Making diabetes care fit: insights, strategies and support

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MAKING DIABETES CARE FIT

Insights, strategies and support

MEREL MARIA RUISSEN

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Voor mijn vrouw,
en onze twee prachtige kinderen

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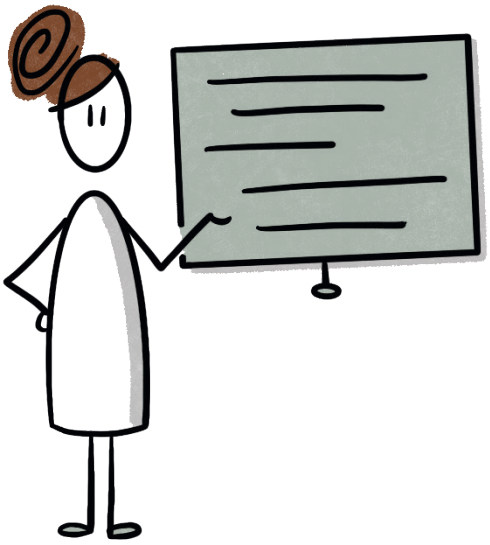

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General introduction and thesis outline

GENERAL INTRODUCTION

Diabetes mellitus

Diabetes mellitus consists of a spectrum of disorders characterized by high blood glucose levels (hyperglycemia)(1). Globally, over 537 million adults are living with diabetes mellitus, and dealing with the continuous burden diabetes and its treatment pose on daily life(2). This results in almost 7 million diabetes-related deaths and roughly a thousand billion US dollars in health expenditure every year(2). During the next decades the incidence of diabetes mellitus is expected to increase even further to 783 million adults living with diabetes in 2045(2), resulting in a tremendous burden on healthcare systems worldwide.

There are two major subtypes of diabetes mellitus to be distinguished: type 1 diabetes (5-10% of cases) and type 2 diabetes (90-95% of cases)(1). Type 1 diabetes is caused by the auto-immune destruction of the insulin producing cells within the pancreas, the beta cells(1). As a result there is an absolute lack of insulin, hampering the uptake and transport of glucose from the circulation into the cells, resulting in hyperglycemia. Patients with type 1 diabetes are often diagnosed early in life and the majority of patients become insulin dependent shortly after diagnosis(3).

Type 2 diabetes often manifests later in life and is usually characterized by insufficient insulin secretion and increased insulin resistance, mitigating the glucose lowering-potential of insulin(3). Altogether, this results in hyperglycemia(1). This hyperglycemia tends to become more severe and more difficult to treat over time(3). Major predisposing risk factors include obesity, a sedentary lifestyle and a positive family history for type 2 diabetes(4).

Whilst lifestyle modifications such as adopting a healthy diet, increasing physical activity and maintaining a healthy body weight, are important for all patients with diabetes, a distinction can be made between treatment of patients with type 1 diabetes and patients with type 2 diabetes.

Treatment of patients with type 1 diabetes

The cornerstone of treatment of patients with type 1 diabetes is insulin. Various types of insulin are available (such as rapid-acting, short-acting, intermediate-acting and long-acting insulin), that can be delivered using insulin pens, which requires patients to inject insulin a few times a day, or via insulin pumps, which deliver insulin continuously throughout the day. Injecting insulin results in a decrease of plasma blood glucose values. In order to prevent both hypoglycemia (blood glucose values

≤3.9 mmol/L)(5) and hyperglycemia (blood glucose values ≥10.0 mmol/L)(6), patients continuously have to manage and adjust their medication, diet and physical activity, and frequently measure their blood glucose values by performing fingerprick measurements or (intermittently scanned) continuous glucose monitoring. The treatment of type 1 diabetes is often complex.

Treatment of patients with type 2 diabetes

For patients with type 2 diabetes, multiple treatment options are available. These treatment options differ in their efficacy and safety, as well as in their burden on patients in terms of self-management, dosing, side effects, and costs. Generally, self-management for patients with type 2 diabetes is less intensive than for patients with type 1 diabetes.

The first line of treatment typically involves lifestyle modifications. When lifestyle modifications alone are not sufficient to achieve adequate glycemic control, medication may be needed in addition. Several oral and injectable glucose-lowering therapies are approved for the treatment of type 2 diabetes, offering a wide choice in appropriate therapeutic combinations. Types of medication often used are metformin, sulfonylurea derivatives (SU-derivatives), dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists. When, despite all efforts, adequate glycemic control is not reached, treatment with insulin may be needed. Most patients with type 2 diabetes start with once a day long-acting insulin, only requiring a fasting blood glucose measurement a few times a week. However, in some cases, multiple day insulin injections or insulin pump therapy are needed, requiring a more intensive self-management and self-monitoring regime.

Diabetes-related complications

When aiming to maintain glucose values as close to normal as possible, both hypoglycemia and hyperglycemia should be prevented. In case of hypoglycemia, patients start to feel unwell and are at increased risk of developing seizures or losing consciousness, resulting in dangerous situations(5). In severe cases, hypoglycemia can even be fatal(7). In turn, hyperglycemia can, in severe cases, result in life-threatening ketoacidosis or nonketotic hyperosmolar syndrome(1). Furthermore, when persistent over a longer period of time, hyperglycemia damages the body's vasculature and nervous system, leading to chronic diabetes-related complications. These complications include retinopathy, leading to loss of vision; peripheral neuropathy, increasing the risk of foot ulcers, amputation and Charcot joints; autonomic neuropathy, causing gastrointestinal, genitourinary and cardiovascular

symptoms and sexual dysfunction; nephropathy, with the risk of progression to renal failure; and cardiovascular diseases(8).

In addition, glycemic dysregulation has shown to be associated with a decrease in quality of life(9, 10) and psychological problems such as depression(11), anxiety(12) and distress(13). Therefore, it is crucial to maintain blood glucose levels as close to normal as possible(14).

Diabetes self-management

To maintain blood glucose values as close to normal as possible, patients need to self-manage their diabetes. Diabetes self-management often is an intensive, complex and time-consuming process(15, 16), requiring adequate knowledge, coping skills and a considerable amount of work on the part of patients. It generally competes with other demands on time, attention and energy and may require adjustments in the patient's daily routines(17). The burden diabetes self-management poses on patients(17, 18) and their families(19) has shown to be associated with a reduction in quality of life(20-22), and psychological problems, such as depression(23). In an effort to reduce this burden, substantial advances have been made during the last decades in terms of behavioral and lifestyle interventions, new types of glucose-lowering drugs and novel technologies, such as smart insulin pens, insulin pumps, closed-loop systems, glucose-measuring devices, and digital tools for diabetes self-management support, such as e-health and mobile health systems(24-28).

At the same time, this expanding number of treatment and self-management options, and the growing information about their risks and benefits, may complicate the decision-making process(29). In order to use the available treatment and self-management options in an effective and timely matter, making sure that the benefits outweigh the burden, care plans should be crafted carefully to fit the individual patient. This implies a need to shift away from care focused primarily on biomedical parameters, such as glycated hemoglobin (HbA1c) and diabetes-related complications, towards well-fitting, person-centered care(8, 30).

Making diabetes care fit

The expanding number of treatment and self-management options may have made it increasingly challenging to make decisions about which care strategy fits the individual patient best. However, especially when care relies predominantly on the patient's daily self-management, providing the patient with a care plan that fits seamlessly in one's daily routines is of major importance(31-35). This means

that the care plan fits the patient's unique situation, is in line with their values and preferences and does not overburden their capacities(31).

Making care fit is an ongoing and iterative process of tailoring both the content as well as the type of communication to the individual patient, their needs and abilities, and their situation. It requires a patient-clinician partnership based on curiosity, mutual respect, humanity, and empathy and the willingness to accept and explore each other's contributions(36).

A distinction can be made between making care fit *at the point of care*, mostly during clinical encounters, and making care fit *at the point of life*, i.e. in daily life(37). At the point of care, care plans should make sense according to the patient's preferences, values, needs and context, whilst minimally disrupting their lives(18, 36). At the point of life, patients need to figure out how to embed these care plans and the demands of diabetes self-management into the challenges of life and living.

Shared decision making

In order to make diabetes care fit, clinicians and patients need to collaborate and share their knowledge and experience – the patient as the expert of their life and preferences and the clinician as the medical expert(34, 35, 38-40). One possible approach to this collaboration is shared decision making (SDM)(41).

SDM finds its place in the midst of two extremes: the paternalistic care approach on one side, focused on the assumption that 'the clinician knows best', and the consumer model on the other side, focused on the patients' autonomy(42). Whilst the term 'sharing of decision making' was already mentioned by Veatch in 1972(43), it took until 1997 before SDM gained more interest and efforts were made to define and give meaning to SDM(38). Nowadays, SDM is considered 'state-of-the-art' and is advocated broadly by leading diabetes institutions like the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA)(30).

In SDM, patients and clinicians partner up and work together to decide on the best available healthcare strategy for the individual patient, taking into account both the best available evidence, and the patient's preferences, needs and context (44). It is often defined as a stepwise process of 1) fostering choice awareness, 2) presenting potential treatment options together with their pros and cons, 3) clarifying the patients preferences, and 4) reaching a final decision(45-48).

Several arguments are driving the current advocacy for SDM. It respects and facilitates the patient's autonomy, without leaving the patient feeling abandoned(49), and aims to support the patient where needed, without being overly directional. A systematic review by Shay et al. showed that SDM improves the patient-clinician relationship by increasing affective-cognitive outcomes such as satisfaction, trust and understanding(50); factors that are crucial when aiming to make care fit.

AIMS AND OUTLINE OF THIS THESIS

This thesis aimed to explore patient and clinician efforts towards **making diabetes care fit**. In this exploration we aimed to provide *insight* in the factors driving the decision making process, discuss various *strategies* to tailor SDM to the patient's situation, needs and preferences, and explore ways to *support* the patient and the patient-clinician partnership in diabetes care.

Diabetes care, and the role the patient and clinician have within the care process, has changed over time. **Chapter 2** contains our viewpoint on the changes in diabetes care from a paternalistic to a person-centered care approach. We discuss the connections between evidence-based medicine, minimal disruptive medicine, SDM and person-centered diabetes care, and provide recommendations for clinical practice.

To increase the chance of patients and clinicians successfully partnering up in SDM and designing care plans that fit the patient's unique situation and preferences, it is crucial to understand which factors play a role in the decision making process. **Chapter 3** assesses which person and disease-related factors are most important to consider during the process of collaborative decision making, according to healthcare professionals.

In addition to tailoring the content of the conversation to the patient and their situation, also the type of communication should be tailored, in order to be effective. **Chapter 4** describes the prevalence of the different forms of problem-based SDM that patients and clinicians use in clinical practice when collaborating, and it illustrates how patients and clinicians flexibly switch between these different forms of SDM. Seeking to better understand the processes defining SDM and their structural elements, **chapter 5** assesses how the problem-based forms of SDM relate to the four steps of canonical SDM.

In our viewpoint in **chapter 6** we elaborate on the conditions necessary for care to flourish and for patients and clinicians to collaborate and communicate effectively. We address the barriers to kind and careful care, posed by the speed and technification with which the current healthcare system must operate, and provide practical suggestions to support the patient-clinician partnership and reduce the risk of poor-quality and ill-fitting care plans.

To support patients and healthcare professionals partnering up in SDM and help patients in their daily diabetes self-management, **chapter 7** describes a randomized controlled multicenter study assessing the effect of an e-health support system, integrating biomedical, behavioral and psychological data. Based on a personalized care plan, and acknowledging the complexity and multifactorial character of diabetes self-management, the support system aims to provide individually tailored practical, psychological and behavioral support and specific interventions to improve diabetes care and quality of life.

In 2020, the severe acute respiratory syndrome-CoV coronavirus-2 (COVID-19) rapidly spread around the world, resulting in a global pandemic. Strict measures and lockdowns were needed to halt the spread of the virus, resulting in social isolation, disruptions in daily routines and restricted healthcare access and support. Amongst other diseases, both type 1 and type 2 diabetes mellitus were considered major risk factors for a severe course of COVID-19 and mortality, especially when blood glucose values were poorly controlled(51, 52). The increased emphasis on diabetes self-management that followed, together with the additional challenges posed by the pandemic, such as the closure of sporting facilities and workplaces, social distancing and coping with anxiety and uncertainty, was expected to majorly impact glycemic control and diabetes self-management. In **chapter 8** we describe how the COVID-19 pandemic and the measures taken to prevent further spreading of the disease, affected biomedical, behavioral and psychological outcomes in patients with type 1 and type 2 diabetes.

Chapter 9 provides a general discussion of the results of this thesis and the implications for policy, practice, education and research.

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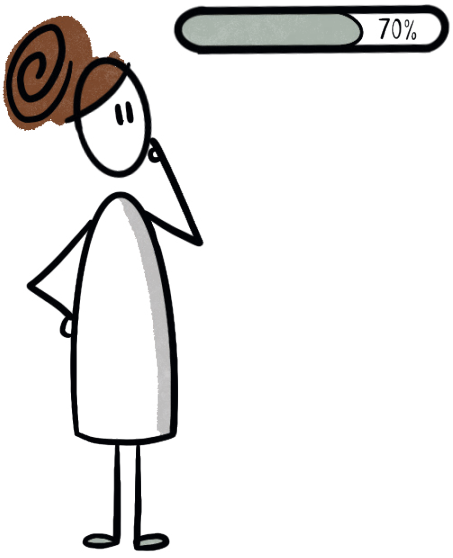
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Making diabetes care fit – are we making progress?

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ABSTRACT

The care of patients with diabetes requires plans of care that make intellectual, practical, and emotional sense to patients. For these plans to fit well, patients and clinicians must work together to develop a common understanding of the patient's problematic human situation and co-create a plan of care that responds well to it. This process, which starts at the point of care, needs to continue at the point of life. There, patients work to fit the demands of their care plan along with the demands placed by their lives and loves. Thought in this way, diabetes care goes beyond the control of metabolic parameters and the achievement of glycemic control targets. Instead, it is a highly individualized endeavor that must arrive at a care plan that reflects the biology and biography of the patient, the best available research evidence, and the priorities and values of the patient and her community. It must also be feasible within the life of the patient, minimally disrupting those aspects of the patient's life that are treasured and justify the pursuit of care in the first place.

Patient-centered methods such as shared decision making and minimally disruptive medicine have joined technological advances, patient empowerment, self-management support, and expert patient communities to advance the fit of diabetes care both at the point of care and at the point of life.

INTRODUCTION

Diabetes care should improve the health-related quality of life of patients with diabetes, both type 1 and type 2 diabetes, and mitigate their risk, morbidity, and mortality from chronic micro- and macrovascular complications. As with any other chronic condition, it is patients and their caregivers who must implement diabetes care plans. These plans should respond to the patient's problematic situation in at least three ways(1). First, they must be scientifically sound, addressing what is known about the determinants of outcomes with evidence-based interventions, favoring interventions that respond well to the situation of the patient and promote outcomes that the patient values. Second, their implementation must be feasible in their daily routines and should disrupt those routines to the least extent possible. Third, patients must feel that the plan is the right thing to do for them at the present time. Plans that make intellectual, practical, emotional sense to patients are said to configure "care that fits." Patients with plans of care that do not fit, "receive tests and treatments they do not need, understand or implement, a result that is wasteful and harmful"(2).

In this perspective, we consider how to make diabetes care fit, the role of patients and clinicians within this process, and potential strategies to do so. A distinction can be made between making care fit at the point of care and at the point of life. Fitting at the point of care occurs mostly during clinical encounters and demands collaboration between patients and clinicians, a term we use capaciously to include physicians, therapists, pharmacists, nurses, and any other professionals with the privilege of directly participating in the patient's care(3). In designing care plans, patients and clinicians must work together to uncover the problematic situation of the patient and to determine how to best respond to it. At the point of life, patients and caregivers must integrate daily the practical demands of the care plan (and, often, of navigating health care) with other demands of life and living. The patient is usually the one person bridging these two efforts to make care fit.

FITTING AT THE POINT OF CARE

The process of making care fit requires attention to the biology and the biography of the patient, to their physiology and their psychology. Care must respond to the problematic biological situation of the patient, be evidence-based, and make sense given a patient's unique context. Within the process of fitting care clinicians should also assess the patient's capacity to carry the burden of disease and treatment and

potential diabetes-related distress, in order to prevent overburdening the patient. In doing so, some barriers emerge, such as restrictions in the individualization of treatment plans and the practical difficulties patients must face when implementing treatments for diabetes and its comorbidities.

In addition to smoking cessation, lipid and blood-pressure control, and aspirin use, intensive glycemic control (i.e., HbA1c ≤7%) is recommended to achieve diabetes care goals(4, 5). And yet, when compared to conventional glycemic control (HbA1c <8.0–8.5%), intensive glycemic control has not consistently reduced the risk of complications of type 2 diabetes, while it has increased the cost and complexity of treatment and the risk for hypoglycemia(6–9). Furthermore, a narrow focus on glycemic control may fail to consider the biological (e.g., comorbidities) and biographical (e.g., values, preferences and financial, family, and social) facets of patients' problematic situations. Guidelines with fixed HbA1c targets and formularies that limit the range and order (i.e., use of first-line agents followed by second-line agents) of the diabetes medications may excessively constrain the possibility of making care fit through treatment individualization. Severe and long-standing type 2 diabetes often requires the use of multiple medications to achieve glycemic control.

Fitting care must consider not just the efficacy of each of these drug regimens but their additive and interacting effects in terms of inconveniences, costs, and harms(10). To illustrate this cumulative burden of treatment, consider how antihypertensives, introduced to reduce cardiovascular risk associated with comorbid hypertension, can cause orthostatic dizziness which may compound dizziness caused by gabapentin introduced to treat painful neuropathy. This treatment burden extends beyond the effects of polypharmacy to also include the demands health care makes on patients in terms of time, energy, and attention given how health care is organized and delivered. Together, the healthcare workload that patients must shoulder lead to reductions in quality of life, a phenomenon sometimes called the burden of treatment(11). These burdens can be tolerated better when they are clearly connected with advancing patient goals and priorities while efforts are put in place to minimally disrupt patient lives(12). The latest guidelines by the American Diabetes Association recognize the need to align diabetes treatment with patient goals, by recommending flexible treatment goals and programs and by recognizing burden of treatment as a key consideration.

PATIENT EMPOWERMENT AND PATIENT-CENTERED CARE

Empowered patients choose personal, meaningful, and realistic goals for care, think critically, act autonomously, and enhance their self-efficacy(13, 14). Empowered patients would therefore be in a better position to take part in fitting of care at both the point of care and at the point of life, where treatment strategies and associated tasks must be carefully woven into that patient's daily routine. Interventions to promote patient empowerment, such as self-management education programs, have shown some benefits in the self-management of patients with diabetes, but their quality is inconsistent, and access remains patchy(15). These programs, however, often seek to improve patients' adherence to recommended care, rather than to increase patient's autonomy and fitness of care(14). This may be frustrating to both patients and clinicians, with patients feeling they are failing and clinicians labeling patients as non-compliant and blaming them for not meeting recommended targets(14). To make care fit, empowerment must not contribute to this conflict but rather promote patient-clinician collaboration.

Patient-centered care describes such a collaboration. Patient-centered care is "respectful of and responsive to individual preferences, needs, and values"(16) through effective communication, partnership, and health promotion(17). Using effective communication, clinicians gain insight into the patients' personal situation, their experiences, their priorities, goals, preferences, and values. This enables patients and clinicians to form a partnership, an alliance to find the treatment plan that best fits the patient's personal situation, and effectively promotes health(18). Furthermore, clinicians need to sufficiently inform patients about potential treatment options and provide them with the opportunity to take advantage of all available resources(19). Patient-centered care is therefore an approach to co-produce sensible plans of care that can feasibly contribute to desirable patient outcomes(2).

SHARED DECISION MAKING IN DIABETES CARE

A person-centered approach to design care plans that fit is shared decision making (SDM)(1, 20). SDM is a conversation in which patients and clinicians develop a common view of the patient's situation and co-create a plan of care to address it. When successful, SDM leads to a care plan that is more likely to respond well to the problematic situation of the patient, to be feasible given the existing demands on the patient's time, energy, and attention, and to be desirable given the patient's expectations, preferences, goals, and values. In this way, SDM contributes to make

sure the plan of care makes intellectual, emotional, and practical sense and therefore fits well within the patient's life(21). In the care of patients with diabetes and other chronic conditions, patients contribute to SDM as experts in the impact of disease and treatment in their personal context(22); over time, patients develop expertise on what is feasible and what not in their unique situation(23). This information and expertise contributes to the biomedical evidence and clinician experience as these partners share the decision-making process.

Since SDM is a method of care, clinicians and patients can determine when and how to engage in this method and whether or not to use supportive tools. Although implementation science is exploring how best to enact shared decision making in practice, its application depends more on how well it can address the patient's problem than on the type of encounter (new or continuity, in-person or remote), the type of clinician, or on the availability of tools.

