report variables concerning experience with participation and opinion about the various intervention components using frequencies, percentages and proportions. In the feasibility study, we also examined differences in the diabetes distress scores reported by male and female participants using t-tests and chi-square tests, and Cronbach's alphas were calculated to estimate the internal consistency of the PROMs.

In the pilot trial analyses, we used t-tests to estimate means, SD and 95% confidence intervals (CI) of SDs of outcome measures for each trial arm at baseline and 12 months. For each of the time points, we used paired t-tests to calculate the within-group variation of paired differences in the outcome measures' means and SDs. To estimate means and 95% CIs of between-group differences, we used a mean-comparison test calculator. We also compared the non-responders with the study population regarding sex, age, diabetes duration and HbA_{1c}. Using Spearman's rho, we estimated correlation with 95% CI between participants' primary outcome measure (DDS) scores at baseline and 12 months. The primary outcome measure's SD, 95% CI of SD and correlation coefficient was used to assist in the sample size calculations for an evaluation trial. In the pilot trial, we did not test the intervention with the intent of inferring or reporting effects; thus, the results are reported without p-values.

3.7.2 Qualitative analyses

We analysed the interview data using Braun & Clarke's thematic analysis (176). The analysis method is theoretically flexible and can be approached inductively or deductively. Thematic analysis focuses on identifying, analysing, and reporting themes (patterned meaning) across a dataset (176, 177). It is characterised as an iterative, thorough six-phase process of data familiarisation, coding, development of themes and revision (Table 3). Further, code development can be semantic and explicit or on a latent level that involves progression from description to interpretation (177). We applied an inductive, data-driven approach for generating codes and themes. Our coding was primarily semantic, focusing on the participants' explicit experiences. However, as the analysis progressed, the code and theme development became more oriented towards the latent level and implicit meaning.

The analysis team consisted of seven researchers, all experienced in the field of diabetes. We followed the six phases of analysis described in Table 3.

Table 3. *Phases of thematic analysis according to Braun & Clarke.*

Phases	Description of the process
1. Familiarising yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report	The final opportunity for analysis. Selection of vivid, compelling extracts, final analysis of selected extracts, relating the analysis back to the research question and the literature, producing a scholarly report of the analysis.

First, we worked individually to familiarise ourselves with the transcribed interview data and to prepare initial ideas of codes (phase 1). Then we met remotely on a video-conference platform for a two-day workshop in May 2020. Each team member first shared their initial ideas about the data. We continued discussing interesting features of the data that were relevant to the aim, which led to us generating initial codes (phase 2). Later we collated the codes by patterns in a schematic overview before searching for potential candidate themes by identifying similarity and clustering (phase 3). After the workshop, the PhD candidate continued reviewing and naming the potential themes and subthemes (phase 3 & 4). When the team met for a second remote workshop in June 2020, we jointly reviewed and refined the themes and subthemes (phase 4 & 5). Defining and naming the themes (phase 5) continued while the written report of the findings was prepared (phase 6). As the manuscript developed, the team members agreed on the themes and subthemes' wording and the selection of quotes.

3.8 Ethics

The studies in this thesis were conducted according to the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (178). The Western Norway Regional Committee for Medical and Health Research Ethics approved the studies. The reference numbers are 2016/2200/REK vest (Appendix 9) and 2017/1506/REK vest (Appendix 10). Haukeland University Hospital is the responsible research organisation. All participants received written study information and provided written consent (Appendices 11 & 12). Digital quantitative datasets and qualitative data (audio recordings and transcripts) are stored on the hospital's secure research server in an encrypted repository only accessible for the PhD candidate and DiaPROM project leader.

In the qualitative study, the pilot trial participants were asked to choose between a face-to-face or telephone interview and to suggest a time and place. Before the interviews started, the interviewer asked for permission to use an audio recorder and emphasised the importance of, e.g., asking her to rephrase questions if they did not

hear or understand. The interviewer started the recordings after the participants had consented, and pauses were provided if needed. Afterwards, the participants were allowed time to debrief. Due to the interviewer's experience as a diabetes nurse specialist, she also provided information about how to get in touch with the outpatient clinic for guidance and support when this seemed necessary.

4. Summary of results

The four papers included in this thesis have different aims and methods. Nonetheless, the papers are interconnected and constitute a project that increases our understanding of the piloted intervention's feasibility and participant acceptability. In the feasibility study (paper I), we gained experience about the acceptability and technical feasibility of completing electronic PROMs on a touchscreen computer. Using electronic PROMs, we identified that about half of the participants reported clinically significant diabetes distress levels (papers I and III). Overall, the studies uncovered uncertainties with intervention feasibility and acceptability, thereby suggesting that we need to undertake modifications and additional development before commencing a full-scale RCT. We also gained insights into how the participants experienced and were affected by completing the PAID and using it in the consultations (paper IV).

Table 4 provides an overview of the characteristics of the study participants. A summary of results from each study will be presented in the following chapters.

Table 4. *Characteristics of the study participants.*

	Feasibility study	**Pilot trial**	**Qualitative study**
Participants (n)	69	79	19
Men/Women	35/34	39/40	8/11
Age (years)	51.0 (40-74)	27.2 ±5.0	29.8 ±5.2
Diabetes duration (years)	26.0 (1-67)	13.7 ±7.0	16.4 ±7.4
Late complications	35 (50.7)	16 (20.3)	4 (21.1)
Retinopathy	28 (40.6)	15 (19.0)	4 (21.1)
Nephropathy	7 (10.1)	1 (1.3)	0 (0.0)
HbA_{1c} (mmol/mol)	60.7 (41.0-107.7)	65.4 ±14.5	59.0 ±11.7
HbA_{1c} (%)	7.7 (5.9-12.0)	8.1 ±1.3	7.5 ±1.1
CSII	26 (37.7)	38 (48.1)	12 (63.2)
CGM	16 (24.2)	22 (27.9)	10 (52.6)

Feasibility study: Data are n/n, n (%) or median (range). Pilot trial & Qualitative study: Data are n/n, n (%) or mean ± SD. HbA_{1c}; Haemoglobin $A_{1c.}$ CSII; Continuous Subcutaneous Insulin Infusion. CGM; Continuous Glucose Monitoring.

4.1 Paper I

In this feasibility study, we experienced that the computer software largely performed as expected, but some minor alterations were performed. Most participants had to be shown the location of the computer. Completing the PROMs took a median time of 8 min 19 sec, and 29 of 69 participants (42.0%) completed the questionnaire without missing items, with an average measure completion rate of 81.4%. Furthermore, the majority of participants reported that the PROMs were understandable and relevant to a large or very large degree, with an acceptable number of items. The participants also reported that they valued that the PROMs covered psychosocial aspects of living with diabetes.

4.2 Paper II

The protocol paper describes the DiaPROM trial design, including a detailed description of its different components and our plans for conducting the pilot trial and qualitative studies. Further, we describe using the MRC framework in the development phase and planning the feasibility and piloting phase before potentially evaluating and implementing this new intervention initiative. The included PROMs with the process leading up to how we chose the specific instruments are also presented. Furthermore, we describe the technical and practical aspects for collecting the PROMs electronically, the intervention using the PAID scale in the diabetes consultations and the additional nurse follow-up of elevated scores, the control procedure and the clinicians' training. We present the outcome measures and data analyses and, finally, discuss key strengths and limitations.

4.3 Paper III

In the pilot trial, we found that it was feasible to recruit and randomise 79 young adults with T1D attending routine diabetes consultations to a trial using the electronically captured PAID to assess diabetes distress and communication techniques as dialogue support tools. Overall, the participants found the PROMs

relevant and were positive towards electronic completion. Twenty-three of the 39 (59%) intervention arm participants reported PAID scores that qualified for additional follow-up; 17 of these were referred, while five did not want a referral and one was not referred by the physician. At 12 months, we were able to retain 67 of the 79 (84.8%) participants. Further, we performed sample size calculations for a full-scale, single-site RCT. However, we identified implementation challenges related to the consultations. In addition, 5 of the 17 (29.4%) participants referred to additional consultations were lost to follow-up at 12 months. The high attrition rate suggests low acceptability or possibly over-inclusion of cases due to our choice of intervention criteria. We concluded that the pilot trial revealed design and deliverability problems, underlining the need to modify the intervention and perform additional testing before initiating a full-scale trial.

4.4 Paper IV

We recruited eight young adults from the control arm and 11 from the intervention arm, of whom six had attended additional diabetes nurse consultations. All 19 participants chose telephone interviews (average duration 39 minutes [range 26-75 minutes]). The thematic analysis of the data generated three themes, each with two subthemes. In the theme *Follow-up with limitations*, the participants shared their experiences with diabetes consultations at the outpatient clinic prior to the pilot trial (Table 5). In the subtheme *Marginal dialogue about everyday challenges*, they conveyed their perceptions about consultations, especially annual check-ups, that predominantly focused on biomedical outcomes without incorporating everyday self-management challenges and distress, which was considered negative. While in the subtheme *Value of supportive relationships and continuity*, they described a lack of continuity in care that hindered the development of trust-based, supportive patient-provider relationships, an important factor regarding their willingness to open up to clinicians and engage in conversations about their diabetes challenges.

The young adults' experiences with completing PROMs were described in the theme *New insights and raised awareness*. The subtheme *More life-oriented insights*

conveyed that the PAID contributed positively by creating an opportunity for reflective thinking about life with diabetes. While in the subtheme *Moving out of the comfort zone*, they shared challenges with completing PROMs and their thoughts about disclosing PAID responses in the follow-up. However, they also expressed appreciation for how the pilot trial addressed diabetes distress. Finally, in the theme *Addressing problem areas with an open mind*, the interviewees shared experiences using the PAID in consultations. The subtheme *Need for elaboration* depicted how completing the questionnaire made them want to disclose reasons for their choice of response options to nuance and explain. Further, in the subtheme *Preparedness for dialogue*, they described using the PAID to facilitate dialogue about diabetes-related challenges. Intervention arm participants also conveyed experiences with the additional follow-up, which suggested that neither they nor the nurses fully engaged with the planned intervention.

Table 5. *Themes and subthemes with quotes from paper IV.*

Theme	**Follow-up with limitations**	
Subthemes	Marginal dialogue about everyday challenges	Value of supportive relationships and continuity
Examples of quotes	*"I feel that I'm only there for them [physicians] to tick off something on a checklist and do their job in a way. … I feel that there's no point in being there then because what do I gain from them weighing me and measuring me? Uh. I don't feel that we're talking about important issues"*	*"A good relation is quite important for you to speak about things you might dread or be ashamed of. Or sorts of things that are about struggling with self-management or other things. So, I think about that relational competence bit and actually appreciating that there's some continuity. I think they still have some way to go in that regard."*
Theme	**New insights and raised awareness**	
Subthemes	More life-oriented insights	Moving out of the comfort zone
Examples of quotes	*"I mean, this is something I'll live with for the rest of my life, so it [diabetes distress] should've been opened quite early, so that one might've been prepared for things that can become difficult and that it can affect your head in many ways, plus your body too, physically. How your psyche and your head are affected by diabetes when you work with it all the time."*	*"Some questions [items] can be somewhat difficult and painful to respond to. If you really answer exactly the right thing, I guess that's really what can be a bit inhibiting, how honest you are with yourself. As a diabetic, you become a bit like... you lie to yourself sometimes (laughs), you think things are somewhat better than they really are. I mean, it's difficult at times, but I think some awareness and thoughts about how you're actually doing is a good thing. I think that's healthy."*
Theme	**Addressing problems areas with an open mind**	
Subthemes	Need for elaboration	Preparedness for dialogue
Examples of quotes	*"I felt that I responded honestly, but it was almost a bit … the nuance that 'yes, I'm very worried and I think this is very scary and…', but it's not as if I can't manage, like, or it's not as if… Yeah, there was a nuance that disappeared somewhat because in a way it's possible to be quite worried but still not so bothered by it."*	*"I think it was all right that the physician could see my [PAID] responses. Then the physician could address problem areas, or what I was dissatisfied with or worried about. We had something constructive to work from, it [the dialogue] didn't get as vague as… Yes, I find it difficult to put into words what I really want from appointments. It probably became more apparent in the questionnaire."*

5. Discussion

The overall aim of this thesis was to feasibility and pilot test the DiaPROM trial, thereby investigating uncertainties associated with running a full-scale RCT. In this section, methodological considerations, strengths and limitations will be discussed first, and then the main empirical findings.

5.1 Methodological considerations

In this thesis, different study designs tailored to our objectives were applied (179). The complexity of conducting the feasibility and pilot testing called for quantitative and qualitative methods, thereby increasing the possibility of achieving a broader understanding of the intervention initiative (180). While investigating the feasibility and acceptability of complex interventions in clinical realities, using both methods pragmatically by collecting multiple data types on objective and subjective aspects from multiple sources is considered advantageous and necessary (142, 143, 145, 181). We approached the investigation by first conducting a feasibility study and then a pilot trial, evaluating the intervention using quantitative methods. However, since humans are inherently complex and diverse, we would probably fail to capture the breadth of the feasibility and acceptability issues by using only quantitative methods. Consequently, we explored the participants' experiences and perceptions about the intervention's components using a qualitative approach. Combining deductive and inductive modes of reasoning provided empirical findings that complemented each other, improving our understanding of pilot trial successes and failures (182). In the pilot trial, we discovered that the intervention required modifications and additional testing. The specific weaknesses will mainly be discussed in the general discussion.

5.1.1 Developing a complex intervention

Developing, testing, evaluating and implementing complex interventions is a lengthy, resource-intensive process (142, 181). The updated MRC guidance highlights that inadequate development, feasibility testing and piloting will most likely result in

poorly designed and delivered interventions, more difficult to evaluate and, therefore, less likely implemented (181).

Intervention development

To address the knowledge gap regarding PROMs in clinical diabetes practice, we initiated the DiaPROM pilot trial development in 2016-2017. During the development phase, the project group decided on an intervention focusing on diabetes distress and consequently, its aim and the primary outcome was to reduce diabetes distress. In this process, user involvement helped us gain insight into patients' perspectives about the follow-up of diabetes-related challenges in general and diabetes distress in particular. The users' contribution in choosing diabetes distress as the intervention's focus and the PROMs to be used aided the development of a relevant and appropriate intervention (152).

Overall, we used validated PROMs found reliable for use among adults with T1D, which is important for a future evaluation trial's internal validity (183). At the time of the intervention development and presently (2021), the PAID and DDS were the standard self-report instruments for assessing and measuring diabetes distress among adults with diabetes (71). Both measures follow the International Society for Quality of Life Research's (ISOQOL) minimum standards for PROMs used in research (184) and are free of charge for clinical practice use. A paper comparing the measures suggested that the PAID covers a greater variety of emotional concerns than the DDS (171). Further, the authors stated that the PAID seemed better suited in the dialogue and for achieving targeted, goal-oriented clinical consultations. Hence, we decided on using the PAID as a tool to identify distress and as a dialogue tool in the follow-up, concentrating on the higher scored items (problem areas). In addition, core aspects of patient empowerment were followed, namely, seeking active participation by the adults with T1D and a person-centred patient-provider dialogue (185).

Another challenge was deciding which diabetes distress measure to use as the primary outcome measure. We sought guidance in the literature and also consulted the health service users. The DDS has demonstrated satisfactory psychometric

properties (64, 75, 155, 163), and in addition, it is recommended for research purposes as it identifies distress subdomains (171). Thus, we chose the DDS scale as the pilot trial's primary outcome measure. However, the DDS was completed on paper as this decision came after the other self-report instruments had been entered into the electronic questionnaire. The administration mode may have increased missingness since paper-based PROMs are more prone to missing than electronic (128-130). Also, most participants completed the DDS after the consultations, which may have affected their responses compared to how they replied on the PAID before the consultations. Furthermore, numerous distress aspects unique to T1D have been identified (70, 93), forming the basis for the development of the T1-DDS (66, 70). However, this instrument has yet to be translated to Norwegian.

In the pilot trial, we decided only to offer face-to-face follow-up. Recently, video consultations have become more relevant in healthcare services; however, there was no infrastructure for this technology at the hospital at the time of the piloting. Nevertheless, providing follow-up by telephone might have improved retention and facilitated more intervention consultations (186). Although telephone and video consulting are generally considered suitable, studies comparing such consultations modes to face-to-face consultations suggest lower quality follow-up as patients present fewer problems and clinicians gather less data and perform less counselling than in face-to-face consultations (187-189). These findings support the continued use of face-to-face follow-up.

Electronic PROMs

The high cost of software and hardware is one of the disadvantages of electronic PROMs, potentially limiting their use (130). On the other hand, a major benefit is that electronic PROMs may be transferred directly to the EPR and health registers. We transformed the original paper-based questionnaires into an electronic format. According to systematic reviews, electronic PROM scores do not diverge from scores obtained from the original paper-based versions (124-127). Nevertheless, certain populations may be excluded from responding. In our studies, we might lack potentially valuable insight regarding the impact of diabetes on the lives of people

who, for various reasons, were unable to complete electronic PROMs. Capturing PROMs with assistance could be an option in routine care, but this administration mode has been found to produce biased scores towards false positive outcomes compared to self-administered PROMs (190). Therefore, paper-based PROMs may be a better option unless eyesight is seriously impaired. However, in research, striving to use the same data collection method for all respondents would be ideal to avoid potential confounding (190).

In the studies, we have focused on collecting PROMs electronically; therefore, limiting our results to people able and familiar with using IT devices. Notwithstanding that, digitisation has come a long way in Norway. According to the European Commission's Digital Economy and Society Index for 2018-2020, ~80% of Norwegians had at least basic digital skills (51% above basic skills); in addition, 97% were internet users, and 90% had submitted electronic government forms (191). This indicates that most Norwegians with T1D should be able to complete PROMs electronically. In parallel with the DiaPROM pilot trial, a web-based interface has also been tested for obtaining PROMs and Patient-Reported Experience Measures (PREMs) for the NDR-A (192). Adding a web-based method to in-clinic electronic PROM collection appears promising for reaching and accommodating more people with diabetes in future research initiatives.

Biases related to self-report

In studies relying on self-reported data, there are potential biases or mechanisms related to the data collection process and/or the data's nature, requiring consideration. Regarding PROMs, measurement biases that may affect the interpretation of results include selective reporting bias, recall bias, social desirability bias and response shift (193, 194). Selective reporting bias is linked to patients consciously or unconsciously ignoring to report problems they consider unrelated to their illness (193). Biased self-report might also include positive or negative responses influenced by current mood and the tendency to avoid the response scale's extremes (central tendency bias). Whereas recall bias typically depends on the time period the questionnaire asks patients to recall. Here, the response is likely to be influenced by the person's current

state of mind. Social desirability bias occurs if the person responds whatever he/she considers the most socially appropriate answer (193). Whether deliberate or not, it may compromise measurement objectivity. Therefore, in trials, measurement bias may increase variability and thereby distort treatment effect estimates and reduce statistical power (193, 195).

Response shift is considered a bias caused by subjective changes in patients' perceptions of a construct over time (194). Not uncommon among patients with chronic diseases, the subjective changes can be a consequence of coping or adapting to one's illness and includes changed expectations and new priorities, which may be affected by changes in person-specific characteristics. However, in clinical practice, one could argue that the patients' current perception is what matters and encourage positive response shifts, although it can obscure assessment of intervention efficacy in full-scale trials (193). A related concept, measurement reactivity (or the question-behaviour effect), occurs when questions answered for research and clinical assessment stimulate new thinking about specific behaviours or activities and introduce action-taking, resulting in changed behaviour or activity (196). However, the overall effects of asking questions on objective and subjective measures of behaviour are typically small, with considerable heterogeneity in effects across studies (196-198).

5.1.2 Feasibility and pilot testing a complex intervention

The feasibility and piloting phase is characterised by small studies that do not test hypotheses about intervention efficacy and are not designed with the generalisation of findings in mind (142, 143, 181). Thus, the key research questions in the studies relate to whether the intervention could be provided as planned and if it was acceptable to the target population, i.e. testing individual components (feasibility testing) and the entire RCT design with all its components (pilot testing) (199). Compared to laboratory experiments, feasibility and pilot work is especially important in healthcare research where the complexity present special challenges related to, e.g., standardising the design, delivering the intervention, context-specific features and potentially organisational difficulties (181). By addressing uncertainties

and establishing feasibility, the internal validity of a future full-scale RCT is strengthened (145, 146). However, pilot studies often uncover intervention weaknesses, revealing the necessity for further feasibility and pilot work. Currently, there are no guidelines to help determine how much an intervention can be modified before another pilot trial is indicated to establish feasibility and acceptability (145).

Using quantitative and qualitative methods to investigate feasibility and acceptability issues in preparation for a full-scale RCT was a major strength (146, 200). Generating rich accounts of the participants' experiences through interviews alongside the quantitative data provided important supplementing information and increased our understanding of how the intervention had played out in the context where it had been delivered (201). However, in such pilot trials, the experiences and opinions from the contributing clinicians' perspective are also essential (145, 202). Therefore, it can be seen as a weakness that only the patients' perspective is included among the studies that make up this thesis. The healthcare providers engaged in the pilot trial have been interviewed (147), and their experiences have provided important knowledge for the implementation of a future full-scale RCT.

Addressing feasibility using quantitative methods

We started the DiaPROM feasibility studies by addressing practical and technical uncertainties in addition to the patients' acceptability of the PROMs and the newly developed electronic procedure for collecting them. An evaluation of these components was necessary to inform the planned pilot trial's further development and execution (199). Therefore, we first performed the feasibility study, a cross-sectional study with field observations (203). This work strengthened the proposed evaluation trial's internal validity. The feasibility study was conducted with participants from an older age group (≥40 years) than the planned pilot trial intervention to avoid depleting the group of eligible pilot trial participants (18-39 years) in this limited outpatient clinic population. The pilot trial and the qualitative study's findings suggest that the younger participants corroborated the older participants' views on acceptability and feasibility of completing PROMs, as found in the feasibility study.

Also, similar proportions of moderate to high diabetes distress were reported by the two study populations.

Publishing a protocol paper allowed for providing more information and details about the pilot trial's development and the intervention itself than would have been permitted in the papers presenting the results. However, one limitation was the lack of explicit criteria for progression from the pilot to a full-scale trial, i.e., listing specific feasibility criteria, planned interpretation of the criteria and how this analysis would inform progression (204). A recent methodological review of pilot RCT protocols published in the period 2013-2017 found that insufficient reporting of progression criteria was common and only reported by 45/227 protocols (19.8%, 95% CI 14.8-25.6) (205). The consequence is that findings may receive a varied interpretation. Therefore, the authors called for the development of formal criteria guidance (205). Nevertheless, protocol papers can function as control measures enabling readers of the final RCT report to evaluate whether the study was carried out according to the original plan.

Although an ideal step to avoid bias, blinding was not an option in the pilot trial since the participants and clinicians had to be involved with the intervention (206). However, we could have piloted the trial without randomisation (199). Advantages of single-arm non-RCT designs are that they are easier to conduct and that larger participants numbers are available for intervention as there are no controls (146, 200). Further, it is possible to undertake more qualitative explorations if all participants have received the intervention. Still, conducting a small-scale version of a full-scale trial is recommended when the research objectives are concerned with study processes and methodologies such as the randomisation procedure, attrition between intervention and control arms, sample size calculations and whether all components work collectively (204). However, there is an ethical dilemma within RCTs where controls are asked to complete questionnaires and then not offered support and further dialogue about their responses (207). Although we could not resolve this dilemma within the design, we applied a measure required by the ethics committee; to check

their WHO-5 and identify scores suggesting depression (≤28) and report this back to the clinicians for further assessment.

The pilot trial was designed as a single-site trial with patient randomisation where participants from both trial arms met the same clinicians. Since we did not monitor the consultations' content, control arm participants may have initiated conversations similar to the intervention arm follow-up after being activated by completing PROMs. Furthermore, by seeing participants from both trial arms, the clinicians' consulting styles may also inadvertently have affected the control arm consultations. Another issue worth considering is how standard 'standard outpatient care' is, as the conditions are often less defined and monitored than an intervention (208). However, patient care within a study is probably often enhanced standard care, dependent on the clinics, the clinicians and their relationship with the patients (208). Achieving strict standard care without any changed behaviour within the control arm is claimed to be virtually unattainable (209). In diabetes care, this is possibly also unethical because treatment and care have to be individually adapted. Moreover, patient randomised evaluation trials are vulnerable to contamination of the control arm through possible intervention 'leakage' and thereby open to type II error, underestimating the intervention's true effect size (206). Cluster-level randomisation is one alternative for reducing contamination bias (204). However, cluster trials are more complicated and resource-intensive and vulnerable to selection bias through potential systematic differences between experimental and control clinics, e.g., regarding standard care implementation. Nevertheless, in the pilot trial, we considered there to be a low risk of contamination since the availability of the PAID data drove the intervention consultations, and it was not accessible in the control arm.

During the pilot trial, we monitored recruitment and retention, checked the randomisation procedure's accuracy and practicality, assessed the feasibility and acceptability of the data collection methods, outcomes and the intervention (204). However, in order to perform a more comprehensive evaluation and gain more understanding about intervention feasibility and acceptability (210), we should have investigated fidelity more thoroughly. Fidelity is defined as *"the degree to which an*

intervention was implemented as was intended" (211, p. 233). Keywords for gaining a broad picture of fidelity are content, frequency, duration, coverage and timeliness. All aspects are important for understanding the specific reason(s) for intervention success or failure. In our data collection, we kept logs and quantified consultations, thereby covering frequency and timeliness. We planned to record consultations to get an overview of exact duration, actual content and coverage, but this was not possible to implement at the time. Observations and registration of what goes on in consultations can be considered invasive, but maybe also to an extent necessary for monitoring whether the intervention is being implemented as planned, thereby ensuring protocol fidelity. However, some argue that strict fidelity may be inappropriate and that allowing local adjustments may lead to better working interventions (181).

