March 19th 2018

Title of the study

The use of Patient-Reported Outcome Measures (PROMs) to promote quality of clinical diabetes consultations: a study protocol for the DiaPROM trial

BACKGROUND

The burden of living with Type 1 Diabetes (T1D) remains a challenge despite new insulin types and advancements in insulin delivery technologies [1]. Many adults with T1D do not reach recommended treatment goals for glycaemic control [2, 3]. The low goal attainment might be due to inappropriate choice of insulin regimen for the individual person with diabetes, but research has also shown psychological and emotional aspects to be important barriers for satisfactory diabetes self-management [4]. Therefore, regular assessment of diabetes distress is recommended [5].

Asking patients questions concerning the impact of their condition and its treatment on their health is known as Patient-Reported Outcome Measures (PROMs) [6]. The integration of PROMs in clinical practice has the potential to improve care for people with diabetes. The present study is part of the implementation of PROMs in the Norwegian Diabetes Register for Adults (NDR-A).

AIM

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

METHODS AND ANALYSIS

Study design and study overview

The study is designed as a randomized controlled intervention trial (RCT) and will consists of several interacting components and a number of behaviours required by those receiving and delivering the intervention. Therefore, we use the Medical Research Council's framework (MRC framework) as a guide when developing the study [7, 8]. 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. In this protocol, we will present the study gradually according to the first three phases.

Phase 1 – Development of the study

The essential tasks in the development phase were to determine [1)] which PROMs to include, [2)] how patient should complete the PROMs, and [3)] which intervention should follow PROMs scores of special concern.

Literature review

We performed systematic literature searches to identify published articles on the use of PROMs in diabetes registers and clinical diabetes intervention studies. Several studies have reported PAID as an appropriate instrument for use in clinical diabetes consultations. This instrument may contribute to improved communication by making the dialogue between healthcare providers and patients more therapeutic and goal oriented [9-15]. The PAID is widely used and is translated into several languages, including Norwegian [16].

User involvement

A crucial question when considering which PROMs to include, was what people with diabetes perceived as the most important and relevant aspects to emphasize in diabetes follow-up. Thus, we consulted several groups of health service users. Further, we have included two health service users in the project-group who will contribute throughout all phases of the study.

Included PROMs

We chose the PAID scale as the tool for dialogue support in the study intervention. The scale consists of 20 statements regarding diabetes distress (e.g. “feeling constantly concerned about food and eating”, “worrying about low blood sugar reactions”) [17-19]. 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.

In addition to PAID, we will include additional PROMs to evaluate the effect of the intervention. Diabetes distress, measured by the Diabetes Distress Scale (DDS), will be the primary evaluation outcome. The DDS contains 17 items and 4 subscales: emotional burden (5 items), physician-related distress (4 items), regimen distress (5 items) and diabetes-related interpersonal distress (3 items) [20]. As secondary evaluation outcomes, the World Health Organization’s 5-item well-being index (WHO-5) [21-23] and the Perceived Competence for Diabetes Scale (PCDS) [24-26] are included for the evaluation of overall well-being and perceived diabetes competence, respectively. In addition to the mentioned PROMs, some standard Norwegian questions about satisfaction with follow-up in health-care will be completed after the consultation.

The method for answering the PROMs

The method for anwering PROMs is decided to be a computer-assisted administration on a touch screen computer in the outpatient clinic.

The study intervention

The starting point for the intervention is when a participant complete the PAID scale and the physician download the scores into the participant’s medical record in connection with an annual consultation. Then the physician reviews and discusses the PAID scores briefly with the participant.

Participants with PAID scores indicated significant diabetes distress, will be referred to additional diabetes nurse consultations. Participants with lower scores will receive regular follow-up as they would otherwise have received. The nurse follow-up for those with PAID scores of concern will consist of at least two consultations. The diabetes nurses review of PAID-scores in the conversation with the participants will follow a communication manual based on key elements from empowerment theory and self-determination theory [27-29]. Approximately 12 months after the inclusion, the participants complete the PAID again prior to the annual consultations with the physician.

Phase 2a - Feasibility study

A feasibility study was conducted in 2017 with the aims to [1)]examine the technical and practical feasibility of the procedure for collecting PROMs on a touch screen computer in the outpatient clinic, and [2)]evaluate the participants' perceived understandability, the number and relevance of items, and the acceptability of completing PROMs annually.

Participants

The participants in the feasibility study were patients with T1D in the age group ≥40 year.

Data collection and outcomes

Regarding the first aim, field observations gave data on the technical and practical procedures related to the completion of PROMs on the touch screen computer. Informal conversations with participants and health care personnel about their experiences of the technical and practical aspects related to the procedures took place, as well. Regarding the second aim, we included a paper-based questionnaire with questions adapted for this study.

Data analysis

The analysis of the field notes from the observations and informal conversations starts with a systematization of the text. Further, the text will be grouped by themes explaining the main content of the field notes. The analyses regarding the second aim will be analysed descriptively.

Phase 2b - Pilot study (RCT-design)

A pilot study will be conducted to test all the components of the coming full-scale evaluation study. The study will be designed as a randomized controlled trial in the same way as planned for the evaluation study. The aims of the pilot study are to: [1)]evaluate the recruitment and the number of dropouts during the intervention, [2)]evaluate the performance of the randomization procedure, [3)]evaluate if the PAID scores qualifying for referral to extra nurse consultations seems suitable, [4)]evaluate the effect measurements and the intervention effect and its variance, [5)]evaluate if the intervention consultations are suitable and conducted in accordance with the given procedure, and

[7)]explore the patients' and health care personnel's experiences with the use of PAID as dialogue support in clinical diabetes consultations.