Interventions to facilitate SDM have been shown to improve patient (risk) knowledge and decisional comfort(24). Importantly, most patients prefer to participate in decision making, when they get the information and knowledge that they need to make decisions(25). As a result, healthcare policies and guidelines recommend SDM and the use of SDM tools(26). These aids can be designed to support the SDM conversation and often offer the necessary information in a useful and accessible form for use in preparation for or during the consultation(25). Tools designed for use during the consultation may be particularly effective in guiding patients and clinicians through the shared decision-making process, such as fostering of choice awareness, discussing the available options, exploring patient priorities, and making a final decision(27, 28). These tools can be easily used by all types of clinicians without substantial training to enable effective and efficient communication and guide the decision-making process to reflect the patients' situation, references, and needs.

Consider the case of a patient with type 2 diabetes and without complications who has implemented a healthy lifestyle and uses metformin without achieving her glycemic target. Her clinician may select a second-line option according to recommended algorithms based on her degree of hyperglycemia and her cardiovascular and renal state. This medication may very well be the right one or may be too burdensome to this patient because of its side effects, complexity of administration, or out-of-pocket costs. Alternatively, her clinician could engage the patient in SDM, even using a validated SDM tool, such as the Diabetes Medication Choice decision aid(29), and improve the likelihood that the medication selected would fit better.

MINIMALLY DISRUPTIVE MEDICINE

Because of how health care is organized and delivered, it often delegates medical errands to patients, transferring navigational and administrative tasks that worsen the burden of treatment and disrupt their lives and the lives of their caregivers. The multiple, often uncoordinated, care paths involved in the care of diabetes and of its associated comorbidities, together with the physical and emotional burden of disease for both the patient and their family may be overwhelming to patients and caregivers with consequent decay in the fidelity with which treatments are implemented at the point of life. When co-creating patient centered plans of care, patients and clinicians pursue patient priorities for health care while minimizing the burden of treatment. Using this approach, sometimes called minimally disruptive medicine (MDM)(12), health care seeks the most effective yet least burdensome treatment for each patient in particular while reducing, in general, the tasks delegated to patients and caregivers. MDM is patient focused to the extent that it respects patients' limited time, energy, and attention, while accounting for patients' usual prioritization of these precious resources to attend the demands their lives and loves place over those placed by the need to complete healthcare tasks when the latter conflict with the former.

In diabetes, MDM is particularly important when patients have to implement complicated treatment regimens: estimate and administer insulin doses, monitor glucose levels, implement an accurate accounting of carbohydrates and caloric intake, and so on. MDM is also critical when patients must implement the care of each of their existing conditions which, in addition to diabetes-specific tasks, often contributes to polypharmacy and complex dietary restrictions. This can easily and frequently lead to an unsustainable burden of treatment which may lead to nonadherence. Mindful of the burden of treatment, clinicians and patients may co-create plans of care that fit the particular needs of the patient in a manner that renders them feasible within their daily routines. Diabetes technologies such as continuous glucose monitors (CGM)(30), continuous subcutaneous insulin infusion (CSII) devices, and automated insulin dosing (AID) systems(31) are now available for the care of patients with type 1 diabetes and severe type 2 diabetes. These systems can contribute to reduce glucose variability and improve glycemic control without a large increase in the risk of hypoglycemia. For patients for whom technology adoption is relatively easy, who can afford these devices, and who can access parts and services with minimal friction and cost, the adoption of these technologies may translate into care with a reduced burden of treatment(32, 33). However, for others these technological advances may increase the burden of disease, time, and treatment and may result in an increase in diabetes

distress(34). These digital advances may therefore cause a divide between patients that benefit from new technology, both biomedically and psychologically, and those for whom these technological advances result in an increased burden and associated diabetes distress.

Some MDM tools, such as the Instrument for Patient Capacity Assessment (I-CAN) (35), exist to make care fit during the consultation by facilitating conversations about treatment burden. This tool supports patients and clinicians in assessing if and how a certain healthcare strategy may interact with the patient's life, and in clarifying how aspects of the patient's life may interact with the treatment plan(36). Most MDM tools (like I-CAN) can be easily used during the consultation by any clinician without additional training.

FITTING AT THE POINT OF LIFE: THE ONGOING WORK OF BEING A PATIENT

Patients and clinicians can work together to make care fit at the point of care, that is, in clinical encounters, but patients will face an ongoing process of fitting care in their personal life. It is at the point of life where some care plans prove feasible or infeasible. Yet, this process, which occupies the vast majority of the time persons experience as patients, is often invisible to clinicians. Advances in diabetes technology and patient communities are contributing to the fitness of care at the point of life.

New Technologies to Support Patients With Diabetes

To support successful implementation of care plans, the last decade has shown an emergence of new self-management technologies, such as smart insulin pens(37), insulin pumps(33), and closed-loop systems (38). Furthermore, glucose monitoring has evolved to include flash glucose sensors(39–41), continuous glucose monitors(30), and e-health systems that support the patient in their diabetes self-management. While able to improve glycemic control and reduce the risk of hypoglycemia, the extent to which these technologies contribute to or reduce diabetes chronic complications and burden of treatment remains uncertain. Technologies such as CGM and CSII can improve patient satisfaction and acceptability, and reduce diabetes worries and interpersonal hassles for some patients(42). This is important as the use of these devices may probably translate into a reduced burden of treatment that can make diabetes treatment more bearable for people with diabetes, particularly those living with type 1 diabetes. However, for some

patients the time and efforts needed to adopt these technological advances and the associated focus on glycemic control may negatively impact the burden of disease and treatment. Furthermore, these new technologies require connection to online platforms or applications and data sharing agreements with third parties. Thus, they contribute to patient work by demanding that patients negotiate difficulties in their usability and reliability and address concerns and worries regarding privacy loss(43).

Communities of Patients

Social media offers an opportunity for persons living with diabetes to access expert peer advice about making care fit. There is scant evidence about the impact of interventions within social media networks on diabetes outcomes(44). A "netnographic" study across social media platforms showed that patients with diabetes gained access to patient experts who offered practical answers and problem-solving tips and hacks, received and offered emotional support, and developed capacity through an enriched sense of connection(45). A 2018 analysis found almost 200.000 persons living with diabetes participating in Facebook diabetes groups, most of which focused on practical problem solving(46). These findings are consistent with a recently published review(47), demonstrating that social media participation may contribute to improve patient capacity to fit care both by contributing to practical know-how and self-efficacy and by the emotional enrichment of taking part in a community of reciprocal relationships.

With the responsibility of self-management residing almost completely with the patient, and the technological advances over the last decades, the diabetes online community (DOC) is growing as an expert support system(48). The DOC is a widely used term, encompassing all people engaging in diabetes-related online activities, e.g., blogs, discussion and support groups, video tutorials, podcasts, and other offerings(49). With patients often reporting diabetes to exert a negative impact on their relationships and their physical health(50), diabetes medication to interfere with living a normal life(50), and having to deal with social stigma(51), support is crucial to reduce associated feelings of distress and burnout(52). With diabetes distress being highly prevalent in patients with diabetes and associated to poor diabetes self-management, reducing diabetes distress is essential to improve diabetes-related outcomes and improve quality of life(52, 53). People with chronic health conditions often endorse feeling more comfortable sharing their experiences and struggles with others who can relate based on their own lived experiences(54). Patients can feel more supported through digital contact with peers and fellow patients which in turn can contribute to improve self-care routines, effective problem-solving and lifestyle adjustments, quality of life, and

outcomes of care(54–57). This work with online peers may be emotionally less "costly" than the support of more immediate family members, also critical as its absence has been associated with low treatment fidelity(58). The value of DOC may continue to increase with increases in the incidence of diabetes distress, high burden of disease and treatment, and social isolation. Fitting care at the point of life will become increasingly important with the advent of innovations such as new therapeutic agents, transplantation of the islets of Langerhans, the introduction of organoids, and the development of high-functioning artificial pancreas systems. Expert patients and DOC will play a central role in the cautious but opportune adoption of these advances, sharing their knowledge and experiences with different treatment options, supporting patients in the decision-making process to adopt new and experimental technologies, manage expectations, and facilitating their normalization within the routines of people's lives. With the evolving role of patients becoming experts in their own medical situation with the help of online communities and social media, it is important for clinicians to adopt an open and supportive approach towards online support.

DISCUSSION

Patient empowerment and patient-centered care are essential for the optimal care of people living with type 1 or type 2 diabetes. Evidence-based diabetes care, to be person centered, demands that clinicians become skilled in supporting SDM and work toward MDM(12). Healthcare systems and policies can promote or hinder this approach, for example, by shifting attention, quality metrics, and financial incentives from technical healthcare outcomes like HbA1c toward more holistic outcomes such as quality of life and burden of treatment. While expert guidelines progress in this direction, and the patient community makes increasingly important contributions to care that fits, implementation currently still lags at the point of care as a result of HbA1c dependent reimbursements by insurance companies and insufficient awareness, knowledge, and practical guidance within clinical practice to improve the fit of care. We must work toward a reality in which each person with diabetes is seen not as an object, a diagnosis, a subject of treatment with a predetermined universal goal, but rather as a complex person within a problematic human situation and imbued of personal and community values for whom an evidence-based care plan must be co-created, crafted carefully to meet her needs and advance her priorities. Clinicians and patients working side-by-side as complimentary experts and partners in implementation, can form not just a plan of care that fits in the clinic, but a safe and effective one that fits well in patients' daily lives.

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3

Key factors relevant for healthcare decisions of patients with type 1 and type 2 diabetes in secondary care according to healthcare professionals

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Patient Preference and Adherence (2022)

ABSTRACT

Purpose

Understanding which factors are important for healthcare decisions of patients with diabetes in clinical practice is important to personalise diabetes care strategies and tailor care plans to the individual. The main drivers for these healthcare decisions remain unclear. This study assessed which key factors are relevant for healthcare decisions during clinical consultations for patients with type 1 diabetes (T1DM) and type 2 diabetes (T2DM), according to healthcare professionals.

Patients and methods

Annual diabetes reviews were performed as part of a trial assessing the impact of a consultation model facilitating person-centred diabetes care in six hospital outpatient clinics. After each consultation we asked healthcare professionals to choose a maximum of three out of 20 factors that were most relevant for healthcare decisions on treatment goals and the professional support needed during the upcoming year. Factors were characterised as either person or disease-related. Percentages reflect the number of annual diabetes reviews in which the key factor was reported.

Results

Seventeen physicians and eight diabetes specialist nurses reported the key factors relevant for healthcare decisions in 285 annual diabetes reviews (T1DM n=119, T2DM n=166). Healthcare professionals most often reported quality of life (31.9%), motivation (27.0%) and diabetes self-management (25.6%), and to a lesser extent glycaemic control (24.2%), to be important for decisions about treatment goals. For decisions about the professional support needed during the upcoming year patient's preferences (33.7%), diabetes self-management (33.3%), quality of life (27.0%) and motivation (25.6%) were most often considered relevant by healthcare professionals.

Conclusion

According to healthcare professionals person-related factors such as quality of life, diabetes self-management and motivation are predominantly relevant for healthcare decisions about treatment goals and the professional support needed during the upcoming year.

INTRODUCTION

The prevalence of diabetes and the complexity of diabetes healthcare are increasing worldwide(19-22). In 2021 diabetes affected approximately 537 million adults, resulting in diabetes-related healthcare costs of over 966 billion dollars per year(2). The growing number of potential treatment options, the expanding online diabetes community in which patients engage in diabetes related online activities, e.g., blogs, discussion and support groups, video tutorials, podcasts and other offerings(23), and the rapid technological advances, are increasing the need for shared decision making and person-centred care strategies, putting even greater emphasis on the role patients have within the decision making process(24).

Whilst the importance of person-centred care is increasingly acknowledged by major leading institutions like the ADA and EASD(25), diabetes care decisions are often still driven by biological outcomes such as HbA1c, lipid levels and blood pressure measurements, suggesting that disease-related factors such as glycaemic control, cardiovascular risk factors, complications of diabetes and comorbidities are considered most important in healthcare decisions. However, treatment success is not so much depending on disease-related factors, but predominantly on factors that influence the patient's diabetes self-management behaviour, like the patient's personal situation and attitudes towards diabetes, social context and psychological wellbeing, which are considered person-related factors(19, 26-28). Understanding which factors predominantly drive patients in the process of decision making is crucial when striving towards person-centred diabetes care(29, 30). Insight in the patient's values, preferences and social context enables effective patient-clinician communication and increases the chance of patients and clinicians successfully partnering up in the process of shared decision making(29, 31, 32). Previous research has shown that engagement of patients and clinicians in shared decision making may result in increased therapy adherence and patient engagement(33-35). In addition, shared decision making helps patients and healthcare professionals to decide on the best available healthcare strategy, reflecting what matters to the patient while using the best available evidence(24). This way, person-centred diabetes care may improve diabetes-related healthcare outcomes on the long term(36).

However, to date it remains unclear to what extent the patient's desires, needs and values are recognised by healthcare professionals as vital factors driving healthcare decisions. Therefore, we assessed which person and disease-related factors were considered most relevant for healthcare decisions according to healthcare professionals, during annual diabetes reviews in patients with type 1

diabetes (T1DM) and type 2 diabetes (T2DM) in secondary care. Furthermore, with physicians and diabetes specialist nurses fulfilling different roles in diabetes care, we assessed differences between the key factors reported by physicians and diabetes specialist nurses and between the key factors considered relevant for patients with T1DM and T2DM.

MATERIAL AND METHODS

Study Design and Setting

Trained healthcare professionals performed outpatient annual diabetes reviews in six hospital clinics in the Netherlands as part of a study assessing the effect of a consultation model promoting person-centred care(37). After every annual diabetes review we asked healthcare professionals to provide the three key factors that, in their perception, determined the patient's healthcare decisions out of a fixed list of twenty factors. Healthcare decisions were divided in decisions about treatment goals for the upcoming year, focused on the patient's needs and desires regarding their diabetes management, and decisions about the professional support needed during the upcoming year, focused on the external help patients wanted and needed from professionals to succeed. The list of potential key factors reflected the current knowledge and literature about relevant factors for care decisions and discussions of organised working groups(37, 38), consisting of people with diabetes, healthcare professionals and scientists.

Key factors were classified to be either person or disease-related. We considered age, ethnicity, level of education, stage of life, quality of life, lifestyle, pregnancy (wish), illness perception, motivation, patient's preferences, self-management knowledge and skills, self-efficacy and opportunities for development, and social context to be person-related factors. Glycaemic control, cardiovascular risk factors, complications of diabetes, comorbidity, duration of diabetes, hereditary factors, use of medication and results of previous treatments were considered disease-related factors.

Patients with T1DM and T2DM were eligible for participation if they fulfilled the following inclusion criteria: age ≥ 18 years, sufficient language comprehension and ability to complete questionnaires. All patients provided written informed consent prior to participation. According to the Medical Ethical Committee of the University Medical Centre of Utrecht official approval of this study was not required under the Medical Research Involving Human Subjects Act (WMO)(39).

Participants

Prior to the annual diabetes review patients completed a questionnaire on age, sex, ethnicity, marital status, education, employment status, illness duration, family history of diabetes, diabetes related complications and comorbidity. Furthermore, they filled out the Patient Activation Measure (PAM-13), a questionnaire consisting of 13 items assessing knowledge, skills and confidence for self-management(37, 40). PAM-13 scores range from 0 to 100, with higher PAM-13 scores indicating a better ability of patients to manage their health. Data on type of diabetes, HbA1c, lipids, blood pressure and BMI were retrieved from electronic health records.

Implementation of the consultation model

Both physicians and diabetes specialist nurses were trained to use the consultation model and were educated about person and disease-related factors that may influence healthcare decisions, the principles of shared decision making, and dealing with disagreement. After two face-to-face training sessions (two hours per session) they applied the consultation model during the annual diabetes review. The consultation model consisted of four steps: 1) discussing person and disease-related factors that influence decisions about treatment goals and the professional support needed during the upcoming year together with the patient; 2) setting person and disease-related goals together; 3) discussing treatment options to reach the goals and making the decision; 4) assessing the professional support needed(37). Whether this step-wise approach was followed during the annual diabetes review and which topics were addressed, depended on the actual situation of the patient and was not protocolled. After the annual diabetes review healthcare professionals were asked to indicate which factors they considered to be most relevant for this individual patient in decisions about treatment goals and decisions about the professional support needed during the upcoming year out of a list of twenty potential factors (**supplementary questionnaire 1**). A minimum of zero and maximum of three factors could be chosen to be relevant for both decisions about treatment goals and the professional support needed during the upcoming year. The factors reported were considered to be of equal importance.

Statistical Analysis

Comparisons between characteristics of patients with T1DM and T2DM and physicians and diabetes specialist nurses were performed using chi square tests for categorical data and independent t-tests for continuous data. PAM-scores were transformed into a standardised activation score ranging from 0 to 100(40). Missing outcome data were handled using multiple imputation, to prevent reduction in statistical power and biased results due to patient exclusion.

Consultation time was compared between physicians and diabetes specialist nurses using independent t-tests. We calculated the frequency of person and disease-related factors reported by healthcare professionals for both decisions about treatment goals and professional support needed during the annual diabetes reviews. Percentages reflect the number of annual diabetes reviews in which the factor was reported. Tests of proportions were used to assess differences between the total number of key factors stated and the frequency of each key factor between physicians and diabetes specialist nurses and patients with T1DM and T2DM. For each key factor a mixed-effects logistic regression analysis was performed, separately for patients with T1DM and T2DM, assessing the association between the factor reported and patient characteristics, with the type of healthcare professional as random factor. Mixed-effects ordinal logistic regression analyses were performed, with the type of diabetes and the type of healthcare professional as random factors, to assess the associations between the number of factors reported for decisions about treatment goals and the professional support needed during the upcoming year and patient characteristics, applicability of the consultation model, gathered insight in the patient's situation and setting of goals at the end of the annual diabetes review.

A p-value <0.05 was considered statistically significant. Data analyses were performed using STATA intercooled version 14.2 (StataCorp LLC, Texas, USA).

RESULTS

Study population and consultation

In total 119 patients with T1DM and 166 patients with T2DM were included in the study. Patients with T1DM had a mean PAM-score of 62.5 (± 15.6) compared to 59.2 (± 12.6) for patients with T2DM. **Table 1** shows the baseline characteristics of the participating patients.

Healthcare consultations were performed by 17 physicians and 8 diabetes specialist nurses in six hospital outpatient clinics. Physicians had a mean age of 50.5 (± 9.2) years and 41% of the physicians was female. Diabetes specialist nurses had a mean age of 48.7 (± 2.6) years and 75% of the nurses was female. In 66.0% of patients the annual diabetes review was performed by a physician. Of all the consultations 67.7% was performed within 25 minutes. This was more often the case for physician-led than for nurse-led consultations (p<0.001).

Table 1. Patient characteristics

	T1DM	T2DM	P-value
N	119	166	
Age (years)*	47.0 (13.5)	64.0 (10.1)	<0.001
Female gender †	58.6	44.6	0.024
Ethnicity †			0.71
Caucasian	92.8	91.6	
Other	7.2	8.4	
Marital status †			0.70
Married or cohabitating	72.1	69.9	
Single	27.9	30.1	
Education level †			<0.001
Low	9.9	30.5	
Intermediate	42.3	46.8	
High	47.8	22.7	
Employment status ‡			<0.001
Having a job	63.0	27.6	
PAM-13 *	62.5 (15.6)	59.2 (12.6)	0.057
Duration of diabetes (years) *	24.5 (14.5)	18.9 (10.0)	<0.001
Number of comorbid conditions *	1.2 (1.6)	2.4 (2.0)	<0.001
Family history of diabetes †	48.7	66.2	0.004
Glucose-lowering medication†			
None	0 0	1.2	0.30
Metformin	5.0	47.6	<0.001
SGLT-2 inhibitors	0	1.8	0.20
Sulfonylurea derivatives	0	7.2	<0.01
DPP-4 inhibitors	0	0.6	0.46
GLP-1 receptor antagonists	1.7	3.0	0.53
Basal insulin only	1.1	21.6	<0.001
Basal-bolus insulin injection regimen	43.3	58.1	<0.05
Insulin pump therapy	54.4	12.8	<0.001
HbA1c*			0.34
mmol/mol Hb	63.6 (11.4)	62.0 (14.6)	
%	8.0 (1.0)	7.8 (1.3)	

Table 1. *(continued)*

	T1DM	T2DM	P-value
Systolic blood pressure (mmHg)*	132.0 (16.0)	141.3 (19.9)	<0.001
Diastolic blood pressure (mmHg)*	77.6 (9.5)	78.3 (11.9)	0.61
LDL cholesterol (mmol/l)*	1.13 (0.35)	1.13 (0.42)	1.0
HDL cholesterol (mmol/l)*	0.80 (0.25)	0.58 (0.22)	<0.001
Total cholesterol (mmol/l)*	2.02 (0.45)	1.99 (0.51)	0.60
Body Mass Index (kg/m^2)*	26.2 (4.2)	31.9 (6.4)	<0.001

SC: Secondary Care; T1DM: Type 1 diabetes mellitus; T2DM: Type 2 diabetes mellitus; PAM-13: Patient Activation Measure-13, with a higher score indicating more knowledge, skill and confidence for self-management of one's health or chronic condition. SGLT-2: sodium glucose co-transporter-2. DPP-4: dipeptidylpetidase-4. GLP-1: glucagon-like peptide 1. LDL: low density lipoprotein. HDL: high density lipoprotein. *Mean (± SD). †%.
P-values <0.05 are considered statistically significant.