Addressing feasibility using qualitative methods

Exploring pilot trial participants' perceptions and experiences with the intervention have been valuable. However, the qualitative methods require further exploration. A continued, complex discussion of different validation standards in qualitative research has resulted in several perspectives with different definitions, descriptions and strategies for enhancement and establishment (212, 213). Creswell & Poth describe validation as a process rather than a verification of trustworthiness and summarise frequently used validation strategies, and offer advice about applying them in studies (212), which align with the quality-enhancement strategies outlined by Polit & Beck (213). The qualitative data collection, researcher conduct, and analysis methods are discussed based on these strategies.

Data collection

We chose to perform individual interviews with participants from each trial arm because they had somewhat different experiences (control arm, intervention arm with or without additional follow-up). Alternatively, we could have organised focus groups (214). The group format's key advantage is that members can react to and stimulate each other. However, we aimed for the individual experiences and perceptions of the pilot trial intervention; therefore, we chose individual interviews.

Overall, telephone interviews are considered valuable for collecting data (215-217). Compared to face-to-face interviews, they are less costly and time-efficient, which can yield better response rates. Another benefit includes potentially more informal interviews that offer privacy and limited distress about talking openly and honestly (217). In terms of power dynamics, not seeing the interviewer may have benefitted the participants (215). Since nonverbal communication was lost, rapport building was challenging (215-217). However, the tone of voice, volume, speed, silence or speech pacing, accentuating both the interviewer and participants' message, was not lost (217). Nevertheless, without visual cues, the interviewer experienced being challenged in communicating active listening, appreciation and acknowledgement of the participants' experiences (215). At present, the telephone's limitations may be more easily addressed using video conferencing and remote interviewing with visual and auditory data.

In qualitative data collection, the researcher is a key instrument (212). Therefore, it could be considered a limitation that the PhD candidate, still a novice with limited experience of qualitative methods, conducted the interviews. Conversely, the inside knowledge of the intervention may have improved the data collection. The PhD candidate had previous experience from the setting but did not know the participants. She was conscious about her background and preunderstanding, the part she played in the study and how her experience could affect the data collection (214). During the piloting phase, she also spent much time in the clinic observing, keeping field notes and later reflective notes about the interviews (212, 213). Despite these efforts, her background likely shaped her approach to the study and interpretation of the data (212). However, clinical experience and knowledge of the context and culture may also have aided rapport building, contributing positively to the participants opening up about their experiences (212).

Analysis

One of the strengths of Braun & Clarke's thematic analysis is its theoretical flexibility (218). We chose to use the analysis method due to its accessibility and flexibility regarding research questions, sample sizes and compositions and data

collection methods (219). However, thematic analysis has been criticised for its lack of a theoretical framework and that it 'simply' refers to a process for identifying patterns. According to the developers, the critique *"relies on the conflation of method and methodology, where the former refers to tools for data analysis (as is the case for thematic analysis), and the latter refers to broader frameworks for research, which more or less predetermine factors like theoretical frameworks, orientation to data, modes of data collection"* (177, p. 24). Also, the focus on patterns may hinder that contradictory accounts among participants are conveyed (218). Nevertheless, thematic analysis offers researchers a systematic method for engaging with qualitative data and developing a robust analysis without predetermined design considerations (177). Our approach for identifying themes or patterns within the dataset was data-driven, which is considered useful when exploring new interventions or areas.

Braun & Clarke are known for stating that themes do not emerge from the data; themes are derived from an interpretation of a dataset (176). In the qualitative study, the analysis collaboration benefitted from the members' complementary backgrounds and experiences, facilitating investigator triangulation (212, 213). Furthermore, three of the seven analysis team members were independent of the quantitative studies, potentially strengthening the combined researcher credibility by adding an external view on the data (213). Transferability was informed through generating thick descriptions or detailed information about the data when reporting themes and subthemes (212, 213). The illustrative, verbatim quotes also contributed to authenticity. In addition, the credibility of our findings was further enhanced by relating the themes and subthemes to the existing literature, thereby seeking confirming evidence (213).

5.2 General discussion

5.2.1 Assessing and addressing diabetes distress

Identifying diabetes distress

The studies that make up this thesis addresses the healthcare service's outpatient follow-up of diabetes distress. In this endeavour, we sought to develop and pilot test an intervention to identify and improve diabetes distress among adults with T1D. Half of the study participants reported clinically significant diabetes distress levels, which is in line with previous research and further suggesting that people with T1D still have unmet needs (66, 72, 101, 105, 169, 220). The qualitative findings corroborate with results from studies conducted in the Netherlands, which indicated that simply monitoring diabetes distress and initiating conversations, where the clinician listens to and shows awareness and understanding of diabetes-related challenges, can have a beneficial impact on the individual (83, 84).

The rationale to deviate from the commonly adopted classification of significant diabetes distress at PAID scores >40 was based on the literature suggesting that milder cases of diabetes distress left unaddressed or untreated may develop into severe and even chronic distress and that, therefore, even moderate distress warrants exploration and intervention (66, 67). Also, all people with diabetes can profit from follow-up where diabetes distress is acknowledged and 'normalised' (61). Furthermore, identifying a specific distress source or sources by targeting items with higher scores is considered beneficial as the focus for intervention, while overall distress level is an important generic indicator of distress (66, 71). This line of reasoning led us to choose the criteria PAID total score ≥30 or items scored ≥3 for referral to the additional follow-up and intervention. Here the 'red flag' approach (155), the initial identification of problem area(s), was aided by colouring the PAID item responses according to the severity. Thereby, the clinicians could more easily spot these items in the EPR.

Living with T1D means being continually warned by one's vulnerability (62). Having to integrate and deal with the intricate diabetes self-management tasks and behaviours

in everyday life can be overwhelming (38, 50, 62). Present study findings and previous publications highlight the importance of addressing diabetes distress in clinical care (61, 62, 70, 71, 84, 93, 102). However, the Norwegian diabetes guideline does not cover diabetes distress as a construct (9). In addition to communication, coping, and motivation, the guideline focuses on psychological disorders, such as depression and anxiety in relation to diabetes, and recommend using a generic PROM and diagnostic interviews. Due to the conceptual overlap, stressful experiences of living with diabetes may be captured by PROMs meant for detecting symptoms of depression (60, 61). However, clinicians and researchers that follow the Norwegian guideline (9) may miss out on capturing diabetes distress (49, 61).

There is no disputing that depression is important for diabetes outcomes due to the increased risk for developing complications and higher mortality rates (221, 222). Untangling diabetes distress from depression is important to avoid false positives pathologising what is considered an expected part of living with diabetes (61, 223). Among adults with T1D, depression prevalence varies between 4-12% depending on publication and screening method (223, 224). In comparison, seriously elevated diabetes distress is found in 20-40% (59, 70). Consequently, to provide proper care and follow-up, it is important to distinguish symptoms of depression from diabetes distress and identify cases where both are present (62, 81). This can be achieved by asking for both constructs, for example, using the PAID and the WHO-5. Nevertheless, the personal and societal costs of reducing diabetes-related emotional challenges through interventions argue for specifically assessing and addressing diabetes distress in routine clinical care (61, 62, 71).

Diabetes distress interventions

There have been relatively few trials of interventions aiming to improve emotional or psychosocial outcomes in young adults with T1D (225). Additionally, those that have been performed are typically found to be of low quality. However, Schmidt and colleagues found that diabetes-tailored interventions were effective in improving diabetes distress in addition to HbA_{1c} (226). Also, a recent trial reported that affective and educational interventions were equally effective in reducing diabetes distress

among adults with T1D (227). Specifically, the affective approach was efficient when emotion regulation was poor and diabetes knowledge adequate, whereas adequate emotion regulation and poor diabetes knowledge favoured the educational approach. These findings underline how multifaceted diabetes distress can be and that distress is amendable and susceptive to intervention (227).

In order to compare the effects of different interventions, the selection of trial outcomes or core outcome sets is central (228). One of the issues with many trials and efforts to collate, synthesise and analyse the findings in systematic reviews and meta-analyses is the wide range of outcome measures used, except glycaemic control measured by HbA_{1c} (207, 228). A core outcome set for studies targeting young adults with T1D has now been proposed (229). The set includes measures of diabetes distress, diabetes-related quality of life, number of severe hypoglycaemic events and instances of ketoacidosis, self-management behaviour, HbA_{1c}, level of clinic engagement and perceived level of diabetes control, which are supported by the DiaPROM studies' findings. In addition, the recently proposed standard set of PROMs in clinical care may also be valuable for research (87).

5.2.2 Using PROMs in the consultations

Our findings suggest that the practical part of capturing the electronic PROMs was appropriate and relatively easy to implement once the participants had found the touchscreen computer. This is essential since straightforward data collection procedures are considered an important reason for study participation (230). Overall, the participants found the questionnaires highly relevant and acceptable. The qualitative data provided awareness of the participants' incentives for completing PROMs and how the measures prompted them to reflect on their diabetes and diabetes-related challenges ahead of the consultations. This finding is supported by a realist review indicating that PROMs may help patients identify and focus on issues that are important to them (136). Some participants also described acquiring a deeper understanding of how T1D affected them, which was mainly appreciated.

Although the pilot trial uncovered uncertainty about the planned intervention's deliverability, the initiative was not futile. Both study participants (paper IV) and healthcare providers were largely positive about the structured focus on diabetes distress (147). Thus, the PAID was deemed purposeful and appropriate for the context (231). The young adults generally described that using the PAID was valuable because it directed the dialogue towards exploring and discussing diabetes-related problem areas, thereby targeting and structuring the consultations. Also resonating with the findings of a recent systematic review (232), the participants reported that the clinicians' understanding of their diabetes-related concerns and needs was improved. Importantly, the PAID 'permitted' and enabled them to raise diabetes-related problems with the clinicians, signalling that diabetes distress was appropriate to address during the consultations.

The participants conveyed that completing the PROMs could be emotionally difficult. Therefore, it is important to keep in mind that completing questionnaires is more than information retrieval (136). The interview data provided insights into how the participants were affected by completing the PAID and how they experienced a need to elaborate on their responses. With this in mind, using the 'red flag' approach to specifically focus on the problematic PAID items (155) was supported. By using solely total scores as criteria for intervention and dialogue, we would have risked losing the various problem areas' descriptive richness, in themselves worthy of exploration (118). A single item response can reveal important issues about the respondent's experience of diabetes-related problems that can be missed by focusing on the total score (118). Further, the participants' reports of moving out of the comfort zone yet benefitting with new insights reinforce the previously identified importance of progressing beyond biomedical outcomes in consultations involving people with T1D (47, 93, 101, 105).

According to the qualitative findings, PROM responses, or at least how specific items were answered, may have been affected by various circumstances, thereby resulting in somewhat biased self-reports (193). Hence, scores should be interpreted cautiously. As previously suggested, the electronic administration mode did not seem

to play a part in this (124-127). Rather, the participants' motives for selective reporting appeared related to previous experiences with the follow-up, which many found unsatisfactory in terms of continuity and patient-provider relationships, and intrinsic factors such as not being completely honest with oneself. However, numerous forms of bias can influence questionnaires, such as the patient's current mood, personal impression of health, inclinations to provide either positive or negative responses, understating or overstating severity, social desirability issues and the tendency to avoid the extremes of the response scale (193). Whether using a PROM or engaging in an ordinary, clinical conversation, clinicians must respect that patients may choose not to be completely honest about how they are doing. They must work towards earning the patients' confidence (103, 105). In the pilot trial setting, the healthcare providers shared experiences of conflicting demands and priorities in their daily work, particularly related to balancing both biomedical assessments recommended by the diabetes guideline and the individual patient's specific challenges and concerns (147). This challenge may have contributed to what the young adults perceived as insufficient follow-up with an excessive focus on biomedical measures. Regardless, our study findings suggest that it is important not to view the PAID responses as 'final truths' about how the patients feel, but rather as starting points for dialogue and relationship building, further supporting the empowerment process.

Empowerment and person-centred communication

In current and previous studies, we have found that one of the healthcare services' main challenges is to organise adult T1D follow-up in a manner that ensures adequate person-centred support with continuity of care and allows patient-provider relationship building (105, 147). Although people with diabetes are expected to actively interact with the healthcare services, lack of individualised care can hinder young adults with diabetes in bringing up problems areas in clinical encounters (93). For healthcare providers, person-centredness is required for understanding the individual patient's rationale for maintaining or improving self-management behaviours. Working towards treating the patient as a unique person with biological, psychological and social dimensions, demonstrating empathy, compassion, dignity

and respect are critical communication strategies (185). As part of individualised diabetes follow-up, routinely screening for diabetes distress and addressing the identified problem areas are clearly indicated and called for (89). Here, empowerment, advocating clarification of what the individual finds important to address, can guide person-centred and collaborative clinical encounters towards optimising people with diabetes' self-management, health outcomes and quality of life (89, 185).

Combined evidence supports using PROMs to enhance person-centred and collaborative communication in clinical settings (122, 233, 234). Also, our study findings were in part confirmatory of previous research papers reporting T1D adults' wishes for continuity of care to build therapeutic relationships with healthcare providers (47, 50, 101, 102, 105). The combination of perception of low follow-up value, lack of relevance and patient-provider relationships has previously been highlighted as key reasons for dissatisfaction and clinic non-attendance among younger adults with T1D (99, 100) and should therefore be taken seriously. However, via a systematic collection of information and communication about everyday life impact and emotional burden of T1D, the DiaPROM intervention aided the clinicians to offer attentive, personalised support to the pilot trial participants, which is in line with patient empowerment and person-centredness (115, 134, 185). Further, by allowing the participants' concerns a voice, the intervention possibly influenced the power balance in the patient-provider relationship and made the consultations more personal and relevant for the participants, which also resonates with previous research (136, 233).

5.2.3 Challenges related to implementing the intervention

Participant-related challenges

Performing an intervention study in clinical practice is challenging. In the recruitment for the feasibility study and the pilot trial, 18% of the eligible participants did not attend their appointments and were consequently not recruited; further, 15% of those attending declined participation. Due to the complex intervention's nature, recruiting and retaining participants is especially demanding (235). Potential consequences of

suboptimal trial recruitment and retention are unrepresentative sampling, underpowered and inconclusive studies, delays and higher expenses. Enrolling and retaining participants is inevitably more challenging if the intervention requires a lot from them compared to a 'simpler' intervention. Therefore, trials should ideally be designed as simple as possible (235). Since we do not know whether the pilot trial participants were representative of the outpatient clinic population, this could have led to selection bias and a threat to internal validity (183). However, in the pilot trial, we were only allowed by the ethics committee to analyse differences in sex, age, diabetes duration and HbA_{1c} between participants and those who declined. The only difference found was that the latter group had a longer diabetes duration.

Regarding other recruitment procedures, relying on posted letters to contact eligible participants and informing them about the studies was not particularly successful. Efficient recruitment and PROM collection were more or less contingent on the presence of a person at the outpatient clinic who could provide information and support. However, the recruitment issues did not appear related to a lack of perceived relevance of the project, a common reason for non-participation (230); rather, the participants had not read the information or forgot about it. In retrospect, one option could have been to send reminders by SMS to the feasibility study and pilot trial participants (235) like we did while recruiting participants for the interviews. However, that would have required additional resources. The recruitment rates may also have been improved if the user group had been involved in developing the written information and consulting on the recruitment procedures (151). Although user involvement cannot solve all recruitment problems, it is important to extend its application to increase implementation chances, reduce costs and enhance study validity (236).

In the pilot trial, 67 of the 79 participants were retained at 12 months, which meant an attrition rate of 15.2%. Attrition or loss to follow-up rates of 20% are commonly expected in trials (235). However, the rates also differed between the trial arms and within the intervention arm, suggesting attrition bias (237). The 29.4% attrition among those referred to additional follow-up was a major concern. Compared to the

control arm's attrition (10.0%) and among the intervention arm participants with lower PAID scores (20.5%), this suggested that participants with higher distress scores were more likely lost to follow-up. In general, it is challenging to reach the patients with what appears to be the greatest need for follow-up to attend consultations and participate in studies. Either they can refrain from participating in the first place (155), or, when recruited, those reporting problems suggesting the most need for support seem more likely to drop out (169). If a full-scale trial failed to achieve sufficient retention, the study would be inconclusive since it would be too small to detect effect sizes. A differential loss to follow-up between trial arms would be considered a potential confounder and a threat to internal validity (235). Attrition also has a cost since trials consistently compensate for participant dropping out by increasing the number of invited participants.

We do not know why the participants lost to follow-up dropped out during the pilot trial. Investigating reasons for non-attendance and loss to follow-up usually provide important insights (209). A recent meta-ethnographic synthesis of studies reporting reasons for trial dropout highlighted the significance of participants' opinions of whether the intervention was sufficiently tailored and helpful (186). Although the pilot trial participants lost to follow-up did not share their opinions or reasons, the general feedback was that the additional nurse consultations' usefulness was moderate. Furthermore, participation may have been too burdensome for some, as it involved attending additional outpatient clinic visits. Participant burden is a common problem for complex interventions (145). Specifically, the participants were asked to come to the clinic 15 minutes before their scheduled appointment at two annual check-ups to complete PROMs and potentially see a diabetes specialist nurse at least twice over three months. Completing PROMs and being asked to talk about one's challenges diverged from the follow-up many were accustomed to; however, among those receiving the physicians' PAID review and discussion, this seemed sufficient on many occasions. Thus, they did not require additional follow-up, which may partially explain non-attendance or postponing appointments. There is also the possibility of over-inclusion of cases due to the choice of PAID scores for referral.

Hence, the intervention's follow-up eligibility criteria are one of the measures that require more consideration before a full-scale evaluation trial (146).

The interviewed participants described not preparing for the nurse follow-up consultations. Engaging trial participants is a known challenge (209). Since full fidelity examination was not performed, e.g., recording consultations, we cannot say whether the young adults or the nurses led the dialogue into other areas. We can only rely on the interviews and the EPR notes. However, if the consultations had been recorded, the nurses and participants could have felt compelled to follow the protocol, potentially contributing to an unnatural atmosphere and time and resource misuse. Some claim that seeing familiar healthcare providers improve protocol fidelity and attrition (209). Present and previous findings suggest that familiarity is not sufficient and that it depends on the relationship's quality (99, 105). When developing and performing intervention studies in a clinical setting, known barriers to clinic attendance must be acknowledged, such as logistical issues and the perceived value of attending (99, 100). In the pilot trial, the additional follow-up could perhaps have been more flexible by allowing the individual more involvement in deciding what follow-up (s)he needed. This was partially fulfilled by facilitating an individualised number of nurse consultations. Nevertheless, the participants' experiences culminated in them not finding the intervention sufficiently useful. Whether this was related to their engagement with the intervention, excessive burden or lack of flexibility, or a combination of these, is still uncertain.

Communication-related challenges

In the interviews, the young adults characterised previous annual check-ups as 'sitting for an exam' where clinicians 'wagged a finger' to signal that their diabetes outcomes were poor. Although this kind of provider interaction may have been unintentional, patient-provider communication is considered the most important factor affecting diabetes self-management (238). The language used by diabetes healthcare providers is increasingly recognised as not always helping people with diabetes (238-240). The pilot trial participants also conveyed that the focus on poor or suboptimal glycaemic control (HbA_{1c}) elicited feelings of failure. Adding unfortunate language in such

situations can trigger reduced self-management commitment and satisfaction with care, adverse clinical outcomes and stigma (239, 240). Therefore, striving to understand the patients' life circumstances and perspectives that affect self-management and health outcomes through respectful, strengths-based and inclusive language is essential for promoting collaboration and person-centredness (240).

The healthcare providers engaged in the pilot trial reported concern with identifying problems that they could not deal with themselves as a barrier to implementing routine diabetes distress assessment (147). In patient care, asking, listening and acknowledging is an essential intervention in itself. The first steps towards understanding what we do not know start with the healthcare providers showing an interest in the persons with T1D, inviting them to talk about diabetes-related problems, listening intently to their experiences ('with the ears turned on') and supporting them (47). Although this may sound straightforward, previous research indicates that it is somewhat more difficult in real-life clinical settings (101, 105). Diabetes treatment and follow-up present unique challenges for healthcare providers. Therefore, it is important to acknowledge that it can be stressful to work with people with a chronic disease where so much of the treatment depends on self-management (241). Providers worry about patient outcomes, limitations of time or resources to provide care and feel responsible for health outcomes (242). They are challenged to deliver person-centred care and recommended medical treatment, balance personal closeness and professional distance, and concurrently develop and strengthen their professional expertise (241).

Clinic-related challenges

The DiaPROM intervention was designed for implementation in a clinical setting without requiring extensive logistical changes. The touchscreen computer and the software were made available to the clinic without costs, but we relied on the clinic to provide clinicians for the consultations. A minimum of three consultations was planned in the protocol: the initial review and discussion of scores with the physician at baseline and two sessions with a diabetes nurse specialist. After the piloting, it became clear that the intervention was not carried out per protocol. The clinic mostly

offered the first nurse consultations in time (within 19-35 days), but many were rescheduled either by the clinic or by the participants and therefore performed within 22-123 days. For some, this meant that the waiting time from PROM completion to the additional consultation was much longer than recommended (71, 168). Similar cancelling or rescheduling tendencies were observed for the second nurse consultations and the 12-month follow-up.

Although much effort was put into intervention development, the pilot trial implementation strategy appeared insufficient. The project was initiated outside the clinic but with its leaders' support and cooperation. Nevertheless, the project lacked local ownership, potentially contributing to the fidelity issues (211). Furthermore, the clinicians described challenges with the interdisciplinary teamwork, and that work-related resource challenges hindered them in facilitating new interventions to enhance care quality (147). Though there was enthusiasm about the project, it seemed challenging for the leaders to set aside sufficient resources. Therefore, more time regarding organisational barriers, ambivalence towards using PROMs and preparing the clinic to take ownership of the project should probably have been invested to facilitate intervention implementation and fidelity (202, 211, 243).

One in 5 intervention arm participants reported that the physicians did not discuss their PAID scores at baseline. Also, one in 4 nurse consultations was not performed per protocol, according to the EPR notes. In clinical practice, ensuring optimal engagement from those providing the intervention is challenging (209). Variation in how and if the clinicians applied the PAID as instructed possibly depended on their engagement and attitudes towards the questionnaire (123, 202). Also, since some did not go into the problems identified, the participants' expectations may have been unmet (233). However, we did not observe these consultations; therefore, not following the protocol may have been justified, although there was no documentation of reasons for straying from the instructions.

According to the interviewed participants, the nurses did not seem sufficiently prepared for the dialogue about diabetes distress. The five nurses had diabetes

specialist education and 15-33 years of work experience in the diabetes field (147). All had previously undertaken extensive training in person-centred communication as part of a guided self-determination trial performed at the clinic (169, 244). Before the piloting commenced, the nurses were provided specific training and written study material (Appendix 7), which we made sure was available to them at the clinic. The practical framework conditions for providing the intervention was in place, and later, the nurses have described being positive about the dialogue tools (147). Regardless, we may have relied too much on their previous experiences and not provided enough support and motivation throughout the piloting.

In retrospect, we may have failed to sufficiently engage the clinicians in the intervention's development phase. Appropriate and sufficient training of the intervention providers is a common problem in complex interventions (145, 245). Perhaps too many providers were involved in the piloting. First, it was challenging to gather and follow the 16 physicians and five nurses (147). Fewer physicians and nurses would have been easier to follow and support. However, reducing the number of providers by solely inviting people with T1D to attend follow-up with a limited group of physicians would entail practical, organisational, ethical and methodological issues. Secondly, many providers carried out few consultations and therefore attained limited experience, which may have increased heterogeneity in the intervention delivery (246). Nevertheless, their training should probably have been more comprehensive as implementing PROMs in consultations is challenging (245). In future work, we must consider flexible training options that support knowledge and experience exchange (245). Facilitation and adaption of the clinicians' training and guidance and support during the trial are essential for successfully engaging them in using the PROMs in consultations and, consequently, implementing and evaluating a full-scale RCT (119, 202, 233).

Healthcare providers in diabetes care are, to an extent, governed by guidelines and performance measures (9, 147). Hence, it may be difficult for them to prioritise care aspects not explicitly covered by the governing documents and measures while balancing the patients' and healthcare service's expectations. Perhaps we need to

define specific emotional and psychosocial support measures in the EPRs, performance measures and health registries to ensure increased attention and follow-up in clinical practice (247). Nevertheless, our combined study findings suggest that the intervention helped healthcare providers gather information about diabetes distress that they otherwise would have had to acquire verbally, thereby saving time and possibly facilitating conversations that might not otherwise have occurred. Also, our experiences have informed a modified intervention study currently being undertaken at Haraldsplass Deaconess Hospital, which uses the PAID as one of its intervention components (Cristin-project ID: 2077355). The results from this study will probably provide valuable information for the conduct of a full-scale RCT.