Participants

We will include 80 participants in the pilot study; 40 in the intervention group and 40 in the control group. The participants have had T1D for at least 1 year, be in the age group ≥18 to <40 year. Eligible participants will receive information and consent form by regular mail prior to the annual diabetes consultation at the clinic.

Randomization procedure

Block-randomization on the patient-level stratified for sex will be applied to secure equal number of participants in the intervention- and the control group respectively, and equal number of men and women in each group. The PROMs scores for participants in the control group will not be accessible in the medical record until the study is completed. They will receive "care as usual" which does not include a structured focus on psychological and emotional diabetes distress.

Data collection and outcomes

All participants complete the study PROMs (before the annual consultation) and a paper-based questionnaire about their experience and satisfaction with the diabetes follow-up (after the annual consultation) at baseline and after 12 months (at the end of the intervention).

We will retrieve demographic and clinical variables from the participants' medical records.

To perform a non-response analysis, the variables sex, age, diabetes duration and HbA_{1c} will be collected from medical records of those who did not consent to participate or did not show up to the annual consultation at the clinic.

To secure that the extra consultations by diabetes nurses are carried out in accordance with the procedure, a random selection of consultations (6-8) will be audiotaped. Qualitative in-depth interviews with patients (15-20 interviews) and health care personnel (physicians and nurses) (8-10 interviews) will be conducted after the intervention is completed to gain knowledge about their experiences with the intervention.

Data analysis

The recruitment of participants, the number of dropouts during the intervention, the performance of the randomization procedure, and the participants' PAID scores will be described descriptively. To evaluate the evaluation measurements and the intervention effect and its variance, we will estimate both mean and SD of the DDS and the other evaluation measurements before and after the intervention period for both the intervention and control group. The audiotaped consultations and qualitative interviews will be analysed by thematic analysis [30].

Phase 3 - The evaluation study (the full scale RCT)

The aim of the full-scale evaluation study is to evaluate the effectiveness of the structured empowerment-based intervention with the use of PROMs as dialogue support in clinical diabetes consultations. Experiences from the feasibility- and pilot studies will constitute the basis for the procedures in the evaluation study.

Participants and sample size calculation

As in the pilot study, participants will be patients with T1D for at least 1 year in the age group ≥18 to <40 year. In order to reach sufficient statistical power to detect a statistical significant difference in DDS means between treatment groups, we will perform power calculations for repeated measures. The power calculations will be based on one-year post-intervention estimates (means and variance) as well as on the estimated correlation between repeated measures obtained from the pilot study (phase 2b). We will assume that the estimated correlation is exchangeable and can be extended to the two-year post-intervention period. Although linear mixed effects models may produce unbiased estimates in the presence of missing outcomes (if the data are missing at random), we will invite more individuals than indicated by the power calculations to account for the number of model parameters and variance parameters to be estimated.

Randomization procedure

If the randomization-procedure performed in the pilot study seems feasible, the same block-randomization on patient-level stratified for sex will be applied in the evaluation study, as well.

Data collection and outcomes

Participants will complete PROMs and the questions on satisfaction with follow-up at baseline, at 12 months (after the intervention) and at 24 months follow-up. Qualitative evaluations of the participants' and health care personnel's experiences will be performed in a similar manner as in the pilot study. However, the experiences from the pilot study will be considered before deciding on the final procedures and strategies.

Data analysis

To assess both short and long-term effects of the intervention, the trial will collect one pre-intervention measure and two post-intervention (after one and two years) measures for both the control and treatment group. Intervention and treatment groups will be compared for each follow-up time using linear mixed effects models with DDS as the primary outcome measure. All models will define treatment, time and treatment-by-time interaction as fixed effects (all categorical), whereas a random intercept will be specified to account for correlated observations of the same individual (an exchangeable correlation structure assumed). To obtain *p*-value for difference in DDS means between the comparison groups at different time points, we will perform a post-hoc test for pairwise

comparison accounting for multiple testing. To test whether the predicted DDS means change differently over time, we will use the likelihood ratio test by comparing the log-likelihood between models with and without the treatment-by-time interaction.

The qualitative evaluation analysis will be performed using thematic analysis as described for the pilot study, with potentially changes based on the experiences from the pilot study.

ETHICS APPROVAL

The Norwegian Regional Committee for Medical and Health Research Ethics has approved the feasibility study (2016/2200/REK west) and the pilot and evaluation study (2017/1506/REK west).

FUNDING

The study is funded by the Norwegian Nurse Association, Western Norway University of Applied Sciences, the Norwegian Diabetes Association and the Norwegian Diabetes Register for Adults.

TIME LINE

The feasibility study was conducted in 2017. The pilot study will start in 2018 and the full-scale RCT (evaluation) study is planned to start autumn 2019.

PROJECT GROUP

The project is a collaboration between Haukeland University Hospital, Western Norway University for Applied Sciences, University of Bergen, the Norwegian Diabetes Register for Adults, DIPS AS and the Norwegian Diabetes Association.

Steering group: Members from each of the collaborating institution.

Management group: Anne Haugstvedt, Postdoctor and Associate Professor, Western Norway University for Applied Sciences (HVL) (Project leader); Ingvild Hernar, Phd-candiate and Diabetes Nurse, HVL and Haukeland University Hospital; Marit Graue, Professor, HVL;
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