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Individual goal-based plan based on nursing theory for adults with type 2 diabetes and self-care deficits: a study protocol of a randomised controlled trial

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ABSTRACT

Introduction The prevalence and costs of type 2 diabetes are increasing worldwide. A cornerstone in the treatment and care of diabetes is supporting each patient in self-management. In Sweden, most patients with type 2 diabetes are cared for in the primary care setting, which is heavily burdened. Because of implementation difficulties regarding evidenced-based diabetes self-management education and support in this setting, there is a need for an instrument that is easy to use and implement. We developed an individual care plan based on the self-care deficit nursing theory of Dorothea Orem as an instrument to facilitate more individualised self-care support for patients with type 2 diabetes. In this study, we aim to determine whether a written, theory-based, individual goal-based plan for patients with type 2 diabetes and self-management deficits can affect their glycaemic control and health-related quality of life, as well as their experiences of living with diabetes and of support from diabetes care.

Methods and analysis The study design is a randomised controlled trial using a quantitative approach. A total of 110 patients will be included. Additionally, a qualitative interview study will be conducted 12 months after the intervention. The primary outcome will be glycosylated haemoglobin levels. Secondary outcomes will be health-related quality of life measured using the RAND-36, and the patient's experience of living with diabetes and of the support from diabetes care measured using the Diabetes Questionnaire. Quantitative data will be analysed using the paired t-test, unpaired t-test, and Mann–Whitney U test with IBM SPSS V.26.0 software. Qualitative content analysis will be used for qualitative data.

Ethics and dissemination This study has been approved by the Ethical Review Authority in Uppsala, Sweden (Etikprövningsmyndigheten, Uppsala, Sverige) (Dnr: 2020-03421). The results will be disseminated in peer-reviewed publications.

Trial registration number ISRCTN10030245.

Strengths and limitations of this study

- The intervention to be evaluated in this study is based on a theoretical nursing framework, and the intervention is well described.
- Using both qualitative and quantitative methods, we can gain wide-ranging understanding of the potential effects of the intervention.
- A limitation of this study is that patients with diabetes who choose to participate are likely to have greater motivation to change.
- Another limitation is that even with training regarding use of the goal based plan, the previous experience and knowledge of diabetes nurses may affect their behaviour in practice.

INTRODUCTION

The prevalence of diabetes is predicted to increase worldwide from 8.4% in 2017 to 9.9% in 2045.[1] In 2019, it was estimated that 463 million people had a diagnosis of diabetes.[2] In Sweden, the cost of treating diabetes and its complications increased by approximately 50% between 2006 and 2014.[3] The total cost for hospital-based care in Sweden for both microvascular and macrovascular diabetes complications was estimated at €232 million for 2016.[4]

Diabetes is a lifelong disease, usually divided into type 1 and type 2 diabetes, with type 2 diabetes being the most prevalent.[1 2] Type 2 diabetes and hyperglycaemia increase the risk of diabetes complications, including microvascular and macrovascular diseases, such as neuropathy, myocardial infarction, stroke and early death.[5 6] The risk of early death is decreased for patients with good glycaemic control and the absence of renal complications.[7] Because diabetes is a serious lifelong disease, there is incentive to find interventions that support affected individuals in adopting a healthy lifestyle.

Previous studies have suggested that people with diabetes experience a need for an encouraging patient–professional relationship that inspires the patient to take a lead role in their own self-management.[8 9] Additionally patients

with diabetes have requested personalised support that is well structured and based on national diabetes guidelines.[10]

According to the self-care deficit nursing theory by Orem, self-care is a human need, and nursing is required in situations of self-care deficits. Self-care deficits can comprise limitations in knowledge, the ability to perform actions, or making decisions.[11] Self-care and self-management are often understood and used as equivalent concepts, without in-depth explanation. In a concept analysis by Richard and Shea,[12] the relationship among a range of concepts, including self-care and self-management, was described and differentiated. Self-management is defined as a part of self-care. Both self-care and self-management are based on the philosophy that individuals are primarily responsible for their own health. Self-management is defined as 'the ability of the individual, in conjunction with family, community and healthcare professionals to manage symptoms, treatments, lifestyle changes and psychosocial, cultural and spiritual consequences of health conditions'.[12] According to Orem, the role of nurses is to support, teach, guide, and provide an environment that supports personal development.[11]