6. Conclusion

The combined findings of the studies constituting this thesis highlight the value of combining quantitative and qualitative methods in feasibility and pilot testing to uncover factors that may impede effective interventions in clinical practice. Capturing electronic PROMs was technically feasible and generally well accepted by the participants. Although they found it somewhat uncomfortable and challenging to disclose their diabetes-related problem areas, addressing diabetes distress as part of the consultations was considered highly relevant and important for future diabetes follow-up. Using the PAID helped the healthcare providers see beyond biomedical outcomes, which promoted patient empowerment and person-centred care and facilitated improved patient-provider relationships.

However, we decided not to proceed directly to a full-scale evaluation trial. This decision was based on findings indicating attrition, fidelity issues related to implementation and low acceptance or over-inclusion of cases, suggesting that the intervention requires additional development. Consequently, before commencing a full-scale RCT, the intervention requires modifications and additional development and possibly further feasibility and acceptability testing, focusing on inclusion criteria, intervention flexibility and healthcare provider training, specifically using the PAID in the patient-provider interaction.

7. Implications and future perspectives

7.1 Clinical practice

The studies that make up this thesis were not designed to evaluate the effect of the DiaPROM's intervention. Potential clinical implications are therefore not clear. Nevertheless, as half of the study participants reported clinically significant diabetes distress levels, the healthcare services should aim to reduce diabetes distress negatively affecting the everyday lives of adults with T1D. However, the current Norwegian diabetes guideline does not specifically cover diabetes distress as a construct (9). The main argument for addressing diabetes distress routinely as an integral part of diabetes care by diabetes healthcare providers is that diabetes distress is intertwined with diabetes self-management and, as a result, a prerequisite for optimal diabetes treatment and health outcomes (71, 90, 168). Therefore, assessment of diabetes distress should be integrated into new guideline updates.

In diabetes care, clinicians must remember the dynamics of diabetes; the constant challenge to make healthy choices that have short-term and long-term consequences while at the same time achieving satisfactory quality of life here and now (248). Although biomedical measures, such as HbA_{1c}, BMI, blood pressure and urine albumin levels, are undeniably vital for the health of people with diabetes, the measures do not necessarily reflect aspects considered most important in everyday life (53, 101). Our study findings suggest that by systematically targeting diabetes-related problem areas, clinicians' attentiveness to the personal experience of living with diabetes may increase and facilitate more discussion of diabetes-related issues not directly linked to biomedicine; however, possibly affecting biomedical and other health outcomes.

People with diabetes receive healthcare services from different clinicians often organised in multidisciplinary teams. Discussions about diabetes distress may require a shift in clinicians' perceptions of what lies within their responsibility to address during consultations (119). Nevertheless, clinicians need to work out what people

with diabetes that attend outpatient clinics find important to facilitate health outcome improvements (249). In addition to gathering biomedical measures, clinicians should elicit people with diabetes' agendas, needs and wishes for the follow-up and ask them about everyday life and self-management struggles; here, PROMs can be particularly helpful.

Capturing PROMs electronically and feeding the data into the EPR relieved much of the workload and logistics compared to using paper-based questionnaires. Also, adding web-based methods to in-clinic electronic collection appears promising for reaching and accommodating more people with diabetes in the future. When successfully implemented, PROMs may have the potential to improve the quality of diabetes care by increasing the focus on challenges that people with diabetes find important. It has been proclaimed that "*what gets measured, gets done*", consequently suggesting that what is not measured is not done (247). This may also apply to using PROMs in clinical practice; care may be improved by identifying more of those who otherwise go under the clinicians' radar. PROMs also may facilitate understanding and better communication. Electronic systems for self-report of other health outcomes ahead of consultations, e.g., smoking habits, physical activity, glucose readings, medication and insulin dosage, may reduce time spent on biomedical checklists and, thereby, free time so that the patients can address issues that are important to them.

7.2 Further research

Based on the studies that constitute this thesis, new questions have emerged that call for further research. Intervention studies using PROMs to assess, address and improve diabetes distress are still needed. In a full-scale DiaPROM RCT, we should consider conducting it as a multicentre trial to compensate for small sample sizes and allow for comparing the use of PROMs in different outpatient clinics with contextual factors potentially influencing follow-up. Furthermore, feasibility and pilot testing of the use of PROMs in clinical consultations among people with T1D of non-Norwegian origin and people with T2D is also warranted.

In the feasibility study and the pilot trial, participant engagement appeared low at recruitment. Therefore, qualitative studies to further explore attrition rates are warranted. Furthermore, half of the study participants reported clinically significant diabetes distress levels. Hence, using PROM data from the NDR-A, prospective studies should be conducted to extend the knowledge on national diabetes distress prevalence. Such population-based studies also allow for examining diabetes distress and its association with other health-related outcomes and may increase our understanding of disease burden.

In the qualitative study, some participants conveyed dissatisfaction with regular outpatient consultations, especially the focus on biomedical outcome measures. This finding should be further investigated in cross-sectional studies across the total population of outpatient clinics. In addition, using focus groups to explore and understand this matter further can be useful to gain more insight into patient-provider communication and outpatient follow-up. Following this line of inquiry, research on training diabetes clinicians in addressing diabetes distress and using dialogue tools at a competent level is needed, e.g., studies regarding effective modes for training, be it web-based programs or peer-support groups. Through interviews and/or surveys, we can investigate what clinicians need to assist them in using dialogue tools. Involving people with diabetes and healthcare providers in observational studies and qualitative studies could further investigate how dialogue tools can support patient-provider communication, patient empowerment and person-centred care.

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Papers I-IV

With supplementary files

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Pilot and Feasibility Studies

RESEARCH Open Access

Electronic capturing of patient-reported outcome measures on a touchscreen computer in clinical diabetes practice (the DiaPROM trial): a feasibility study

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Abstract

Background: Living with type 1 diabetes (T1D) is demanding, and emotional problems may impair ability for diabetes self-management. Thus, diabetes guidelines recommend regular assessment of such problems. Using patient-reported outcome measures (PROMs) to assess diabetes-related distress and psychological well-being is considered useful. It has been proposed that future work should examine the use of PROMs to support the care of individual patients and improve the quality of health services. To our knowledge, the use of PROMs has not been systematically evaluated in diabetes care services in Norway. Electronically captured PROMs can be directly incorporated into electronic patient records. Thus, the study's overall aim was to examine the feasibility and acceptability of capturing PROMs electronically on a touchscreen computer in clinical diabetes practice.

Methods: Adults with T1D age ≥ 40 years completed PROMs on a touchscreen computer at Haukeland University Hospital's diabetes outpatient clinic. We included 46 items related to diabetes-related distress, self-perceived diabetes competence, awareness of hypoglycaemia, occurrence of hyperglycaemia, hypoglycaemia and fluctuating glucose levels, routines for glucose monitoring, general well-being and health-related quality of life. Participants subsequently completed a paper-based questionnaire regarding comprehension and relevance of the PROMs, acceptance of the number of items and willingness to complete electronic PROMs annually. We wrote field notes in the outpatient clinic based on observations and comments from the invited participants.

Results: During spring 2017, 69 participants (50.7% men), age 40 to 74 years, were recruited. Generally, the touchscreen computer functioned well technically. Median time spent completing the PROMs was 8 min 19 s. Twenty-nine (42.0%) participants completed the PROMs without missing items, with an 81.4% average instrument completion rate. Participants reported that the PROMs were comprehensible ($n = 62$) and relevant ($n = 46$) to a large or very large degree, with an acceptable number of items ($n = 51$). Moreover, 54 were willing to complete PROMs annually. Participants commented that the focus on living with diabetes was valued.

Conclusions: Capturing PROMs on a touchscreen computer in an outpatient clinic was technically and practically feasible. The participants found the PROMs to be relevant and acceptable with a manageable number of items, and reported willingness to complete PROMs annually.

Keywords: Patient-reported outcome measures, Electronic data collection, Feasibility, Diabetes practice, Type 1 diabetes, Routine assessment, Diabetes-related distress, Psychological well-being

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Background

Living with type 1 diabetes (T1D) is demanding. The condition requires lifelong insulin therapy and constant attention to complex self-management tasks. Among adults with T1D, more than half do not reach recommended treatment goals for glycaemic control [1–3]. Although this could be explained by improper treatment regimen, psychological and psychosocial aspects may be significant barriers for diabetes self-management and glycaemic control [4–6]. Consequently, several diabetes guidelines recommend regular assessment of psychological well-being and diabetes-related distress in people with diabetes [7–9]. Although essential in recognition of individual needs [10, 11], psychological and psychosocial aspects are greatly underreported in clinical care [6, 12, 13].

Patient-reported outcome measures (PROMs) have been developed to assess patients' perceptions of living with a condition and its impact on health status, health-related quality of life and/or other health-related constructs [14, 15]. PROMs are used in clinical trials to assess the effect of interventions on health-related outcomes, but are also useful in enabling patients with chronic conditions to raise or share concerns with healthcare providers in clinical consultations [16]. PROMs are typically self-administered and can be administered on paper or by electronic devices, either in the patient's home or at the clinic [17–19]. Transferring paper-based instruments to electronic interfaces may produce data with psychometric equivalence as long as substantive content alterations are not made [18, 20, 21].

Compared to paper-based PROMs, electronic systems have potential benefits such as reducing missing and unusable data by not allowing people to continue registration without completing all items, and only allowing one response option per item [19, 22]. Some claim scoring on paper is more time consuming compared to electronic scoring [23]. While the logistics of entering paper data into the electronic patient records (EPR) raise questions regarding responsibility for the data entry, electronically captured PROMs can be directly incorporated into the EPR resulting in less administrative burden [16, 19, 22]. In recent years, the use of self-report instruments to monitor quality of care has increased, with data also being fed into medical quality registers [16]. It has been proposed that future work should examine the use of PROMs to support the care of individual patients and at the same time improve the quality of health services [14, 24].

To our knowledge, the use of PROMs has not been systematically evaluated in diabetes care services in Norway. In accordance with the UK Medical Research Council's framework for researching complex interventions [25, 26], we have therefore designed the DiaPROM trial (ClinicalTrials.gov ID: NCT03471104) for people with type 1 diabetes, where electronically captured PROMs will be used to identify individual needs and promote goal-oriented clinical diabetes consultations. The findings of the present feasibility study will inform a pilot randomised controlled trial (RCT).

Methods

Aim

The overall aim of the present study was to examine the feasibility and acceptability of capturing PROMs electronically on a touchscreen computer in clinical diabetes practice.

Our specific objectives were:

1. To evaluate our proposed recruitment strategy by estimating the proportion of eligible participants who consent to participate.
2. To examine the feasibility of the technical and practical procedures for collecting PROMs on a touchscreen computer in the outpatient clinic.
3. To assess the participants' perceptions about the PROMs used, including their comprehension of items, acceptability of number of items, relevance of items and willingness to complete electronic PROMs at their future annual clinical consultations.

Design

We undertook an uncontrolled feasibility study using cross-sectional data and field observations to examine crucial elements of a subsequent pilot RCT.

Setting and participants

The study was conducted at Haukeland University Hospital in Western Norway covering about one million inhabitants including both rural and urban areas. We recruited participants with T1D aged ≥ 40 years during 6 weeks from April to June 2017. The reason for choosing this age group was to not include potential participants for the coming pilot RCT, which is planned for young adults < 40 years [27]. We identified eligible participants from the endocrinology outpatient clinic's planned consultations. Approximately 1 week prior to the consultations, administrative staff sent a written information and consent form by postal mail inviting eligible participants to take part in the study. We asked the patients to come to the hospital at least 10 min before the scheduled consultation. People who were unable to read or complete the PROMs on the touchscreen computer were excluded. Furthermore, we did not invite patients with the following conditions recorded in their medical records: cognitive deficiency (e.g. Down's syndrome, Alzheimer), severe medical 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 the burden to complete PROMs might be too challenging.

Data collection

Sample characteristics

We collected the following sociodemographic and diabetes-related information from the participants' EPR: age, sex, ethnicity, diabetes type, diabetes duration, diabetes long-term complications, glycosylated haemoglobin (HbA_{1c}) level and insulin injection device. We also obtained self-report data on first language, current educational level, marital/cohabitation status and work affiliation. In addition, the ethical committee permitted us to register age and sex of those who declined participation, using the EPR's patient administration system.

Recruitment

We recorded the number of eligible participants who were invited to participate, number of people who attended consultations, and number of people who agreed to participate. In addition, we observed whether eligible participants approached the touchscreen computer by themselves or if they needed a reminder from a project member (IH, RBS or AH), who were present in the waiting area during the recruitment period.

Technical and practical procedures for collecting PROMs

The touchscreen computer (17″ screen) was placed inside a metal cabinet (kiosk). We gathered data on the technical and practical performance of the computer and observed participants' ability to complete the PROMs. The leading supplier of eHealth systems to Norwegian hospitals, DIPS AS [28], developed the technical application which included the software for completing the PROMs, a secure data repository for temporary PROMs data storage and the method for transferring the PROMs data to the participants' diabetes-specific health records. This diabetes-specific record is also the Norwegian Diabetes Register for Adults' electronic tool for collecting register data from outpatient clinics [29]. We used the hospital's wireless local area network (WLAN) and a USB dongle to boost connectivity. The kiosk was situated next to the outpatient clinic's waiting area to ensure visibility. "Questions for people with diabetes" was displayed on the screen and a poster with information was placed next to the screen. By tapping the screen, information concerning the data collection procedure and the measured constructs were displayed, and the PROMs appeared one item at a time. Respondents could either tap "next" or wait 2 s for the computer to automatically continue to the next item. In addition, respondents could also tap "back" to review or change their previous responses. On the top of the screen, a row of small boxes signalled how many of the items were responded to and the number left to complete.

The software utilised time stamps to track time needed (minutes and seconds) for completing the PROMs. Participants were not required to log in using personal identification; instead, the application generated a four-character code with a mix of letters (A–Z, except I and O) and numbers (1–9) for each session. Participants were instructed to write down their unique code on a paper form placed next to the computer and to bring this form to the consultation. The code was then used to download the PROM data from the secure data repository to the diabetes-specific records.

Instruments and participants' perceptions about the PROMs

We used the Problem Areas in Diabetes scale (PAID) to assess diabetes-related distress related to living with diabetes and its treatment [30–32]. This instrument is considered appropriate in achieving therapeutic and goal-oriented consultations [33, 34]. We used the Perceived Competence for Diabetes Scale (PCDS) to map self-perceived ability for diabetes self-management [35, 36], and "The Gold" scale to assess awareness of hypoglycaemia [37]. In addition, we developed three questions asking the participants to assess self-perceived occurrence of hyperglycaemia, hypoglycaemia and fluctuating glucose levels over the latest couple of weeks. Furthermore, we included the World Health Organization 5-Well-Being Index (WHO-5), a generic measure for psychological well-being [38, 39], and the RAND-12 Health Status Inventory (RAND-12) to assess health-related quality of life [40, 41]. Finally, we added items related to the use of glucose monitoring devices and frequency of glucose measurements. In total, 47 items were included in the questionnaire. A description of the included PROMs is shown in Additional file 1. Acceptable psychometric properties have been reported for the PAID [42], the PCDS [43], "the Gold" [37], the WHO-5 [39], and the RAND-12 [40]. Cronbach alphas in the present study were PAID 0.94, PCDS 0.94, WHO-5 0.84, and RAND-12 0.89.

The PROMs were originally developed for paper-based administration, with an introductory sentence preceding all items. In our electronic versions, one item appeared at a time, thus the introductory sentences were adapted and placed directly above all items to avoid respondents having to scroll back and forth to read this information. We did not alter the wording of any items or response options. However, for the response options to fit the screen, we had to alter the layout from horizontal to vertical positioning for all instruments, except "the Gold". In addition, we added "unanswered" as the default response option for all items, allowing participants to skip

a question and proceed to the next one, and it was only possible to choose one response option per item.

The participants also responded to a paper-based questionnaire concerning their perceptions about the PROMs. The questionnaire comprised questions regarding comprehension, perceived relevance, and acceptance of the number of items included in the PROMs. Finally, we asked about participants' willingness to complete electronic PROMs annually. We looked to the Norwegian Institute of Public Health's user experience questionnaires for item wording and response alternatives [44]. Finally, we added space for individual written feedback and encouraged the participants to comment on the procedures, the included items and scales in their own words. In addition, the project member present in the clinic was available if any of the participants preferred to share opinions verbally. We wrote field notes based on observations and comments from participants and those who were invited to participate but declined.

Analysis

We used Stata SE 15 for Windows for all statistical analyses [45]. We applied descriptive statistics for demographic characteristics. In order to estimate the proportion of participants who would meet the inclusion criteria for the planned pilot RCT [46], we calculated the proportion of participants with single-item PAID scores ≥ 3 or total scores ≥ 30. Prior to analyses, we substituted missing PAID items by participants' mean score if minimum 18 (of 20) items were completed [47, 48]. Furthermore, we examined differences between male and female participants regarding total PAID scores, PAID ≥ 30, PAID ≥ 40 and item scores ≥ 3.

In order to evaluate the recruitment strategy, we registered the number of invited participants. Then we calculated the number and percentage of people who attended consultations and number and percentage of people who agreed to participate. We quantified the proportion of missing items (frequencies and percentages) and calculated the duration of the PROM sessions (median, minimum and maximum). In addition, we quantified the variables concerning comprehension of the PROMs, acceptability of number of items, relevance of PROMs and willingness for annual completion of electronic PROMs using frequencies and percentages.

Finally, we organised the field notes concerning our observations of technical and practical aspects and participants' comments chronologically by the date these were collected. Two of the researchers (IH and RBS) independently read the document and summarised the content describing the activities that took place in the waiting area. The text was adjusted and agreed by the project members who had been present in the waiting area.

Results

Recruitment

We invited 137 adults with T1D (72 men, 65 women) of whom 24 (17.5%) did not attend their scheduled outpatient clinic consultations (median age 47 yrs. (41–71), 58.3% men), leaving 113 potential participants (51.3% men) (Fig. 1). Five eligible participants (2 men, 3 women) did not participate due to technical ($n = 2$) or medical ($n = 3$) issues, and 20 (17.7%) declined participation (median age 48 yrs. (40–71), 55% men). On occasions where project members were not available for guidance at the outpatient clinic, 19 (out of 32) eligible participants did not approach the kiosk and thus did not participate (median age 48 years (41–59), 52.6% men). Finally, 69 (61.1%) participants (35 men, 34 women) completed the PROMs on the touchscreen computer. Most of the invited participants had to be reminded about the invitation and shown the location of the kiosk. Therefore, we included a picture of the kiosk in the

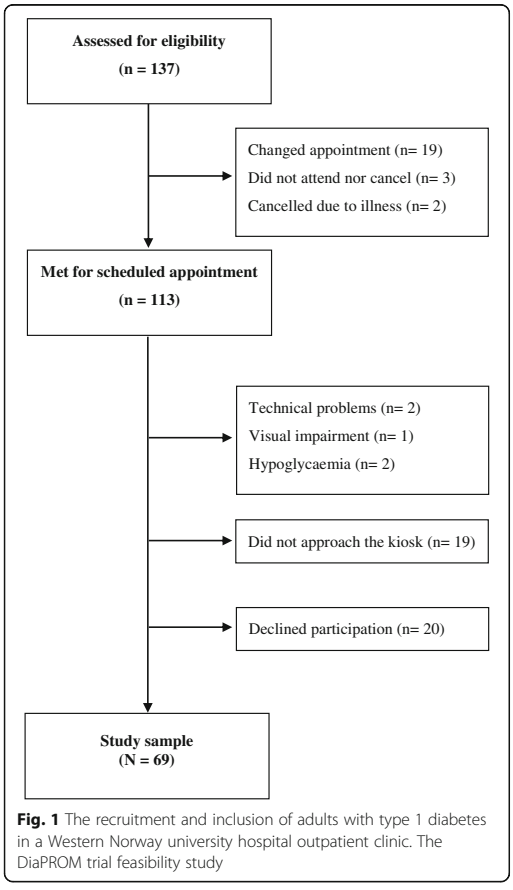

Fig. 1 The recruitment and inclusion of adults with type 1 diabetes in a Western Norway university hospital outpatient clinic. The DiaPROM trial feasibility study

information letter halfway through the recruitment period, which appeared to lead to more participants finding the kiosk by themselves.

Characteristics of the participants are presented in Table 1. All but three reported Norwegian as their first language. Over one half reported having university or college education, and 27 (41.5%) were in full-time employment. Women were slightly older than men, but men had longer diabetes duration (31 vs. 19 years). The median HbA1c value was 60.7 mmol/mol (7.7%). Thirty-five (50%) participants had at least one diabetes long-term complication, and retinopathy was the most frequent complication seen in 28 (40.6%). We found that nearly half of the participants met the inclusion criteria for the planned pilot RCT, and that two thirds of these were women (Table 2).

Table 1 Demographic characteristics among adults with type 1 diabetes attending an outpatient clinic in a Western Norway university hospital

Total	*N* = 69
Male sex, *n* (%)	35 (50.7)
Age (years) (median, min-max)	51.0 (40–74)
First language, *n* (%) [2]	
Norwegian	62 (95.4)
Other Scandinavian language	1 (1.5)
Other European language	2 (3.1)
Educational level, *n* (%) [3]	
Primary school	5 (7.8)
Secondary school	25 (39.1)
University/college ≤ 4 years	17 (26.55)
University/college > 4 years	17 (26.55)
Work affiliation, *n* (%) [2]	
Full-time work	27 (41.5)
Part-time work	9 (13.9)
Unpaid work	2 (3.1)
Unemployed	2 (3.1)
On sick leave/benefits	16 (24.6)
Retired	6 (9.2)
Other/not specified	3 (4.6)
Living alone, *n* (%) [2]	9 (13.9)
Diabetes duration (years) (median, min-max)	26.0 (1–67)
HbA_{1c} (mmol/mol) (median, min-max)	60.7 (41.0–107.7)
HbA_{1c} (%) (median, min-max)	7.7 (5.9–12.0)
At least one long-term complication, *n* (%)	35 (50.7)
Insulin injection device, *n* (%)	
Pen	43 (62.3)
Pump	26 (37.7)
Glucose monitoring device, *n* (%) [1]	
SBGM	47 (71.2)
FGM	3 (4.6)
CGM	16 (24.2)

HbA_{1c} haemoglobin A_{1c}, *SBGM* self-blood glucose monitoring, *FGM* flash glucose monitoring, *CGM* continuous glucose monitoring
[1] $n = 66$, [2] $n = 65$, [3] $n = 64$ due to missing data

Technical and practical procedures for collecting PROMs

The touchscreen computer mostly functioned well. However, we noticed that PROM sessions had been started but not finished on several occasions, which meant that sometimes a participant who was to start a new session found parts of the PROMs displayed instead of the start screen. As a result, technicians from DIPS programmed the application to display a 1 min inactivity notification with a 15-s countdown, and to stop the session if the screen was not touched during the countdown. Participants' median duration (minutes and seconds) for completing PROMs was 8 min 19 s (min 3 min 41 s–max 24 min 54 s) (Fig. 2). One man and one woman used > 20 min.

Comments expressed by the participants and logged in the field notes, indicated that participants in general expressed a positive attitude towards completing PROMs in the waiting area, favouring this option compared to an internet-based solution (e.g. from home). However, limited time spent in the waiting area ahead of the consultation was stated as a motive for wanting to complete PROMs at home in the future. Some participants found the two methods for proceeding to the next item confusing and suggested that it should be either automatic or touch-based. Regarding the four-character code, some handwritten letters and numbers were difficult to interpret (e.g. A and 4, B and 8, G and 6 and also Z and 2). Consequently, we will avoid these letters in the pilot RCT.

Participants' perceptions about the PROMs

Of the 69 participants, 65 completed the paper questionnaire regarding their perceptions about the PROMs. The PROM items were reported to be comprehensible to a large or very large degree by 62 (95.4%) participants, and 46 (70.8%) found the PROMs relevant at least to a large degree (Fig. 3). Fifty-one (78.1%) participants reported that the number of items was acceptable to a large or very large degree, and 54 (83.1%) reported willingness to complete PROMs annually at least to a large degree. Twenty-nine (42.0%) participants completed all PROMs without any missing items, 13 (18.8%) had one missing item, 12 (17.4%) had two missing items and the remaining 15 (21.2%) had three to 12 missing items (Table 3). The instruments' completion rates varied from 72.5 to 91.3% (Table 3) with an average rate of 81.4%.

In the field notes, we found that the majority of participants who commented verbally on the PROMs'

Table 2 PAID scores in adults with type 1 diabetes, including the proportion eligible for extra follow-up according to the planned intervention inclusion criteria. The DiaPROM trial feasibility study

	Total (*N* = 69)	Men (*n* = 35)	Women (*n* = 34)
PAID score (0–100) [1]			
Median (min-max)	22.4 (1.3–65.0)	21.3 (1.3–58.8)	32.5 (2.5–65.0)
Mean (SD)	25.9 (16.2)	21.4 (13.8)	31.1 (17.3)
PAID score ≥ 30, *n* (%) [1]	26 (39.4)	9 (25.7)	17 (50.0)
PAID score ≥ 40, *n* (%) [1]	11 (16.7)	3 (8.6)	8 (25.8)
Minimum one PAID item ≥ 3, *n* (%)	28 (40.6)	11 (31.4)	17 (50.0)
[#]PAID score ≥ 30 and/or minimum one item scored ≥ 3, *n* (%)	34 (49.3)	12 (34.3)	22 (64.7)

[#]The planned intervention inclusion criteria for the DiaPROM trial are a total score ≥ 30 or single-item PAID scores ≥ 3
[1] *n* = 66 due to missing data (3 women)

contents found them relevant and valued the focus on experiences of living with diabetes. However, participants interpreted the question concerning relevance of items differently. Some regarded it as being relevant to them personally at that point in time, while the question was intended to ask about general relevance for people with diabetes. Some questions were reported by participants as somewhat overlapping, but it was noted by other participants that some overlap could yield more nuanced information.