Key factors for decisions about treatment goals

Overall, quality of life (31.9% of annual diabetes reviews), motivation (27.0%), self-management knowledge and skills, self-efficacy and opportunities for development (25.6%) and glycaemic control (24.2%) were the key factors most often reported by healthcare professionals to be important for decisions about treatment goals (**figure 1**).

A similar distribution was found in patients with T1DM, however, in patients with T2DM quality of life (34.9%), motivation (27.7%), patient's preferences (27.7%) and self-management knowledge and skills, self-efficacy and opportunities for development (26.5%) were reported to be the most important factors for decisions about treatment goals (**table 2**).

Patient's preferences was more often reported as a key factor of importance for patients with T2DM than for patients with T1DM (T1DM: 16.0%; T2DM: 27.7% of annual diabetes reviews, p=0.020) (**table 2**).

Table 2. Person and disease-related factors reported by healthcare professionals to influence healthcare decisions about treatment goals for the upcoming year

Factors provided				
	Overall	**T1DM**	**T2DM**	**P-value**
Quality of life	31.9	27.7	34.9	0.20
Motivation	27.0	26.1	27.7	0.76
Self-management knowledge and skills, self-efficacy and opportunities for development	25.6	24.4	26.5	0.69
Glycaemic control	24.2	24.4	24.1	0.95
Patient's preferences	22.8	16.0	27.7	0.020*
Illness perceptions	21.8	18.5	24.1	0.26
Complications of diabetes	14.7	12.6	16.3	0.39
Social context	10.5	9.2	11.4	0.55
Lifestyle	8.1	7.6	8.4	0.81
Results of previous treatments	7.4	4.2	9.6	0.085
Stage of life	6.3	5.9	6.6	0.81
Duration of diabetes	5.6	5.9	5.4	0.86
Use of medication	5.6	4.2	6.6	0.38
Cardiovascular risk factors	5.6	4.2	6.6	0.38
Comorbidity	5.3	2.5	7.2	0.079
Level of education	4.6	5.9	3.6	0.36
Age	2.5	1.7	3.0	0.23
Ethnicity	0.7	0.0	1.2	0.48
Hereditary factors	0.4	0.8	0.0	0.25
Pregnancy (wish)	0.0	0.0	0.0	-

Person-related factors are in bold. Percentages represent the number of annual diabetes reviews in which the factor was reported (total n=285, T1DM n=119, T2DM n=166). T1DM: Type 1 diabetes mellitus; T2DM: Type 2 diabetes mellitus.
*Significant difference between patients with T1DM and T2DM.

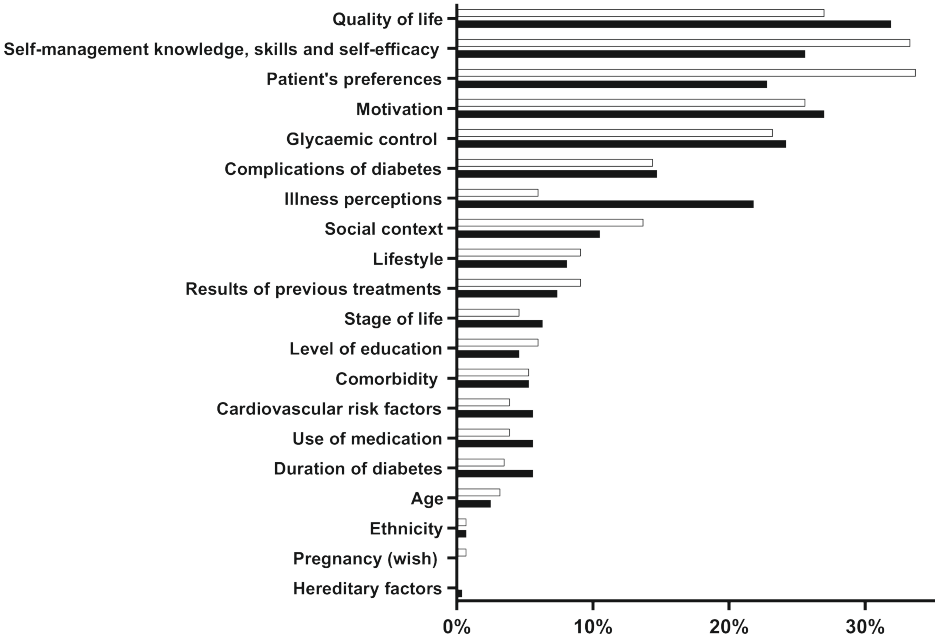

Figure 1. Person and disease-related factors relevant for healthcare decisions for patients with T1DM and T2DM, according to healthcare professionals. After the consultation healthcare professionals indicated the most important factors (max. three factors) determining decisions about treatment goals and the professional support needed during the upcoming year. Bars represent the percentage of annual diabetes reviews in which each factor was reported by healthcare professionals for decisions about treatment goals (black bars) and the professional support needed (white bars).

Key factors for decisions about professional support

For decisions about the professional support needed during the upcoming year, healthcare professionals considered patient's preferences (33.7% of annual diabetes reviews), self-management knowledge and skills, self-efficacy and opportunities for development (33.3%), quality of life (27.0%) and motivation (25.6%) to be the most important factors overall (**table 3**).

Small, but distinct differences were found between the key factors reported for patients with T1DM and T2DM. For patients with T1DM self-management knowledge and skills, self-efficacy and opportunities for development (39.5%), patient's preferences (27.7%), motivation (27.7%) and glycaemic control (26.1%) were considered most important (table 3). For patients with T2DM healthcare professionals reported patient's preferences (38.0%), quality of life (34.3%), self-management knowledge and skills, self-efficacy and opportunities for development (28.9%) and motivation (24.1%) to be most important (table 3).

Table 3. Person and disease-related factors reported by healthcare professionals to influence healthcare decisions about the professional support needed during the upcoming year

Factors provided				
	Overall	**T1DM**	**T2DM**	**P-value**
Patient's preferences	33.7	27.7	38.0	0.070
Self-management knowledge and skills, self-efficacy and opportunities for development	33.3	39.5	28.9	0.062
Quality of life	27.0	16.8	34.3	0.0010*
Motivation	25.6	27.7	24.1	0.49
Glycaemic control	23.2	26.1	21.1	0.32
Complications of diabetes	14.4	10.9	16.9	0.15
Social context	13.7	10.1	16.3	0.13
Lifestyle	9.1	5.0	12.0	0.043*
Results of previous treatments	9.1	5.0	12.0	0.043*
Illness perceptions	6.0	2.5	8.4	0.038*
Level of education	6.0	8.4	4.2	0.14
Comorbidity	5.3	1.7	7.8	0.023*
Stage of life	4.6	4.2	4.8	0.81
Cardiovascular risk factors	3.9	2.5	4.8	0.32
Use of medication	3.9	2.5	4.8	0.32
Duration of diabetes	3.5	5.0	2.4	0.24
Age	3.2	0.8	4.8	0.056
Ethnicity	0.7	0.0	1.2	0.23
Pregnancy (wish)	0.7	0.8	0.6	0.84
Hereditary factors	0.0	0.0	0.0	-

Person-related factors are in bold. Percentages represent the number of annual diabetes reviews in which the factor was reported (total n=285, T1DM n=119, T2DM n=166). T1DM: Type 1 diabetes mellitus; T2DM: Type 2 diabetes mellitus.
*Significant difference between patients with T1DM and T2DM.

The key factors quality of life (T1DM: 16.8%; T2DM: 34.3%, p=0.0010), lifestyle (T1DM: 5.0%; T2DM: 12.0%, p=0.043), results of previous treatments (T1DM: 5.0%; T2DM: 12.0%, p=0.043), illness perceptions (T1DM: 2.5%; T2DM: 8.4%, p=0.038) and comorbidities (T1DM: 1.7%; T2DM: 7.8% of, p=0.023) were all considered to be of more importance for patients with T2DM in decisions about the professional support needed during the upcoming year, than for patients with T1DM (**table 3**).

Key factors reported by healthcare professionals

Healthcare professionals indicated the key factors relevant for decisions about treatment goals and about the professional support needed in respectively 81.8% and 80.7% of the annual diabetes reviews. Diabetes specialist nurses more often reported key factors than physicians (treatment goals: physicians: 73.9%; nurses: 94.8%, p<0.001, professional support needed: physicians: 73.4%; nurses: 94.8%, p<0.001). No differences were found in the number of key factors reported by physicians or diabetes specialist nurses between patients with T1DM and T2DM.

For decisions about treatment goals, diabetes specialist nurses more often reported the key factors glycaemic control (nurses: 43.2%; physicians: 14.4%, p<0.001), quality of life (nurses: 41.2%; physicians: 27.1%, p=0.016), cardiovascular risk factors (nurses: 11.3%; physicians: 2.7%, p=0.003) and results of previous treatments (nurses: 12.4%; physicians: 4.8%, p=0.020) to be of importance, compared to physicians (**supplementary table 2**). Physicians more often indicated social context to play an important role (nurses: 5.2%; physicians: 13.3%, p=0.035) (**supplementary table 2**).

For decisions about the support needed during the upcoming year, diabetes specialist nurses more often reported glycaemic control (nurses: 40.2%; physicians: 14.4%, p<0.001), cardiovascular risk factors (nurses: 7.2%; physicians: 2.1%, p=0.034) and results of previous treatments (nurses: 14.4%; physicians: 6.4%, p=0.026) to be important, compared to physicians (**supplementary table 3**). Level of education however, was more often mentioned by physicians to be of importance (nurses: 1.0%; physicians: 8.5%, p=0.011) (**supplementary table 3**).

Association between patient characteristics and reported key factors

Healthcare professionals reported a mean of 2.31 (SD 1.18) factors for decisions about treatment goals and a mean of 2.27 (SD 1.20) factors for decisions about the professional support needed during the upcoming year per consultation. No difference was found between the number of factors reported for patients with T1DM and patients with T2DM.

For patients with T1DM more key factors were indicated when patients were older (treatment goals: OR 1.06, p=0.013, professional support: OR 1.07, p=0.004), had a shorter illness duration (treatment goals: OR 0.95, p=0.023, professional support: OR 0.95, p=0.025) or when they received a high level of education (professional support: OR 4.2, p=0.058). When patients with T1DM already suffered from comorbidities, complications was more often considered key for healthcare decisions (treatment goals: OR 2.25, 95% CI: 1.24; 4.08, p=0.008, professional support OR 1.72, 95% CI:

1.04;2.84, p=0.034) (**supplementary table 4 and 6**). For patients with T1DM that received a high level of education, motivation (OR 3.65, 95% CI 1.32;10.05, p=0.012) and social context (OR 28.9, 95% CI: 1.50;558, p=0.026) were considered to play an important role in decisions about the professional support needed during the upcoming year (**supplementary table 6**).

For patients with T2DM, more factors were indicated when patients were female (treatment goals: OR 4.9, p=0.009, professional support OR 4.9, p=0.011). When patients had a higher BMI, motivation was more often indicated as a key factor for decisions about treatment goals (OR 1.10, 95% CI: 1.03;1.18, p=0.007), whilst quality of life and illness perceptions were considered less important (quality of life: OR 0.93, 95% CI: 0.86-0.99, p=0.049, illness perceptions: OR 0.92, 95% CI: 0.84-0.99, p=0.044) (**supplementary table 5**). Furthermore, when patients were older, glycaemic control was less often considered important for decisions about the professional support needed during the upcoming year (OR 0.95, 95% CI: 0.90;0.99, p=0.027), whilst the patient's age, stage of life and comorbidity were considered more important (age: OR 1.40, 95% CI:1.04-1.87, p=0.027; stage of life: OR 1.24, 95% CI:1.01-1.53, p=0.045; comorbidity: OR 1.11, 95% CI:1.00-1.24, p=0.049) (**supplementary table 7**).

DISCUSSION

Our study shows that, whilst traditionally biological outcomes are often used to measure care performance and are presumed to be of major importance for healthcare decisions, healthcare professionals considered person-related factors most important for the decision making process. Quality of life, motivation, self-management knowledge and skills, self-efficacy and opportunities for developments and patient's preferences in particular were indicated as vital factors for healthcare decisions. This suggests that the focus during the decision making process predominantly lies on the patient's capacities, preferences and needs rather than on biological outcomes, and that healthcare professionals attempt to tailor care decisions to the individual.

Some distinct differences could be found between the factors reported for patients with T1DM and T2DM. These differences might reflect the characteristics of the pathophysiology of the two diseases, with T1DM being an auto-immune disease occurring independently of lifestyle and BMI and T2DM being strongly associated to a sedentary lifestyle and obesity.

Despite person-centred care now being acknowledged as state-of-the-art medicine by leading associations like the ADA and EASD(25), research on factors that drive patients in the decision making process is sparse. Most research has been focused on factors that influence decisions made by healthcare professionals alone or the role of the clinical environment in which the decision making process takes place(41-43). There is one open ended interview assessing which factors drive patients' healthcare decisions in which the researchers found that, according to healthcare professionals, healthcare decisions during clinical consultations often relied on perceived social, cognitive and psychological characteristics of the patient, including intellectual ability, motivation, quality of social support, lifestyle, anxiety levels and style of interaction(44). Physical symptoms and individual demographic characteristics were considered less important. These results support our findings, indicating person-related factors predominantly driving healthcare decisions rather than disease-related factors. A study about factors that influence the intensity of care for patients with T2DM, mainly treated in primary care, found that person-related factors predominantly influenced the intensity of care chosen, further underlining our findings(45).

While our study provides important knowledge about the key factors that are valuable to address during clinical consultations, it must be taken into account that these key factors were reported by healthcare professionals after each annual diabetes review and not by the patient. Thus our data describe the healthcare professional's viewpoint. It remains unclear whether the perspectives of the patients align with those of the healthcare professionals. Healthcare professionals that participated in this study were trained to explore the patient's situation and which factors played an important role in the decision making process. This training may have helped healthcare professionals to identify factors relevant for healthcare decisions. During the training person and disease-related factors were presented to be of equal importance, preventing any bias towards the type of factor reported. The list of 20 key factors that was provided to the healthcare professional to choose from after each consultation reflects the current knowledge on person and disease-related factors that may play an important role in healthcare decisions and determine self-management. We did not assess any order effect. Additionally, there was no option to add other factors to this list or to further elaborate on the decision. The reasoning behind factors chosen remains a topic that needs to be investigated further.

Potential patient and healthcare professional bias, cannot be ruled out, although both patients and healthcare professionals did not receive any incentive for

participation. Furthermore, this study was conducted in patients with type 1 and type 2 diabetes in secondary care. Whether our results are generalisable to other healthcare settings and patient populations remains to be investigated.

This study helps to clarify which factors are important drivers for healthcare decisions in secondary diabetes care. Healthcare professionals can benefit from this knowledge by being more aware of the important role that person-related factors may play in healthcare decisions during clinical consultations. Discussing these person-related factors openly and elaborately will help patients and healthcare professionals gain a better understanding of the situation and the patient's needs and desires, which may increase the chance of building a solid partnership and deciding on care plans that fit the individual patient and their unique situation. This is expected to eventually improve healthcare outcomes.

In addition, our findings further emphasize the need to measure healthcare outcomes and quality of care in a different way. Currently healthcare systems and insurance companies still measure the quality of care by biological outcomes such as HbA1c, blood pressure and lipid levels, whilst our findings indicate that person-related factors such as quality of life are predominantly important for healthcare decisions.

CONCLUSIONS

In conclusion, whilst biomedical and disease-related factors are often presumed to be of major importance in diabetes care decisions, we now show that person-related factors are predominantly driving decisions in diabetes care, according to healthcare professionals. Exploring these person-related factors more elaborately during clinical consultations may help patients and healthcare professionals to successfully partner up in shared decision making and create care plans that reflect the patient's needs and values, eventually improving healthcare outcomes.

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SUPPLEMENTARY MATERIAL

Supplementary questionnaire 1.
Questionnaire of the healthcare professional to complete after annual diabetes review

1. Which three factors influenced decisions about treatment goals for the upcoming year the most, according to you?
   - Glycaemic control
   - Cardiovascular risk factors
   - Complications of diabetes
   - Comorbidity
   - Duration of diabetes
   - Hereditary factors
   - Use of medication
   - Results of previous treatments
   - Age
   - Level of education
   - Ethnicity
   - Stage of life
   - Quality of life
   - Lifestyle
   - Pregnancy (wish)
   - Illness perceptions
   - Motivation
   - Patient's preferences
   - Self-management knowledge and skills, self-efficacy and opportunities for development
   - Social context

2. Which three factors influenced decisions about the professional support needed during the upcoming year the most, according to you?
   - Glycaemic control
   - Cardiovascular risk factors
   - Complications of diabetes
   - Comorbidity
   - Duration of diabetes
   - Hereditary factors
   - Use of medication
   - Results of previous treatments

- Age
- Level of education
- Ethnicity
- Stage of life
- Quality of life
- Lifestyle
- Pregnancy (wish)
- Illness perceptions
- Motivation
- Patient's preferences
- Self-management knowledge and skills, self-efficacy and opportunities for development
- Social context

Supplementary table 1. Disease and person-related factors reported by healthcare professionals to influence decisions about treatment goals

Factors provided			
	Physicians	**Nurses**	**P-value**
Quality of life	**27.1**	**41.2**	**0.016**
Motivation	**28.2**	**24.7**	**0.53**
Self-management knowledge and skills, self-efficacy and opportunities for development	**25.0**	**26.8**	**0.74**
Glycaemic control	14.4	43.2	<0.001
Patient's preferences	**24.5**	**19.6**	**0.35**
Illness perceptions	**23.4**	**18.6**	**0.35**
Complications of diabetes	13.8	16.5	0.54
Social context	**13.3**	**5.2**	**0.035**
Lifestyle	**6.9**	**10.3**	**0.32**
Results of previous treatments	4.8	12.4	0.020
Stage of life	**5.9**	**7.2**	**0.67**
Duration of diabetes	4.8	7.2	0.40
Use of medication	4.3	8.2	0.18
Cardiovascular risk factors	2.7	11.3	0.003
Comorbidity	6.9	2.1	0.086
Level of education	**5.9**	**2.1**	**0.15**
Age	**1.6**	**4.1**	**0.20**
Ethnicity	**0.5**	**1.0**	**0.62**
Hereditary factors	1.6	0	0.21
Pregnancy (wish)	**-**	**-**	**-**

Person-related factors are in bold. Percentages represent the amount of annual diabetes reviews in which the factor was reported (total n=285). Physicians: n=17. Diabetes specialist nurses: n=8.

Supplementary table 2. Disease and person-related factors reported by healthcare professionals to influence decisions about the professional support needed during the upcoming year

Factors provided	**Physicians**	**Nurses**	**P-value**
Quality of life	**24.5**	**32.0**	**0.18**
Motivation	**25.0**	**26.8**	**0.74**
Self-management knowledge and skills, self-efficacy and opportunities for development	**34.6**	**30.9**	**0.53**
Glycaemic control	14.4	40.2	<0.001
Patient's preferences	**34.0**	**33.0**	**0.87**
Illness perceptions	**7.4**	**3.1**	**0.15**
Complications of diabetes	13.8	15.5	0.70
Social context	**16.0**	**9.3**	**0.12**
Lifestyle	**8.5**	**10.3**	**0.62**
Results of previous treatments	6.4	14.4	0.026
Stage of life	**4.8**	**4.1**	**0.79**
Duration of diabetes	2.7	5.2	0.28
Use of medication	3.2	5.2	0.41
Cardiovascular risk factors	2.1	7.2	0.034
Comorbidity	6.4	3.1	0.24
Level of education	**8.5**	**1.0**	**0.011**
Age	**2.1**	**5.1**	**0.17**
Ethnicity	**0.5**	**1.0**	**0.62**
Hereditary factors	0.5	-	0.49
Pregnancy (wish)	2.1	**1.0**	**0.50**

Person-related factors are in bold. Percentages represent the amount of annual diabetes reviews in which the factor was reported (total n=285). Physicians: n=17. Diabetes specialist nurses: n=8.