Orem's ontological assumption is that human beings are unique individuals with a shared basic need to maintain their living conditions. People are independent and responsible for their own self-care.[13] Self-care is a conscious action with the purpose of meeting a specific need. Conscious actions are not inherent but instead are learnt through communication and interactions with others. Both nurses and patients are seen as conscious, rational and action-oriented people who have the ability to act purposefully and in their own best interest.[11]

There is an abundance of research and guidelines regarding diabetes self-management education and support (DSMES). Nevertheless, there is a knowledge gap regarding the effect of individual DSMES on glycaemic control. In a Cochrane review,[14] the authors stated that the effect of individual DSMES on glycaemic control needs to be addressed in further studies. Research conducted in recent years suggests that individual DSMES can reduce glycosylated haemoglobin (HbA1c) levels[15–22] whereas other findings imply that individual DSMES has no, or negative, effects on HbA1c.[23–27] There is heterogeneity regarding the theoretical framework and execution of studies within this area, and there is an absence of studies regarding individual DSMES within the theoretical field of nursing.[15 17–27] Most published studies have no clear description of the intervention carried out in the study. A description of the intervention is a prerequisite for replication, which can in turn yield robust evidence regarding individual DSME.[28 29] Additionally, there are difficulties related to implementing evidence-based individual patient education in routine practice in the primary care setting.[25 30] Two studies regarding a specific written care plan among patients with type 2 diabetes demonstrated some evidence for improved clinical outcome measures; both studies concerned individual care plans for pharmaceutical diabetes care.[31 32]

Rationale

There is a need for further studies regarding individual DSMES. In Sweden, most patients with type 2 diabetes are treated and receive DSMES in the primary care setting. Diabetes nurses are responsible for DSMES; however, there is a knowledge gap in this area. In Swedish primary care, there is no consensus on how DSMES should be performed.

The intention of the present randomised controlled trial is to evaluate whether an individualised goal-based plan (online supplemental file 1) can reduce this knowledge gap, and to develop and evaluate this aid for diabetes nurses and adults with diabetes type 2 in the primary care. The purpose of the individual written plan is to set goals in diabetes self-care that are easy to understand and manageable for the patient. Additionally, these goals should be established in a collaboration between patient and diabetes nurse.

Objectives

We aim to evaluate whether an individual goal-based plan based on nursing theory can affect glycaemic control and health-related quality of life, as well as the experience of living with diabetes and support from diabetes care among adults with type 2 diabetes. We further aim to increase the understanding of patients' experience in using this goal-based plan.

METHODS AND ANALYSIS

Trial design

The design of the study is a randomised controlled trial with a quantitative approach. A qualitative interview study will be conducted 12 months after the intervention.

Study setting

Recruitment of participants will be conducted at several primary care units in the Region of Uppsala, Sweden.

Eligibility criteria

Patients over the age of 18 years will be included if they have HbA1c ≥58 mmol/mol and a diabetes duration ≥5 years. Exclusion criteria will be cognitive impairment, inability to read and understand Swedish language, and inability to independently complete the questionnaires owing to physical impairment.

Intervention

The present intervention is based on the theoretical framework of Orem[11] and inspired by the American Association of Diabetes Educators 7 Self-Care Behaviours regarding healthy eating, being active, taking medications and support problem solving.[33] The underlying assumption is that nurses can facilitate the action of self-care by clarifying the patient's self-care requisites and can support the patient to express this both verbally and in

writing. To inspire the patient to reflect on self-care in a structured way using four predetermined questions, the nurse and the patient in collaboration can determine which available care interventions can increase the patient's knowledge, ability to perform self-care actions and capacity to make decisions, in accordance with Orem's self-care deficit theory. Additionally, using the individual goal based plan, diabetes nurses together with the patient can identify and clarify ways for the patient to overcome self-care deficits. This collaboration can also increase the use of resources that already exist in the primary care setting, such as dietitians, physiotherapists and counsellors. As a result, the patient can become more self-sufficient regarding self-care.