Discussion

In this study, we found that using a touchscreen computer for capturing PROMs electronically in our outpatient clinic setting was technically and practically feasible. The majority of participants reported the included PROMs to be acceptable and relevant. One half of the participants had either a PAID score ≥ 30 or a minimum one item scored ≥ 3, which indicated diabetes-related distress of concern, and participants with such scores qualify for extra follow-up in the upcoming pilot RCT. The mean PAID scores were in line with other studies of similar patient groups [43, 49]. Nearly two thirds of participants with elevated diabetes-related distress scores were women. Others have reported similar sex differences, especially in younger adults with T1D [50, 51].

Recruitment strategy

The recruitment of the 69 participants took 6 weeks. Keeping track of eligible participants who changed or did not keep their appointments was demanding. We observed that only a handful of invited participants who attended the clinic seemed to have considered participation prior to coming to the hospital, and the majority did not approach the touchscreen computer by themselves. After we included a picture of the kiosk in the information letter, more participants approached it without guidance. Nonetheless, efficient recruitment appeared to depend on the presence of a person who could

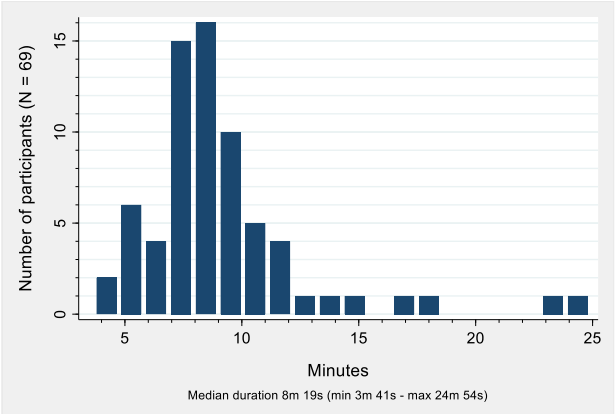

Fig. 2 Time needed to complete an electronic questionnaire on a touchscreen computer by adults with type 1 diabetes in an outpatient clinic at a Western Norway university hospital. The DiaPROM trial feasibility study

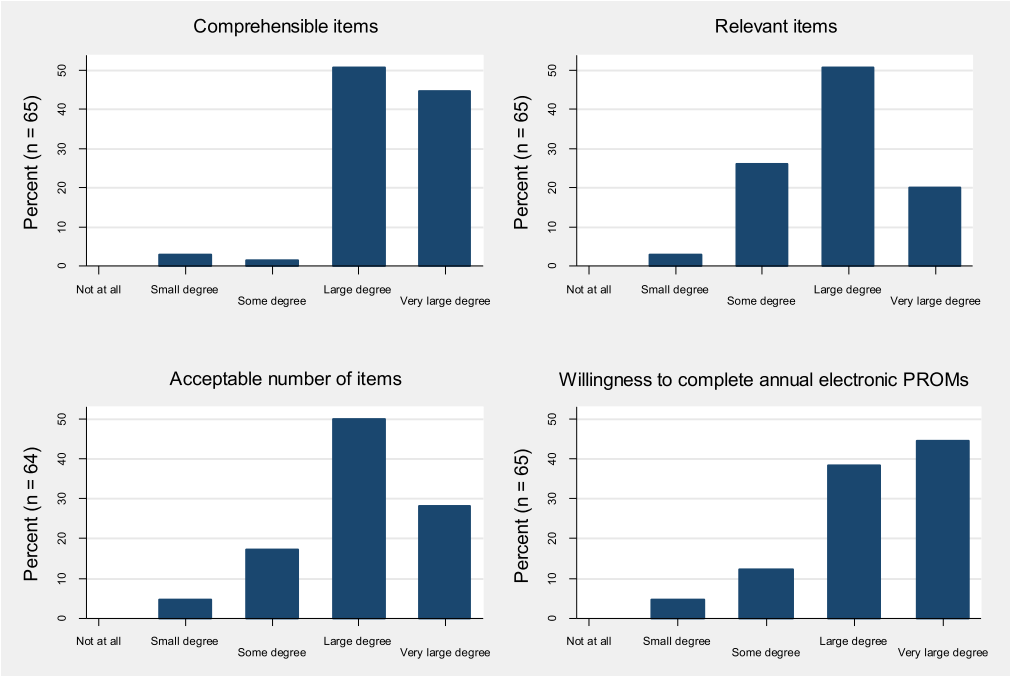

Fig. 3 Adults with type 1 diabetes and their perceptions about completing an electronic questionnaire on a touchscreen computer in an outpatient clinic at a Western Norway university hospital. The DiaPROM trial feasibility study

provide information, support participants and manage the recruitment logistics, a phenomenon also identified by Treweek [52]. Establishing new routines is in general challenging and will often require extra resources, especially in the earlier phases of implementation initiatives. Those who arrived shortly before the consultation did not have time to complete the PROMs and could therefore not participate unless the healthcare personnel was delayed. This may indicate that our recommendation of coming to the clinic at least 10 min ahead of the appointment was not adequately emphasised in the information letter. Preparing written study information requires the researchers to carefully consider wording and amount of text. The ethics committees' demands for compulsory text makes this task even more demanding. Thus, user involvement in preparing information is of utmost importance.

Technical and practical procedures for collecting PROMs

Electronic capturing of PROMs using a touchscreen computer was the only administration method offered in this feasibility study. Although we found no indication

Table 3 Number of individuals, *n* (%) with missing PROMs items among adults with type 1 diabetes attending an outpatient clinic in a Western Norway university hospital. The DiaPROM trial feasibility study

Self-report instruments	No. items	0 missing	1 missing	2 missing	3 missing	4 missing	5 missing
The WHO 5-Well-Being Index (WHO-5)	5	50 (72.5)	16 (23.2)	3 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)
The Problem Areas in Diabetes scale (PAID) [1]	20	53 (76.8)	10 (14.5)	3 (4.35)	1 (1.45)	0 (0.0)	1 (1.45)
Perceived Competence in Diabetes Scale (PCDS)	4	59 (85.5)	8 (11.6)	1 (1.45)	0 (0.0)	1 (1.45)	–
Perceived elevated, low and varied blood glucose values	3	59 (85.5)	5 (7.25)	0 (0.0)	5 (7.25)	–	–
Awareness of hypoglycaemia ("Gold")	1	63 (91.3)	6 (8.7)	–	–	–	–
RAND-12 Health Status Inventory (RAND-12) [2]	12	53 (76.8)	9 (13.0)	3 (4.35)	1 (1.45)	2 (2.9)	0 (0.0)

PROMs patient-reported outcome measures
[1] One person had seven missing PAID items. [2] One person did not complete the RAND-12 ($n = 68$)

that the data collection method represented an obstacle for participation, it may have influenced recruitment due to perceived technology barriers or the location of the kiosk. Recent meta-analyses and reviews refer to mixed results on preferences for electronic versus paper-based administration, ranging from 50% [18] to 87% [53] in favour of the electronic format. This suggests that patients of all ages have become increasingly more familiar with electronic devices, and using multiple methods for collecting PROMs and allowing multiple places for completing them might improve response rates [54]. However, the general recommendation is to avoid mixing modes within a study [22], since different administration methods require somewhat different skills and resources of those completing the PROMs [23].

We had to perform some minor layout changes when we adapted the paper-based PROMs to the electronic interface, but this was done in accordance with recommendations supporting equivalence of paper- and computer-administered PROMs [19–21]. However, the visual look thus turned out to differ a bit as multiple items are generally presented on the same page in paper-based PROMs, whereas electronic formats present one item at a time [20, 22]. We used a relatively large screen (17″), but still it was not possible to retain all items and response options of each self-report instrument on the same screen without compromising the font size. Hence, we chose the single item per screen approach to provide consistency across all instruments [22]. This also meant that we could present the items with relatively large fonts, making it more accessible to people with minor visual impairments.

We chose to locate the kiosk in close proximity to the outpatient clinic's waiting area to make it visible and easy to access, but at the same time not too close to the seating area for privacy reasons [23]. We received no negative comments on the location, neither about how the PROM items were presented on the screen. However, 19 out of 32 eligible participants did not approach the kiosk when the project members were not available for guidance. Furthermore, we registered that a number of PROM sessions had been started but not finished. This could be a result of questions being presented one at a time and the total number of items appearing to be too many for some people. In addition, people not eligible for the study might have been curious about the screen and its contents and thus might have started a PROM session without finishing. According to recommendations [55], completing PROMs in a clinical setting should not take more than 12–15 min. In our study, the median session duration was less than 9 min. Nonetheless, 16 participants (23.1%) used more than 10 min and 4 (5.7%) used more than 15 min. Hence, in similar studies, participants completing a questionnaire of 47 items should be encouraged to come to the clinic at least 15 min before their consultation.

We experienced few technical and practical problems during the study. WLAN connectivity problems could have been avoided using a cabled network. Due to possible misinterpretation of handwriting, we considered using printers for delivering the four-character code on slips of paper, but this could entail other logistical and technical issues, plus extra costs. Other in-clinic PROM studies report involving clinicians for logging the respondents into the electronic solution [56]. We did not develop this option as the outpatient clinic leaders were clear that it would not be possible to allocate personnel for this task in the future. In addition, we chose to avoid personal identification solutions such as BankID, a Norwegian cloud infrastructure allowing electronic ID, authentication and signing [57]. Due to the application's integration with the EPR, this would involve greater system security needs. Using the personal codes as described, the participants were in charge and control of their codes, available for interpretation, and we avoided security risks.

Participants' perceptions about the included PROMs

We chose a mix of generic and diabetes-specific instruments, which could have affected the perceived relevance of the PROMs. However, combining generic and condition-specific PROMs may result in a more in-depth assessment of health-related outcomes [23]. Although generic measures might not be considered relevant in follow-up of diabetes, condition-specific instruments may miss other health-related dimensions possibly unrelated to the condition, but still affecting patients [17, 58]. Several participants' expressed appreciation of the focus on psychosocial aspects of living with diabetes. Using PROMs to capture the participants' perceptions of their own health and thereby informing clinical practice thus has the potential to facilitate increased person-centred care [14, 17, 55].

The average PROM completion rate of 81.4% was relatively high. Therefore, our method for electronic capturing of data seems adequate. In addition, it might also reflect that the number and relevance of the questions were acceptable. Some argue that electronic PROM systems can lead to more complete and accurate datasets due to a reduction of missing or unusable data [16, 17, 19]. The method ensures that out-of-range, contradictory and/or extraneous responses are not possible. Furthermore, data entry errors are minimised since manual punching is not needed [17, 19, 23]. Although computer technologies require investment in software and hardware, collecting PROMs electronically is regarded as more economical concerning time and personnel resources compared to traditional paper-based collection

[23, 59]. However, 40 (58.0%) participants did not respond all items, where 25 (37.9%) completed all but one or two items. Except for one case, the missing data were due to incomplete instrument sections. The results are similar to another recent feasibility study reporting on collecting electronic PROMs (33 items), where 47.1% of the participants completed all items [56]. Lack of complete datasets is one of the greatest practical challenges related to the use of PROMs. Unfortunately, there is no generally accepted standard approach for handling missing PROMs data, and preventing missing data with a design that supports PROM completion is probably the most effective solution [60].

Strengths and limitations

We consider it a strength that the study included both men and women with long diabetes duration and experience with attending outpatient clinic consultations. Moreover, we collaborated with healthcare professionals with highly specialised information technology (IT) competence who had the skills to make necessary and timely improvements of the touchscreen application. Furthermore, it is a strength that we incorporated healthcare user involvement from the beginning of the design and development of the study in accordance with the GRIPP2 short form [61].

A relatively small, homogenous Norwegian sample limits generalisability. The findings were analysed descriptively due to the small sample and cross-sectional design. Recruitment was challenging since most participants had to be reminded about the study invitation and therefore did not approach the kiosk by themselves. Non-response is always a concern in recruitment and data collection since non-responders may be systematically different from those providing complete data [62], and the distribution of missing data across a range of measures also suggests this. Since we only used an electronic method for collecting PROMs, participation was limited to individuals capable of and interested in using the touchscreen computer. Therefore, participation may have been biased towards educated and younger informants. Our sample's educational level was higher than the Norwegian average for 40- to 67-year-olds, where 35% have university or college education and 22% have primary school only [63]. Consequently, our results may be limited to those familiar with electronic devices. Notwithstanding that, the public is becoming more experienced with using IT [53]. According to the 2018 Digital Economy and Society Index, 77% of Norwegian people have basic digital skills at least, and 96% are internet users [64], indicating capability of using a computer. By excluding groups of people unable to complete the electronic PROMs, we might lack potentially valuable insight regarding the impact of diabetes on these people's lives. For this group, completing PROMs with assistance could be an option. At this point, we chose to focus on an electronic data collection method. Finally, we consider it a limitation that the healthcare service users were not involved in preparing the written information for the present study.

Conclusions

We found that capturing PROMs on a touchscreen computer in the waiting area in connection with attending an outpatient clinic consultation was technically and practically feasible, and we identified only minor technical issues that will be improved prior to the pilot study. The majority of participants found the PROMs relevant and acceptable with a manageable number of items, and reported willingness to complete electronic PROMs annually in the future.

Additional file

Additional file 1: The included patient-reported outcome measures (PROMs) in the DiaPROM trial feasibility study. (PDF 123 kb)

Abbreviations

CGM: Continuous glucose monitoring; EPR: Electronic patient records; FGM: Flash glucose monitoring; IT: Information technology; PAID: Problem Areas in Diabetes scale; PCDS: Perceived Competence in Diabetes Scale; PROMs: Patient-reported outcome measures; RAND-12: The RAND-12 Health Status Inventory; RCT: Randomised controlled trial; SBGM: Self-blood glucose measurement; T1D: Type 1 diabetes; WHO-5: World Health Organization 5-Well-Being Index; WLAN: Wireless local area network

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Availability of data and materials

The datasets generated during the current study are available from the corresponding author on reasonable request.

Authors' contributions

AH, MG, IH and RBS designed the study. IH coordinated the data collection where AH and RBS also contributed in the recruitment process. IH drafted the manuscript. AH, DR, RBS, RMN, GT and MG revised the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Regional Committee for Medical and Health Research Ethics (reference number 2016/2200) and was performed according to the Declaration of Helsinki. Participants provided informed written consent and were free to withdraw their consent at any time without explanation and without any consequence for further follow-up at the outpatient clinic.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Additional file 1: The included patient-reported outcome measures (PROMs) in the DiaPROM trial feasibility study

PROMs	# items	Scoring	Score	Interpretation	
Problem Areas in Diabetes scale (PAID) [11, 27]	20	**5 point Likert scale** 0 "not a problem" → 4 "serious problem" Scores are summated. Raw score 0 to 80 is transformed to 0-100 by multiplying by 1.25.	0-100 Item scores	≥ 40 ≥ 30 ≥ 3	Serious diabetes-related distress. Moderate diabetes-related distress. Somewhat serious to serious distress regarding a particular topic.
Perceived Competence in Diabetes Scale (PCDS) [33]	4	**7 point Likert scale** 1 "strongly disagree" → 7 "strongly agree" Scores are summated and divided by 4 to form a mean score.	1-7	-	Higher scores indicate better perceived competence.
Awareness of hypoglycaemia [34]	1	**Visual analogue scale of 1 to 7** 1 "always aware" → 7 "never aware" Item score.	1-7	-	Higher scores indicate lower awareness of hypoglycaemia. A score of ≥4 implies impaired awareness of hypoglycemia.
High/Low/Varied blood glucose	3	**Visual analogue scale of 1 to 7** 1 "not at all" → 7 "most of the time" Item scores.	1-7	-	Lower scores indicate better perceived control over blood glucose fluctuations.
WHO-5 Well-being index (WHO-5) [35]	5	**6 point Likert scale** 0 "never" → 5 "all of the time" Scores are summated. Raw score 0 to 25 is transformed to 0-100 by multiplying by 4.	0-100	≤ 50 < 28	Indication of suboptimal well-being and further testing is recommended. Likely depression.
RAND-12 Health Status Inventory (RAND-12) [37, 38]	12	Response options differ. 6 items create the physical health component (PHC) and 6 items create the mental health component (MHC).	PHC & MHC	> 50 40-49 30-39 < 30	Indicates person is likely to be well. Indicates person has mild disability. Indicates person has moderate disability. Indicates person has severe disability

Electronic capturing of patient-reported outcome measures on a touchscreen computer in clinical diabetes practice (the DiaPROM trial): a feasibility study.
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Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomised controlled trial pilot study

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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 recognised and often under-reported 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 randomised 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 using the Problem Areas In Diabetes (PAID) scale in clinical diabetes consultations in order to conclude whether a fully powered trial is appropriate and/or feasible. The study will also include qualitative indepth interviews with participants and healthcare providers. Our objectives are to (1) evaluate the recruitment procedures and attrition rates; (2) evaluate the performance of the randomisation 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 healthcare 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). We will present the findings from the study phases at national and international conferences and submit manuscripts to peer-reviewed journals and popular science journals.

Trial registration number NCT03471104; Pre-results.

Strengths and limitations of this 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 randomised controlled trial (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 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 as important barriers for satisfactory diabetes self-management.[6]

The psychological and emotional impact of living with diabetes is often unrecognised and/or under-reported 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 well-being followed by a discussion of outcomes improves psychological well-being in both adults and youth with diabetes.[14 18 19] In the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) Monitoring of Individual Needs in Diabetes (MIND) study,[14] the skills used in discussions of PROMs data regarding diabetes distress and well-being were based on empowerment theory and patient-centred communication. Empowerment in nursing and healthcare 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 healthcare 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 *et al*[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-centred 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 well-being, 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 randomised 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. We wanted to design a study to test a method for using 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 commonly used PROMs to measure diabetes distress. We recognised 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 which 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] emphasise the necessity of a justified choice of measurement and recommend the use of the PAID when the clinical purpose is to bear in

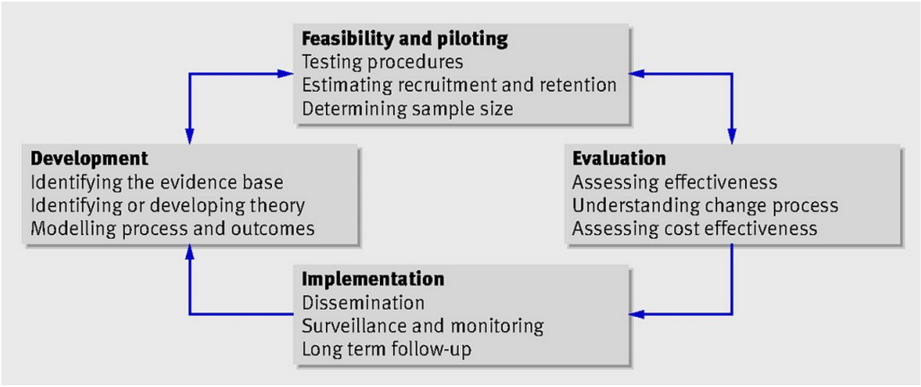

Figure 1 Key elements in the Medical Research Council's guidance for developing, evaluating and implementing complex interventions (MRC framework). Reproduced from Craig et al[22] with permission.

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 healthcare 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 Guidance for Reporting Involvement of Patients and the Public 2 (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 emphasise 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 (eg, WHO's 5-Item Well-Being Index [WHO-5], RAND-12 Health Status Inventory, Patient Activation Measure) and diabetes-specific instruments (eg, 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 (eg, '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-based 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 (EPRs) 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 on 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.

Aims

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. The following are our objectives:

1. Evaluate the recruitment procedures and attrition rates.
2. Evaluate the performance of the randomisation 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.
5. Explore patients' and healthcare 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 healthcare providers' views of the DiaPROM intervention initiative. We report our protocol here using the Standard Protocol Items: Recommendations for Interventional Trials 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 women, patients with known and recorded cognitive deficiency (eg, Down's syndrome, Alzheimer), severe somatic comorbidity (eg, end-stage renal disease, severe heart failure, severe cancer), and/or a major psychiatric diagnosis (eg, severe depression or bipolar disorder, schizophrenia) as diabetes distress is often neither ethical nor possible to discuss with these groups 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.

Randomisation procedure and allocation concealment

We will randomise eligible and consenting participants, using computer-generated block randomisation 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 computerised 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 healthcare providers.

Trial intervention

After participants have completed the PAID scale, physicians download the scores into the participants' EPR as part of the annual consultation (figure 2). Physicians then review and discuss the PAID scores briefly with the 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 4 weeks after randomisation, and the second within a further 3 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 the PAID scores and discuss the reported problem areas and distress with participants by following a communication manual based on key elements from

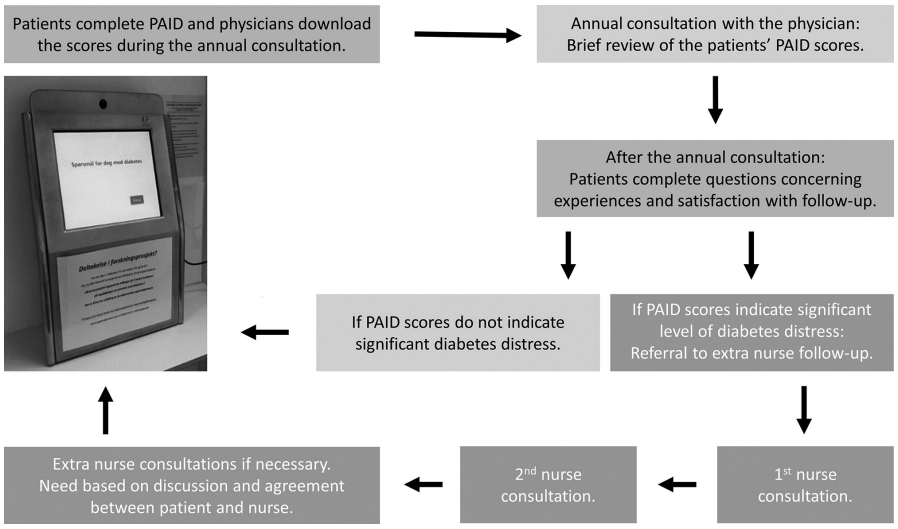

Figure 2 The study intervention in the Diabetes Patient-Reported Outcome Measures trial (DiaPROM). PAID, Problem Areas In Diabetes scale.

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 1 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 constitutes 'care as usual'. Although all participants will complete the PAID before randomisation, 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 the PAID data. We will identify to what extent such discussions have taken place by reviewing participants' EPR.

Training of healthcare providers

Before the study commences, we will have a 1-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 2×1 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 on 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 the number of eligible participants invited, number of invited people declining participation, number of people who attended the clinic, number of intervention participants who attended the nurse consultations and number of consultations conducted. We will also observe and document the technical performance of the randomisation 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 computerised retrieval of the following variables from the participants' EPR: sex, age, ethnicity, body mass index, diabetes duration, haemoglobin A1c (HbA1c) (secondary outcome), insulin regimen, insulin doses, severe hypoglycaemic episodes needing assistance in the past year, hospitalisations, comorbidities and diabetes late complications.

The outcome measures to evaluate the effect of the intervention in the evaluation phase of the study (phase

III) were chosen based on a literature review and considerations among the researchers and the health service users. We decided on the DDS as primary outcome. DDS measures diabetes distress and contains 17 items and 4 subscales: emotional burden (five items), physician-related distress (four items), regimen distress (five items) and diabetes-related interpersonal distress (three items).[41] 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.[42] The 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 identification of subdomains of distress.[11 25 36] To measure the secondary outcomes, overall well-being 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 healthcare providers (physicians and diabetes nurses) participating in the intervention group to individual indepth 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 healthcare 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 V.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 analyse between-group calculations. The participants' PAID scores will be analysed descriptively (mean, SD), as well.

We will transcribe verbatim and analyse participants' and healthcare 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 rereading, (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

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 principal 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 ethics committee and ClinicalTrials.gov. Further information can be obtained from ClinicalTrials.gov, trial 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 (eg, 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 health service user groups. One of the health service users included in the project group 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 fully 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 III), 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 to 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 distress and improving glycaemic control. A previous literature review by Carlsen *et al*[51] found that the use of PAID could benefit patients but emphasised 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 using 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 has advantages for use in clinical trials, because it also contributes to identifying subdomains 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 well-being and perceived competence. Snoek *et al*[14] indicated an overlap between predictors for diabetes distress and general well-being 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 EPRs of participants in the control group.

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Contributors All authors have contributed in accordance with the criteria for authorship. AH and MG applied for funding of the trial. AH, IH, MG and RBS designed the study with involvement of GST, DAR 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 Obtained.

Ethics approval The Western Norway Regional Committee for Medical and Health Research Ethics has approved the study (2017/1506/REK west).

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

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.

BACKGROUND

Type 1 diabetes (T1D) is a chronic, autoimmune 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, glycosylated 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 ketoacidosis 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 affiliation. 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 seriously 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 depression.[46 47] A 10-point change is considered clinically relevant.[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).