Supplementary table 3. Odds ratios of the chance that a certain factor was indicated by healthcare professionals to influence decisions about treatment goals based on the baseline characteristics of patients with type 1 diabetesPerson-related factors are in bold. *p-value<0.05; **p-value<0.01; - statistical testing not possible due to low power/no available cases.

Baseline characteristics	Age	Gender (female)	Ethnicity	Marital status	Education level	Duration of diabetes	Number of cormorbid conditions	HbA1c (mmol/mol)	BMI
Factors provided									
Quality of life	1.03	0.44	0.29	1.32	1.38	1.00	1.00	1.04	0.81*
Motivation	1.01	1.59	0.48	1.00	1.53	0.98	1.05	1.03	0.95
Self-management knowledge and skills, self-efficacy and opportunities for development	1.03	1.56	3.24	0.33	1.90	0.98	0.89	0.99	1.13
Glycaemic control	1.01	1.18	4.22	1.36	0.85	0.99	0.64	0.98	1.12
Patient's preferences	1.05	4.47*	1.67	1.25	0.70	1.00	1.04	0.99	1.01
Illness perceptions	1.05	0.36	1.44	0.28	1.01	0.99	1.00	1.05	0.83
Complications of diabetes	1.04	0.70	-	0.76	2.02	0.95	2.25**	0.93	1.06
Social context	0.99	0.52	-	1.26	6.31	0.90	1.90	1.02	1.60**
Lifestyle	-	-	-	-	-	-	-	-	-
Results of previous treatments	1.04	0.23	2.32	-	0.77	1.05	1.55	1.02	1.05
Stage of life	0.90	0.35	4.06	-	0.86	1.05	0.59	1.00	1.10
Duration of diabetes	1.01	7.23	-	0.38	1.26	1.09	0.90	0.95	0.99
Use of medication	1.08	0.39	23.0	-	0.24	0.79*	0.36	1.10	0.78
Cardiovascular risk factors	1.17*	0.14	-	-	1.62	0.88	0.86	1.05	1.17
Comorbidity	0.83	-	-	3.87	0.50	1.18	0.74	0.93	0.96
Level of education	1.09	5.55	-	1.69	0.78	0.93	0.82	0.85	1.49
Age	-	-	-	-	-	-	-	-	-
Ethnicity	-	-	-	-	-	-	-	-	-
Hereditary factors	-	-	-	-	-	-	-	-	-
Pregnancy (wish)	-	-	-	-	-	-	-	-	-

Person-related factors are in bold. *p-value<0.05; **p-value<0.01; - statistical testing not possible due to low power/no available cases.

Supplementary table 4. Odds ratios of the chance that a certain factor was indicated by healthcare professionals to influence decisions about the professional support needed during the upcoming year based on the baseline characteristics of patients with type 1 diabetes

Baseline characteristics	Age	Gender (female)	Ethnicity	Marital status	Education level	Duration of diabetes	Number of cormorbid conditions	HbA1c (mmol/mol)	BMI
Factors provided									
Quality of life	1.04	0.77	-	0.27	1.48	0.94*	1.00	1.03	0.91
Motivation	1.03	0.50	0.34	1.25	3.65*	0.94*	1.28	1.03	1.12
Self-management knowledge and skills, self-efficacy and opportunities for development	1.01	1.55	7.09	0.98	1.29	1.01	0.84	0.97	0.95
Glycaemic control	1.04	1.70	3.25	1.00	1.08	0.98	0.75	0.97	1.07
Patient's preferences	1.04	1.71	5.30	1.51	0.87	1.01	0.81	1.01	0.94
Illness perceptions	0.98	0.32	-	0.97	1.34	1.08	1.02	1.08	0.59
Complications of diabetes	1.02	0.41	-	0.96	1.42	0.98	1.72*	0.95	1.07
Social context	1.06	0.22	-	1.43	28.93*	0.77	3.38	1.09	2.04*
Lifestyle	0.91	-	-	1.19	1.25	0.90	1.05	0.78	1.05
Results of previous treatments	1.05	1.77	5.02	0.36	0.53	1.02	1.55	1.03	0.86
Stage of life	0.89	0.084	-	0.32	85.53	0.79	2.10	0.97	1.17
Duration of diabetes	1.03	6.65	-	0.43	1.73	1.09	0.86	0.95	0.97
Use of medication	-	-	-	-	-	-	-	-	-
Cardiovascular risk factors	-	-	-	-	-	-	-	-	-
Comorbidity	0.90	3.31	92.0	-	0.33	1.23	0.86	0.83	1.30
Level of education	1.10*	14.05*	-	0.91	1.51	0.99	0.86	1.01	1.01
Age	-	-	-	-	-	-	-	-	-
Ethnicity	-	-	-	-	-	-	-	-	-
Hereditary factors	-	-	-	-	-	-	-	-	-
Pregnancy (wish)	-	-	-	-	-	-	-	-	-

Person-related factors are in bold. *p-value<0.05; - statistical testing not possible due to low power/no available cases.

Supplementary table 5. Odds ratios of the chance that a certain factor was indicated by healthcare professionals to influence decisions about treatment goals based on the baseline characteristics of patients with type 2 diabetes

Baseline characteristics	Age	Gender (female)	Ethnicity	Marital status	Education level	Duration of diabetes	Number of cormorbid conditions	HbA1c (mmol/mol)	BMI
Factors provided									
Quality of life	0.99	1.33	0.13	0.36*	1.03	1.07**	0.78*	1.04*	0.93*
Motivation	1.02	0.90	0.66	0.82	1.13	0.98	1.05	1.01	1.10**
Self-management knowledge and skills, self-efficacy and opportunities for development	0.99	1.64	1.65	0.84	1.27	0.99	1.05	1.00	0.97
Glycaemic control	0.98	1.22	4.27	0.59	0.75	0.97	0.92	1.00	1.02
Patient's preferences	1.03	1.92	0.66	0.38	0.91	1.03	0.70*	0.98	1.03
Illness perceptions	1.02	1.22	5.02*	1.96	1.41	0.98	0.97	1.01	0.92*
Complications of diabetes	0.97	1.07	1.28	1.04	0.94	0.99	1.41**	1.01	1.00
Social context	1.02	0.99	1.08	1.18	0.86	0.98	1.26	1.01	0.96
Lifestyle	-	-	-	-	-	-	-	-	-
Results of previous treatments	0.98	0.83	8.2	0.63	0.26*	0.97	0.58	0.95	1.09
Stage of life	1.05	0.17	1.49	1.98	2.31	0.93	1.34	1.01	1.04
Duration of diabetes	1.11	4.37	-	1.16	0.81	1.00	0.78	1.02	1.03
Use of medication	0.98	0.62	-	1.79	0.57	1.01	1.01	0.99	0.92
Cardiovascular risk factors	1.08	1.46	1.60	2.95	2.74	0.99	1.44*	0.97	0.86
Comorbidity	1.02	3.23	-	1.82	4.93	0.95	1.65*	1.01	0.94
Level of education	1.01	1.46	-	-	1.02	0.95	0.83	1.00	0.93
Age	1.15	7.19	-	11.1	0.24	1.04	1.32	0.94	0.93
Ethnicity	-	-	-	-	-	-	-	-	-
Hereditary factors	-	-	-	-	-	-	-	-	-
Pregnancy (wish)	-	-	-	-	-	-	-	-	-

Person-related factors are in bold. *p-value<0.05; **p-value<0.01; - statistical testing not possible due to low power/no available cases.

Supplementary table 6. Odds ratios of the chance that a certain factor was indicated by healthcare professionals to influence decisions about the professional support needed during the upcoming year based on the baseline characteristics of patients with type 2 diabetes

Baseline characteristics	Age	Gender (female)	Ethnicity	Marital status	Education level	Duration of diabetes	Number of cormorbid conditions	HbA1c (mmol/mol)	BMI
Factors provided									
Quality of life	1.02	1.16	0.79	0.96	1.14	1.03	1.02	0.99	0.96
Motivation	1.02	1.67	1.63	0.56	1.02	0.98	0.94	1.01	1.04
Self-management knowledge and skills, self-efficacy and opportunities for development	0.99	1.15	2.13	1.03	0.90	0.98	0.99	1.00	0.97
Glycaemic control	0.95*	0.74	0.68	1.07	0.60	1.01	0.91	0.99	1.02
Patient's preferences	1.01	0.86	0.42	0.99	1.15	1.01	0.92	1.01	1.01
Illness perceptions	1.06	2.85	-	0.28	1.82	0.96	1.15	0.99	1.01
Complications of diabetes	1.00	1.13	2.32	0.58	1.29	1.01	1.18	1.03	1.01
Social context	1.02	3.90*	0.89	0.54	1.35	1.00	1.02	1.01	0.95
Lifestyle	0.99	0.71	-	1.74	1.02	0.99	0.82	0.94**	1.07
Results of previous treatments	0.95	0.70	14.38**	0.39	0.76	0.94	0.80	0.97	1.01
Stage of life	1.24*	0.087	0.95	26.35	12.09*	1.02	0.62	1.07	1.11
Duration of diabetes	-	-	-	-	-	-	-	-	-
Use of medication	0.96	2.91	-	0.44	0.70	1.04	1.29	1.06	0.86
Cardiovascular risk factors	1.07	0.13	4.07	3.08	1.01	0.96	1.56*	0.98	0.86
Comorbidity	1.11*	9.98*	-	1.34	2.64	0.90	1.59	0.97	1.01
Level of education	1.01	0.80	-	1.12	1.19	0.90	0.82	0.97	0.91
Age	1.40*	1.67	-	4.15	0.35	1.06	0.56	0.96	0.92
Ethnicity	-	-	-	-	-	-	-	-	-
Hereditary factors	-	-	-	-	-	-	-	-	-
Pregnancy (wish)	-	-	-	-	-	-	-	-	-

Person-related factors are in bold. *p-value<0.05; **p-value<0.01; - statistical testing not possible due to low power/no available cases.

4

Problem-based shared decision making in diabetes care: a secondary analysis of videorecorded encounters

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ABSTRACT

Objectives
To describe the range of collaborative approaches to shared decision making (SDM) observed in clinical encounters of patients with diabetes and their clinicians.

Design
A secondary analysis of videorecordings obtained in a randomized trial comparing usual diabetes primary care with or without using a within-encounter conversation SDM tool.

Setting
Using the purposeful SDM framework, we classified the forms of SDM observed in a random sample of 100 video-recorded clinical encounters of patients with type 2 diabetes in primary care.

Main outcome measures
We assessed the correlation between the extent to which each form of SDM was used and patient involvement (OPTION12-scale).

Results
We observed at least one instance of SDM in 86 of 100 encounters. In 31 (36%) of these 86 encounters we found only one form of SDM, in 25 (29%) two forms, and in 30 (35%) we found ≥3 forms of SDM. In these encounters, 196 instances of SDM were identified, with weighing alternatives (n=64 of 196, 33%), negotiating conflicting desires (n=59, 30%) and problem-solving (n=70, 36%) being similarly prevalent and developing existential insight accounting for only 1% (n=3) of instances. Only the form of SDM focused on weighing alternatives was correlated with a higher OPTION12-score. More forms of SDM were used when medications were changed (2.4 SDM forms (SD 1.48) vs. 1.8 (SD 1.46); p=.050).

Conclusions
After considering forms of SDM beyond weighing alternatives, SDM was present in most encounters. Clinicians and patients often used different forms of SDM within the same encounter. Recognizing a range of SDM forms that clinicians and patients use to respond to problematic situations, as demonstrated in this study, opens new lines of research, education, and practice that may advance patient-centered, evidence-based care.

INTRODUCTION

Biomedical and technological advances in healthcare have resulted in an increased array of treatment options available to improve healthcare outcomes. This is especially pertinent in diabetes care, where the development of e.g. novel pharmacological agents such as glucose-like peptide-1 (GLP-1) receptor agonists(1, 2) and sodium-glucose cotransporter-2 (SGLT-2) inhibitors(1, 2), but also technological innovations, such as flash glucose monitoring(3-6), smart insulin pens(6, 7) and pumps(6) and the artificial pancreas(8, 9), are rapidly changing the field. To form sensible plans of care that respond well to and advance the situation of the individual patient, i.e. to make care fit, patients and clinicians must collaborate to determine what to do, work often referred to as shared decision making (SDM)(10-13). SDM is crucial for the practice of evidence-based medicine(14).

To ensure that evidence-based diabetes care is personalized, international diabetes guidelines emphasize the importance of SDM(15). In theory, SDM is frequently considered a process for decisions in care which are subject to patient preferences ('preference-sensitive') and in which a stepwise approach can be used of fostering choice awareness, discussing options, discussing preferences and making a final decision(16-18). It is often focused on "taking the right steps, in the correct sequence, at the right time"(19). Although it may seem useful to circumscribe SDM to this particular practice, SDM, defined in this way, is reported as rare in practice, even as clinicians report "doing SDM" routinely(20). In practice, however, patients and clinicians must respond to a broad range of situations collaboratively. The problems they face may call for different manners of making decisions together other than selecting from a set of established alternatives as they form plans of care that make sense as possible ways to respond to the problematic situation of each patient(21, 22). Hargraves et al have proposed that there may be different forms of SDM depending on the situation that needs to be resolved(23). This "purposeful SDM framework" proposes that the situation the patient is facing determines the way in which patients and clinicians interact and collaborate in the decision making process. Purposeful SDM identifies at least four forms of SDM appropriate for different situations: 1) weighing treatment alternatives, 2) negotiating conflicting desires, 3) solving problematic situations and 4) developing existential insight(23) (**box 1**). The framework thus suggests that in addition to the canonical form of SDM in which alternatives are weighed, there are at least three other SDM forms in which patients and clinicians jointly and deliberately engage in conversations to decide how to address the patient's situation. Hargraves et al do not consider

these forms to be separate entities, but rather a spectrum of collaborative decision making processes.

To date, it is unknown how the different problem-based forms of SDM manifest in daily clinical encounters. The primary aims of our study were to assess 1) which forms of SDM are used in clinical diabetes care, 2) how these forms of SDM relate to the final treatment decision, 3) how they correlate with scores on clinicians' efforts to involve patients in decision making, and 4) the extent to which within-encounter conversation aids promoting SDM affect the prevalence and distribution of the different forms of SDM. In SDM, decisions are to be made based on patients' informed preferences or desires, and these desires – focusing on an option, a personal want or disposition, a situation, or integrity of self – may be an important driver for the most appropriate way for patients and clinicians to collaborate. Therefore, the secondary aim of our study was to assess what kind of desires patients and clinicians voiced during the consultation and how these desires are associated to the forms of SDM used during the clinical encounter.

Box 1.

Forms of purposeful SDM	Type of decision sought	Example
1. Weighing alternatives	A determination that pros, cons, and preferences are optimally balanced in the selected option	Emma, a 52-year-old woman, has had type 2 diabetes for over 10 years. Her HbA1c has been rising for over 9 months. She is increasingly fatigued and would like to feel better soon. With her clinician, she decided that it is time to change her diabetes medication regime. After **considering the different medications available** and their respective pros and cons, they decided to start basal insulin.
2. Negotiating conflicting desires	An agreement reconciling conflicting positions or desires within or between parties to decision making	Emma has been on insulin for a few years now. Her fear of complications has led to a program of care with which she has frequent and dangerous severe hypoglycemic events. These are scary to her and her family, who is pushing Emma to stop or cut back on her medicines. Emma **feels torn between** easing her glycemic control to reduce the incidence of hypoglycemia, but potentially also increasing the risk of complications due to hyperglycemia. Together with her clinician she develops a compromise by which she will reduce the intensity of her program, discontinuing insulin, and switches to a nonhypoglycemic agent.

3. Solving problematic situations	The conclusion that different potential ways of understanding and advancing the problematic situation have been sufficiently uncovered, evaluated, and co-ordinated	With the oral medication in combination with diet and regular exercise, Emma's diabetes has been regulated well over time. Over the last few months, however, she has become the primary caregiver of her spouse, who was diagnosed with cancer. With caring for him taking up most of her time, she struggles with sticking to her diet and regular exercise. Together Emma and the clinician try to find ways to stay healthy physically and emotionally, that will **fit with the demands and limitations of her new situation**. They come up with a plan to try out and refine over the upcoming months.
4. Developing existential insight	The existential insight into what ultimately matters that has developed sufficiently that what to do becomes obvious and meaning is found in the splintered elements of a person's life	At 81, Emma has been receiving dialysis for end-stage diabetes-related kidney disease for three years. As they talk, it tearfully emerges how **life-diminishing** dialysis is becoming for her and how she feels that her life is breaking apart. Together Emma and her clinician develop an understanding that it might be time to step away from dialysis and to implement a palliative care approach.

Based on Hargraves, et al. Patient Educ Couns. 2019(23); Hargraves, et al. Patient Educ Couns. 2020(24); and Hartasanchez, et al. Patient Educ Couns. 2021(25).

METHODS

Data source

This is a secondary analysis of the TRICEP study (Registration #NCT01293578 ClinicalTrials.gov), a multicenter randomized trial (n=350 patients) which compared primary care as usual with and without using a within-encounter SDM conversation aid(26). This conversation aid presents general considerations and adverse effects of diabetes medication, organized by topics that matter to patients, such as weight change, daily routine, "blood sugar" levels (HbA1c), daily "blood sugar" testing, hypoglycemia, and cost. The latest version of the tool is freely available at https://diabetesdecisionaid.mayoclinic.org/(26). The study took place between July 2010 and May 2014 across 20 rural, suburban, and inner-city primary care practices from six health systems in the Midwest (Minnesota, Wisconsin), United States. The video-recordings of the patient-clinician encounters were used in this secondary analysis. The Mayo Clinic Institutional Review Board approved the original study and this secondary analysis (IRB #10-006952 and #19-011553). All participating patients and clinicians provided written informed consent.

Sample size and study design

This is an observational, cross-sectional retrospective study using video-recordings. Using a random number generator, we selected a random convenience sample of 100 video-recorded clinical encounters, irrespective of the TRICEP trial arm. We selected 20 encounters from TRICEP as a training set to practice the self-designed coding scheme and subsequently coded the remaining 80 selected encounters. Patients and members of the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Measures

Given the novelty of coding various forms of SDM, we used a self-developed coding scheme to count, characterize and time-stamp the forms of SDM used and desires stated by patients and clinicians (**supplement 1**). Two team members (M.M.R. and M.K.) drafted the coding scheme based on theories presented in a previous publication on SDM forms(23) and discussed it with the rest of the team. In the coding scheme, SDM forms were categorized as 1) weighing treatment alternatives, 2) negotiating conflicting desires, 3) solving problematic situations and 4) developing existential insight. We pilot tested the coding scheme on encounters until we felt no further changes to the scheme were needed (after n=14 encounters). The encounters in this pilot were not included in our final sample.

Pilot testing showed that multiple forms of SDM could be used in the same encounter and that it was difficult to determine when a form of SDM finished – other than when another form of SDM started. We therefore allowed multiple SDM forms per encounter and coded only the start of the form of SDM. In addition we also collected and coded voiced desires of both patients and clinicians and characterized them into desires towards 1) an option, 2) a personal want/disposition, 3) a situation or 4) integrity of self, in line with the classification used by Hargraves et al(23). We used 20 videorecorded encounters to practice the coding scheme. These videorecorded encounters were included in the analyses. Two investigators (M.M.R., a medical doctor, and M.K., a clinical linguist and decision scientist) coded all encounters in duplicate and independently. All codings were discussed in regular meetings and disagreements were resolved by discussion and consensus.

Data extracted

We extracted patient and clinician characteristics along with the assigned study arm from the TRICEP database. In addition, from the database we extracted scores from the 12-item Observing Patient Involvement in Decision Making (OPTION12) scale for each encounter, a validated observer-based scale used to quantify the extent

to which clinicians involve patients in the decision making process(27). Researchers scored the encounters with the OPTION12-scale in the original trial, prior to this secondary analysis, and thus blinded to our research questions. Scores are reported on a 0-100 scale, with higher scores implying more behaviors to involve patients. The reviewers of this secondary analysis were blinded to the OPTION12 scores while coding.

Statistical analyses

We used descriptive statistics to report on participant characteristics and numerical estimates, mean and standard deviations for continuous variables and counts and frequencies for categorical variables. To compare study arms, we used a Kruskal-Wallis test for continuous and a Chi-square test for categorical variables. To assess SDM instances an ANOVA was conducted, where the number of instances was categorized into groups, adjusted by whether a medication change occurred as well as the intervention arm. We used an alluvial plot to represent the instances and forms of SDM used and the order they occurred within the encounter. We used a boxplot to show the distribution of the OPTION12 score for encounters focused on weighing alternatives, either as the only form of SDM used or as part of multiple forms used, or encounters that were not focused towards weighing alternatives. We collected data in REDCap (Grant UL1TR002377) and conducted our analysis in SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Participants

In total, we included and coded 100 video-recorded clinical encounters (intervention arm: n=69, control arm: n=31). Of the 100 participating patients, 59 were men. Patients had a mean age of 60 years (range: 41-85 years) and a mean BMI of 36.7 (SD 9.14) kg/m2. The average HbA1c was 8.9% (SD 1.26%) and most patients (54%) had an HbA1c > 8.5%. A third of the patients had lived with diabetes for over 10 years (**table 1**). Patients in the intervention arm were younger compared to those in the control arm (59 vs 63, p<0.03). Otherwise, all patient characteristics were comparable between arms (**supplementary table 1)**.