The intervention has been tested in a pilot study in an unpublished master's thesis In the intervention group, HbA1c decreased by 8.8 mmol/mol (SD=14.7) after 3 months (p=0.027) while the control group showed no change in HbA1c. However, no significant difference in HbA1c was demonstrated between the intervention group and the control group (p=0.08).[34]

The diabetes nurses participating in this study will include registered nurses with higher education training in diabetes care. Nurses will attend a 2-hour educational session regarding the theoretical framework of the intervention and how to apply it in practice. This educational training will be conducted by a doctoral candidate on the research team with knowledge of the nursing theory adopted in this study. Diabetes nurses will be encouraged to discuss and reflect on use of the individual goal based plan among themselves and with the doctoral candidate so as to complete the educational process. Diabetes nurses are informed that both the intervention and control group should receive equal pharmaceutical treatment for type 2 diabetes in accordance with current guidelines.

During a routine appointment, participants in the intervention group will be given the opportunity to set their personal goals in collaboration with a diabetes nurse, using the individual goal-based plan. The care plan is intended to support patients in establishing relevant and feasible goals regarding their diabetes self-care. The goal-based plan is designed based on the principles of Orem's self-care deficit theory and addresses the patient's abilities in self-care.

Patients will have the opportunity to reflect on the following questions:

What is important to me regarding my diabetes care?

What are my personal treatment goals and when do I want them to be achieved?

What am I doing at the moment and what do I plan to do to achieve my goals?

How do I want the primary care centre to support me in achieving my goals?

Nurses will encourage each patient to write down their individual reflections and goals regarding their self-care. The participant's current and target values for HbA1c, low-density lipoprotein, and blood pressure are to be written in the care plan. A blank space is provided in the plan to write in additional target values.

Each participant will receive a copy of the individual goal based plan and a customised follow-up plan will be drafted. The follow-up plan is individualised according to the patient's self-care goals. The goals and follow-up plan are documented in the patient chart.

On the back of the plan, there is brief information regarding support and care for type 2 diabetes that is offered at the primary care centre as well as brief information about pharmaceutical treatment for diabetes, blood pressure and blood lipids. Furthermore, the care plan includes an explanatory scale of the relationship between blood glucose and HbA1c.

Participants in both the intervention and control groups will receive usual care, and the intervention group will additionally receive the individual goal-based plan.

Patient and public involvement

There was no formal patient or public involvement in the design, choice of outcome measures, or recruitment in this study. However, the intervention and research question was designed with reference to previous studies concerning the experiences of living with diabetes.

Outcomes

At baseline, sociodemographic data will be collected regarding participants' age, sex and education level. Data will also be collected from the Swedish National Diabetes Registry (NDR) on the diabetes duration, treatment regimen (insulin, oral drugs and/or glucagol-like peptide-1), other pharmaceutical treatment (antihypertensive, lipid-lowering drugs) comorbidity (ischaemic heart disease, cerebrovascular disease) and late complications (nephropathy, retinopathy, foot complications). Data regarding body mass index, blood pressure, low-density lipoprotein, high-density lipoprotein, cholesterol, urine albumin and albumin to creatinine ratio will also be collected from NDR. The NDR is a national registry in Sweden, launched in 1996, which contains data transferred from patient records in both primary and hospital care. The registry had a coverage rate of 87% in the year 2020.[35]

The primary outcome measure is HbA1c which will be measured using the capillary electrophoresis method and reported in mmol/mol, in accordance with the IFCC standard.[36] The secondary outcome measure will be blood pressure, lipids, and patient-reported outcome measures based on the validated questionnaires 'The Diabetes Questionnaire' and RAND-36. The Diabetes Questionnaire is a scale used to measure a patient's experience of living with diabetes and of support from healthcare.[37] The RAND-36 is a general health-related quality of life instrument.[38] As a supplement to these, qualitative interviews will be conducted.