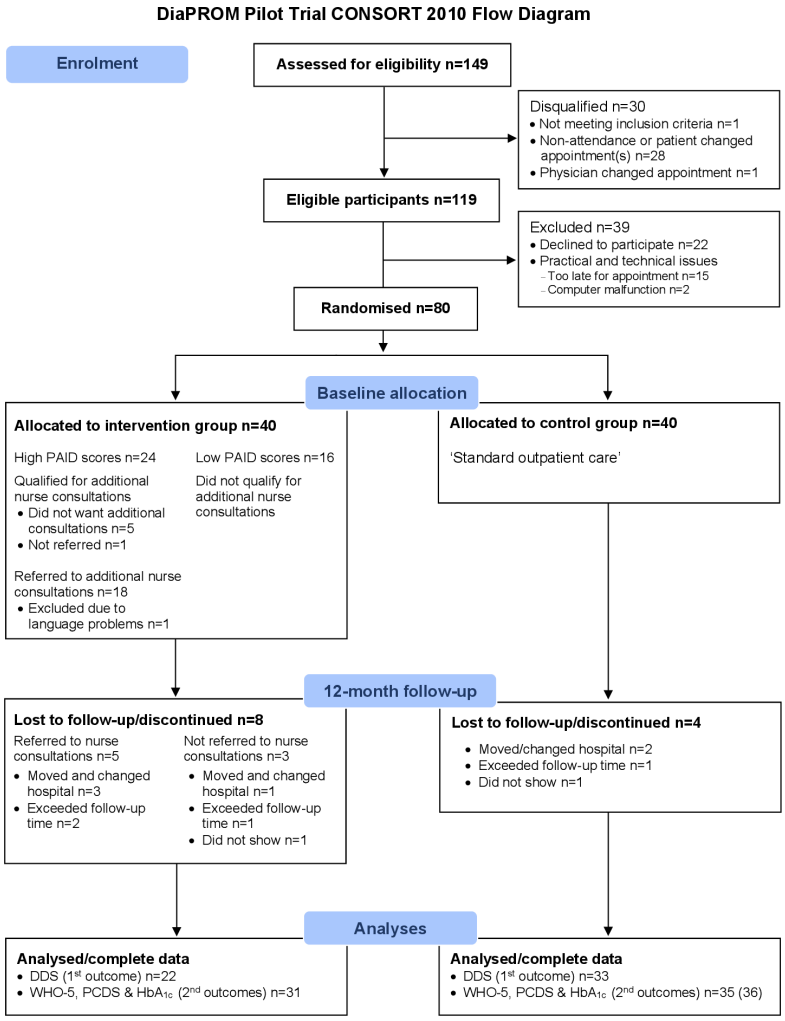

Figure 1 The DiaPROM pilot trial's consolidated standards of reporting trials flow diagram. (CONSORT, Consolidated Standards of Reporting Trials; DiaPROM, Diabetes Patient-Reported Outcome Measures; DDS, Diabetes Distress Scale; PAID, Problem Areas In Diabetes; PCDS, Perceived Competence for Diabetes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

		Baseline				12 months				Change from baseline to 12 months			Between-group difference¶	
Outcome measure	**Participants**	**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

		Baseline				12 months				Change from baseline to 12 months			Between-group difference**	
Outcome measure	**Participants**	**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 (0.5x 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.

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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Contributors All authors have contributed in accordance with the criteria for authorship. AH and MG applied for funding. AH, IH, MG and RBS designed the study with involvement of GST, DAR, RMN, MR, KFL and TVM. IH wrote the first draft of this manuscript. AH, MG, DAR, RBS, RMN and GST gave substantial contributions to the interpretation of data and revised the manuscript critically. All other authors have edited and critically reviewed the manuscript. Finally, all authors read and approved the final version of the paper.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study was approved by the Regional Committee for Medical and Health Research Ethics (reference number 2017/1506/REK vest) and was undertaken in accordance with the Declaration of Helsinki. All study data have been stored on a secure research server at Haukeland University Hospital, the responsible research institution. Participation was voluntary and participants gave informed written consent. Participants were free to withdraw their consent at any time without explanation, and withdrawal would not affect their further follow-up at the outpatient clinic.

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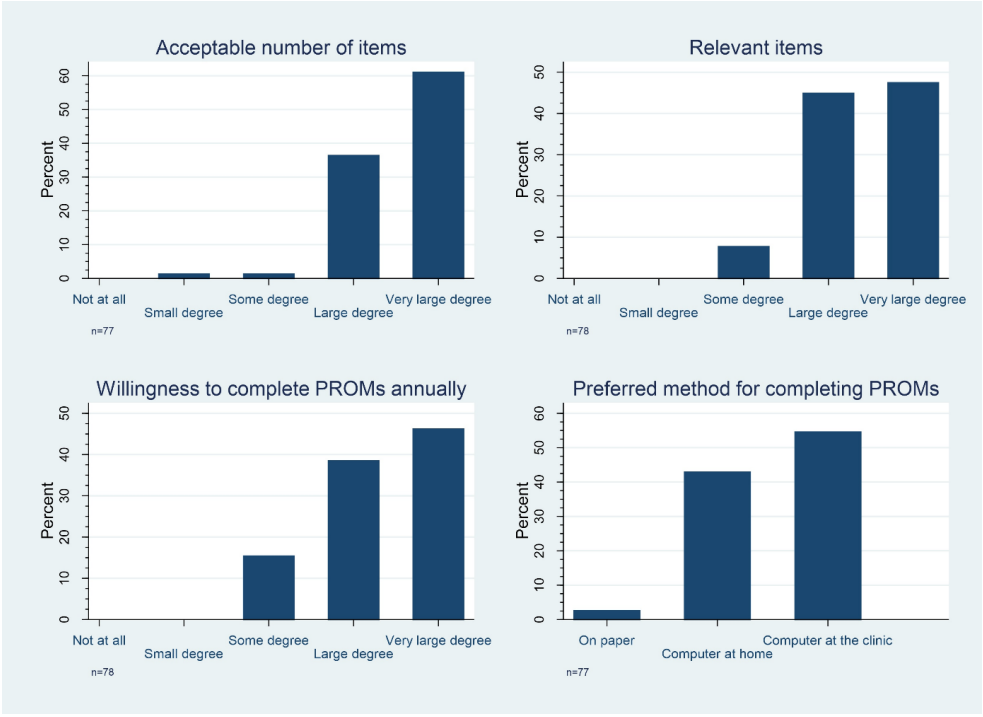
DiaPROM pilot trial supplementary figure

Supplementary figure 1: Young adults' (18-39 years) perceptions about completing electronic PROMs at baseline - the DiaPROM pilot trial.



Hernar I, Graue M, Richards DA, Strandberg RB, Nilsen RM, Rekdal M, et al. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: the DiaPROM randomised controlled pilot trial. BMJ Open. 2021;10.1136/bmjopen-2020-042353.

Supplementary tables – DiaPROM pilot trial

Supplementary table 1: Summary of Problem Areas In Diabetes (PAID) scores ≥30 or ≥40 and items scored ≥3 - the DiaPROM pilot trial.

	Baseline			12-month follow-up		
	Total	**Control group**	**Intervention group**	**Total**	**Control group**	**Intervention group**
PAID[1]	N=79	n=40	n=39	N=67	n=36	n=31
Total score ≥30	29 (36.7)	14 (35.0)	15 (38.5)	25 (37.3)	16 (44.4)	9 (29.0)
At least one item scored ≥3	41 (51.9)	19 (47.5)	22 (56.4)	29 (43.3)	18 (50.0)	11 (35.5)
Total score ≥30 and/or item ≥3	42 (53.1)	19 (47.5)	23 (59.0)	33 (49.3)	20 (55.6)	13 (41.9)
Total score ≥40	13 (16.5)	5 (12.5)	8 (20.5)	10 (14.9)	6 (16.7)	4 (12.9)

Data are n (%).[1] Problem Areas in Diabetes scale.

Supplementary table 2: Summary of missing PROM items (< 50% or ≥ 50% missing items) and complete data at baseline and 12-month follow-up - the DiaPROM pilot trial.

	Baseline				12-month follow-up			
Outcome measure	**n**	**< 50% missing**	**≥ 50% missing**	**Complete**	**n**	**< 50% missing**	**≥ 50% missing**	**Complete**
DDS[1]	79	5 (6.3)	7 (8.9)	67 (84.8)	67	2 (3.0)	7 (10.4)	58 (86.6)
WHO-5[2]	79	1 (1.3)*	0 (0.0)	78 (98.7)	67	1 (1.5)*	0 (0.0)	66 (98.5)
PCDS[3]	79	0 (0.0)	0 (0.0)	79 (100.0)	67	0 (0.0)	1 (1.5)	66 (98.5)
PAID[4]	79	10 (12.7)*	0 (0.0)	69 (87.3)	67	8 (11.9)*	0 (0.0)	59 (88.1)

Data are n (%). [1] Diabetes Distress Scale, [2] World Health Organisation five-item wellbeing index,
[3] Perceived Competence for Diabetes Scale, [4] Problem Areas in Diabetes scale, * single missing items.

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Supplementary table 3: Correlation between participants' outcome measure scores at baseline and 12-month follow-up – the DiaPROM pilot trial.

Association	Participants	n	Spearman's ρ	95% CI around Spearman's ρ
Primary outcome				
DDS[1] score at baseline and 12 months	All	55	0.8	0.7, 0.9
	Intervention	22	0.8	0.6, 0.9
	Control	33	0.8	0.6, 0.9
Secondary outcomes				
WHO-5[6] score at baseline and 12 months	All	67	0.5	0.3, 0.7
	Intervention	31	0.5	0.2, 0.7
	Control	36	0.5	0.2, 0.7
PCDS[7] score at baseline and 12 months	All	66	0.7	0.5, 0.8
	Intervention	31	0.6	0.3, 0.7
	Control	35	0.8	0.6, 0.9
HbA_{1c} value[8] at baseline and 12 months	All	66	0.7	0.5, 0.8
	Intervention	31	0.6	0.3, 0.7
	Control	35	0.7	0.5, 0.8

[1] Diabetes Distress Scale (1-6), [2] Emotional burden (1-6), [3] Physician-related distress (1-6), [4] Regimen-related distress (1-6), [5] Interpersonal distress (1-6), [6] World Health Organisation five-item wellbeing index (0-100), [7] Perceived Competence for Diabetes Scale (1-7), [8] Haemoglobin A_{1c} (target for glycaemic control in mmol/mol).

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Supplementary table 4: Participants' diabetes distress score (DDS) categories at baseline and 12-month follow-up – the DiaPROM pilot trial.

	Baseline			12-month follow-up		
	Total	**Intervention group**	**Control group**	**Total**	**Intervention group**	**Control group**
DDS[1] overall score	N=72	n=33	n=39	N=60	n=26	n=34
Little or no distress (<2.0)	39 (54.2)	15 (45.5)	24 (61.5)	32 (53.3)	15 (57.7)	17 (50.0)
Moderate distress (2.0-2.9)	22 (30.6)	15 (45.5)	7 (18.0)	24 (40.0)	10 (38.5)	14 (41.2)
High distress (≥3.0)	11 (15.3)	3 (9.0)	8 (20.5)	4 (6.7)	1 (3.8)	3 (8.8)
Emotional burden	N=72	n=33	n=39	N=60	n=26	n=34
Little or no distress (<2.0)	26 (36.1)	11 (33.3)	15 (38.5)	20 (33.3)	9 (34.6)	11 (32.3)
Moderate distress (2.0-2.9)	24 (33.3)	10 (30.3)	14 (35.9)	25 (41.7)	11 (42.3)	14 (41.2)
High distress (≥3.0)	22 (30.6)	12 (36.4)	10 (25.6)	15 (25.0)	6 (23.1)	9 (26.5)
Physician-related distress	N=67	n=33	n=34	N=59	n=26	n=33
Little or no distress (<2.0)	55 (82.1)	26 (78.8)	29 (85.3)	49 (83.1)	21 (80.8)	28 (84.8)
Moderate distress (2.0-2.9)	8 (11.9)	4 (12.1)	4 (11.8)	7 (11.9)	4 (15.4)	3 (9.1)
High distress (≥3.0)	4 (6.0)	3 (9.1)	1 (2.9)	3 (5.1)	1 (3.8)	2 (6.1)
Regimen-related distress	N=70	n=32	n=38	N=60	n=26	n=34
Little or no distress (<2.0)	24 (34.3)	10 (31.3)	14 (36.8)	22 (36.7)	9 (34.6)	13 (38.2)
Moderate distress (2.0-2.9)	28 (40.0)	14 (43.8)	14 (36.8)	30 (50.0)	16 (61.5)	14 (41.2)
High distress (≥3.0)	18 (25.7)	8 (25.0)	10 (26.4)	8 (13.3)	1 (3.9)	7 (20.6)
Interpersonal distress	N=65	n=30	n=35	N=60	n=26	n=34
Little or no distress (<2.0)	45 (69.2)	20 (66.7)	25 (71.4)	40 (66.7)	19 (73.1)	21 (61.8)
Moderate distress (2.0-2.9)	12 (18.5)	8 (26.7)	4 (11.4)	14 (23.3)	7 (26.9)	7 (20.6)
High distress (≥3.0)	8 (12.3)	2 (6.6)	6 (17.2)	6 (10.0)	0 (0.0)	6 (17.6)

Data are presented as n (%).[1] Diabetes Distress Scale – scores ≥2.0 are considered clinically relevant.

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RESEARCH:CARE DELIVERY

Young adults with type 1 diabetes and their experiences with diabetes follow-up and participation in the DiaPROM pilot trial: A qualitative study

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Abstract

Aim: To explore young adults' experiences of outpatient follow-up appointments, completing electronic Patient-Reported Outcome Measures (PROMs), and using the Problem Areas In Diabetes (PAID) scale during the Diabetes Patient-Reported Outcome Measures (DiaPROM) pilot trial.

Methods: We performed a qualitative study among 19 young adults (aged 22–39 years) with type 1 diabetes who participated in the pilot trial. Between February and June 2019, we conducted individual, semi-structured telephone interviews with participants from the intervention and control arms. We analysed the data using thematic analysis.

Results: Our analyses generated three themes, each with two subthemes: (1) Follow-up with limitations; (i) Marginal dialogue about everyday challenges, (ii) Value of supportive relationships and continuity, indicate that previous follow-up had been experienced as challenging and insufficient. (2) New insights and raised awareness; (i) More life-oriented insights, (ii) Moving out of the comfort zone, suggest mostly positive experiences with completing questionnaires and discussing the PAID scores. (3) Addressing problem areas with an open mind; (i) Need for elaboration, (ii) Preparedness for dialogue, indicate that both openness and explanations were vital in the follow-up.

Conclusions: Participants characterised the previous follow-up as challenging and insufficient. They described completing and using the PAID as somewhat uncomfortable yet worthwhile. Our findings also suggest that by utilising diabetes distress data alongside health and biomedical outcomes, consultations became more attuned to the young adults' wishes and needs, mainly because the dialogue was more focused and direct. Hence, the PAID has the potential to facilitate person-centredness and improve patient–provider relationships.

KEYWORDS
diabetes mellitus, empowerment, outpatient care, patient-centred care, professional–patient relations, self report, type 1 adult

1 | INTRODUCTION

Managing type 1 diabetes is a persistent activity performed outside the diabetes care setting. Due to the nature of the disease, self management extends beyond glycaemic control and other biomedical outcomes, also affecting emotional health and social functioning.[1] Finding a balance between diabetes and living can be challenging regardless of age but especially so in young adulthood.[2] Experiences of burden, stress, anxiety and/or concern that arise from daily self management are referred to as diabetes distress.[3] About one-third of adults with type 1 diabetes will experience distress levels likely to impact on self management and clinical outcomes.[4] Furthermore, diabetes distress is more prevalent in younger adults than other age groups[2] and associated with problematic self management behaviours and poor glycaemic control.[5,6] However, achieving recommended glucose targets does not necessarily exclude distress.[3] Diabetes distress is viewed as a predictable response to having diabetes, not as psychopathology, and should, therefore, be addressed in routine diabetes care.[3]

For more than two decades, diabetes guidelines and position statements have acknowledged person-centred approaches to promote optimal well-being and disease management.[7] Recommendations include routine assessment of psychological, emotional and psychosocial factors, such as diabetes distress, to identify problems and improve health outcomes. Diabetes distress can be assessed using Patient-Reported Outcome Measures (PROMs).[3] Previous research suggests that PROMs can improve chronic care delivery by assessing, identifying and monitoring health outcomes, improving patient–provider communication, and promoting involvement in self management.[8] However, recent studies indicate that healthcare providers (HCPs) still place excessive focus on biomedical outcomes compared to those that people with diabetes find important.[9,10]

Guided by the Medical Research Council's framework for developing and evaluating complex interventions,[11] we have designed, feasibility tested and piloted an intervention to address diabetes distress in the Diabetes Patient-Reported Outcome Measures (DiaPROM) trial.[12-14] The pilot trial targets young adults (age ≥18 to <40) with type 1 diabetes receiving outpatient follow-up and is described in detail elsewhere.[12] Briefly, we used the 20-item Problem Areas in Diabetes (PAID) scale to identify distress sources and intensity.[15,16] Items are scored from 0 'not a problem' to 4 'serious problem' and transformed to a 0–100 scale, where scores ≥40 are considered seriously elevated. Before the annual appointment with a physician, all participants (N = 79) completed the PAID on an in-clinic touchscreen computer and were randomly assigned (1:1) to an intervention (n = 39) or control arm (n = 40). In the intervention arm, physicians reviewed and discussed the PAID with the participants, guided by a manual about how to interpret and act on the scores. Twenty-three individuals reported a score ≥30 or at least one item scored ≥3, therefore qualifying for additional diabetes specialist nurse consultations, of which 17 accepted. To lessen or prevent serious distress, the nurses reviewed and discussed reported problem areas with the participants, guided by a study manual with specific person-centred communication techniques (active listening, asking open questions, responding, summing up and agreeing on goals and actions to take). Control arm participants received standard outpatient care with no review of scores. Finally, all participants completed the PAID again at 12 months (reported elsewhere).

We have conducted two qualitative studies alongside the DiaPROM pilot trial to inform the quantitative findings by exploring participants' and HCPs' experiences and views on feasibility and acceptability.[12] The findings from HCP experiences are published.[17] In the present study, we aimed to explore young adults' experiences of outpatient follow-up appointments, completing electronic PROMs, and using the PAID scale during the DiaPROM pilot trial.

Whats' New?

- Diabetes distress is common among young adults with type 1 diabetes.
- We found that the Problem Areas in Diabetes (PAID) scale encouraged reflective thinking, promoted the young adults' narratives and facilitated person-centred dialogue in consultations.
- Implications are that healthcare services need to adapt to and acknowledge young adults' wishes by addressing diabetes distress during appointments. However, continuity of care and development of young adult–provider relationships are essential ingredients for utilising the PAID in the follow-up.

2 | PARTICIPANTS AND METHODS

2.1 | Study design

We performed an exploratory qualitative study among DiaPROM pilot trial participants. Our approach was inductive and descriptive, focusing on experiences with outpatient appointments and specific pilot trial components.

2.2 | Setting and participants

We undertook the randomised controlled pilot trial and qualitative studies at a Norwegian diabetes outpatient clinic.[13] The clinic employs endocrinologists, physicians specialising in endocrinology (or other internal medicine specialities), diabetes nurse specialists and health service secretaries. About 1500 adults with type 1 diabetes were registered there in 2019. Our eligibility criteria for the present study were pilot trial participation with completed 12-month follow-up. We sent study invitations to the 67 eligible participants 3–7 days after their 12-month follow-up and asked them to respond by e-mail, telephone or SMS. None replied within 14 days; therefore, we sent SMS reminders. Finally, 19 individuals responded positively: age 22–39 years, diabetes duration 5–32 years (Table 1); eight control arm and 11 intervention arm participants, of which six had received additional nurse follow-up.

TABLE 1 Characteristics of adults with type 1 diabetes participating in the DiaPROM pilot trial interview study

	Total	Intervention arm	Control arm
Participants	19 (100)	11 (58)	8 (42)
Women	11 (58)	6 (55)	5 (63)
Referred to nurse follow-up	6 (32)	6 (55)	NA
Age (years)	30 ± 5.2	29 ± 4.3	31 ± 6.3
Diabetes duration (years)	16 ± 7.4	17 ± 8.0	16 ± 7.1
Late complications*	4 (21)	2 (18)	2 (25)
Insulin pump therapy	12 (63)	7 (64)	5 (63)
Continuous glucose monitor	10 (53)	6 (55)	4 (50)
HbA1c (mmol/mol)	59 ± 11.7	58 ± 9.1	59 ± 15.3
HbA1c (%)	7.5 ± 1.1	7.5 ± 0.8	7.5 ± 1.4

Data are n (%) or mean ± SD. NA = not applicable.

*All cases of untreated retinopathy.

2.3 | Data collection

We offered individual interviews face-to-face or by telephone. All participants chose telephone interview. Between 26 February and 24 June 2019, the first author conducted and audio-recorded the interviews (average duration 39 minutes). The semi-structured interview guide received minor adjustments after the first two interviews (Data S1). First, participants in both trial arms were invited to share experiences with previous follow-up. Next, all participants were asked about electronic completion and relevance of the PROMs. Also, we encouraged intervention arm participants to share experiences with the physicians' review of the PAID scores and, where relevant, with attending additional nurse follow-up. The first author transcribed the interviews verbatim and checked the transcripts against the recordings for accuracy. We obtained clinical and socio-demographic characteristics from the pilot trial dataset. At the time, these characteristics were unknown to the interviewer.

2.4 | Data analysis

We analysed the data using thematic analysis, which focus on identifying, analysing and reporting patterned meaning (themes) across a dataset.[18] Thematic analysis is theoretically flexible and characterised by an iterative, rigorous process of data familiarisation, open-coding, development of themes and revision. We applied an inductive approach and combined semantic and latent levels of analyses. The Norwegian-speaking authors (IH, MG, RBS, SSL, AKS, BCHK, AH) which constituted the analysis team, first read and reread all interviews to familiarise with the dataset. Next, each author recorded their preliminary ideas and generated initial codes. The team then met for two workshops. In the first workshop, each member shared initial thoughts and preliminary codes. We discussed features relevant to the aim, collated codes by pattern, prepared a schematic overview and formed candidate themes by identifying similarity and clustering. In the second workshop, we reviewed, discussed and revised the candidate themes, which also included creating new codes and themes for data falling outside the previous coding. IH continued the process and drafted the paper. Finally, we identified meaningful, coherent patterns and agreed on themes and subthemes.

2.5 | Ethics

The study received ethical approval by the Western Norway Regional Committee for Medical and Health Research Ethics (2017/1506/REK vest). This study was specifically described in the pilot trial's written information. All participants provided written consent and could withdraw at any

time, without giving a reason and without it affecting their follow-up. Participants chose the interview method and decided on timing. Audio-recordings were started after the interviewee had consented and pauses were provided if needed. Afterwards, participants were given time to debrief and, if deemed necessary by the interviewer, provided with information on clinical supervision and support. Participants' identifying information was removed from the transcripts before a digitally encrypted document was shared with the analysis team. Data are stored on Haukeland University Hospital's secure research server.

3 | RESULTS

The analyses generated three themes: 'Follow-up with limitations', 'New insights and raised awareness' and 'Addressing problem areas with an open mind', each with two subthemes (Table 2).

3.1 | Follow-up with limitations

The participants described previous outpatient follow-up as challenging and insufficient, which is further explored in the subthemes 'Marginal dialogue about everyday challenges' and 'Value of supportive relationships and continuity'.

3.1.1 | Marginal dialogue about everyday challenges

Several participants characterised the follow-up as challenging and conveyed hesitance and reluctance about attending, especially physician check-ups. One expressed:

> "[It is] a bit like sitting for an exam, going to a check-up. I don't think it's deliberate, but you feel a bit like they're wagging a finger, right. You worry about your HbA1c because then you might be seen as 'a not so good diabetic'. That kind of follow-up is the reason why I've hardly attended. It's been a problem."
>
> (Participant 8, control arm)

TABLE 2 Themes and subthemes generated by the analyses of interviews with 19 young adults with type 1 diabetes their experiences with outpatient follow-up and participation in the DiaPROM pilot trial

Themes	Subthemes
Follow-up with limitations	Marginal dialogue about everyday challenges
	Value of supportive relationships and continuity
New insights and raised awareness	More life-oriented insights
	Moving out of the comfort zone
Addressing problems areas with an open mind	Need for elaboration
	Preparedness for dialogue

According to interviewees, annual check-ups typically focused on biomedical 'numbers', for example, blood tests, glucose values and insulin doses, often at the expense of conversations about everyday life. However, opinions varied. Some experienced that such check-ups were not worthwhile. One participant put it like this:

> "I feel that I'm only there for them [physicians] to tick off something on a checklist and do their job in a way. … I feel that there's no point in being there then because what do I gain from them weighing me and measuring me? Uh. I don't feel that we're talking about important issues."
>
> (Participant 19, control arm)

Others stated that check-ups provided a sense of security about their disease management. While some did not know what to expect beyond information about test results. In addition, experiences were compared to previous paediatric follow-up, as described by one:

> "I do expect to be able to talk to someone about diabetes itself and not just how the test results are, you know, bodily in a way. At the paediatric clinic, they were much better at that because there was more of a holistic focus there I felt. When I was transferred to the adult clinic, I felt they were less focused on that."
>
> (Participant 15, intervention arm)

The young adults conveyed being accustomed to questions like *'How are you doing?'*. However, such inquiries were often perceived as superficial and difficult to address and therefore often answered half-heartedly, without promoting dialogue where they opened up. Although stating a wish to be asked about the emotional aspects of self management, they also expressed ambivalence due to previous unpleasant experiences. One said:

> "I think it's a good idea to ask patients questions about what we think about our lives, our diabetes and situation. We're after all the ones who know best, but at the same time, I quickly feel that I'm put on the spot and that I have to answer very properly, and then I, like, don't really get to

answer what I think. I feel that it's a pressured situation. Uhm yeah."