The clinical encounters involved 89 clinicians, of which 44 (49%) were male. On average clinicians had been working in practice for 12 years (SD 10.4) and 79% of clinicians had completed their medical training (**table 1**). The average length of the clinical encounter was 17.0 minutes (range: 4.0-43.6 minutes).

Table 1. Participant demographics

Patient demographics	**N=100**
Study arm (n)	
Primary care (control)	31
Primary care using a within-encounter conversation aid (intervention)	69
Age, years (mean, SD)	60.0 (9.7)
Women (n)	41
Body mass index, kg/m^2 (mean, SD)	36.7 (9.1)
Race (n)	
White	85
Black	9
Other	6
Education† (n)	
High School or less	29
Vocational/4-year college degree	46
Graduate degree	9
HbA1c, % (mean, SD)	8.9 (1.3)
Years with diabetes† (n)	
<5	27
5 to < 10	32
>10	30
Literacy† (n)	
Inadequate	9
Adequate	81
Clinician demographics	**N=89**
Age, years (mean, SD)	45.2 (11.3)
Women (n, %)	45 (50.6)
Years in practice (mean, SD)	12.0 (10.4)
# of encounters included (mean, SD)	3.8 (3.3)

†Self-reported by patients, missing responses are not represented in counts or percentages.

Forms of SDM used

In 86 of 100 clinical encounters, we identified at least one form of SDM. In 31 (36%) of these 86 encounters we identified one single form of SDM, two forms in 25 (29%), and three or more instances in 30 (35%) encounters. **Figure 1** depicts the instances in which patients and clinicians switched to a different form of SDM during the clinical encounter.

Of the observed total of 196 instances of SDM, 70 (36%) were focused on solving a problematic situation, 64 (33%) on weighing treatment alternatives and 59 (30%) on negotiating conflicting desires. Three (1%) of the instances sought to develop existential insight.

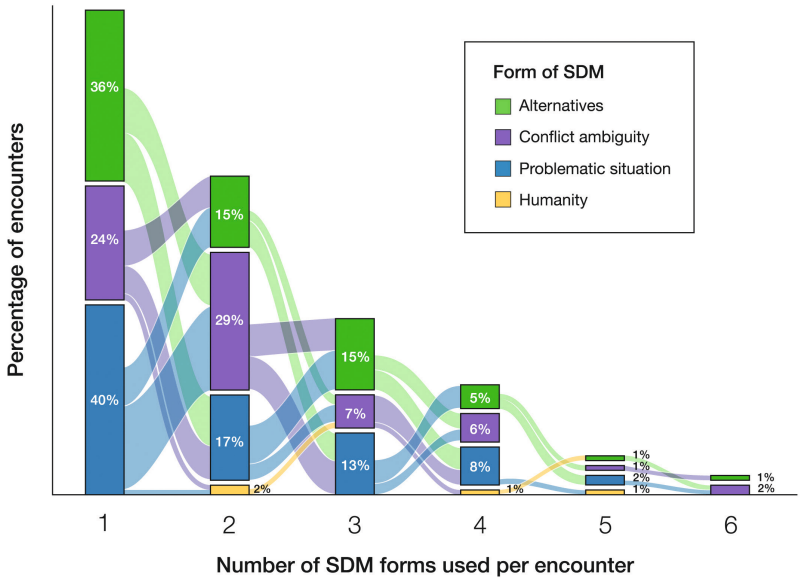

Figure 1. Switches in forms of SDM used during clinical encounters.
Light colored waves reflect changes from one SDM form to another. Percentages reflect the frequency of SDM form used. X-axis represents the instances of SDM used within the encounter. Only consultations in which at least one form of SDM was used were included in this figure (n=86). SDM: shared decision making.

Treatment decisions

Patients and clinicians decided in 27 of the 100 encounters to change the medication of the patient, with no differences between study arms. A change in medication was related to more instances of SDM used during the encounter (no change: 1.8 instances of SDM (SD 1.46); change: 2.4 instances of SDM (SD 1.48), p=.050). This effect was maintained after adjusting for the use of a conversation tool.

Patient involvement in decision making

When patients and clinicians used SDM focused on weighing different treatment alternatives, either as the only form of SDM used or as one of multiple forms of SDM used during the encounter, this was related to a higher OPTION12 score compared to when they used other forms of SDM (26.4 (SD 9.6) vs. 20.5 (SD 8.9), p=.0056), even when adjusted for the use of a within-encounter conversation aid (**supplementary figure 1**). In the 14 of 100 encounters in which we identified no form of SDM, the scores on OPTION12 were lower (mean: 17.3 (SD 16.3)), irrespective of the use of a conversation aid (**figure 2 and supplementary figure 1**).

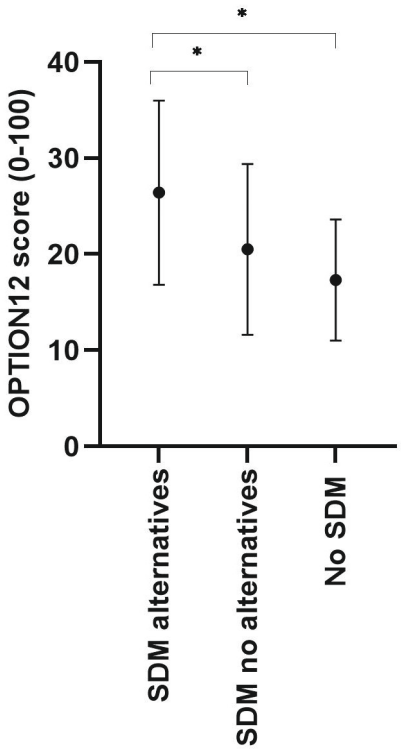

Figure 2. Association between OPTION12 score and SDM for weighing alternatives vs. other forms of SDM.

SDM: shared decision making. Dots represent means, bars represent standard deviations. OPTION12 score quantifies efforts clinicians make to involve patients in SDM. Scores range from 0 to 100, with higher scores indicating more observed clinician behaviors of involving patients in decision making. SDM alternatives: encounters in which SDM was present and focused on weighing alternatives solely or as part of other forms of SDM used (n=52). Other forms of SDM: encounters in which SDM was present but not focused on weighing alternatives (n=33). No SDM: encounters in which no SDM was observed (n=14). *p-value<0.05.

Conversation aid intervention

The use of a conversation aid during the consultation did not affect the amount of forms of SDM used (use of within conversation aid: mean: 2.08; 95% CI (1.88; 2.27), without use of within conversation aid: mean: 1.88; 95% CI (1.55; 2.21), p=0.32) or type of forms of SDM used during the consultation (p=0.51, **table 2**).

Table 2. Use of the different forms of SDM in encounters with and without the use of a conversation aid intervention

Form of SDM	Not using a within-encounter conversation aid (n=31)	Using a within-encounter conversation aid (n=69)	Total
Weighing alternatives	12 (24%)	51 (35%)	63 (32%)
Negotiating conflicting desires	17 (34%)	43 (29%)	60 (31%)
Solving problematic situations	20 (40%)	49 (34%)	69 (35%)
Developing existential insight	1 (2%)	3 (2%)	4 (2%)
Total	50 (100%)	146 (100%)	196 (100%)

Numbers represent the amount of occurrences (counts (%)) of a particular form of SDM in a total of 100 encounters (without conversation aid: n=31, with conversation aid: n=69). P-value 0.51 (Fisher's exact test).

Secondary aim: Desires

In 83 of the 100 encounters, we identified at least one voiced desire, resulting in a total of 247 voiced desires with a mean of 2.5 (95% CI: 2.07-2.87) desires per encounter. Most encounters contained one (n=23, 28%), two (n=14, 17%), three (n=19, 23%) or four (n=12, 15%) desires (**supplementary table 2**). Desires were more often stated by patients than by clinicians (N=157, 64% vs N=90, 36%, p<.001) (**supplementary table 3**). Voiced desires were directed towards a personal want or disposition (n=132/247, 53%), a type of medication or lifestyle (n=81/247, 33%), a situation (n=27/247, 11%), or about the integrity of self (n=7/247, 3%).

We found that the use of a conversation aid did not significantly affect the number of desires voiced during the clinical encounter (2.6 desires (95% CI: 2.1-3.1) with the use of the conversation aid vs. 2.2 (95% CI: 1.5-2.9) without the conversation aid, p=.42), or the type of desire voiced.

The correlation between forms of SDM and voiced desires

In the 55 encounters in which we identified multiple instances of SDM, we observed 107 switches between forms of SDM, of which half (N=53 switches) were directly preceded by a desire voiced by either the patient or the clinician. Of these 53

switches, 39 (64%) preceding desires were in line with the form of SDM used, e.g., an SDM conversation focused on solving a problematic situation following a desire voiced towards a situation.

DISCUSSION

Here we show that in diabetes care, patients and clinicians use a variety of SDM forms during clinical encounters. SDM focused on solving a problematic situation was the form of SDM most often used, exceeding the use of SDM focused on weighing treatment alternatives. Thus, restricting SDM to deliberative conversations focused on matching patient preferences to treatment options will underestimate the prevalence of SDM in practice. This leaves efforts of patients and clinicians unacknowledged and hampers the successful, flexible, and meaningful implementation of SDM in clinical practice.

Scores on clinician's efforts to involve patients in decision making, measured by OPTION12, were associated with SDM focused on weighing treatment alternatives. This finding is in line with our hypothesis, based on a paper recently published by Hartasanchez, et al.(25), that showed SDM measures to predominantly measure collaborative processes focused on decision making when weighing multiple options, only one form of SDM used during patient-clinician collaborations.

We found that patients and clinicians often switched between different forms of SDM during their encounter. In half of the cases, a desire – voiced by a patient or clinician – preceded a switch in the SDM form used and, usually, the focus of the voiced desire was in line with the form of SDM that followed its utterance. Whilst the exact meaning of these switches remains a topic to be investigated further, we propose that these switches reflect a change in the purpose of the collaborative deliberation, i.e., patients and clinicians alter their deliberative approach to better respond to the situation as it becomes clearer during the conversation. In this way, a voiced desire may flag a change in needs and therefore may be the starting point of a different form of SDM.

There is substantial debate as to SDM's nature and boundaries. Nearly 30 years ago, SDM stood between the paternalistic form of decision making and so-called informed decision making, in which the responsibility of the decision lied with the patient(28, 29). Over the last decades, SDM has evolved with the identification of steps and "talks"(18, 30), the development of conversation tools(31), and their

implementation through policy and practice(32). Throughout this evolution, SDM has referred narrowly to situations in which the fundamental process is to rationally match the patient's preferences to the pros and cons of the available options(30, 33, 34). At the same time, research indicates SDM is rare in practice, even as clinicians insist that they "do SDM all the time"(20, 35, 36). This may be explained in part by what actions have counted as "doing SDM". Assuming that a single method should be used to address the broad range of problematic situations patients and clinicians collaborate to advance may have hindered the study and optimal practice of SDM (21, 22).

In 2019, Hargraves et al expanded the remit of SDM by proposing that the nature of the problem that the patient and clinician are trying to solve determines the form of SDM they adopt to address it(23). This was supported by Shoesmith et al in 2022, when trying to develop a scale to measure patient-, carer- and clinician-collaboration in clinical care. They found that shared problem solving was an important component of collaboration, together with shared decision making(37). To acknowledge the range of forms of SDM used in response to the problem that needs to be solved, Hargraves et al proposed a framework of "purposeful SDM". Purposeful SDM states that each form of SDM involves the use of form-specific and general elements, such as communication, information sharing, and collaborative deliberation, with different emphases and roles depending on the situation(24). Adding to the knowledge about purposeful SDM, Hartasanchez et al recently showed that the current available observer-based SDM measures all describe behaviours that are pertinent to all forms of SDM, but fail to distinguish between them(25). Our study now adds to this knowledge with evidence from real-life clinical practice on the prevalence and use of different forms of SDM in primary diabetes care, further emphasizing the need to move away from an overly narrow definition of SDM (that ultimately describes only one of the forms of SDM observed in practice, and not the most common one) and expand its remit from the preference-sensitive selection among alternatives to a method of care that practically contributes to the work patients and clinicians do together to address problems of care. How these problem-based forms of SDM relate to the conventional steps of SDM will be discussed in a different manuscript(38).

There are some limitations to be considered. First, we used video-recorded clinical encounters of the TRICEP trial, a study implementing a within-encounter conversation aid in primary diabetes care(26). Our study was a secondary analysis making use of videos of encounters with and without the conversation aid. Our analysis did not show any statistically significant differences in the amount and

type of SDM forms used, nor in the amount and types of desires voiced between the study arms. Second, with this study being conducted in primary diabetes care in the Midwest of the United States, it remains unclear whether our findings are generalizable to other healthcare settings and patient populations. Diabetes care visits may involve problem solving SDM more often than preventive care visits in which deciding whether to participate in cancer screening programs may require weighing options SDM. SDM focused on developing existential insight is particularly appropriate in situations where the patient is troubled by issues of existential fracture or transition. Studies in oncology or the intensive care unit, particularly at the end of life, may involve this form of SDM frequently, whilst a rare finding in the diabetes care setting. Finally, with no validated coding scheme available regarding this subject, we self-developed a coding scheme based on the available literature on forms of purposeful SDM. This coding scheme was not externally validated, but we aimed to optimize the reliability of our data by coding all encounters independently and in duplicate, by two researchers with different backgrounds, and resolving all disagreements through consensus. Strengths of this study are the large sample size, and the use of a random selection of video-recordings from the TRICEP database.

Notably, this study provides evidence of the presence of multiple forms of SDM within diabetes care encounters. It does not evaluate the quality of the SDM form used, for example, the appropriateness, effectiveness, grace, or adequacy with which a form of SDM was utilized or moved away from. Furthermore, we did not assess the ability of SDM to form care plans that fully make sense for the patient and their situation(26) or the effects of SDM on clinical or quality of life outcomes or treatment adherence. These gaps should be addressed to identify any needs or opportunities for further supporting, improving, and promoting the use of multiple forms of SDM and to develop and evaluate interventions that will enable their optimal use in care.

Clinicians that are able to flexibly dance across the different forms of SDM with their patient to find out the one that better helps advance the patient's situation may increase the chance that the resulting care plans will respond to the patient's situation and fit within their life and living (39, 40). In this manner, investments in purposeful SDM can contribute to improved patient-centered care and outcomes, in line with the recommendations of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)(15) and will provide new insights for training and teaching healthcare professionals.

CONCLUSION

This study shows that SDM occurs often in diabetes care, particularly when deliberative approaches beyond weighing treatment alternatives are considered. We found SDM focused on solving problematic situations together to account for over a third of the SDM forms observed in primary diabetes care. Weighing alternatives, the only form of SDM usually considered in the literature, and negotiating conflicting desires each accounted for approximately another third of the instances of SDM. Furthermore, patients and clinicians often switched from one form of SDM to another, a behaviour that was even more pronounced when a change in medication was warranted.

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SUPPLEMENTARY MATERIAL

Supplement 1. Coding scheme and manual

General notes:

- Only code utterances made when both patient and clinician were present in the room
- Code utterances of patient's significant other as the patient's, unless the patient explicitly disagrees/contradicts. Desires stated by next of kind will be coded as desire of the patient itself
- Sometimes there is a logical healthcare choice, for example if things are going well and no adjustment is needed. This is coded as an obvious next step. If there is an obvious next step during the consultation, SDM steps and/or forms of SDM may still be coded, since clinicians and patients may not be on the same line of thought.
- Every type of desire, even when stated in one sentence, will be coded as a separate desire.
- Increasing dose of medication should be coded as 'to start medication'.

Definitions:

Desire: Any vocalized desire or utterance with a valuative element for a certain treatment option or strategy towards the patients' diabetes care. Code as 'yes' if you experience even the smallest 'maybe' during the consultation.

Providing information: Information provided by the care provider concerning various treatment options and strategies and potential harms and benefits.

General

Study ID: _____ Coder: _____

Date: _____ (mm/dd/yyyy)

1. Was the patient accompanied by a caregiver?

☐	No_0 (*do not see, hear, or positively ID someone else in the room*)
☐	Yes_1 (*partner, relative, friend or significant other*)

2. Was there an obvious next step concerning future treatment?

☐	No_0
☐	Yes_1 *(no decision making on treatment, because of logical next step)*

3. What was the total time of the consultation (patient and clinician together in consultation room)?

_____

Desires

4. Number of desire:
5. Time of stated desire:
6. Stated by: patient/clinician

7. Who initiated the comment on desires?

☐	$Patient_1$
☐	$Clinician_2$

Explain: _____(write in text)

8. What was the desire about? (more than one may apply)

☐	An option$_1$ *(medication or lifestyle)*
☐	A personal want/disposition$_2$ *(e.g. I don't like needles, I'm not giving up my glass of wine)*
☐	A situation$_3$ *(e.g. we've got to do something about all the hypos you've been having)*
☐	Integrity of self$_4$ *(e.g. I wish I wasn't like this, It's good—I'm figuring this out)*
☐	Other$_5$_____ (write in text)

Utterance (entire quote): _____(write in text)

SDM

9. State which steps of SDM you encountered during the consultation video in chronological order. Choose from: choice awareness (1), providing information (2), deciding on final treatment (3)

Step of SDM	Starting time	Citation

10. Which forms of SDM did you see? (see table 1 and 2 listed below) Multiple forms of SDM are possible during one consultation. Please enter forms in chronological order during the conversation. Choose from no form of SDM to be defined (0), weighing treatment alternatives (1), negotiating conflicting desires (2), solving problematic situations (3) and developing existential insight (4).

Form of SDM	Starting time	Citation

Supplementary table 1. Patient characteristics per study arm

Patient demographics	Intervention (n=69)	Control (n=31)	p-value
Age, years (mean, SD)	59 (9)	63 (10)	0.03
Gender, female (n, %)	25 (36)	16 (52)	0.15
BMI (mean, SD)	36.3 (9.6)	37.5 (8.3)	0.30
Race (n, %)			0.83
White	58 (84)	27 (87)	
Black	7 (10)	2 (6.5)	
Other	4 (6)	2 (6.5)	
Education (n, %)			0.87
High School or less	20 (36)	9 (31)	
Vocational/4 year college degree	29 (53)	17 (59)	
Graduate degree	6 (11)	3 (10)	
HbA1c, % (mean, SD)	8.9 (1.3)	9.0 (1.2)	0.53
Years with diabetes (n, %)			0.30
<5	20 (33)	7 (24)	
5 to <10	23 (38)	9 (31)	
>10	17 (28)	13 (45)	
Literacy (n, %)			0.17
Inadequate	8 (13)	1 (4)	
Adequate	54 (87)	27 (96)	

BMI: body mass index; HbA1c: glycated hemoglobin; SD: standard deviation. The intervention consisted of the use of a within-encounter conversation aid. P-value <0.05 is considered statistically significant.

Supplementary table 2. Number of desires voiced per study arm

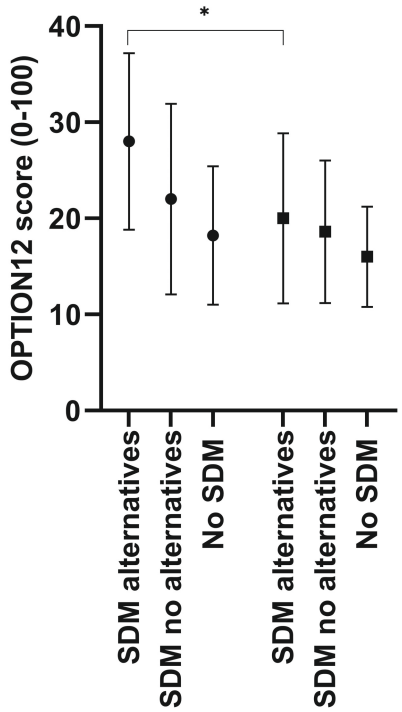
Number of desires voiced	Study arm		Total
	Intervention	Control	
0	11 (15.94)	6 (19.35)	17
1	14 (20.29)	9 (29.03)	23
2	12 (17.39)	2 (6.45)	14
3	11 (15.94)	8 (25.81)	19
4	11 (15.94)	1 (3.23)	12
5	3 (4.35)	2 (6.45)	5
6	2 (2.90)	3 (9.68)	5
7	4 (5.80)	0 (0.00)	4
8	1 (1.45)	0 (0.00)	1
Total	69	31	100

The intervention consisted of the use of a within-encounter conversation aid.