The diabetes questionnaire

The Diabetes Questionnaire is a diabetes-specific questionnaire developed by the NDR. The questionnaire encompasses patient-reported outcome measures and was developed with a focus on allowing the patient's voice to be heard.[39] The instrument includes two parts: how the patient feels and how they are managing with diabetes, and how diabetes care providers support them in dealing with diabetes. The results are compiled into 12 dimensions, with each scored from 0 to 100. The 12 dimensions are: general well-being, mood and energy, being free from worries, managing diabetes, diet and exercise, not being limited by diabetes, not being limited by blood sugar, support from others, support from diabetes care, access to diabetes care, continuity in diabetes care and medical devices/medical treatment.[40]

RAND-36

The RAND-36 is a widely used survey instrument that measures health-related quality of life. It includes 36 items that assess eight dimensions: physical functioning, role limitations caused by physical health limitations, role limitations caused by emotional problems, social functioning, emotional well-being, energy/fatigue, pain and general perceptions.[41] Scoring the questionnaire is a two-step procedure. First, for each item, the response category is recoded to a numeric value according to a scoring key; second, all specific items in the same subscale are averaged to create the eight subscale scores. Scores may be treated as an ordinal scale or as an approximation of an interval or ratio level scale. Scores on the subscales range from 0 to 100, with 100 representing the best level of health status. A difference of 3–5 points in the RAND-36 subscales is considered clinically important. The Swedish translation of the instrument has been validated.[38]

Qualitative interviews

The qualitative interviews will be semistructured and will be conducted following an interview guide. Questions are primarily focused on the participant's self-management capability in their daily life, for example, 'Are you satisfied with the way you take care of your diabetes disease?' and 'How do you measure your blood sugar and what does the measured value tell you?' A second focus of the questions will be the participant's thoughts and attitudes toward the goal based plan after the implementation, for example, 'Are there any advantages/disadvantages to using the goal based plan?' Supplementary questions such as 'Can you give me a concrete example?' or 'Can you tell me more about that?' will be asked as necessary to gain a deeper understanding of the participant's thoughts.

Table 1 Interventional trials Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure—schedule of enrolment, intervention and assessments

	Study period			
	Enrolment	**Allocation**	**Postallocation**	**Close-out**
Time point	Prerandomisation	During routine visit	6 months	12 months
Enrolment				
Eligibility screening	X			
Informed consent	X			
Allocation		X		
Interventions				
Goal-based plan		X		
Assessments				
Sociodemographic		X		
Diabetes duration		X		
Treatment regimen		X		
Late complications		X		
HbA1c		X	X	X
Lipids		X	X	X
Blood pressure		X	X	X
RAND-36		X	X	X
The Diabetes Questionnaire		X	X	X
Qualitative				
Interviews				X

HbA1c, glycosylated haemoglobin.

Participant timeline

Data will be collected before randomisation and at 6-month and 12-month routine follow-ups (table 1). Twelve months after the intervention, 20 participants will be asked about their participation in an interview.

Sample size

To detect differences regarding a change in HbA1c levels of 6 mmol/mol between the study arms, the sample size should be 46 participants in each group (p=0.05; power=80%, assuming baseline mean=69.8; SD=10.3). Considering potential dropouts, we will include 55 participants in each group. Twenty study participants from the intervention group will later be asked to take part in the qualitative interview study.

Recruitment and allocation

The recruitment and randomisation process will be conducted according to the following:

1. Patients with type 2 diabetes will be invited to participate in the study via a mailed invitation letter (online supplemental file 2), in connection with their annual appointment.
2. If the patient wishes to participate in the study, they will sign the informed consent form (online supplemental file 2) and complete the RAND-36 and The Diabetes Questionnaire.
3. Patients will return the signed informed consent form and questionnaires during their annual appointment.
4. A diabetes nurse will ensure that each participant meets the stipulated inclusion criteria.
5. Each patient will be randomised to either the intervention or control group, with a 1:1 allocation.