(Participant 16, intervention arm)

Moreover, participants specified that the pilot trial's focus on diabetes distress further highlighted that previous follow-up had been deficient. One stated:

"That [questionnaire] underlined the fact that there are very many issues a physician can bring up. So, I mean, a lot is missing there. At least when you're there just once a year and if you're a 'good patient'."

(Participant 15, intervention arm)

3.1.2 | Value of supportive relationships and continuity

The young adults expressed a wish to be met as a *person with diabetes*, not a *diabetes patient*, by empathetic and caring HCPs with diabetes expertise and communication competencies. However, many described negative experiences with the existing services, such as considering whether they were comfortable opening up to HCPs. This consequently affected conversations. One said:

"Everyone is probably professionally skilled, but not everyone, maybe, uh, I call it human understanding, communicates equally well. It's a bit to do with confidence, and it's to do with chemistry, but you don't want to automatically open up to everyone. While with physicians you know listen to what you say, it's okay to maybe open up a bit more."

(Participant 6, intervention arm)

In seeking trust-based and supportive relationships, they described wanting to become comfortable with sharing concerns and challenges, but with as few HCPs as possible. However, many had experienced rarely meeting the same physician twice. One participant described the importance of relational competence and continuity like this:

"A good relation is quite important for you to speak about things you might dread or be ashamed of. Or sorts of things that are about struggling with self-management or other things. So, I think about that relational competence bit and actually appreciating that there's some continuity. I think they still have some way to go in that regard."

(Participant 18, control arm)

The participants also reflected on the need for HCPs to be attentive to individual wishes and needs for them to experience being seen and heard. Compared to challenges usually conveyed to physicians, they expressed that they more often addressed emotional and psychosocial concerns with nurses. These challenges were considered less specific and more complex than biomedical outcomes. One described a diabetes nurse's contribution:

"The focus [in nurse appointments] is what's difficult. That's kind of the question when I come in. Like what's challenging and then we take it from there. So, I get to be a lot more involved, and I feel that I'm seen and heard, and if I'm having a bad day, she doesn't give up, and I think that's very nice."

(Participant 19, control arm)

3.2 | New insights and raised awareness

The young adults conveyed experiencing new-found insights and awareness concerning the complexity of diabetes after completing PROMs, which is described in two subthemes: 'More life-oriented insights' and 'Moving out of the comfort zone'.

3.2.1 | More life-oriented insights

Completing questionnaires made the young adults reflect upon their everyday lives, which enabled further insight about their situation, also regarding issues that some had not previously thought about. The realisation or increased consciousness about emotional and psychosocial aspects of diabetes self-management helped participants from both trial arms to reflect upon how they were feeling before engaging with HCPs. It also helped them understand that they were not alone in being faced with diabetes-related challenges, as described by one participant:

"I think the questions are very good, and I think they might help you think of other things to discuss with the physician. The way the questions are set up, and that maybe you feel that you're not the only one who can think about different things. That you're not alone with those thoughts and what you feel about your diabetes."

(Participant 17, control arm)

Furthermore, the PAID items were characterised as highly relevant, concrete diabetes-related concerns and challenges put into words. As some were made aware of possible yet unfamiliar

diabetes-related challenges, they expressed that inquiry into diabetes distress should have been part of the existing follow-up. One said:

> "I mean, this is something I'll live with for the rest of my life, so it [diabetes distress] should've been opened quite early, so that one might've been prepared for things that can become difficult and that it can affect your head in many ways, plus your body too, physically. How your psyche and your head are affected by diabetes when you work with it all the time."
>
> (Participant 3, intervention arm)

3.2.2 | Moving out of the comfort zone

Although the questionnaires mostly contributed positively, interviewees from both trial arms also shared a variety of challenges. In general, they found it difficult to decide on response options and characterised this as rating or placing themselves on a scale. The reflectiveness and increased awareness also evoked rather demanding thoughts about life with diabetes. Completing the items and the prospect of disclosing responses were labelled as moving outside one's comfort zone. They used words like *vulnerable, uncomfortable, exposed, scary, super close, genuine and real*. One participant articulated it like this:

> "It's quite scary because you feel so exposed in one respect, and no one's seen that before… It's crazy how things get so real, both to yourself and to others when you sit and tick off 'how you feel' or 'how you are', or what you've been thinking and stuff."
>
> (Participant 19, control arm)

The young adults also revealed insights about sincerity while completing PROMs, which varied between finding it unproblematic to choosing to size up the situation. They communicated that responses could be affected by insecurity about which HCP they were seeing afterwards. In addition, they conveyed that openness was interconnected with willingness for self-sincerity and evaluating this against sharing one's true problems. One said:

> "Some questions [items] can be somewhat difficult and painful to respond to. If you really answer exactly the right thing, I guess that's really what can be a bit inhibiting, how honest you are with yourself. As a diabetic, you become a bit like… you lie to yourself sometimes (laughs), you think things are somewhat better than they really are. I mean, it's difficult at times, but I think some awareness and thoughts about how you're actually doing is a good thing. I think that's healthy."
>
> (Participant 11, intervention arm)

Overall, participants expressed appreciation about the emphasis on diabetes distress, which covered areas many were unfamiliar with discussing and could struggle with addressing at appointments.

3.3 | Addressing problem areas with an open mind

When using the PAID in consultations, the participants highlighted the importance of addressing problem areas with an open mind. This is further exemplified in the subthemes 'Need for elaboration' and 'Preparedness for dialogue'.

3.3.1 | Need for elaboration

Young adults in both trial arms communicated a need to elaborate on and share underlying experiences associated with their PAID responses. This was also deemed necessary by intervention arm participants since some experienced that HCPs placed greater importance into their responses than was intended. Hence, nuances, clarity and/or explanations were particularly important. One said:

> "I felt that I responded honestly, but it was almost a bit … the nuance that 'yes, I'm very worried and I think this is very scary and…', but it's not as if I can't manage, like, or it's not as if… Yeah, there was a nuance that disappeared somewhat because in a way it's possible to be quite worried but still not so bothered by it."
>
> (Participant 9, intervention arm)

In addition, some discovered that the physicians were surprised by their diabetes distress scores but experienced increased understanding since the distress was acknowledged. They characterised this as sharing new insights into the challenges of seemingly 'well-functioning patients' and viewed it as an opportunity for physicians to engage with their distress and initiate dialogue.

3.3.2 | Preparedness for dialogue

Interviewees characterised the PAID as a tool used to focus on diabetes-related issues ahead of check-ups. Intervention

arm participants further stated that it served as a vent to communicate frustration and, without them having to initiate, as a conversation starter that facilitated a more constructive dialogue. One said:

> "I think it was all right that the physician could see my [PAID] responses. Then the physician could address problem areas, or what I was dissatisfied with or worried about. We had something constructive to work from, it [the dialogue] didn't get as vague as… Yes, I find it difficult to put into words what I really want from appointments. It probably became more apparent in the questionnaire."
>
> (Participant 16, intervention arm)

Completing the questionnaire made it difficult to postpone challenging issues. However, getting on track was considered positive, and using the PAID also contributed to an experience of being taken seriously. Nevertheless, intervention arm participants referred to additional nurse follow-up, conveyed not preparing for these appointments. Some also described a lack of flexibility where the PAID took up too much space and characterised the dialogue as unnatural and difficult for both parties. Furthermore, they conveyed that the nurses did not seem sufficiently prepared to receive, attend to or discuss their problems. Therefore, the follow-up did little to alleviate their distress. One depicted a consultation like this:

> "It was a bit like: 'Yes, do you want to say anything about what you find difficult? No? Then we'll move on to the next item.' So, it was a bit like you felt that you exposed yourself a bit more than she was comfortable with."
>
> (Participant 6, intervention arm)

However, some participants defended the nurses and argued that they simply followed the study manual, further specifying that the PAID had set the agenda. Nevertheless, the overall essence communicated by the young adults, was that using the PAID was somewhat uncomfortable but still worthwhile.

4 | DISCUSSION

In this study, young adults described finding previous follow-up lacking in content and continuity of care, hindering the development of supportive patient–provider relationships. Furthermore, our data provided insights about how they experienced and were affected by completing the PAID and the importance of an open-minded approach while addressing diabetes distress in consultations. We have identified, therefore, important considerations for further trial development.

In keeping with other studies, we identified that young adults want the complexity of diabetes to be addressed at appointments.[19-21] Their calls for continuity in care and person-centred, holistic approaches to follow-up extending beyond biomedicine and highlighting motivational and emotional challenges, are also supported in the literature.[9,10,19,22] Biomedical outcomes are undeniably important but do not necessarily reflect aspects most important to people with diabetes.[9,23] In this pilot trial context, participants conveyed appreciation about the PAID's content in addition to how it functioned as an eyeopener and promoted dialogue about important matters. In accordance with PROM literature, it created an opportunity for reflective thinking and validated their narrative,[8,24,25] which in turn seemed to facilitate and enhance the patient–provider dialogue.[8]

Our findings also support the 'red flag' approach (targeting higher scored items), which can help identify specific distress sources and thereby narrow the focus in consultations.[3,16] However, sharing PROM data can be difficult due to individual factors and/or patient–provider interpersonal factors. This suggests that when collecting PROMs in clinical settings, we need to be aware of selective reporting and other biases possibly affecting self-report and subsequently score interpretation.[26] Furthermore, our data emphasised the initiation of dialogue about underlying rationales behind responses to specific items, providing further insights about the young adults' lived experience. In a related study, HCPs described striving to balance recommendations for biomedical measurements with addressing young adults' emotional concerns due to limited resources and organisational challenges.[17] However, this clinical conflict was not linked to unwillingness in applying supportive, person-centred strategies.

For people with diabetes, relationships with providers are essential for their ability to self-manage and have been shown to influences behavioural, emotional and biomedical outcomes.[27] Likewise, good quality relationships seem imperative for the beneficial use of PROMs in the clinical context. Adding the PAID may serve as a catalyst for starting dialogues about diabetes distress and may provide important insights that complement biomedical measures. However, for this approach to contribute, the essential ingredients are how the PAID information is used and how clinicians communicate.[24] Overall, the HCPs require further training in using dialogue tools. Since the development of the pilot trial, new evidence-based resources are available that will be useful for this purpose.[3,28]

4.1 | Strengths and limitations

We have previously reported quantitative data regarding the feasibility and acceptability of the proposed DiaPROM trial.[13,14] In this study, all interviews were performed after

the 12-month follow-up to avoid influencing quantitative data and outcomes.[29] We consider the qualitative approach a strength for the research project as it allowed for further exploration of the participants' experiences. We have gained insights about contextual factors such as the follow-up the participants were accustomed to before the pilot trial, in addition to intervention acceptance, fidelity and delivery that will aid further trial development.[11] Credibility and confirmability were strengthened by the research team's extensive diabetes knowledge and by involving researchers with considerable qualitative research experience in the analysis.[30] Furthermore, we used reporting standards to improve study transparency and credibility.[29] However, interviews concerning the previous follow-up should ideally have been performed prior to the pilot trial. Also, we had limited information about the HCPs previous training and general attitudes towards consultations, which may have affected the participants' experiences. Although our findings may not be directly transferable to other contexts, we believe that HCPs and people with diabetes will recognise at least parts.

5 | CONCLUSION

Our data provide insights into how young adults with type 1 diabetes experienced the DiaPROM pilot trial's contextual circumstances. Participants characterised the previous follow-up as challenging and insufficient. They further described completing and using the PAID as a somewhat uncomfortable yet worthwhile experience. Our findings also suggest that by utilising electronic self-reported diabetes distress data alongside health and biomedical outcomes, consultations became more attuned to the young adults' wishes and needs, mainly because the dialogue was more focused and direct. Therefore, the PAID has the potential to facilitate person-centredness and improve patient–provider relationships.

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CONFLICT OF INTEREST

None declared. Views expressed are those of the authors and not necessarily those of the Norwegian Nurses Association, the Western Norway University of Applied Sciences, the Norwegian Diabetes Association, or the National Institute for Health Research (UK).

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Additional appendices

1. The Patient-Reported Outcomes Measures completed by participants.
2. Paper-based questionnaire, feasibility study (Paper I).
3. Paper-based questionnaire, baseline pilot trial (Paper III).
4. Paper-based questionnaire, 12-month follow-up pilot trial (Paper III).
5. Interview guide, qualitative study (Paper IV).
6. Physicians' study manual, baseline pilot trial (Paper III).
7. Nurses' study manual and communication guide, pilot trial (Paper III.)
8. Physicians' study manual, 12-month follow-up pilot trial (Paper III).
9. Regional Ethics Committee Approval, feasibility study.
10. Regional Ethics Committee Approval, pilot trial and qualitative study.
11. Written information and consent form, feasibility study.
12. Written information and consent form, pilot trial and qualitative study.

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

DiaPROM
Fokus på livet med diabetes

WHO-5 Well-being Index - Spørsmål om trivsel og velvære

Ved å svare på de neste 5 spørsmål kan du gi oss et bilde av hvor bra eller dårlig du føler deg for tiden.

	I de siste to ukene har jeg…	Hele tiden	Det meste av tiden	Mer enn halve tiden	Mindre enn halve tiden	Av og til	Aldri
1.	følt meg glad og i godt humør	5	4	3	2	1	0
2.	følt meg rolig og avslappet	5	4	3	2	1	0
3.	følt meg aktiv og sterk	5	4	3	2	1	0
4.	følt meg opplagt og uthvilt når jeg våkner	5	4	3	2	1	0
5.	følt at mitt daglige liv har vært fylt av ting som interesserer meg	5	4	3	2	1	0

PAID - Problem Areas In Diabetes – Diabetesrelaterte problemområder

De neste utsagnene handler om vanlige diabetesrelaterte utfordringer.
Hvilke av de følgende forhold er for tiden et problem for deg?

		Ikke et problem	Mindre problem	Middels problem	Nokså alvorlig problem	Alvorlig problem
1.	Har ikke klare og konkrete mål for diabetesomsorgen min	0	1	2	3	4
2.	Behandlingsplanen for min diabetes gjør meg motløs	0	1	2	3	4
3.	Føler meg engstelig når jeg tenker på at jeg må leve med diabetes	0	1	2	3	4
4.	Opplever ubehagelige sosiale situasjoner knyttet til min diabetesomsorg (f.eks. folk som forteller meg hva jeg bør spise)	0	1	2	3	4
5.	Føler forsakelse og tap i forhold til mat og måltider	0	1	2	3	4
6.	Føler meg deprimert når jeg tenker på at jeg må leve med diabetes	0	1	2	3	4
7.	Vet ikke om humøret eller følelsene mine er knyttet til diabetes	0	1	2	3	4
8.	Føler meg overveldet av diabetes-sykdommen	0	1	2	3	4
9.	Bekymrer meg for å få føling	0	1	2	3	4
10.	Føler sinne når jeg tenker på at jeg må leve med diabetes	0	1	2	3	4
11.	Føler meg konstant opptatt av mat og spising	0	1	2	3	4
12.	Bekymrer meg for fremtiden og sjansen for alvorlige komplikasjoner	0	1	2	3	4
13.	Føler skyld og/eller engstelse når jeg kommer ut av rytme i håndteringen av min diabetes	0	1	2	3	4
14.	“Aksepterer” ikke at jeg har diabetes	0	1	2	3	4
15.	Føler meg misfornøyd med diabeteslegen min	0	1	2	3	4

(Fortsettelse)

Hvilke av de følgende forhold er for tiden et problem for deg?

		Ikke et problem	Mindre problem	Middels problem	Nokså alvorlig problem	Alvorlig problem
16.	Føler at diabetes tar for mye av min fysiske og psykiske energi i det daglige	0	1	2	3	4
17.	Føler meg alene med min diabetes	0	1	2	3	4
18.	Føler at familie og venner ikke støtter meg i mine anstrengelser for å håndtere min diabetes	0	1	2	3	4
19.	Å kunne mestre komplikasjoner til min diabetes	0	1	2	3	4
20.	Føler meg "utbrent" av den konstante anstrengelsen diabeteshåndteringen krever	0	1	2	3	4

PCDS - Perceived Competence in Diabetes Scale - oppfatning av egen diabeteskompetanse

I hvor stor grad stemmer de følgende fire påstandene for deg når det gjelder hvordan du håndterer din diabetes?

		Stemmer ikke i det hele tatt		Stemmer noe				Stemmer helt
1.	Jeg føler meg trygg på at jeg klarer å håndtere min diabetes	1	2	3	4	5	6	7
2.	Jeg er i stand til å håndtere min diabetes nå	1	2	3	4	5	6	7
3.	Jeg klarer å utføre diabetesomsorgen min nå	1	2	3	4	5	6	7
4.	Jeg føler at jeg klarer å møte utfordringen med å regulere min diabetes	1	2	3	4	5	6	7

Spørsmål om blodsukker og blodsukkermåling

Nå følger 4 spørsmål om ditt blodsukker og symptomer på lavt blodsukker.

1.	**Hvor ofte har blodsukkeret etter din mening vært for høyt de siste ukene?**						
	Ikke i det hele tatt						Mesteparten av tiden
	1	2	3	4	5	6	7
2.	**Hvor ofte har blodsukkeret etter din mening vært for lavt de siste ukene?**						
	Ikke i det hele tatt						Mesteparten av tiden
	1	2	3	4	5	6	7
3.	**I hvilken grad har blodsukkeret etter din mening svingt for mye de siste ukene?**						
	Ikke i det hele tatt						Mesteparten av tiden
	1	2	3	4	5	6	7
4.	**Kjenner du selv når blodsukkeret er i ferd med å bli for lavt?**						
	Kjenner det alltid						Kjenner det aldri
	1	2	3	4	5	6	7

Nå følger noen spørsmål om utstyr og hyppighet av blodsukkermålinger.

Hvilken målemetode bruker du vanligvis for å måle blodsukker/glukoseverdier?
Sett kryss på det som passer

- Vanlig blodsukkerapparat *(Glukometer) med strimler e.l.* ☐1
- Flash glukosemåler *(Freestyle Libre)* ☐2
- Kontinuerlig glukosemåler *(CGM)* ☐3
- Måler ikke selv ☐4

Dersom du har svart 1 eller 2 på spørsmålet over, ønsker vi å vite hvor ofte du sjekker blodsukkeret:

A. Hvor ofte sjekker/måler du vanligvis blodsukker/glukoseverdier?

- Daglig ☐1 *(gå videre til spørsmål B)*
- Ukentlig ☐2 *(gå videre til spørsmål C)*
- Sjeldnere enn ukentlig ☐3 *(gå videre til neste skjema – RAND-12 på s. 5)*

Dersom du svarte at du sjekker/måler daglig på spørsmål A:

B. Hvor mange ganger per dag sjekker/måler du vanligvis blodsukker/glukoseverdier?

- 1-3 ganger per dag ☐1
- 4-6 ganger per dag ☐2
- 7-10 ganger per dag ☐3
- Mer enn 10 ganger per dag ☐4

Dersom du svarte at du sjekker/måler ukentlig på spørsmål A:

C. Hvor mange ganger per uke sjekker/måler du vanligvis blodsukker/glukoseverdier?

- 1-3 ganger per uke ☐1
- 4-6 ganger per uke ☐2
- 7-10 ganger per uke ☐3
- Mer enn 10 ganger per uke ☐4

RAND-12 (12 spørsmål om generell livskvalitet)

De siste spørsmålene handler om hvordan du oppfatter helsen din. Disse opplysningene vil hjelpe oss til å forstå hvordan du føler deg og hvor godt du er i stand til å utføre dine vanlige aktiviteter.

1. Stort sett, vil du si at helsen din er:

Utmerket	Veldig god	God	Nokså god	Dårlig
☐	☐	☐	☐	☐

2. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå?

		Ja, begrenser meg mye	Ja, begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a	**Moderate aktiviteter** som å flytte et bord, støvsuge, gå en spasertur eller drive med hagearbeid	☐	☐	☐
b	Gå opp trappen **flere** etasjer	☐	☐	☐

3. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av din fysiske helse?

		Ja	Nei
a	**Fått gjort mindre** enn du ønsket	☐	☐
b	Vært begrenset i type **arbeidsoppgaver** eller andre aktiviteter	☐	☐

4. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidet ditt eller i andre daglige aktiviteter på grunn av følelsesmessige problemer (som å føle seg engstelig eller deprimert)?

		Ja	Nei
a	**Fått gjort mindre** enn du ønsket	☐	☐
b	Utført arbeid eller andre aktiviteter **mindre grundig** enn vanlig	☐	☐

5. I løpet av de siste fire ukene, hvor mye har smerter påvirket det vanlige arbeidet ditt (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt	Litt	Moderat	Ganske mye	Ekstremt mye
☐	☐	☐	☐	☐

6. De neste spørsmålene handler om hvordan du føler deg og hvordan du har hatt det i løpet av de siste fire ukene. For hvert spørsmål, ber vi deg velge det svaret som best beskriver hvordan du har følt deg.

Hvor ofte i løpet av de siste fire ukene:

		Hele tiden	Mesteparten av tiden	En god del av tiden	Noe av tiden	Litt av tiden	Aldri
a	Har du følt deg rolig og avslappet?	☐	☐	☐	☐	☐	☐
b	Har du hatt mye overskudd?	☐	☐	☐	☐	☐	☐
c	Har du følt deg nedfor og deprimert?	☐	☐	☐	☐	☐	☐

7. I løpet av de siste fire ukene, hvor mye av tiden har den fysiske helsen din eller følelsesmessige problemer påvirket dine sosiale aktiviteter (som å besøke venner, slektninger osv.)?

Hele tiden	Mesteparten av tiden	En del av tiden	Litt av tiden	Aldri
☐	☐	☐	☐	☐

TAKK FOR AT DU SVARTE PÅ SPØRSMÅLENE!

HELSE BERGEN
Haukeland Universitetssjukehus

Høgskulen på Vestlandet

UNIVERSITETET I BERGEN

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

SKRIV FIRETEGNSKODEN SOM ER OPPGITT PÅ PC-SKJERMEN HER:

Ta koden med inn til lege eller sykepleier.

EVALUERING

Takk for at du har besvart vårt elektroniske spørreskjema. Vi ønsker at du svarer på spørsmålene under og deretter legger skjemaet i postkassen ved PC-en i korridoren, etter at konsultasjonen hos lege/sykepleier er ferdig. På forhånd takk!

Spørsmål om den elektroniske utfyllingen du har gjennomført:

1. I hvilken grad var spørsmålene/utsagnene du besvarte på pc-skjermen forståelig for deg?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Kommentar? _____

2. I hvilken grad var spørsmålene/utsagnene relevante for deg?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Kommentar? _____

3. I hvilken grad var informasjonen og forklaringene som ble gitt på skjermen, forståelig for deg?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Kommentar? _____

Se bakside!

4. Hvor misfornøyd eller fornøyd var du med antall spørsmål som ble stilt?

Svært misfornøyd	Ganske misfornøyd	Både og	Ganske fornøyd	Svært fornøyd
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Kommentar? _____

5. I hvilken grad vil du være positiv til å fylle ut et elektronisk diabetes-relatert spørreskjema én gang i året før poliklinisk diabetesoppfølging?

Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Kommentar? _____

Noen spørsmål om deg:

6. Hva er din formelle utdannelse? *(Sett kryss på det alternativet som passer best for deg.)*

Grunnskole	Videregående skole	Høgskole/universitet <4 år	Høgskole/universitet ≥4 år
☐ 1	☐ 2	☐ 3	☐ 4

7. Hva er din arbeidstilknytning nå? *(Sett kryss på det alternativet som passer best for deg.)*

Hjemme-værende	Lønnet arbeid, heltid	Lønnet arbeid, deltid	Arbeidsledig/ permittert	Pensjonert	Sykemeldt/ trygdet	Annet
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

8. Hva er din samlivsstatus nå? *(Sett kryss på det alternativet som passer best for deg.)*

Bor alene	Bor med partner	Bor med barn uten partner	Bor med partner òg barn	Bor med foreldre	Annet
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

9. Hva er ditt morsmål? *(Sett kryss på det alternativet som passer best for deg.)*

Norsk	Annet nordisk språk	Annet europeisk språk	Ikke-europeisk språk
☐ 1	☐ 2	☐ 3	☐ 4

TAKK!

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

DiaPROM
Fokus på livet med diabetes

Vi vil gjerne ha tilbakemelding på hvor tilfreds du er med oppfølgingen du får ved diabetespoliklinikken.

FYLL INN FIRETEGNSKODEN DU FÅR OPPGITT PÅ PC-SKJERMEN HER OG PÅ NESTE ARK:
Ta koden med inn til lege eller sykepleier.