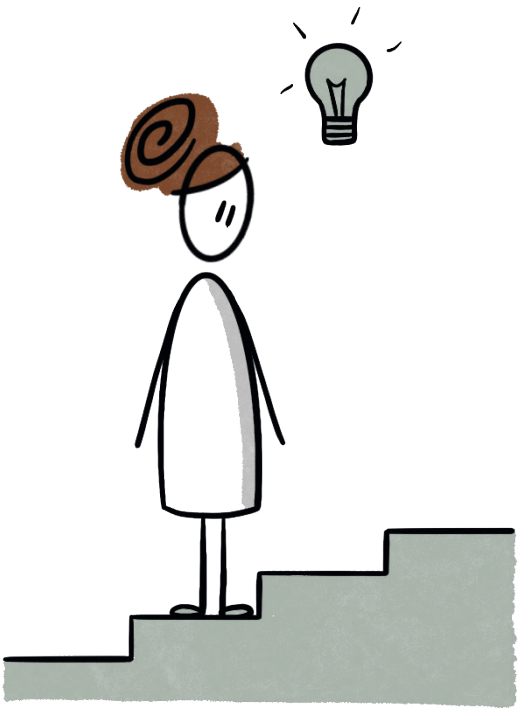
Supplementary table 3. Type of desire stated by patient or clinician per study arm

Desire	Study arm		p-value
	Intervention	Control	
Overall			0.07
Patient	107 (60%)	50 (72%)	
Clinician	71(40%)	19 (28%)	
Medication/Lifestyle			0.03
Patient	18 (29%)	10 (56%)	
Clinician	45 (71%)	8 (44%)	
Personal want			0.89
Patient	65 (74%)	33 (75%)	
Clinician	23 (26%)	11 (25%)	
Problematic situation			>0.99
Patient	20 (87%)	4 (100%)	
Clinician	3 (13%)	0 (0%)	
Integrity of self			~
Patient	4 (100%)	3 (100%)	
Clinician	0 (0%)	0 (0%)	

The intervention consisted of the use of a within-encounter conversation aid. P-value <0.05 is considered statistically significant.



Supplementary figure 1. Association OPTION12 score and weighing of alternatives per study arm. CA: conversation aid; SDM: shared decision making. Figures represent means, bars represent standard deviations. Dots: consultations in which a within-conversation aid was used. Squares: consultations in which no within-conversation aid was used. SDM alternatives; consultations in which SDM was present and focused on weighing alternatives solely or as part of multiple forms of SDM used (CA: n=42, no CA: n=10). SDM no alternatives; consultations in which SDM was present but not focused on weighing alternatives (CA: n=18, no CA: n=15). No SDM; consultations in which no form of SDM was observed (CA: n=8, no CA: n=6). OPTION12 score: score measuring the clinician's efforts to involve a patient within a consultation. Scores range from 0 to 100, with higher scores indicating more aspects of SDM present.*p-value<0.05.



5

Problem-based shared decision making: The role of canonical SDM steps

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Health Expectations (2022)

ABSTRACT

Objective

To evaluate the extent to which the canonical steps of shared decision making (SDM) take place in clinical encounters in practice and across SDM forms.

Methods

We assessed 100 randomly selected video-recorded primary care encounters, obtained as part of a randomized trial of an SDM intervention in patients with type 2 diabetes. Two coders, working independently, noted each instance of SDM, classified it as one of four problem-based forms to SDM (weighing alternatives, negotiating conflicting issues, solving problems, or developing existential insight), and noted the occurrence and timing of each of the four canonical SDM steps: fostering choice awareness, providing information, stating preferences, and deciding. Descriptive analyses sought to determine the relative frequency of these steps across each of the four SDM forms within each encounter.

Results

There were 485 SDM steps noted (mean 4.85 steps per encounter), of which providing information and stating preferences were the most common. There were 2.7 (38 steps in 14 encounters) steps per encounter observed in encounters with no discernible SDM form, 3.4 (105 steps in 31 encounters) with one SDM form, 5.2 (129 steps in 25 encounters) with two SDM forms, and 7.1 (213 steps in 30 encounters) when ≥3 SDM forms were observed within the encounter. The prescribed order of the four SDM steps was observed in, at best, 16 of the 100 encounters. Stating preferences was a common step when weighing alternatives (38%) or negotiating conflicts (59.3%) but less common when solving problems (29.2%). The distribution of SDM steps was similar to usual care with or without the SDM intervention.

Conclusion

The normative steps of SDM are infrequently observed in their prescribed order regardless of whether an SDM intervention was used. Some steps are more likely in some SDM forms but no pattern of steps appears to distinguish among SDM forms.

INTRODUCTION

Clinical care requires noticing the problematic human situation of patients and responding with plans of care that fit. This has been defined as the work patients and clinicians do to iteratively develop a plan of care that is maximally responsive to this problematic situation, maximally supportive of patient goals, and minimally disruptive of each person's life and loves(1). One process by which patients and clinicians work together to figure out what to do is called shared decision making (SDM). Guidelines and other policy instruments increasingly recommend and promote the use of SDM in clinical practice(2,3).

Conventionally, SDM is framed as a decision-making process involving patients choosing between multiple acceptable treatment options(4). Experts describe SDM as consisting of four consecutive steps: (1) fostering choice awareness, (2) providing information about the available options and their pros and cons, (3) deliberating about these options based on patient preferences, and (4) making a final decision(5,6). This form of SDM is considered relatively rare in practice, its use is hampered by lack of time and other supportive resources (e.g., SDM tools), clinician's lack of ability or willingness, and other barriers(7).

This canonical form of SDM, however, seems inappropriate as a tactic to address problems that require a method of making collaborative decisions other than weighing alternative options based on patient preferences. Recently, Hargraves and colleagues have proposed that the appropriate SDM method must purposefully match the kind of problematic situation patients and clinicians are facing(8).

Recognizing a range of situations for which SDM is appropriate, purposeful SDM proposes four SDM forms, one for each kind of problematic situation: (1) weighing treatment alternatives, (2) negotiating intra-, or interpersonal conflicting issues, (3) problem solving and (4) developing existential insight(8). After re-analysing a database of video recordings of clinical encounters between patients with diabetes and their clinician, Ruissen et al.(9) found that clinicians and patients frequently used SDM in practice, in 86 of 100 encounters, with the canonical SDM form of weighing treatment alternatives comprising only 33% of all purposeful SDM forms used.

After recognizing that SDM is common in the care of chronic patients and that a range of forms is used in practice, we sought to determine how often are the canonical steps of SDM seen in practice, appear in their normative order or at all within each of the forms of SDM observed. We hypothesized that the steps of SDM

appear in the order prescribed when the canonical form of SDM is used (weighing treatment alternatives) but are less appropriate to describe other forms to SDM.

METHODS

We used the same data set developed for the study by Ruissen et al.(9) for this analysis. Briefly, M.M.R. used a random-number generator to randomly select 100 video-recorded encounters of the 350 encounters from both arms (without stratification by arm) of a multicenter clinical trial assessing the effect of a within-encounter SDM conversation aid (intervention) versus usual primary diabetes care for patients with type 2 diabetes in the United States (ClinicalTrial.gov: NCT01293578) (10). The trial database was the source of patient and clinician characteristics and trial arm (usual care with or without SDM intervention) allocation. The Mayo Clinic Institutional Review Board approved this secondary analysis before coding. Patients and clinicians provided written informed consent about the use of trial data and video recordings for research before the encounter.

Purposeful SDM provided the underpinning of the coding scheme to determine the form or forms of SDM used in an encounter(8). When a form of SDM was identified, a distinction was made between SDM concerning (1) weighing treatment alternatives (canonical SDM), (2) negotiating intra-, or interpersonal issues, (3) problem solving or (4) developing existential insight. Only the start of the SDM process was coded, given the fact that a clear end of SDM can often not be distinguished. We then noted when the following conventional SDM steps appeared during the consultation: (1) fostering choice awareness, (2) providing information (including the pros/cons of available options), (3) expression of patient preference or desire, and (4) making a final decision. We developed and refined a coding scheme based on 14 videorecorded encounters not included in our sample. Of the 100 included videos, 20 were used to train, and test the self-developed coding scheme. These videos and the other 80 recordings were coded using the final version of the coding scheme. All encounters were coded in duplicate by two investigators from different backgrounds (M.M.R., a medical doctor, and M.K., a clinical linguist and decision scientist). Disagreements were resolved by discussion and consensus.

Statistical analyses

We tested associations using the Kruskal–Wallis test for continuous variables and the $\chi 2$ test statistic for categorical variables. To visualize the distribution of purposeful forms and canonical steps within the encounters, we created a swimmer plot. Encounters

were grouped into the plot by the number of forms present in each encounter (none, one, two, or three or more forms). The relative occurrence in time of each form noted or of each step identified is presented as the fraction of the encounter duration (i.e., from greeting to end of the visit indicated by the clinician and/or patient leaving the room or end of the recording) at which time the form or step started, expressed as a percentage of the encounter duration. Study data were collected and managed using REDCap electronic data capture tools, hosted at Mayo Clinic thanks to its Center for Clinical and Translational Science (funded by the National Institutes of Health—NCATS UL1TR002377)(11,12). Analyses were completed in SAS v9.4 (SAS, Inc.).

RESULTS

Participants

Table 1 describes the 100 patients (41% women, average age 60, 85% white) and 52 clinicians (28% women, average age 47) involved in the encounters included and coded. The average length of the clinical encounter was 17.0 min (range: 4.0–43.6 min).

Table 1. Participant characteristics

Patient characteristics	**Patients (n=100)**
Encounter, usual care without / with SDM tool, n	31 / 69
Age, years, mean (SD)	60.0 (9.7)
Women, n	41
Body mass index, mean, (SD)	36.7 (9.1)
Race, Black / White / other, n	9 / 85 / 6
Insurance, private / government / other, n	52 / 29 / 7
Education, high school or less, n	29
HbA1c, mean (SD)	8.9% (1.3)
Years in relationship with clinician, n	
< 5	43
5 to < 10	22
>10	25
Adequate health literacy, n*	81

Table 1. *(continued)*

Clinician characteristics	Clinicians (n= 52)
Age, years, mean (SD)	46.9 (11.2)
Women, n (%)	25 (48%)
Years in practice, mean (SD)	13.6 (10.5)
Number of encounters, mean (SD)	1.9 (1.3)
Median (IQR)	1 (1, 3)

*, based on "never" or "rarely" answers to the Single Item Literacy Screener ("How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?")[18]

Purposeful forms and canonical steps of SDM

One or more SDM forms could be identified in 86 of 100 encounters. A single SDM form was evident in 31 encounters, 2 forms in 25, and 3 or more SDM forms in 30 encounters. Situations in which treatment alternatives were weighed accounted for 33% of the SDM forms used during the consultation, compared with 30% in which negotiating intra- or interpersonal conflicting issues was used, and 36% in which a problem-solving form was used. Developing existential insight accounted for 1% of the observed SDM forms.

Table 2 describes the distribution of SDM steps within the encounters. In these 100 encounters, we observed 485 steps or an average of 4.85 steps per encounter. In encounters with no discernible purposeful SDM form, we observed 2.7 (38 steps in 14 encounters) steps per encounter. In encounters with one SDM form, we observed 3.4 (105 steps in 31 encounters) steps per encounter.
We observed 5.2 (129 steps in 25 encounters) steps per encounter in encounters with two SDM forms and 7.1 (213 steps in 30 encounters) steps per encounter in encounters with ≥3 SDM forms observed within the encounter. The most common steps were 'giving statements of preference or desire' during deliberations and 'providing information'; both steps were present in about a third of encounters with one or more purposeful SDM forms. 'Choice awareness' and 'deciding' were evident in a fifth of purposeful SDM forms.

When purposeful SDM was not evident, 'giving statements of patient preference or desire' during deliberation was less common (15.8% vs. 30.5%–43.7% when a form of purposeful SDM was observed) and 'deciding' (28.9% vs. 12.7%–21% when a form of purposeful SDM was observed) was more common. SDM steps appeared in the canonical order (i.e., starting with fostering choice awareness and finishing with making a final decision) in 18 encounters. In 16 of these encounters, these sets of ordered steps were preceded or followed by other steps (**table 2**). The distribution of steps within forms was similar whether the encounter was allocated to usual care with or without the SDM intervention (**supplement A**).

Table 2. Distribution of shared decision making steps and forms within encounters

	Encounters by number of SDM forms observed				
	None (n=14)	One (n=31)	Two (n=25)	≥3 (n=30)	**All encounters (n=100)**
Steps, n (%)					
SDM steps observed[1]	38	105	129	213	**485**
Choice awareness	8 (21.1)	19 (18.1)	22 (17.1)	40 (18.8)	**89 (18.4)**
Providing information	13 (34.2)	32 (30.5)	39 (30.2)	53 (24.9)	**137 (28.2)**
Deliberating with statement of preferences	6 (15.8)	32 (30.5)	46 (35.7)	93 (43.7)	**177 (36.5)**
Deciding	11 (28.9)	22 (21.0)	22 (17.1)	27 (12.7)	**82 (16.9)**
Encounters with SDM steps in order, n (%)[2]	0 (0)	3 (9.7)	5 (20.0)	8 (26.7)	**16 (16.0)**

[1]Chi-Square test, p=.048; [2]Fisher's exact test, p<.001; SDM: shared decision making

Table 3 shows the distribution of SDM steps within each of the four forms to purposeful SDM. 'Stating preferences' was a common step when participants engaged in SDM by weighing treatment alternatives (38%) or negotiating intra-interpersonal conflicts (59.3%), but less common when they worked on solving problems (29.2%) or developing an existential insight (27.3%). **Supplement B** shows that allocation to the SDM intervention did not affect the frequency of steps observed in total or within each SDM form. Similarly, our post hoc exploration of the duration of the care relationship (<5 vs. ≥5 years) did not affect the results (data not shown).

Table 3. Distribution of shared decision making steps by the form of shared decision making in which they were observed

	SDM form[1]				
	Weighing alternatives	Negotiating conflict	Solving problems	Developing insights	**Total**[2]
Steps, n (%)					
SDM steps observed	137	108	120	11	**376**
Choice awareness	24 (17.5%)	10 (9.3%)	22 (18.3%)	4 (36.4%)	**60 (16%)**
Providing information	34 (24.8%)	18 (16.7%)	39 (32.5%)	3 (27.3%)	**94 (25%)**
Deliberating with statement of preferences	52 (38%)	64 (59.3%)	35 (29.2%)	3 (27.3%)	**154 (41%)**
Deciding	27 (19.7%)	16 (14.8%)	24 (20%)	1 (9.1%)	**68 (18.1%)**

[1]Chi-Square p-value = .0011; [2]Data limited to encounters in which a step followed the onset of an SDM form (i.e., 83 of the 86 encounters in which an SDM form was observed); SDM: shared decision making.

Figure 1 describes the steps observed within SDM forms presented by whether purposeful SDM was either not observed or when 1, 2 or 3 or more forms were observed.

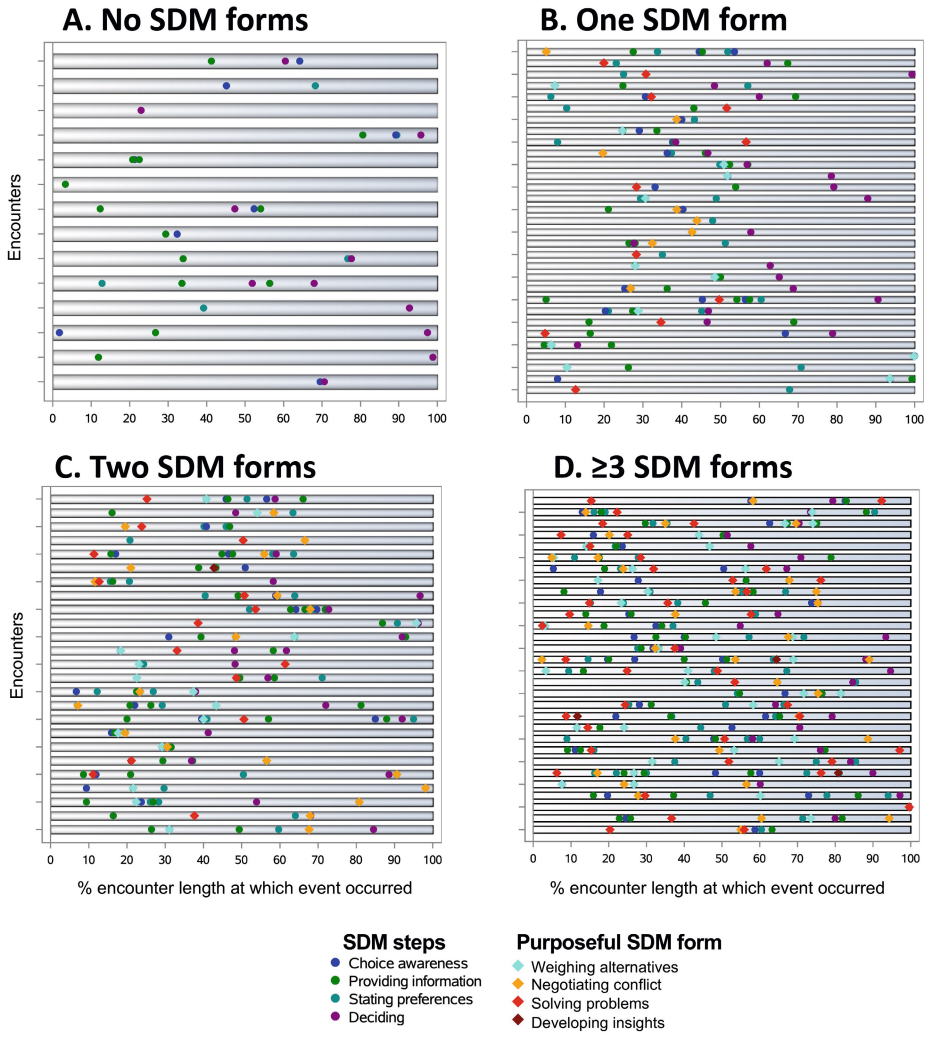

Figure 1. Occurrence of shared decision making steps and forms within encounters grouped by the number of SDM forms observed per encounter.
Panel A: encounters in which no shared decision making form was observed (n=14). Panel B: encounters in which one form was observed (n=31). Panel C: encounters in which two forms were observed (n=25). Panel D: encounters in which three or more forms were observed (n=30). Each row represents an encounter, with its duration represented on a 100% scale.

DISCUSSION

In this set of 100 clinical encounters obtained from a practice based randomized trial of usual diabetes care with or without an SDM tool, in which two-thirds of patients with diabetes and their primary care clinicians used an SDM tool, we found that patients and clinicians engaged in SDM without necessarily completing the canonical SDM steps or following them in their prescribed order. We found that the canonical steps of SDM were present when no specific purposeful SDM form was identified. These steps also were commonly present when one or more purposeful SDM forms were used (of which the canonical form of SDM represented about a third), were similarly present regardless of which SDM form was used, and were present in the normative order in, at best, 16% of encounters. In 70% of encounters, clinicians and patients took different SDM steps as they entered and switched across different forms to SDM. These results suggest that, even under stimulated conditions of adding an SDM intervention, clinicians and patients infrequently follow the normative order of SDM steps to make decisions with patients in practice.

Along with the report by Ruissen et al.(9), which found that almost 90% of these encounters demonstrated some form of SDM (with the canonical form representing about a third of the observed instances), this report documents the relative frequency of SDM steps in these

encounters and the timing of their appearance within each encounter. The results are not directly comparable to other studies in which the frequency of steps has been analysed as if each encounter had only one form of SDM. Kunneman et al., for example, documented that choice awareness appeared in 53% of clinical encounters drawn from a similar sample of video-recorded encounters within clinical trials of SDM tools(13).

The results call into question SDM measurement forms that rely on the presence of SDM steps to determine the occurrence or quality of SDM(14-16). SDM steps occurred, in one instance in the normative order, even when no purposeful SDM form was evident. The most assessed step of SDM, providing information(15), appears in less than a third of instances of SDM.

These results, while novel, have limitations. Video recordings were randomly drawn from a set of encounters produced during the experimental evaluation of the use of an SDM intervention. The presence of the conversation aid, the video recorder, or of the randomized trial procedures may have affected the observations

reported herein. We intuit that the direction of effect of these factors would have been to normalize the encounters to what is expected (i.e., a higher prevalence of the canonical form of SDM with the steps in the expected order). That, despite these factors, we found high variability in the range of purposeful SDM forms and canonical steps may thus represent a best-case scenario. These findings must be evaluated in independent data sets by other research groups. On the other hand, the carefully developed yet ad-hoc coding scheme based in part on purposeful SDM and its use by a clinician and an expert in SDM on actual clinical encounters across multiple primary care practices represent the strengths of this investigation.