Simple randomisation based on a single sequence of random assignments will be computer-generated using IBM SPSS V.26.0 software.[42] A person who is not involved in the study will prepare and seal opaque envelopes marked and numbered from 1 to 110 containing the group assignment. An envelope will be opened by the diabetes nurse each time a participant is included in the study, and the patient's serial number and personal identification number will then be recorded.

Statistical methods

Unpaired t-tests will be used to compare HbA1c between the groups regarding differences at baseline and at two time points (6 months and 12 months). Paired t-tests will be used to detect differences regarding HbA1c within each group. The Mann-Whitney U test will be used to compare ordinal data (RAND-36 and The Diabetes Questionnaire) at 6 months and 12 months. Missing data will be handled using multiple imputation.[43] The significance level will be set at p<0.05. All statistical analyses will be performed using IBM SPSS V.26.0 software (IBM). A statistical analysis plan inspired by Gamble[44] is provided in table 2.

Qualitative analysis

The recorded interviews will be transcribed verbatim. The transcripts will then be read by the research team to get a sense of the content. Qualitative content analysis[45] will be performed using the following steps:

Units of meaning are identified in the text by individual researchers on the research team. The units are then condensed.

Table 2 Statistical analysis plan

Sample size		**n=110**
Significance level		P<0.05
Trial objectives		The objectives are to evaluate whether an individual goal-based plan based on nursing theory can affect glycaemic control (HbA1c) and health-related quality of life (RAND-36), as well as the experience of living with diabetes and support from diabetes care (The Diabetes Questionnaire) among adults with type 2 diabetes
Population		Adults with type 2 diabetes within primary care in Region Uppsala (Sweden)
Data sources		National Diabetes Registry (HbA1c) Self-administered surveys: RAND-36 The Diabetes Questionnaire
Timing of outcome assessments		6 and 12 months
Analysis methods	Parametric statistic: HbA1c (mmol/mol)	Unpaired t-test, between groups analysis, paired t-test, within group analysis 6 and 12 months
	Non-parametric statistic: RAND-36 and The Diabetes Questionnaire	Mann-Whitney U test, between groups analysis 6 and 12 months
Missing data		Multiple imputation
Statistical software		IBM SPSS V.26.0 software

The entire research team meets to reach a consensus regarding the units of meaning.

The condensed units are coded by two researchers in collaboration.

The codes are sorted into subcategories by the members of the research team.

The research team will then create manifest categories based on the subcategories.

Any latent categories will be identified by the research team in collaboration.

ETHICS AND DISSEMINATION

All enrolled study participants will provide their written informed consent for study inclusion at their primary care appointment. Participants will be informed that they can withdraw from the study at any time without any effect on the received care.

This study is not associated with any known increased risks. The RAND-36 instrument has been widely used in previous studies and the Diabetes Questionnaire is used by numerous diabetes clinics and primary care centres as a part of diabetes care. All data will be coded and stored in a digital format in encrypted files or in a locked cabinet. All personal data will be processed in accordance with the General Data Protection Regulation.

The study has been approved by The Ethical Review Authority in Uppsala, Sweden (Etikprövningsmyndigheten, Uppsala, Sverige) (Dnr: 2020-03421).

The study results will be published in peer-reviewed journals and will be disseminated to patients and the public via a plain language summary in publications addressed to people with diabetes and their caregivers.

Trial status

The trial is currently in the prerecruitment phase. Recruitment started in August 2021. A total of five diabetes nurses have volunteered to participate in the recruitment process.

Contributors JR, JL, JWE, MM and ALO developed the research conception, design and methods and wrote the initial draft of the manuscript. JR and JL critically revised and contributed to the contents of this manuscript. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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