Spørsmålene nedenfor besvares **etter** konsultasjonen hos lege/sykepleier. Det er plass til å skrive kommentarer på siste side. Etter utfylling legges skjemaet i postkassen ved PC-en i korridoren sammen med signert samtykkeerklæring.

Om oppfølgingen ved diabetespoliklinikken *(Kryss av på det alternativet som passer best for deg)*

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
1.	Alt i alt, er du fornøyd med oppfølgingen du mottar ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2.	Blir du møtt med høflighet og respekt ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3.	Opplever du at helsepersonellet tar dine bekymringer på alvor?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.	Har du utbytte av oppfølgingen ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		Under 6 måneder	Fra 7 til 12 måneder	Fra 13 måneder til 3 år	Mer enn 3 år
5.	Hvor lenge har du vært pasient ved denne poliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4

		For mange	Passe antall	Litt for få	Altfor få	Har ikke ønsket konsultasjon	Ikke aktuelt
6.	Hva synes du om antall konsultasjoner du har fått ved diabetespoliklinikken det siste året?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Om utfylling av det elektroniske spørreskjemaet *(Kryss av på det alternativet som passer best for deg.)*

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
7.	Var spørsmålene forståelig for deg?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8.	Var antallet spørsmål akseptabelt for deg?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
9.	Opplevde du spørsmålene som relevante for personer med diabetes?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10.	Er du positiv til årlig utfylling av et slikt diabetesrelatert spørreskjema?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		PC på poliklinikken	Hjemmefra via internett	På papir hjemme/poliklinikk	Ønsker ikke fylle ut
11.	Hvordan vil du foretrekke å fylle ut spørreskjema i fremtiden?	☐ 1	☐ 2	☐ 3	☐ 4

Om bruk av spørreskjema i samtalen med behandler *(Kryss av på det alternativet som passer best for deg.)*

		Ja	Nei	Skjemaet var ikke tilgjengelig
12.	Fikk du se svarene på spørreskjemaet ditt på behandlers PC-skjerm?	☐ 1	☐ 2	☐ 3
13.	Ble svarene på spørreskjemaet ditt snakket om i konsultasjonen?	☐ 1	☐ 2	☐ 3

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
14.	Dersom svarene spørreskjemaet ble snakket om, hadde du utbytte av samtalen?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

		Jeg tok initiativ	Behandler tok initiativ	Ikke aktuelt
15.	Var det du eller behandler som tok initiativ til å snakke om innhold i spørreskjemaet?	☐ 1	☐ 2	☐ 3

Noen spørsmål om deg *(Kryss av på det alternativet som passer best for deg.)*

		Grunnskole	Videregående skole	Høgskole/ universitet <4 år	Høgskole/ universitet ≥4 år
16.	Hva er din høyeste formelle utdannelse?	☐ 1	☐ 2	☐ 3	☐ 4

		Hjemme-værende	Lønnet arbeid, heltid	Lønnet arbeid, deltid	Arbeids-ledig	Under utdanning	Syke-meldt/ trygdet	Annet
17.	Hva gjør du til daglig?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7

		Bor alene	Bor med partner	Bor med barn uten partner	Bor med partner òg barn	Bor med foreldre	Annet
18.	Hva er din samlivsstatus nå?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

		Norsk	Annet nordisk språk	Annet europeisk språk	Ikke-europeisk språk
19.	Hva er ditt morsmål?	☐ 1	☐ 2	☐ 3	☐ 4

Nedenfor følger en liste over 17 mulige problemområder personer med diabetes kan erfare. Vurder i hvilken grad hvert av punktene har bekymret deg eller plaget deg i løpet av den siste måneden. Sett ring rundt tallet som passer best.

Hvis du føler at et bestemt punkt ikke er et problem eller en plage for deg, kan du sette ring rundt "1". Hvis det er til stor plage for deg, kan du sette ring rundt "6".

		Ikke ett problem		Middels problem		Alvorlig problem	
1.	Jeg føler at diabetes tar for mye tid av min fysiske og psykiske energi hver dag.	**1**	**2**	**3**	**4**	**5**	**6**
2	Jeg føler at legen min ikke vet nok om diabetes og diabetesomsorg.	**1**	**2**	**3**	**4**	**5**	**6**
3.	Jeg føler meg sint, redd og/eller deprimert når jeg tenker på at jeg må leve med diabetes	**1**	**2**	**3**	**4**	**5**	**6**
4.	Jeg føler at legen min ikke gir meg klare nok retningslinjer for hvordan jeg skal håndtere min diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
5.	Jeg føler at jeg ikke måler blodsukkeret mitt ofte nok.	**1**	**2**	**3**	**4**	**5**	**6**
6.	Jeg føler at jeg ofte mislykkes med diabetes-regimet mitt.	**1**	**2**	**3**	**4**	**5**	**6**
7.	Jeg føler at venner og familie ikke støtter meg nok i mine anstrengelser for å ta vare på meg selv (f.eks. ved å planlegge aktiviteter på tvers av min timeplan, eller oppmuntre meg til å spise "feil" mat).	**1**	**2**	**3**	**4**	**5**	**6**
8.	Jeg føler at diabetes kontrollerer livet mitt.	**1**	**2**	**3**	**4**	**5**	**6**
9.	Jeg føler at legen min ikke tar bekymringene mine alvorlig nok.	**1**	**2**	**3**	**4**	**5**	**6**
10.	Jeg føler meg usikker på min egen evne til å håndtere min diabetes i hverdagen.	**1**	**2**	**3**	**4**	**5**	**6**
11.	Jeg føler at jeg vil ende opp med alvorlige senkomplikasjoner, uansett hva jeg gjør.	**1**	**2**	**3**	**4**	**5**	**6**

		Ikke ett problem		Middels problem		Alvorlig problem	
12.	Jeg føler at jeg ikke følger en god måltidsplan nøye nok.	**1**	**2**	**3**	**4**	**5**	**6**
13.	Jeg føler at venner og familie ikke har forståelse for hvor vanskelig det kan være å leve med diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
14.	Jeg føler meg overveldet av utfordringene ved å leve med diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
15.	Jeg føler at jeg ikke har en lege jeg kan kontakte regelmessig angående min diabetes	**1**	**2**	**3**	**4**	**5**	**6**
16.	Jeg føler meg ikke motivert til å fortsette å håndtere min diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
17.	Jeg føler at venner og familie ikke gir meg den følelsesmessige støtten jeg ønsker.	**1**	**2**	**3**	**4**	**5**	**6**

SKRIV GJERNE KOMMENTARER OM DINE ERFARINGER MED DELTAKELSE I PROSJEKTET:

TAKK FOR AT DU TOK DEG TID TIL Å SVARE!

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

DiaPROM
Fokus på livet med diabetes

FYLL INN FIRETEGNSKODEN DU FÅR OPPGITT PÅ PC-SKJERMEN HER OG I TILSVARENDE BOKSER:
Ta koden med inn til lege eller sykepleier.

Vi vil gjerne ha tilbakemelding på hvor tilfreds du er med oppfølgingen du får ved diabetespoliklinikken og med deltakelse i prosjektet. Spørsmålene nedenfor besvares **etter** konsultasjonen hos lege/sykepleier. Etter utfylling legges skjemaet i postkassen ved PC-en i korridoren.

Om oppfølgingen ved diabetespoliklinikken *(Kryss av på det alternativet som passer best for deg)*

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
1.	Alt i alt, er du fornøyd med oppfølgingen du mottar ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2.	Blir du møtt med høflighet og respekt ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3.	Opplever du at helsepersonellet tar dine bekymringer på alvor?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4.	Har du utbytte av oppfølgingen ved diabetespoliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		Under 6 måneder	Fra 7 til 12 måneder	Fra 13 måneder til 3 år	Mer enn 3 år
5.	Hvor lenge har du vært pasient ved denne poliklinikken?	☐ 1	☐ 2	☐ 3	☐ 4

		For mange	Passe antall	Litt for få	Altfor få	Har ikke ønsket konsultasjon	Ikke aktuelt
6.	Hva synes du om antall konsultasjoner du har fått ved diabetespoliklinikken det siste året?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

Om bruk av spørreskjema i samtalen med legen *(Kryss av på det alternativet som passer best for deg.)*

		Ja	Nei
7.	Så du på svarene på spørreskjemaet ditt sammen med legen?	☐ 1	☐ 2
8.	Ble svarene på spørreskjemaet ditt snakket om i legekonsultasjonen?	☐ 1	☐ 2

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
9.	Dersom svarene spørreskjemaet ble snakket om, hadde du utbytte av samtalen?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

		Jeg tok initiativ		Legen tok initiativ		Ikke aktuelt
10.	Var det du eller legen som tok initiativ til å snakke om innhold i spørreskjemaet?	☐ 1		☐ 2		☐ 3
		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
11.	Har utfylling av spørreskjema før konsultasjon medført at du har tatt initiativ til å samtale med legen om diabetesrelaterte utfordringer som du ellers ikke ville tatt opp?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12.	Synes du at utfylling av det diabetesrelaterte spørreskjemaet har vært positivt for deg?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Til deg som har fått ekstra oppfølging hos diabetessykepleier grunnet svarene på spørreskjemaet

(Kryss av på det alternativet som passer best for deg.)

		Ja		Nei		Ikke aktuelt	
13.	Fikk du se svarene på spørreskjemaet ditt på diabetessykepleierens PC-skjerm?	☐ 1		☐ 2		☐ 3	
14.	Ble svarene på spørreskjemaet ditt snakket om i konsultasjonen med diabetessykepleier?	☐ 1		☐ 2		☐ 3	
		Jeg tok initiativ		Sykepleier tok initiativ		Ikke aktuelt	
15.	Var det du eller diabetessykepleieren som tok initiativ til å snakke om innhold i spørreskjemaet?	☐ 1		☐ 2		☐ 3	
		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
16.	Dersom svarene spørreskjemaet ble snakket om, hadde du utbytte av samtalen?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
17.	Har utfylling av spørreskjema medført at du har tatt initiativ til å samtale med diabetessykepleier om diabetes-relaterte utfordringer som du ellers ikke ville tatt opp?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18.	Har du hatt utbytte av den ekstra oppfølgingen og bruk av spørreskjemaet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19.	Har du fått nok tid til samtaler med diabetessykepleier etter utfylling av spørreskjemaet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

TIL ALLE

Noen spørsmål om deg *(Kryss av på det alternativet som passer best for deg.)*

20.	Hva er din høyeste formelle utdannelse?	Grunnskole ☐ 1	Videregående skole ☐ 2	Høgskole/ universitet <4 år ☐ 3	Høgskole/ universitet ≥4 år ☐ 4		
21.	Hva gjør du til daglig?	Hjemme-værende ☐ 1	Lønnet arbeid, heltid ☐ 2	Lønnet arbeid, deltid ☐ 3	Arbeids-ledig ☐ 4	Under utdanning ☐ 5	Syke-meldt/ trygdet ☐ 6	Annet ☐ 7
22.	Hva er din samlivsstatus nå?	Bor alene ☐ 1	Bor med partner ☐ 2	Bor med barn uten partner ☐ 3	Bor med partner òg barn ☐ 4	Bor med foreldre ☐ 5	Annet ☐ 6	

Spørsmål om mulige diabetes-relaterte problemområder

Nedenfor følger en liste over 17 mulige problemområder personer med diabetes kan erfare. Vurder i hvilken grad hvert av punktene har bekymret deg eller plaget deg i løpet av den siste måneden. Sett ring rundt tallet som passer best.

Hvis du føler at et bestemt punkt ikke er et problem eller en plage for deg, kan du sette ring rundt "1". Hvis det er til stor plage for deg, kan du sette ring rundt "6".

		Ikke ett problem		Middels problem		Alvorlig problem	
1.	Jeg føler at diabetes tar for mye tid av min fysiske og psykiske energi hver dag.	**1**	**2**	**3**	**4**	**5**	**6**
2	Jeg føler at legen min ikke vet nok om diabetes og diabetesomsorg.	**1**	**2**	**3**	**4**	**5**	**6**
3.	Jeg føler meg sint, redd og/eller deprimert når jeg tenker på at jeg må leve med diabetes	**1**	**2**	**3**	**4**	**5**	**6**
4.	Jeg føler at legen min ikke gir meg klare nok retningslinjer for hvordan jeg skal håndtere min diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
5.	Jeg føler at jeg ikke måler blodsukkeret mitt ofte nok.	**1**	**2**	**3**	**4**	**5**	**6**
6.	Jeg føler at jeg ofte mislykkes med diabetes-regimet mitt.	**1**	**2**	**3**	**4**	**5**	**6**

		Ikke ett problem		Middels problem		Alvorlig problem	
7.	Jeg føler at venner og familie ikke støtter meg nok i mine anstrengelser for å ta vare på meg selv (f.eks. ved å planlegge aktiviteter på tvers av min timeplan, eller oppmuntre meg til å spise "feil" mat).	**1**	**2**	**3**	**4**	**5**	**6**
8.	Jeg føler at diabetes kontrollerer livet mitt.	**1**	**2**	**3**	**4**	**5**	**6**
9.	Jeg føler at legen min ikke tar bekymringene mine alvorlig nok.	**1**	**2**	**3**	**4**	**5**	**6**
10.	Jeg føler meg usikker på min egen evne til å håndtere min diabetes i hverdagen.	**1**	**2**	**3**	**4**	**5**	**6**
11.	Jeg føler at jeg vil ende opp med alvorlige senkomplikasjoner, uansett hva jeg gjør.	**1**	**2**	**3**	**4**	**5**	**6**
12.	Jeg føler at jeg ikke følger en god måltidsplan nøye nok.	**1**	**2**	**3**	**4**	**5**	**6**
13.	Jeg føler at venner og familie ikke har forståelse for hvor vanskelig det kan være å leve med diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
14.	Jeg føler meg overveldet av utfordringene ved å leve med diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
15.	Jeg føler at jeg ikke har en lege jeg kan kontakte regelmessig angående min diabetes	**1**	**2**	**3**	**4**	**5**	**6**
16.	Jeg føler meg ikke motivert til å fortsette å håndtere min diabetes.	**1**	**2**	**3**	**4**	**5**	**6**
17.	Jeg føler at venner og familie ikke gir meg den følelsesmessige støtten jeg ønsker.	**1**	**2**	**3**	**4**	**5**	**6**

SKRIV GJERNE KOMMENTARER OM DINE ERFARINGER MED DELTAKELSE I PROSJEKTET.

TAKK FOR AT DU TOK DEG TID TIL Å SVARE!

Interview guide paper IV

All participants:

- What are your experiences with and thoughts about routine diabetes follow-up?
- What do you expect from the follow-up?
- How did you experience the technical aspects regarding completing the electronic PROMs?
- What are your thoughts about the included items/scales?
- What was it like for you to complete the questionnaires in this way?

Control arm:

- Did the questionnaires prompt you to talk about the content and your answers with the physician?

Intervention arm:

- Can you describe how PAID was used in the medical consultation?
- How did you experience sharing diabetes-related problems with the physician?
- Did the PAID completion result in additional follow-up, and if so, what were your experiences with the additional nurse follow-up?
- What are your experiences with and thoughts about how PAID was used in the nurse consultations?
- How did you experience sharing diabetes-related problems with the nurse?
- How did the nurse apply the PAID?
- Did you find it helpful/useful to discuss the diabetes-related challenges with the nurse?

All:

- What are your thoughts about participating in the study?
- What are your thoughts about the future routine use of PROMs at the diabetes outpatient clinic?

DiaPROM

VEILEDER FOR BEHANDLERE
Baseline 2018

LESES OG UTFØRES AV BEHANDLER:

1. Nedlasting av PROM-svar til Noklus diabetes for alle pasienter (18-40 år) som har med seg en firetegnskode til konsultasjonen.

Takk for at du spør pasienten om samtykkeskjema er signert! *(Evt. ser til at det signeres.)*

Se baksiden for utfyllende informasjon om nedlasting av PROM til diabetesjournalen ved hjelp av firetegnskoden.

2. Randomisering

Når firetegnskoden legges inn i Noklus Diabetes, skjer randomiseringen automatisk.

- For pasienter som randomiseres til intervensjonsgruppen, vil spørreskjemaene bli synlig i diabetesjournalen.
- For de som randomiseres til kontrollgruppen, vil det bli gitt beskjed om at skjemaene er arkivert. Skjemaene er ikke synlig i journalen. Du informerer så pasienten om dette.

3. Gjennomgang av PAID* for pasienter i intervensjonsgruppen

Se på pasientens PAID-scorer sammen med pasienten. PAID er intervensjonens hovedinstrument.
De øvrige instrumenter er studiens effektmål og skal ikke diskuteres om ikke det er spesielt ønsket av pasienten.

*Problem Areas in Diabetes scale

4. Henvisning til sykepleier

Deltakere med PAID **sumscore ≥30** eller **score 3 eller 4 på minimum ett utsagn** (markert med rød stolpe i Noklus diabetes), kvalifiserer for henvisning til videre oppfølging hos diabetessykepleier.

Henvisning gjøres i Dips: Legg til «Ny kontakt» med *ressurstype* sykepleier og skriv **DiaPROM** som «Kontaktårsak». Send gul lapp til «*So hau med endokrin pol kontor*» med beskjed om **deltakelse DiaPROM.**

OBS WHO-5 score

Det anbefales å ta en titt på deltakernes WHO-5 score. Totalscore under 28 kan indikere alvorlig psykologiske problemer (depresjon) og henvisning til psykolog/psykiater bør vurderes.

Informasjon om oppfølgingen hos sykepleier

Oppfølgingen hos diabetessykepleier består av minimum 2 konsultasjoner i løpet av det kommende året. Den første sykepleierkonsultasjonen bør finne sted innen 4 uker. Sykepleierkonsultasjon nr. 2 gjennomføres maksimum 3 måneder senere. Utover de to «obligatoriske» sykepleierkonsultasjonene, avklarer sykepleier og pasient behov for ekstra møter eller telefonkontakt frem mot neste årskontroll.

Neste årskontroll

Ved neste årskontroll fyller pasienten igjen ut PROM-spørsmålene.

Takk for at du minner pasienten på å besvare papirspørreskjemaet om tilfredshet etter konsultasjonen.

Ved spørsmål - ta gjerne kontakt med Ingvild Hernar på 906 83 641 eller iher@hvl.no.

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

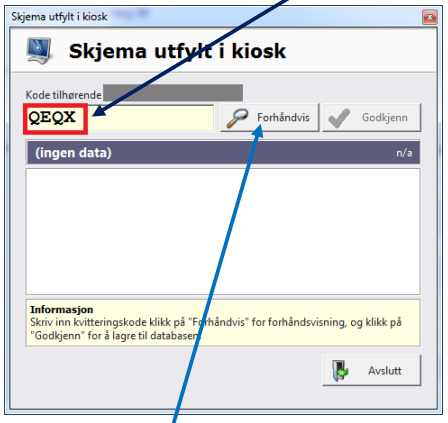
MANUAL FOR NEDLASTING AV SPØRRESKJEMA FRA KIOSK TIL NOKLUS DIABETES

1. Åpne Noklus Diabetes og sjekk at du har aktivert riktig journal.
2. Se etter knappen «***PROMs***» oppe til venstre i skjermbildet.

   Klikk på trekanten og velg «***Hent pasientskjema fra kiosk***».

3. Deltakeren har notert en firetegnskode på et eget skjema.

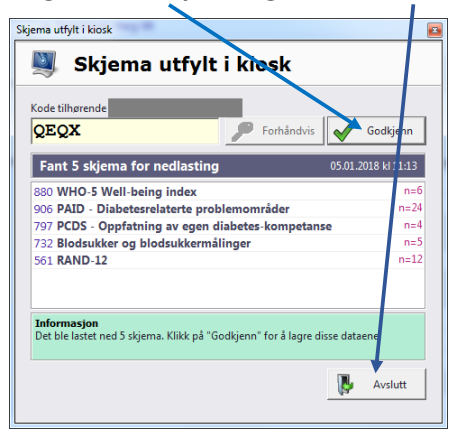
   Denne koden taster du inn her.



   Klikk så på «***Forhåndvis***».

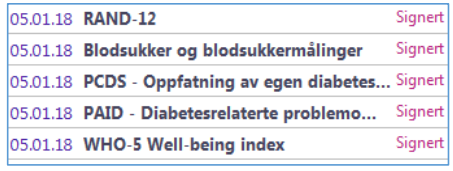
4. Du vil så se en liste over de ulike spørreskjemaene.

   Velg først «***Godkjenn***» og deretter «***Avslutt***».



5. De ulike skjemaene lagres nå i Noklus Diabetes, men blir kun synlig hos pasienter som trekkes til intervensjonsgruppen.

   Skjemaene kan gjenåpnes og endres på om ønskelig.



6. Husk å gi pasienten skjemaet med firetegnskoden tilbake.

   Spørsmålene på skjemaet besvares av pasienten og legges i postkassen på korridoren sammen med samtykkeerklæringen.

VEILEDER FOR KOMMUNIKASJON

(Forklaringer for hvert av punktene er gitt på baksiden)

1. ÅPNING

Ønsk velkommen og avklar konsultasjonens fokus/innhold.

2. SE GJENNOM PAID-SVAR SAMMEN MED PASIENTEN

Hva er rapportert som problematisk/utfordrende? Se på svarene sammen med pasienten.

3. STILL SPØRSMÅL

Hvis pasientene har rapportert flere problemområder som ikke kan sees i sammenheng:
Spør hva pasienten vil at dere skal gripe fatt i først (og legg eventuelt en plan for når de øvrige problemområder skal tas fatt i).
Spør videre: Fortell meg mer om utfordringen? Hvordan er dette vanskelig for deg?

4. LYTT

Lytt til pasienten i omlag 5 minutter uten å gi råd eller bryte inn i pasientens fortelling.
Hvis pauser oppstår, kan du utfordre pasienten til å fortelle mer ved å respondere på en av følgende måter:

- Empatisk respondering: «Det høres ut som om dette er utfordrende for deg. Fortell meg mer.»
- Utforskende spørsmål: «Fortell meg litt mer om hvordan dette er for deg i din hverdag?»
- Speiling: «Jeg hører du sier….. Stemmer det? Kan du si litt mer om det?»

5. RESPONDÉR

Etter omlag 5 minutter kan du respondere på pasientens fortelling om sitt problem/sin utfordring.
Følgende spørsmål kan være nyttige:

- Hva tenker du må endre seg for at du skal oppleve å ha det bedre med dette problemet?
- Har du prøvd å gjøre noe med problemområdet/utfordringen tidligere?
- Kan du tenke deg noe du kan gjøre for å komme nærmere en løsning på problemet/utfordringen?
- Hva kan jeg gjøre for å hjelpe deg på veien mot en løsning?

6. AVSLUTNING: OPPSUMMER OG UTARBEID MÅL/PLAN FOR VIDERE ARBEID

«Skal vi oppsummere og bli enige om en plan for videre arbeid med problemet/utfordringen?»

- Lag en skriftlig plan med målsetting og tiltak. Bruk eget utviklet skjema for dette formål.
- Gjør de nødvendige avtaler for videre arbeid og videre oppfølging.

Forklaringer til kommunikasjonsprinsippene:

1. ÅPNING

Det er viktig å skape en god tone og en god relasjon til pasienten innledningsvis. Videre er det viktig å avklare konsultasjonens agenda og tiden en har til rådighet.

2. SE GJENNOM PAID-SVAR SAMMEN MED PASIENTEN:

Det er viktig at pasienten får se besvarelsen på skjermen sammen med deg. Ta for dere de utsagn hvor pasienten har svart enten 3 (nokså alvorlig problem) eller 4 (alvorlig problem). Det er først og fremst disse utsagnene man deretter jobber videre med. Dersom pasienten har svart 3 eller 4 på flere utsagn, må dere bli enige om hvilke utsagn som skal prioriteres først. Vær oppmerksom på at noen kan ha behov for å endre på ett eller flere svar.

3. STILL SPØRSMÅL

Ofte er barrierer eller utfordringer knyttet til god egenbehandling av diabetes skjult fordi vi ikke spør de rette spørsmålene. I dette prosjektet vil pasientens PROM-svar hjelpe oss i gang. Videre må vi lytte til pasientens historie knyttet til de rapporterte problemområder/utfordringer.

4. LYTT

Utfordringen for deg som sykepleier er å forstå hva problemområdet består av og hva som er den viktigste utfordringen for pasienten. Videre å kunne samarbeide og hjelpe pasienten med å lage en plan for det videre arbeid med problemområdet/utfordringen. Dette krever at du først gir deg tid til å lytte til pasienten.

5. RESPONDÉR

Du skal hjelpe pasienten i en prosess hvor vedkommende i størst mulig grad selv finner løsninger. For å lykkes med den daglige håndteringen av diabetes er det helt sentralt at vi hjelper pasientene mot mest mulig selvstendighet (autonomi) og tro på egen mestring. Det å gjøre gode valg for seg selv i hverdagen og det å ha tro på egen mestring krever imidlertid en opplevelse av å ha tilstrekkelig kompetanse og det krever at en ikke opplever å være alene om problemet/utfordringen. Vi som helsepersonell skal være gode støttespillere og samtidig gi pasientene nødvendig kunnskap til å kunne håndtere hverdagen.

6. AVSLUTNING: UTARBEID MÅL OG PLAN FOR VIDERE ARBEID OG OPPFØLGING

Det er viktig å sikre at du som hjelper og pasienten har den samme oppfatning av situasjonen og pasientens problemområde før konsultasjonen avsluttes. Det er også viktig å sikre at dere har en plan for det videre arbeid som begge er innforstått med. Til slutt er det viktig å gi pasienten en opplevelse av at vedkommende ikke er alene om sitt problem. En klar plan og en enighet om den videre oppfølging hos deg kan bidra til en slik opplevelse.