These results, particularly the patterns observed in **figure 1**, suggest a highly variable approach to SDM in primary care practice. This variability could be an indication of poor participant skill, or that the SDM intervention, present in two-thirds of visits, provided insufficient support in structuring the encounter. Alternatively, this variability could represent the natural process of trial-and-error, of uncovering how might a problem be addressed, that patients and clinicians use during consultations.

The most common depiction of SDM, by Charles et al.(6), refers to stages (information exchange, deliberation, decision making) in which each one leads to the next. The Three Talk Model by Elwyn et al(17). suggests, instead, a cyclical process by which patient and clinician move along the steps of SDM, a process that may very well describe the observations here, particularly those within the canonical form of SDM (weighing alternatives). Both models assume that a problem is defined at the start of the process and that the exchange focuses on how to solve it.

Conversely, a major advantage of the purposeful SDM framework is the recognition that the nature of the problem and of how to respond to it can emerge from the joint effort of clinician and patient(8). This view matches better with the observations reported here of multiple forms to SDM and multiple steps taken as the patient and clinician talk, think, and feel their way through the uncertain and problematic human situation of the patient. The variability observed may in fact suggest flexibility in the use of clinical skills within a participatory and empathic collaboration. This possibility may need to be explored using content analysis of the encounters.

These findings, if confirmed, would give credence to the purposeful SDM model and challenge ways of training, measuring, and assessing for SDM that rely on (a) a single canonical form of SDM, and (b) a set order of steps to do SDM well. This challenge may lead to new SDM tools designed to create the conditions for flexible

collaboration, supporting whichever form appears more conducive to addressing the problematic situation of the patient.

Our findings may also challenge the notion that the key problem SDM addresses is patient participation when it seems as if both patient and clinician must take part in determining together what the problem is and how to address it in an iterative and, to the outside observer, somewhat chaotic process of exploration, discovery, and experimentation.

Finally, our findings challenge existing measures of the occurrence and quality of SDM that rely on detecting only one form of SDM and one set of steps(14). Indeed, when clinicians say 'but I do SDM already' they may be referring to the processes depicted here, which depart in important ways from what has counted as SDM hitherto.

In conclusion, we found that the canonical steps of SDM are infrequently observed in their normative order in usual clinical practice (as observed in a practice-based randomized trial of adding or not an SDM intervention), regardless of whether an SDM tool was used. These steps do not appear more likely to follow a particular order when one or more SDM forms are used within a clinical encounter. The most common steps are for patients to state their preferences or desires during deliberation and for clinicians to share information. These observations should be considered when developing new measures of SDM and interventions—for example, training and tools—to promote its optimal and purposeful use as a method of care in practice.

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SUPPLEMENTARY MATERIAL

Supplement A. Table of shared decision making (SDM) steps observed classified by (a) whether the encounter was allocated to usual care with or without the use of an SDM intervention, and (b) number of SDM forms observed.

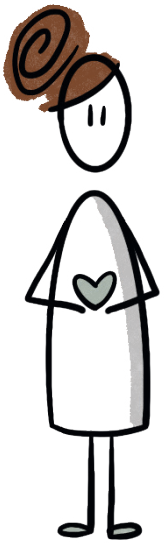
Steps, n (%)	SDM forms observed per encounter				All	P-value
	No SDM form	One form	Two forms	Three or more forms		
SDM intervention	N=23	N=64	N=89	N=172	N=348	0.040[1]
Choice awareness	4 (17.4)	10 (15.6)	14 (15.7)	33 (19.2)	61 (17.5)	
Providing information	8 (34.8)	20 (31.3)	28 (31.5)	42 (24.4)	98 (28.2)	
Deliberating with statement of preferences	3 (13.0)	19 (29.7)	30 (33.7)	76 (44.2)	128 (36.8)	
Deciding	8 (34.8)	15 (23.4)	17 (19.1)	21 (12.2)	61 (17.5)	
Usual care	N=15	N=41	N=40	N=41	N=137	0.96[1]
Choice awareness	4 (26.7)	9 (22.0)	8 (20.0)	7 (17.1)	28 (20.4)	
Providing information	5 (33.3)	12 (29.3)	11 (27.5)	11 (26.8)	39 (28.5)	
Deliberating with statement of preferences	3 (20.0)	13 (31.7)	16 (40.0)	17 (41.5)	49 (35.8)	
Deciding	3 (20.0)	7 (17.1)	5 (12.5)	6 (14.6)	21 (15.3)	

[1]Chi-Square p-value; SDM: shared decision making

Supplement B: Table of shared decision making (SDM) steps observed classified by (a) whether the encounter was allocated to usual care with or without the use of an SDM intervention, and (b) by the SDM form within which the step was observed.

SDM steps within a form, n (%)	SDM Form[1]				Total
	Weighing alternatives	Negotiating conflict	Solving problems	Developing insights	
SDM intervention[1]	N=106	N=69	N=88	N=8	N=271
Choice Awareness	18 (17.0%)	5 (7.2%)	14 (15.9%)	2 (25.0%)	39 (14.4%)
Providing information	23 (21.7%)	11 (15.9%)	28 (31.8%)	2 (25.0%)	64 (23.6%)
Deliberating with statement of preferences	43 (40.6%)	42 (60.9%)	28 (31.8%)	3 (37.5%)	116 (42.8%)
Deciding	22 (20.8%)	11 (15.9%)	18 (20.5%)	1 (12.5%)	52 (19.2%)
Usual Care[2]	N=31	N=39	N=32	N=3	N=105
Choice Awareness	6 (19.4%)	5 (12.8%)	8 (25.0%)	2 (66.7%)	21 (20.0%)
Providing information	11 (35.5%)	7 (17.9%)	11 (34.4%)	1 (33.3%)	30 (28.6%)
Deliberating with statement of preferences	9 (29.0%)	22 (56.4%)	7 (21.9%)	0 (0.0%)	38 (36.2%)
Deciding	5 (16.1%)	5 (12.8%)	6 (18.8%)	0 (0.0%)	16 (15.2%)

[1]Chi-Square p-value= 0.052; [2]Chi-Square p-value= 0.072; SDM: shared decision making



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Shared Decision Making as a method of care

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ABSTRACT

Care happens in interaction between the patient and the clinician, in conversation. Within this conversation, the patient and clinician uncover or develop a shared understanding of the problematic situation of the patient and identify, discover, or invent ways to make that situation better, given what each patient prioritizes and seeks(1). Thus, to get the right care for each patient, patient and clinician collaborate and deliberate together to figure out what to do(2).

Anytime a patient and clinician figure out together what to do about the patient's situation, they are doing shared decision making (SDM). Although there are multiple models and accounts of what SDM is and is not(2-6), in practice, SDM starts by determining the nature of the problematic situation the patient is experiencing. This often requires considering insights that only the patient and perhaps their family can share, insights about both the patient's biology and biography. This diagnostic process goes beyond identifying, classifying, and naming, e.g., "you have mild type 2 diabetes mellitus". Rather they must uncover how medical conditions manifest in daily life and how treatments fit into daily routines, and how, in turn, symptoms and treatments affect living.

After developing a shared and useful formulation of the problem, clinicians must mobilize their competence and compassion to work with patients to develop a sensible care plan that responds to the situation as understood, is based on relevant evidence, attends to the emotional aspects of the problem, and is feasible and sustainable for the patient(7,8).

Therefore, SDM is not about eliciting and documenting patient preferences in the medical record, distributing educational pamphlets or decision aids for patients to come prepared to the consultation, or leaving clinical decisions for patients to make on their own after receiving a clinician's recommendation. Rather, SDM is as central to the clinician's art as history taking, the physical examination, the selection and interpretation of diagnostic tests, and patient education and counseling. This makes SDM not "another thing clinicians must do", not just an expression of patient-centered care or a way of involving patients, or a mere antidote to medical paternalism or low-value care. Rather, SDM is a method of care.

The practical method to implement SDM as a method of care proposed below seeks to make as few demands as possible of both patients, who are taxed by the demands of self-care and of navigating a labyrinthine healthcare system while responding to the demands of living(9-12), and of clinicians, who, despite some evidence of the contrary(13,14), often express their worries about SDM adding time to their encounters(15,16).

HOW TO IMPLEMENT SDM IN PRACTICE

Here we propose a simple four-step method to implement SDM in practice (**table 1**).

Table 1. Steps for shared decision making in practice

(1) Foster a conversation
(2) Purposefully select and adapt the shared decision making (SDM) process
(3) Support SDM
Protect the space
Make the most of participation
Deploy useful tools
Advocate for care
(4) Evaluate and learn SDM
Evaluate beyond outcomes
Share the evaluation
Seek joint improvement

(1) Foster a conversation

The first step in implementing SDM in practice is to foster conversations that invite patients and clinicians to collaborate, support their collaboration, and lead to the formulation of a co-developed care plan.

In this conversation, the clinician curiously works to understand which aspect of the patient's problematic human situation requires action(5). This could be an unaddressed medical problem, such as a new symptom, concern, sign, or complication. It could also be a change in life circumstances that affects how the medical condition manifests or that affects the practicality of the existing plan to address it. It could be signs that the plan of care in place is not helping, or even hurting, or that it has become impractical or unfeasible. The patient and clinician must collaborate to arrive at a useful formulation of the problem. For example, will the change in insurance coverage change the patient's ability to afford the treatment prescribed given their income and other expenses they must cover? Is the increase in pain in the feet impairing living? The inquiry then seeks to uncover the action that the situation requires(1). It may be necessary to conduct new tests, change the care plan, or provide additional support.

The process of noticing and responding is iterative(1,17), and continues until a response emerges that makes intellectual sense (i.e., it is an evidence-based response(18) to the situation as understood), practical sense (i.e., it is feasible and minimally disruptive of personal and social routines), and emotional sense (i.e., it accounts for the emotional dimensions of the situation and feels like the right thing to do now) to patients and clinicians(8). Confronting the actions available to respond to the situation may lead to reframing the situation itself and reformulating the problem to address. For example, a patient facing a cancer with a very poor prognosis and seeking a cure may discover that the treatments have a low likelihood of success and a high likelihood of harm. The unattractiveness of these options may lead to a recasting of the situation as one in which the patient is facing death because of cancer and now seeks ways to die well. The options identified in the first instance fail to be a sensible response to this new formulation of the situation and new options must be identified, uncovered, or invented.

As plans are co-created and implemented, it is the patient as care-receiver who is in the best position to provide feedback about the plan's adequacy as a response to their situation, its acceptability in relation to the burdens and costs it imposes by itself and in interaction with other treatments and daily routines, and in its efficacy in improving the situation.

It may be helpful to be aware of some stumbling blocks to fostering SDM conversations:

- In some cases, patients may not be aware that SDM is an appropriate method of care since there is no one technically correct solution to their problem. Clinicians can helpfully state so and invite the patient into the process of figuring out together what to do(19,20). This renders irrelevant that the patient "did not go to medical school," creating the space and momentum for collaboration.
- An eager desire to be helpful may compel clinicians to curtail the conversation by prematurely making a recommendation(19). Rarely, patients may open the conversation by making a demand(21). The clinician's recommendation and the patient's demand act as anchors reducing the responsiveness of the clinician to new insights and complicating the patient-clinician relationship if the action recommended or demanded proves inadequate. A desire to avoid conflict may lead to either party acquiescing, which is why policies (e.g., guidelines, pathways, formulary restrictions, pre-authorizations) and marketing campaigns (e.g., detailing to clinicians, direct-to-consumer advertising and "ask your doctor about…" ads) can unduly shape care(22,23).

The conversation is, therefore, the workshop in which patients and clinicians co-create plans of care together. Fostering these conversations is the first step in doing SDM in practice. The next step is to determine the method used to jointly arrive at a sensible response.

(2) Purposefully select and adapt the shared decision making process

The second step to implement SDM in practice is for patients and clinicians to purposefully select the appropriate SDM process. There are four distinct ways in which they can work together to address the patient's problematic situation: (a) focusing on matching preferences, (b) reconciling conflicts, (c) problem solving, or (d) meaning making.[5] Each of these forms of SDM is best suited to address one of four different kinds of problematic situations **(tables 2A and 2B**). Clinicians need to be aware of these forms of SDM to intentionally select the form best suitable to respond to the situation at hand, avoid selecting the wrong one, and nimbly switching to a different form when the situation becomes clearer or changes(24).

In our observations, clinicians and patients who do SDM well, work within a form of SDM until a better one becomes apparent and they flexibly, gracefully, and perhaps intuitively switch according to the challenges uncovered during the conversation(24). For example, a conflict requiring reconciliation ("I will never use insulin because I am not allowed to use needles at my job") can become a problem requiring solving ("Is there a way to use insulin such that it is only administered at home?"). A problem can be solved by recognizing that there are several reasonable options ("There are several insulin preparations that are longer acting and can be used once or twice a day"), and the selection of those options may call for matching preferences ("I rather use a once-a-night insulin because my mornings are hectic, and I often forget my morning medicines"). Perhaps the best option selected is not readily available or affordable, and this problem is solved by implementing the second best, while resources are mobilized to access and afford the best one ("Let's start with the twice-a-day insulin while we work with your insurance to gain access to the once-a-day preparation.").

Table 2A. Forms of shared decision making

SDM form method description	Situations in which this form will be preferred
Matching preferences	
Patients and clinicians compare features (i.e., efficacy, burdens, side effects) of the available options and match them with the patient's values, preferences, goals, and priorities. They may use an SDM tool to share information about the options. Patient and clinician deliberate until the best match is identified.	Deciding whether participating in a screening program is a desirable way to address the threat of breast cancer. Selecting which of the available diabetes medications to use to achieve glycemic control.
Reconciling conflicts	
Using a collaborative process, the clinician helps the patient articulate the reasons for their position while reconciling those reasons with the varying possibilities ahead.	Opting to take an antidepressant or not for mild depression in a patient who, up to now, thinks that psychoactive medications must be avoided. Determining whether to curtail driving privileges in an elderly patient with potentially dangerous levels of visual and cognitive impairments.
Problem solving	
Potential solutions are tested – in conversation or therapeutic trials – and become justified based on the extent to which these can demonstrably and successfully address the problem and improve the patient's situation.	Determining how far to reduce blood pressure in a patient with hypertension and frailty with a tendency to fall and a history of taking medications erratically. Deciding when to discharge a patient home from the hospital, figuring out what accommodations and ongoing support and care will be needed and who will ensure the patient receives it.
Meaning making	
Using conversations, patient and clinician develop insight into what the patient's situation means, at a deep level, to the patient and their community and to find the reasons within that process for pursuing a particular approach.	Deciding how the dying patient will transition off life-support technologies in preparation for death. Planning the extent, type, and timing of gender affirming therapies in individuals transitioning to a different gender.

Table 2B. Practical differences between the forms of shared decision making

What is the problem?	You and your patient are talking about…	The conversation or the decision is difficult because…	The patient may be feeling…	You and your patient can use this form of SDM to…
Matching preferences				
The problem is clearly defined and can often be established ahead of the conversation. Its solution is in one of the options presented.	The likely positive and negative effects of a specific illness and its treatment options.	It is uncertain what will happen, and hence which option is preferable.	Uncertain, fearful of what could happen, and worried about making a wrong choice.	Address uncertainty by matching the threat of what could happen to the benefits, harms, and burdens that the patient prefers to take.
Reconciling conflicts				
The problem involves an internal (two values or goals in tension) or external (disagreements with important others or with the clinician) conflict.	The stance on an issue (e.g., disease, diagnosis, treatment, guidelines, relationships) taken by the patient, clinician, or others.	There is conflict or tension within the patient or between the patient and other parties.	Disoriented, pulled in multiple directions, torn, guilty, ashamed, adamant, indecisive, not knowing who or what to trust, relationally hurt.	Reconcile conflicts within the patient or between parties so that an acceptable, honest, comfortable, self-aware, or committed position on next steps is found.
Problem solving				
The problem is not clearly understood prior to the conversation. The problem comes into sharper focus as it is used to find reasons to proceed in one way or another.	A difficult situation	The situation is practically and emotionally troubling, due to multiple, often unclear, competing or limiting factors with limited capacity to rectify.	Stuck, incapacitated, diminished, trapped, threatened, hopeless.	Change the situation by problem solving–uncovering the actionable factors contributing to the situation, generate ideas for changing them, and experimenting with them in the conversation.
Meaning making				
The problem involves an existential threat or transition.	A person's or community's meaning or identity and what ultimately matters in the situation.	Who the person and their community is in the face of life changes is in question or threatened.	Splintered, lost, no longer themselves, resigned, fearful, not at peace, deprived of what makes them whole and gives life meaning.	Work with the patient and their community to make meaning and find a way to feel at peace or whole again, secure in the knowledge of what ultimately matters in the situation

Also in our observations, the situations adverse to care emerge when clinicians use an unhelpful SDM form or inflexibly insist on using a particular SDM form after it has proven unsuitable. This can be observed when a clinician offers distressed patients and family members a menu of life-sustaining therapies and demand they select what they would prefer from it; or when a clinician insists on reviewing the pros and cons of insulin without addressing the patient's inaccurate understanding that starting insulin causes amputations or dialysis. Selecting the right approach requires clinicians to be present, competent, flexible, and attuned to whether the conversation is helping the patient with what they are struggling.

(3) Support SDM

The third step to implement SDM in practice is to find useful, usable, and desirable ways to support SDM in each encounter.

Protect the space

Shared decision making is work for both patients and clinicians(25). The conversation is the workspace within which this work takes place. The space for the conversation must be set up to be supportive of this work(26-28). Clinical spaces can be cluttered with visual (posters behind office doors, clinical equipment) and auditory (overhead announcements, ringtones) distractions. Demands for entries from the medical record system can interrupt conversations. Thus, clinicians must be deliberate about protecting the space and the time allocated for these conversations. This is less about new investments in interior design and more about securing agreements and arrangements (e.g., team policy to avoid interrupting clinicians when in consultation with patients; minimize pop-up alerts and mandatory data entry in the design of medical records) that eliminate distractions, disruptions, and interruptions. The setup should clearly signal the intention: the clinician and patient are here to have an unhurried conversation – not necessarily a long one – to work through what to do about the patient's problems today and going forward.

Make the most of participation

Having set the stage for an unhurried conversation(29), it is necessary to determine who should participate in that conversation. Patients and clinicians in continuous relationships of care may be optimally situated to have unhurried conversations. When the issue requires specialized technical knowledge, or access to educational materials, longer consultations, and decision-making tools, it may be optimal to bring into the conversation clinicians specialized in the matter, either to co-create the plan of care with the patient or to assist the established patient-clinician dyad in their decision-making process. A similar choice needs to be made about the

participation of informal caregivers, who in their roles at the patient's side, often have expertise about and experience with the patient and may be responsible for the plan's implementation.

Deploy useful tools

Clinicians and patients may want to thoughtfully consider which tools are allowed into the conversation, including specialized tools designed to support specific SDM forms that have shown to be useful, usable, and desirable. Given the situation at hand, different tools can support the decision-making process:

Self-management logs, patient-reported outcome trends, results from ancillary laboratory and imaging tests can all support the problem-solving mode of SDM.

Patients and clinicians could consider using home visits, photographs, narrative accounts of daily living, the "My Healthcare, My Life" conversation tool(30,31), and other ways to develop a joint understanding of the social and economic challenges the patient faces routinely, and how these conditions promote or hinder health and the implementation of treatments.

Tools to support SDM conversations can help patients and clinicians select together which treatments to implement to reduce the risk of adverse disease outcomes(32,33). These tools should be easy to use, use helpful ways to communicate pertinent evidence and numerical risk information(33,34), and should support the conversation without intruding. Some tools which have been found to be useful in randomized trials are available free of use(35).

Teach-back could be used to verify that patients and clinicians understood the information shared by each other(36).

Stories and accounts of how patients lived their lives may be helpful to their family and clinicians in determining together whether and for how long to implement intensive life-support interventions in the care of a critically ill patient.

Advocate for care

Access and efficiency imperatives abbreviate and accelerate consultations to the point that SDM and other forms of care cannot be adequately implemented. Algorithms and guidelines may enable bypassing the messy process of co-creation, offering a right answer for "patients like this" which may or may not fit "this patient". SDM may get outsourced to third parties, offered to privileged patients (and less

to those who need interpreters, racialized patients, patients with cognitive and sensorial challenges, and those seen in high-volume or understaffed clinics), or reduced to the distribution of SDM tools(37).

Like careful and kind care(37-40), SDM is not a luxury. And yet, it often seems as if high-quality SDM is a method of care that healthcare cannot afford to offer everyone. Clinicians and patients must play an active role in advocating and working toward healthcare that enables and supports SDM. This work can focus on reprioritizing care over efficiency, advancing unhurried care conversations(29,37), reorienting healthcare innovations to advance rather than replace SDM, and on ensuring SDM for all patients(41).