TEORETISK FORANKRING

Denne veilederen er basert på de grunnleggende elementer i ***empowerment-teori*** *som handler om å skape en prosess hvor individet mobiliserer ressurser til å håndtere sine utfordringer selv. Videre er veilederen basert på* ***self-determination theory*** *hvor autonomi, kompetanse og støtte fra andre løftes frem som sentrale elementer som bidrar til mestring.*

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- Deci, E.L. and Ryan, R.M. (2002) *Handbook of self-determination research*. Rochester, N.Y: University of Rochester Press.

Arbeid med diabetesrelaterte utfordringer

MÅL OG TILTAK

Plan for mål og tiltak er utarbeidet

dato: ……

i samarbeid mellom:

…… og …..……
(pasientens navn) (diabetessykepleiers navn)

MÅL	**TILTAK** (Inkludert tidsperspektiv)

VEILEDER FOR BEHANDLERE
12 mnd oppfølging 2019

1. Nedlasting av PROM-svar til NOKLUS diabetes

DiaPROM-deltakere svarer på PROM i forkant av konsultasjonen og har med seg en firetegnskode til konsultasjonen (diabetes type 1, 18-40 år). Koden brukes til å laste ned PROM-svar til diabetesjournalen. Se baksiden for utfyllende informasjon om nedlasting.

2. Intervensjonsgruppe og kontrollgruppe

Da firetegnskoden ble lagt inn i Noklus Diabetes ved baseline 2018, skjedde en automatisk randomisering.

- PROM-svar er synlig for intervensjonsgruppen.
- PROM-svar er **ikke** synlig for kontrollgruppen (blir synlig etter prosjektslutt).

3. Gjennomgang av PROM for deltakere i intervensjonsgruppen

1. Vurdere og se på **PAID*-scorer** sammen med pasienten.
Ved baseline ble totalscore ≥30 eller enkeltscorer ≥3 brukt som kriterier for henvisning til ekstra oppfølging hos diabetessykepleier.

2. Vurdere **WHO-5[#] score**.
Totalscore <28 kan indikere alvorlige psykologiske problemer (depresjon) og henvisning til psykolog/psykiater bør vurderes.

De andre PROM-skjemaene kan diskuteres dersom du eller pasienten har et spesielt ønske om det.

*Problem Areas in Diabetes scale. [#]WHO (Five) Well-being Index.

4. Videre oppfølging

DiaPROM pilotstudie avsluttes med denne 12mnd-datasamlingen. Du og pasienten avtaler derfor videre oppfølging uten tanke for prosjektet.

5. Papirspørreskjema om erfaringer

Takk for at du minner pasienten på å besvare papirspørreskjemaet om erfaringer med prosjektdeltakelsen etter konsultasjonen.

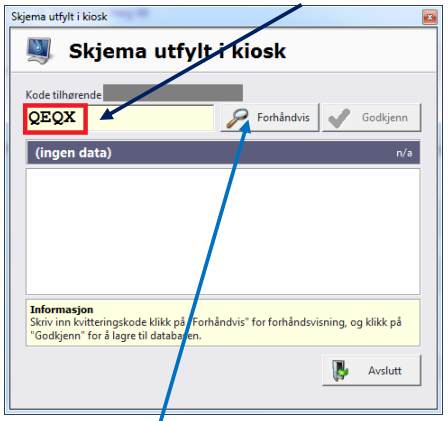
Ved spørsmål - ta gjerne kontakt med Ingvild Hernar på 906 83 641 eller iher@hvl.no.

Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes

MANUAL FOR NEDLASTING AV SPØRRESKJEMA FRA KIOSK TIL NOKLUS DIABETES

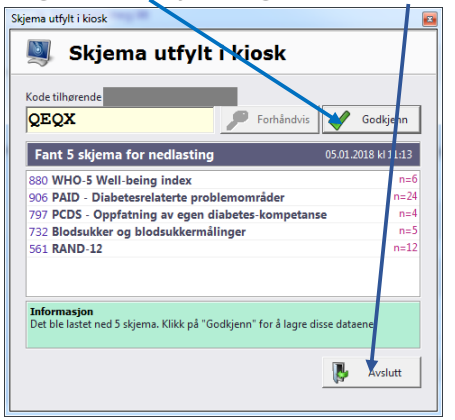
1. Åpne NOKLUS Diabetes og sjekk at du har aktivert riktig journal.
2. Se etter knappen «***PROMs***» oppe til venstre i skjermbildet.
   Klikk på trekanten og velg «***Hent pasientskjema fra kiosk***».

3. Deltakeren har notert en firetegnskode på et eget skjema.
   Denne koden taster du inn her.



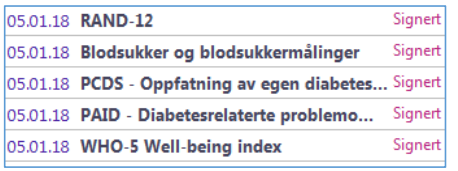
   Klikk så på «***Forhåndvis***».

4. En liste over de ulike spørreskjemaene vises.
   Velg først «***Godkjenn***» og deretter «***Avslutt***».



   (Glemmer du «Godkjenn» og går rett til «Avslutt» må du gjenta fra punkt 2.)

5. De ulike skjemaene lagres nå i Noklus Diabetes, men blir kun synlig hos pasienter er trukket til intervensjonsgruppen.
   Skjemaene kan gjenåpnes og endres på om ønskelig.



6. Husk å gi pasienten skjemaet med firetegnskoden tilbake.
   Spørsmålene på skjemaet besvares av pasienten og legges i postkassen på korridoren.

Prosjektnummer: 2017/1506/REK vest

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Øyvind Straume	55978497	31.01.2017	2016/2200/REK vest
			Deres dato:	Deres referanse:
			06.12.2016	

Vår referanse må oppgis ved alle henvendelser

Ingvild Hernar
Institutt for sykepleiefag

2016/2200 Bruk av pasientrapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes - en feasibility studie.

Forskningsansvarlig: Helse Bergen HF - Haukeland universitetssykehus
Prosjektleder: Ingvild Hernar

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 12.01.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Studien skal teste gjennomførbarheten av ulike elementer som skal inngå i en større studie. 100 personer over 40 år med type 1 eller type 2 diabetes skal inkluderes til å svare på spørreskjema. Formålet er 1) å teste ut de tekniske prosedyrer knyttet til innsamling av pasientrapporterte data på pc i ventearеal og overføring av data til pasientens elektroniske journal, 2) innhente deltakernes opplevelse av spørsmålenes relevans og omfang, og den generelle opplevelsen av å besvare PROMdata elektronisk på venterommet før en konsultasjon, samt 3) studere forskjeller mellom grupper når det gjelder selvrapportering av generell helse og velbefinnende, psykososiale problemområder og opplevelse av egen diabeteskompetanse.

Vurdering
Søknad/protokoll
REK vest vurderer dette til å være en godt beskrevet studie som er forsvarlig å gjennomføre. Komiteen bemerker at antallet deltakere er høyt for en feasibiltystudie, og anbefaler at prosjektleder vurderer å redusere antallet noe.

Informasjonsskrivet
Informasjonen til deltakerne er tydelig og god, men det er ikke gitt noen informasjon om mulig fremtidig intervju. REK vest setter som vilkår deltakerne informeres om dette. Et revidert informasjonsskriv skal sendes til REK vest på epost post@helseforskning.etikkom.no.

Vilkår

- Informasjonsskrivet skal revideres i tråd med ovennevnte merknad.

Vedtak
REK vest godkjenner prosjektet på betingelse av at ovennevte vilkår tas til følge.

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 31.05.2021, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning
Prof. dr.med
Komiteleder

Øyvind Straume
rådgiver

Kopi til:postmottak@helse-bergen.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Trine Anikken Larsen	55978498	15.02.2017	2016/2200/REK vest
			Deres dato:	Deres referanse:
			02.02.2017	

Vår referanse må oppgis ved alle henvendelser

Ingvild Hernar
Institutt for sykepleiefag

2016/2200 Bruk av pasientrapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes - en feasibility studie.

Forskningsansvarlig: Helse Bergen HF - Haukeland universitetssykehus
Prosjektleder: Ingvild Hernar

Vi viser til søknad om prosjektendring datert 02.02.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Vurdering
Omsøkt endring

Prosjektleder søker om tillatelse til å gjennomføre følgende endringer i prosjektet:

1. Inkludere to nye prosjektmedarbeidere
2. Redusere antall forskningsdeltakere
3. Nytt informasjonsskriv og samtykkeerklæring
4. Endring av spørreskjema til deltakerne

Vurdering

Grethe Seppola Tell og Roy Miodini Nilsen skal inkluderes i prosjektet som nye prosjektmedarbeidere. REK vest har ingen innvendinger til dette.

I opprinnelig søknad til REK skulle til sammen 100 personer med diabetes inkluderes i studien. I vedtak datert 31.01.2017, skrev imidlertid REK at antallet var høyt og ba om at dette ble redusert. Det søkes nå om å inkludere til sammen 60 deltakere. REK vest mener at dette er et tilstrekkelig antall for å kunne besvare forskningsspørsmålene i prosjektet.

Spørreskjema til deltakerne er endret. Prosjektleder ønsker at deltakerne noterer en firetegnskode fra PROM-datainnsamlingen på papirskjemaet. I tillegg er spørsmålene om kjønn, alder og diabetestype fjernes, mens spørsmål om utdannelse, arbeidstilknytning, samlivsstatus og morsmål lagt til. REK vest har ingen innvendinger til dette.

Nytt informasjonsskriv er lagt ved endringssøknaden. REK vest setter som vilkår at deltakerne informeres om at det vil bli hentet ut opplysninger fra deres pasientjournal, samt informasjon om hvilke opplysninger dette gjelder. I tillegg må det fremgå av informasjonsskrivet hvorfor firetegnskoden fra PROM-datainnsamlingen skal nedtegnes på papirskjemaet og hva det skal brukes til. Revidert informasjonsskriv sendes til e-postadressen post@helseforskning.etikkom.no.

Vilkår

- Informasjonsskrivet må revideres i henhold til ovennevnte merknader. Skrivet sendes til REK vest.

Vedtak

REK vest godkjenner prosjektendringen på betingelse av at ovennevnte vilkår tas til følge.

Klageadgang

Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning
Prof. dr.med
komitéleder

Trine Anikken Larsen
seniorkonsulent

Kopi til: *postmottak@helse-bergen.no*

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Anna Stephansen	55978496	16.05.2017	2016/2200/REK vest
			Deres dato: 03.05.2017	

Vår referanse må oppgis ved alle henvendelser

Ingvild Hernar
Institutt for sykepleiefag

2016/2200 Bruk av pasientrapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes - en feasibility studie

Forskningsansvarlig: Helse Bergen HF - Haukeland universitetssykehus
Prosjektleder: Ingvild Hernar

Vi viser til søknad om prosjektendring datert 03.05.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatsleder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Vurdering
Den omsøkte endringen gjelder utvidelse av aldersgruppen. Formålet med endringen er å raskere oppnå antall studiedeltakere (n=60).

Prosjekt lederen skriver at i etterkant av denne feasibility-studien planlegges det en pilotstudie og deretter en intervensonsstudie, samt en registerstudien for alle personer med diabetes.

Vurdering
REK vest har ingen innvendinger til prosjektendringen og gjør oppmerksom på at dersom det blir aktuelt med flere studier, må REK vest søkes på nytt.

Vedtak
REK vest godkjenner prosjektendringen.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Anna Stephansen
Kontorsjef

Kopi til: *postmottak@helse-bergen.no*

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Anna Stephansen	55978496	29.09.2017	2017/1506/REK vest
			Deres dato:	
			08.08.2017	

Vår referanse må oppgis ved alle henvendelser

Helse Bergen HF

2017/1506 DiaPROM

Forskningsansvarlig: Helse Bergen HF - Haukeland universitetssykehus
Prosjektleder: Anne Haugstvedt

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 14.09.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Prosjektomtale
Dette er en intervensjonsstudie. Prosjektgruppen skal gjennomføre både en pilotstudie og en fullskala evalueringsstudie (RCT). Hensikten med studien er å utvikle, teste og evaluere effekten av en strukturert empowerment-basert intervensjon med bruk av pasientrapporterte data. Hypotesen er at intervensjonen vil redusere deltakernes diabetesrelaterte problemer. Sekundært er hypotese at intervensjonen dermed også vil 1) bedre deltakernes blodsukkerreguleringen (HbA1c), 2) bedre deltakernes generelle velbefinnende, 3) bedre opplevelsen av egen kompetanse til å håndtere sin diabetes i hverdagen og 4) bedre deltakernes tilfredshet med oppfølgingen de mottar i helsetjenesten.

Vurdering
Randomisering:
Prosjektgruppen legger opp til blokkrandomisering (på pasientnivå). Randomiseringen skjer etter utfylling av PROM. Når behandler laster ned firetegnskoden fra utfyllingen av spørreskjemaene (PROM-utfyllingen) til Noklus diabetesjournal, vil han/hun få melding på skjermen om hvilken gruppe de er trukket til. Behandler formidler til deltakeren hvilken gruppe vedkommende er trukket til.

Beredskapsplan:
Komiteen reiste spørsmål ved beredskapsplanen i prosjektet. Utfylling av de omfattende spørreskjemaene(PROM) kan hos noen aktivere/bevisstgjøre psykososiale problemer. Det oppfattes som problematisk at behandler ikke får se PROM-resultatene på de som blir randomisert til kontrollgruppen. Dette innebærer at beredskapsplanen er avhengig av at pasienten selv gir beskjed om eventuell aktivering av problemer for å kunne få tilbud om oppfølging. REK vest forstår det slik at nå ikke har prosjektgruppen mulighet til å fange opp at kontrollgruppen trenger oppfølging.

En måte å ivareta kontrollgruppen vil være at kontrollgruppen også fyller ut papirspørreskjemaene etter konsultasjonen om hvor fornøyde de var/er med oppfølgingen i helsetjenesten. Disse kan videre bli lest av behandler som kan igangsette oppfølgingstiltak ved behøv.

Forsvarlighet:
Komiteen kommenterer at 3 måneders diabetesvarighet er noe lite siden situasjon i de første måneder etter

debut ofte er vesensforskjellig fra senere i «karrieren» med DM1. Studien vurderes som forsvarlig å gjennomføre.

Samtykke:
Aktuelle deltakere får tilsendt informasjonsskriv og samtykkeskjema i posten før timen til årskontroll på diabetespoliklinikken. REK vest har ingen innvendinger til dette.

Bortfallsanalysen:
Prosjektleder kommer ikke direkte inn på de etiske aspektene ved frafallsanalysen, men begrunner behovet for å gjennomføre denne type analyse fra et metodisk perspektiv. REK vest vurderer det slik at frafallsanalysen inkluderer opplysninger som oppfattes å ikke være spesielt sensitive, og tillater dermed frafallsanalysen. Deltakere skal opplyses om frafallsanalysen og gis adgang til å reservere seg fra dette.

Informasjonsskriv:

- REK vest har følgende merknader til informasjonsskrivet:
- Det er behov for informasjon til deltakerne om frafallsanalysen og reservasjonsretten.
- Informasjonsskrivet må merkes med logo til de forskningsansvarlige.
- Dato for prosjektslutt må stå i infoskrivet.
- Det må tydeliggjøres hvilke data som vil bli innhentet dersom man velger å ikke delta i prosjektet. Det må være samsvar mellom variabler som nevnes i søknaden og det som står i informasjonsskrivet.

Prosjektslutt og håndtering av data:
Prosjektslutt er satt til 01.10.2021. Datamaterialet avidentifiseres ved prosjektslutt. REK vest har ingen innvendinger til dette så fremt ingen identifiserbar informasjon lagres utover prosjektslutt.

Vilkår:

- Det skal legges opp til beredskap for kontrollgruppen.
- Informasjonsskrivet skal revideres og ettersendes REK vest.

Vedtak
REK vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 01.04.2022, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning
dr.med. professor
komitéleder

Anna Stephansen
sekretariatsleder

Kopi til:lars.birger.nesje@helse-bergen.no

Prosjektnummer: 2016/2200

HELSE BERGEN - ALT HANDLAR OM MENNESKE
Haukeland universitetssjukehus

Forespørsel om deltakelse i forskningsprosjekt med tittelen:

«Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes»

Dette er et spørsmål til deg om å delta i et forskningsprosjekt ved medisinsk poliklinikk på Haukeland Universitetssykehus. Hensikten er å gjøre oppfølgingen av personer med diabetes mer målrettet mot det den enkelte opplever som utfordrende i sin hverdag.

Hva innebærer prosjektet?

Deltakelse innebærer å besvare et elektronisk spørreskjema neste gang du kommer til diabetesoppfølging i poliklinikken. Spørsmålene vil handle om generell helse og diabetesrelaterte forhold som kan oppleves som utfordrende eller problematisk. Når du kommer til poliklinikken, vil du se en PC i korridoren ved venteareal, samt en detaljert oppskrift på hvordan du går fram for å besvare spørsmålene. Det vil ta mellom 5 og 10 minutter å fylle ut det elektroniske spørreskjemaet. Vi ber derfor om at du kommer ca. 10 minutter før timeavtalen.

I forbindelse med den elektroniske utfyllingen, får du oppgitt en firetegnskode på PC-skjermen. Du vil bli bedt om å notere den på et papirskjema som vil være tilgjengelig ved PCen. Papirskjemaet tas med til lege/sykepleier som bruker firetegnskoden til å knytte dine svar på det elektroniske spørreskjemaet til din diabetesjournal. På det samme papirskjemaet vil du også bli bedt om å svare på noen spørsmål om hvordan du oppfattet det elektroniske spørreskjemaet og utfyllingen av det, samt noe bakgrunnsinformasjon. Disse svarene vil også kunne knyttes til din elektroniske besvarelse via firetegnskoden. Det vil ta få minutter å fylle ut papirspørreskjemaet, og det leveres i en merket postkasse i korridoren ved venteareal når du er ferdig på poliklinikken. På et senere tidspunkt kan det bli aktuelt å intervjue en mindre gruppe deltakere. Du vil i tilfelle få en egen henvendelse om det.

I prosjektet vil vi innhente og registrere opplysninger om deg. Utover spørreskjemaopplysningene (elektronisk og på papir), vil vi hente følgende opplysninger fra din sykehusjournal: kjønn, alder, etnisitet, diabetestype, diabetesvarighet, siste HbA_{1c}-verdi, insulinbehandling, evt. antall tilleggssykdommer og evt. senfølger som følge av diabetes.

Mulige fordeler og ulemper

Utover tiden det tar å fylle ut spørreskjemaet vil ikke deltakelse i dette prosjektet medføre noen andre endringer eller mulige ulemper for deg.

Prosjektnummer: 2016/2200

Frivillig deltakelse og mulighet for å trekke sitt samtykke

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side og gir den til din behandler. Du kan når som helst og uten å oppgi grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for den øvrige oppfølging og behandling ved Haukeland Universitetssykehus.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Informasjon om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt. Opplysningene du registrerer i det elektroniske spørreskjemaet blir overført til din journal og kan dermed leses av behandler.

Prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk (2016/2200).
Har du spørsmål om prosjektet kan du kontakte prosjektleder: Anne Haugstvedt, e-post: ahau@hvl.no, tlf: 47 82 92 20 eller diabetessykepleier/stipendiat: Ingvild Hernar, e-post: iher@hvl.no, tlf: 90 68 36 41.

Bergen, 16. februar 2017

Vennlig hilsen

Anne Haugstvedt	*Hrafnkell B. Thordarson*	*Ingvild Hernar*
Prosjektleder/førsteamanuensis Høgskulen på Vestlandet (HVL)	Seksjonsoverlege Helse Bergen	Diabetessykepleier/stipendiat Helse Bergen/HVL

Prosjektnummer: 2016/2200

«Bruk av pasient-rapporterte målinger for å bedre kvaliteten på oppfølgingen av personer med diabetes»

Samtykke til deltakelse i prosjekt

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Dato: …….

Signatur: …….

Navn med blokkbokstaver: …….

HELSE BERGEN Haukeland Universitetssjukehus · Høgskulen på Vestlandet · UNIVERSITETET I BERGEN

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET:

BRUK AV PASIENT-RAPPORTERTE MÅLINGER FOR Å BEDRE KVALITETEN PÅ OPPFØLGINGEN AV PERSONER MED DIABETES

DiaPROM
Fokus på livet med diabetes

Dette er et spørsmål til deg med type 1 diabetes i aldersgruppen 18-39 år om å delta i et forskningsprosjekt ved medisinsk poliklinikk på Haukeland Universitetssykehus. Hensikten med studien er å prøve ut et tiltak for å gjøre diabetesoppfølgingen ved poliklinikken mer målrettet mot forbedring av det som kan oppleves som utfordrende i hverdagen med diabetes.

HVA INNEBÆRER PROSJEKTET?

Du møter på poliklinikken 15 minutter før avtalt time til årskontroll. **Før** årskontrollen besvarer du et spørreskjema om generell helse og diabetesrelaterte forhold på en PC ved poliklinikkens venterom (se bildet). Dette gjør du også ved neste årskontroll.

Det vil ta ca. 10 minutter å svare på spørsmålene. Du får oppgitt en kode på PC-skjermen som du blir bedt om å notere på et eget papirskjema som tas med inn til legen.

Legen laster ned svarene dine til diabetesjournalen ved hjelp av koden. Du fordeles deretter tilfeldig til enten å være i prosjektets tiltaksgruppe eller i en kontrollgruppe. Deltakelse i prosjektet innebærer følgende:

For tiltaksgruppen: Legen ser gjennom svarene du gav på spørreskjemaet sammen med deg. Dersom du rapporterte noen problemer som krever oppfølging, vil du få tilbud om minimum 2 ekstra oppfølgings-samtaler hos diabetessykepleier i perioden frem mot neste årskontroll.

For kontrollgruppen: Dine svar vil ikke bli synlig i journalen din. Det skjer først etter at forskningsprosjektet er avsluttet. Din behandler vil dermed ikke kunne ta initiativ til å diskutere svarene dine med deg i denne konsultasjonen.

I etterkant av årskontrollen vil alle deltakere, fra både tiltaks- og kontrollgruppen, bli bedt om å svare på et papir-spørreskjema om tilfredshet med oppfølgingen ved poliklinikken, samt noen diabetesrelaterte spørsmål. Det utfylte papirskjemaet leveres i en postkasse ved PC'en ved venteareal et før du forlater poliklinikken.

Utover informasjonen du har gitt på spørreskjemaet, vil følgende opplysninger hentes fra din sykehusjournal: kjønn, alder, etnisitet, høyde og vekt, hvor lenge du har hatt diabetes, siste HbA1c-verdi, type insulinbehandling, doser og eventuelt skifte av behandlingsopplegg, mulige komplikasjoner som følge av diabetes (inkludert alvorlig hypoglykemi, senkomplikasjoner og eventuelle sykehusinnleggelser som følge av dette), samt eventuelle andre sykdommer.

MULIGE FORDELER OG ULEMPER

Det tar noe tid å fylle ut spørreskjemaene på PC og papir. En fordel med prosjektet er at helsepersonell får mer kunnskap om utfordringer personer med type 1 diabetes kan oppleve, og om det å diskutere disse utfordringene i oppfølgingen bidrar til en bedre hverdag med diabetes. Å besvare skjemaene kan fremkalle vonde følelser hos noen. Deltakere i tiltaksgruppen vil få tilbud om ekstra oppfølging for nettopp dette, mens deltakere i kontrollgruppen vil stå fritt til å ta opp sine følelser/utfordringer med behandler.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på **siste side**. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke få konsekvenser for din videre behandling og oppfølging ved Haukeland Universitetssykehus. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede har inngått i ferdige analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder/postdoktor Anne Haugstvedt, e-post: anne.haugstvedt@hvl.no, tlf: 47 82 92 20 eller stipendiat/diabetessykepleier Ingvild Hernar, e-post: ingvild.hernar@hvl.no, tlf: 90 68 36 41.

HVA SKJER MED INFORMASJONEN OM DEG?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien øverst på første side. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Prosjektet har fått tillatelse til å registrere kjønn, alder, diabetes varighet og HbA1c på dem som takker nei til deltakelse i studien. Denne informasjonen vil kun bli brukt til å gjøre en frafallsanalyse, dvs. til å evaluere prosjektets tiltak. Dersom du ønsker å reservere deg mot dette kan du melde fra til prosjektledelsen.

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og for at opplysninger om deg blir behandlet på en sikker måte. Informasjonen om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt.

OPPFØLGINGSPROSJEKT

På et senere tidspunkt kan det bli aktuelt å intervjue en mindre gruppe blant alle som har deltatt i prosjektet. Du vil i så tilfelle få en egen henvendelse om det.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk, saksnr. (2017/1506/REK vest). Prosjektet avsluttes 01.10.2021.

Dersom du ønsker å delta, signerer du samtykkeskjemaet på neste side og tar det med til poliklinikken.

Bergen, 20. november 2017
Vennlig hilsen

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SAMTYKKE TIL DELTAKELSE I PROSJEKTET:

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JEG ER VILLIG TIL Å DELTA I PROSJEKTET

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