Evaluate and learn SDM

The fourth step to implement SDM in practice is to evaluate how well SDM is happening and learn how and to what extent SDM as practiced is contributing to care.

When done well, SDM should contribute to improve the patient's problematic situation. Being able to co-create and jointly revise plans of care may reduce the risk of a poor-quality decision, that is, one that does not respond sensibly to the problem, fails to support patient goals and priorities, and maximally disrupts patient lives and loves(17). Doing SDM can deepen the relationship between patient and clinician and this relationship can offer resilience to adverse patient outcomes(42). In turn, joint evaluation of how well the patient and clinician are doing SDM can motivate improvement of SDM skills and further their partnership. In this way, care and learning to care are intertwined, and are both reliant on unhurried conversations and SDM.

Evaluate beyond outcomes

It is not adequate to judge the quality of the SDM process by patient outcomes, as the link between decisions and outcomes is weak as many outcomes result from highly complex interactions, multiple decisions over time, and chance. Short of general patient satisfaction questions, to our knowledge, there are no practical means available for external evaluators to assess how well a healthcare system, a clinician, and a patient implemented SDM and how well this process contributed to advance the patient's problematic situation.

A way forward may require defining a good decision by the way it was produced (evidence-based, co-created), by the goals that animated the decision-making process (advancing the patient situation in a sensible way), and by the nature of the

care plan that emerged from it (maximally supportive of the patient situation and goals, minimally disruptive of the live routines of patients and their community (17)).

Share the evaluation

Beyond external assessments, the most important evaluation needs to take place within the patient-clinician relationship. The patient and clinician may want to ask each other how well the conversation went and to seek feedback from each other about how they went about working out what to do, i.e., how well they did SDM. This may be particularly necessary early in the dyad's decision-making experience so that their performance can improve over time and be increasingly readier to face more difficult situations. By seeking feedback, clinicians exercise their humble commitment to meet the patient where they are and to care well for, about, and with the patient.

Seek shared improvement

The shared work of SDM demands that both parties learn from their experience. Since clinicians and patients with chronic conditions face a lifetime of decisions, this learning is life long and ongoing. Few opportunities exist to improve together. Clinicians can access courses in communication, but often these courses pay limited attention to the co-creation of a plan of care, instead focusing on explaining the plan to the patient. Patients are often trained to ask questions (e.g., what are my options, what are their pros and cons, how likely are these pros and cons to happen(43)), but there is little training about the different ways in which they can contribute depending on the forms of SDM used. Resources to improve the performance of both patients and clinicians, including joint skill building opportunities, need to be made available to promote high quality SDM(36,44).

CONCLUSION

The number of tasks assigned to clinicians seem to increase in inverse proportion to the time allotted to execute them. In this context, SDM may seem like just one more box to tick, or a skill clinicians have no time to learn or use. But SDM is not an add-on. Clinicians are already engaging patients in conversations to work through a plan of action because that is what is required to formulate the best plan.

As with every other aspect of caring for patients, this method of care must continue to be subject of innovation and improvement(45), including the preparation of both

patients and clinicians (and the healthcare systems within which they meet)(38) to better contribute to the joint work of making care fit(17).

The ubiquitous nature of SDM means that every conversation with a patient is an opportunity to get care right—intellectually, practically, and emotionally – for that person. In these conversations, patients and clinicians can find problems that matter along with possible ways of addressing them, deciding amongst the possibilities, and putting it all together in a plan that the patient wants, is likely to help, and is feasible and sustainable.

Within the constraints of any situation, including systemic constraints, SDM is a method of creating the best care, it is also the human, kind, and caring thing to do—the sort of thing that breathes life, joy, and purpose into the practice of medicine.

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Clinical impact of an integrated e-health system for diabetes self-management support and shared decision making (POWER2DM) – a randomised controlled trial –

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ABSTRACT

Aims

There is a lack of e-health systems that integrate the complex variety of aspects relevant for diabetes self-management. We developed and field-tested an e-health system (POWER2DM) that integrates medical, psychological and behavioural aspects and connected wearables to support patients and healthcare professionals in shared decision making and diabetes self-management.

Methods

Participants with type 1 or type 2 diabetes (aged >18 years) from hospital outpatient diabetes clinics in the Netherlands and Spain were randomised using randomisation software to POWER2DM or usual care for 37 weeks. This RCT assessed the change in HbA1c between the POWER2DM and usual care groups at the end of the study (37 weeks) as a primary outcome measure. Participants and clinicians were not blinded to the intervention. Changes in quality of life (QoL) (WHO-5 Well-Being Index [WHO-5]), diabetes self-management (Diabetes Self-Management Questionnaire – Revised [DSMQ-R]), glycaemic profiles from continuous glucose monitoring devices, awareness of hypoglycaemia (Clarke hypoglycaemia unawareness instrument), incidence of hypoglycaemic episodes and technology acceptance were secondary outcome measures. Additionally, sub-analyses were performed for participants with type 1 and type 2 diabetes separately.

Results

A total of 226 participants participated in the trial (108 with type 1 diabetes;118 with type 2 diabetes). In the POWER2DM group (n=111), HbA1c decreased from 60.6±14.7 mmol/mol (7.7±1.3%) to 56.7±12.1 mmol/mol (7.3±1.1%) (means ± SD, $p<0.001$), compared with no change in the usual care group (n=115) (baseline: 61.7±13.7 mmol/mol, 7.8±1.3%; end of study: 61.0±12.4 mmol/mol, 7.7±1.1%; p=0.19) (between-group difference 0.24%, p=0.008). In the sub-analyses in the POWER2DM group, HbA1c in participants with type 2 diabetes decreased from 62.3±17.3 mmol/mol (7.9±1.6%) to 54.3±11.1 mmol/mol (7.1±1.0%) ($p<0.001$) compared with no change in HbA1c in participants with type 1 diabetes (baseline: 58.8±11.2 mmol/mol [7.5±1.0%]; end of study: 59.2±12.7 mmol/mol [7.6±1.2%]; p=0.84). There was an increase in the time during which interstitial glucose levels were between 3.0 and 3.9 mmol/l in the POWER2DM group, but no increase in clinically relevant hypoglycaemia (interstitial glucose level below 3.0 mmol/l). QoL improved in participants with type 1 diabetes in the POWER2DM group compared with the usual care group (baseline: 15.7±3.8; end of study: 16.3±3.5; p=0.047 for between-group difference). Diabetes self-

management improved in both participants with type 1 diabetes (from 7.3±1.2 to 7.7±1.2; p=0.002) and those with type 2 diabetes (from 6.5±1.3 to 6.7±1.3; p=0.003) within the POWER2DM group. The POWER2DM integrated e-health support was well accepted in daily life and no important adverse (or unexpected) effects or side effects were observed.

Conclusion

POWER2DM improves HbA1c levels compared with usual care in those with type 2 diabetes, improves QoL in those with type 1 diabetes, improves diabetes self-management in those with type 1 and type 2 diabetes, and is well accepted in daily life.

INTRODUCTION

Diabetes mellitus imposes a major disease burden on both individuals and healthcare systems (1). The goals of treatment for diabetes are to prevent or delay complications and optimise quality of life (QoL) (2). To prevent diabetes related complications, blood glucose values need to be kept as close to normal as possible using medication, diet, physical activity and glucose monitoring (3–5). Treatment and self-management plans should be created in consultation with people with diabetes based on their individual preferences, values and goals (2). Diabetes self-management involves a significant investment of time and effort, and may therefore pose a large burden on individuals, both practically and emotionally (6, 7). Consequently, psychological issues related to diabetes outcomes and barriers to diabetes self-management are commonly observed (8, 9), resulting in suboptimal self-management, a reduction in QoL or poor healthcare outcomes (7). Despite self-management support now being acknowledged as one of the most important factors in diabetes care (10), healthcare systems often still focus on biomedical outcomes and screening for complications, rather than on the burden of disease and potential barriers to self-management, or facilitating support and strategies that help improve patient empowerment (11, 12). This results in a divide between patients' needs and the healthcare support provided (13, 14).

Acknowledging patients' needs for more self-management support, a variety of mobile technologies (m-health) and e-health interventions have been developed (15–19) that have often been shown to be accepted by patients as a helpful tool to optimise, facilitate or enable self-management and improve glycaemic control (20–22). However, most of these interventions involve 'stand-alone' systems or apps that are used by patients but are not accessible to healthcare professionals. These fragmented applications, which often only focus on one specific aspect such as carbohydrate intake, exercise or glucose monitoring, do not acknowledge the complexity of self-management and impede the uptake of such systems and use of the resulting data in standard diabetes care. Therefore there is a need for integrated digital systems that support all aspects of diabetes (self-)management, facilitate shared decision making (SDM) between patients and healthcare professionals, and enable integration of behavioural, psychological and medical data in diabetes care.

To fulfil this need and provide both patients and healthcare professionals with a digital tool to facilitate self-management (support) and SDM, we developed the POWER2DM integrated e-health support system. This self-management support system collects, integrates and presents a variety of data in a dashboard for patients and healthcare professionals, supports patients in self-management in daily life, and

creates insights into potential barriers, behaviours and outcomes. This information may help patients and healthcare professionals to collaborate and engage in SDM. As people with type 1 and type 2 diabetes have different needs and require different types of support, the POWER2DM support system aims to be flexible, patient-centred and adjustable by individuals themselves to their wishes and needs.

The aim of this study was to assess whether the POWER2DM integrated e-health support system is effective and safe in improving glycaemic control and QoL compared with usual care for people with type 1 or type 2 diabetes.

RESEARCH DESIGN AND METHODS

Overall Design

This RCT (NCT03588104, ClinicalTrials.gov) aimed to test the effectiveness and safety of an integrated e-health system (POWER2DM) to support individuals with diabetes and healthcare professionals in diabetes self-management and SDM compared with usual care during 37 weeks of follow-up. The study was performed using the same methods in both the Netherlands and Spain. The study was approved by the Medical Ethical Committee Leiden/Den Haag/Delft under the Medical Research Involving Human Subjects Act, and by the Research Ethics Committee of Reina Sofía University Hospital as part of the Sistema Sanitario Público de Andalucía Research Ethics Committee Network, and complies with the Declaration of Helsinki.

The POWER2DM integrated e-health system

The POWER2DM integrated e-health system is a clinical based support system that was developed to create insight into an individual's medical, behavioural and psychological data, to support the individual and healthcare professionals collaborating in SDM and creating a treatment plan that fits the individual's situation, and to support the individual in daily life to reach their self-management goals (**figure 1**). The system has two components: the web-based shared decision-making dashboard (SDMD) (**ESM figure 1**), used by individuals together with healthcare professionals during clinical consultations, and a self-management support system (SMSS) (23) that is available as a mobile application (**ESM figure 2**) and webpage (**ESM figure 3**) for people to use at home and in daily life. Clinical consultations were performed by diabetes nurses and clinicians who were part of the study team, and who were self-trained (using an instruction guide and by trial and error) to work with the technological systems involved. Individuals were instructed on how to use the SMSS by the nurse/clinician who performed the randomisation visit, and online support videos were available to use at home.

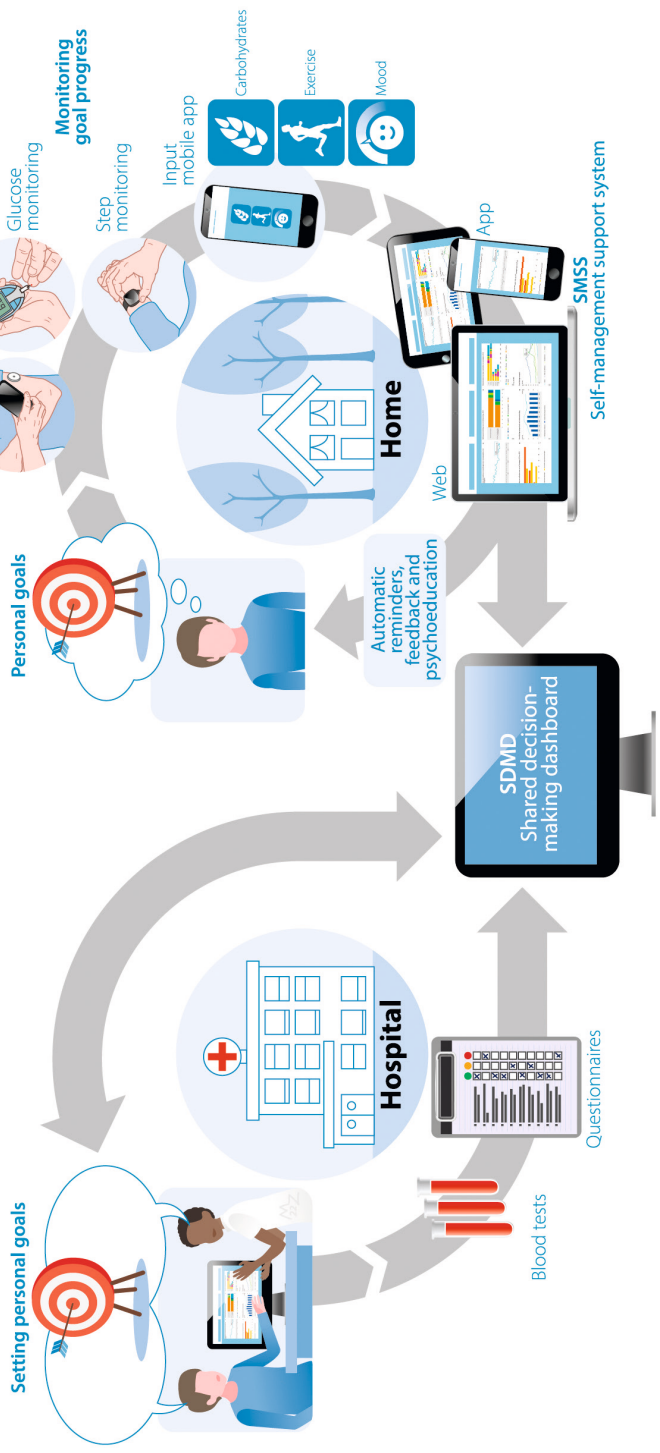

Figure 1. POWER2DM intervention. Personal goal setting is first carried out by the participant and the healthcare professional using SDM and the data from the POWER2DM SDMD during clinical consultation. The participant then tries to reach these personal goals through use of the POWER2DM SMSS and multiple connected wearables, while receiving automatic reminders, feedback and psychoeducation.

The POWER2DM Shared Decision Making Dashboard (SDMD)

The SDMD is a tool for healthcare professionals and individuals to use together during clinical consultations. It provides a visual overview of medical, behavioural and psychological data gathered by the individual. These data may be manually entered into the mobile app, such as blood glucose values, carbohydrate intake or exercise, or collected by connected wearables that were provided to participants as part of the intervention. Physical activity was measured using a Fitbit Charge 2 (Fitbit Health Solutions, USA), blood glucose values were measured using an iHealth BG5 glucometer (iHealthlabs, Australia), and interstitial glucose values were measured using blinded (Freestyle Libre Pro) or unblinded (Freestyle Libre) glucose monitoring devices (Abbott Laboratories, USA). The structured visual data overview in the SDMD aims to help individuals and healthcare professionals to obtain valuable insights about the individuals' situation and reveal potential targets for improvement. Furthermore, the SDMD automatically identifies potential barriers to self-management based on behavioural data entered in the mobile app and the outcomes of questionnaires that the participants filled in during study visits.

The web-based and mobile POWER2DM Self-Management Support System (SMSS)

The SMSS consists of a webpage and mobile app for individuals to use during their daily life to set goals, track their goal progress, and receive support to reach their goals. Goals are set by individuals and healthcare professionals together during clinical consultations using the SDMD, or by the individual alone using the SMSS webpage. The SDMD and SMSS automatically transfer the goals to the mobile app. The mobile app then combines manually entered data and data from the connected wearables that were provided to participants as part of the intervention to automatically track goal progress over time, and send reminders for planned tasks. If the SMSS registers that an individual has failed to complete a pre-planned task, it automatically refers them to the SMSS webpage and guides them through a barrier identification process to identify potential issues preventing them from reaching their goal(s). If barriers for self-management are detected, targeted interventions, psychological exercises and psychoeducation are automatically provided by the webpage to help overcome these barriers. Alternatively, individuals can choose to adapt their self-management goals.

The POWER2DM intervention

The POWER2DM intervention comprised a non-protocolised, multifaceted intervention, combining the use of the POWER2DM integrated e-health system with SDM and personal goal setting during clinical consultations, and manual and automated data collection, overview and feedback (**figure 1**). Participants were

allowed to use the elements of the support system as they saw fit, in line with their self-management goals.

Population

People with type 1 or type 2 diabetes who were receiving care at the hospital outpatient diabetes clinics of the Leiden University Medical Center and affiliated teaching hospitals or the Reina Sofía University Hospital were eligible for participation if they fulfilled the following inclusion criteria: age ≥ 18 years, ability to self-monitor and work with a computer and smartphone with internet connection, sufficient language comprehension and the ability to complete questionnaires. People who were eligible for participation were proactively identified at the outpatient clinic and asked to participate. A more detailed description of inclusion and exclusion criteria is given in **ESM methods 1**.

Randomization, interventions, subsequent care and follow up visits

This RCT consisted of a data collection and handling period of 4 weeks, and three consecutive intervention periods of 11 weeks (total duration 37 weeks) (**ESM figure 4**). After providing informed consent, participants were randomised in a 1:1 ratio to either the POWER2DM group or the usual care group in strata of equal size for type 1 or type 2 diabetes using randomisation software (Castor EDC, Castor, the Netherlands). The primary outcome was the difference in change in HbA1c between the POWER2DM and usual care groups during the study period. Secondary outcomes analysed in this paper were changes in QoL (assessed using the WHO-5 Well-Being Index [WHO- 5] (24)), diabetes self-management (assessed using the Diabetes Self-Management Questionnaire – Revised [DSMQR] (25)), glycaemic profiles obtained using continuous glucose monitoring devices, hypoglycaemia awareness (assessed using the Clarke hypoglycaemia unawareness instrument (26)), number of hypoglycaemic episodes and technology acceptance (assessed using the Technology Acceptance Questionnaire (27); see **ESM Technology Acceptance Questionnaire [TAQ]**). A more detailed description of the outcomes measured and a complete list of secondary outcome measures are given in **ESM methods 2**.

To assess glycaemic control, each participant in the POWER2DM and usual care groups was provided with a blinded continuous glucose monitor for 2 consecutive weeks at the start of the study (weeks 0–2) and the end of the study (weeks 35–37). The study visits in participants included in the POWER2DM group focused on SDM and goal setting for self-management behaviour, using the POWER2DM integrated e-health system. Clinical information about glycaemic control and diabetes-related outcomes was gathered, and laboratory tests, anthropometric measurements and

questionnaires were completed at baseline (week 0), week 11, week 22 and week 37. At week 4, week 15 and week 26, all gathered information was used by the clinicians and participants to engage in SDM and set personalised treatment goals together. The participants would then try to achieve these goals with the help of the mobile application and webpage of the SMSS, which they used whenever they felt appropriate. Twice during the study (weeks 11–13 and 22–24), participants in the POWER2DM group received a non-blinded intermittently scanned continuous glucose monitoring device (FreeStyle Libre) to provide an additional learning opportunity and mimic real-life clinical practice, in which measurements from intermittently scanned continuous glucose monitoring devices are widely available and used. For participants in the usual care group, regular care visits with their usual diabetes care team were continued, together with reporting on glycaemic control and diabetes-related outcomes, laboratory tests, anthropometric measurements and questionnaires at baseline (week 0), week 11, week 22 and week 37. **ESM figure 4** gives details of the visits in each group.

Statistical Methods

Details regarding sample size and power calculations are given in **ESM methods 3**. Analyses were performed from an intention-to-treat perspective. Missing data were handled by multiple imputation (five imputed datasets) by chained equations. Stata version 16 (StataCorp, USA) was used to perform all analyses. All outcomes from the participant and clinical perspective were analysed using the Stata mixed command for multi-level linear regression. For all outcomes, we performed an overall analysis of all participants (participants with type 1 and type 2 diabetes combined) as well as subsequent separate analyses for participants with type 1 or type 2 diabetes. Data in the text are reported as means ± SD. A p value <0.05 was considered statistically significant. A more detailed description of the statistical analyses performed is given in **ESM methods 3**.

RESULTS

A total of 226 participants with diabetes were recruited from outpatient clinics in the Netherlands and Spain, including 108 from Leiden University Medical Center and affiliating teaching hospitals (83 with type 1 diabetes; 25 with type 2 diabetes) and 118 from Reina Sofía University Hospital, Córdoba, Spain (25 with type 1 diabetes; 93 with type 2 diabetes). Of these, 111 were randomized to the POWER2DM group and 115 to the usual care group (**table 1 and figure 2**).

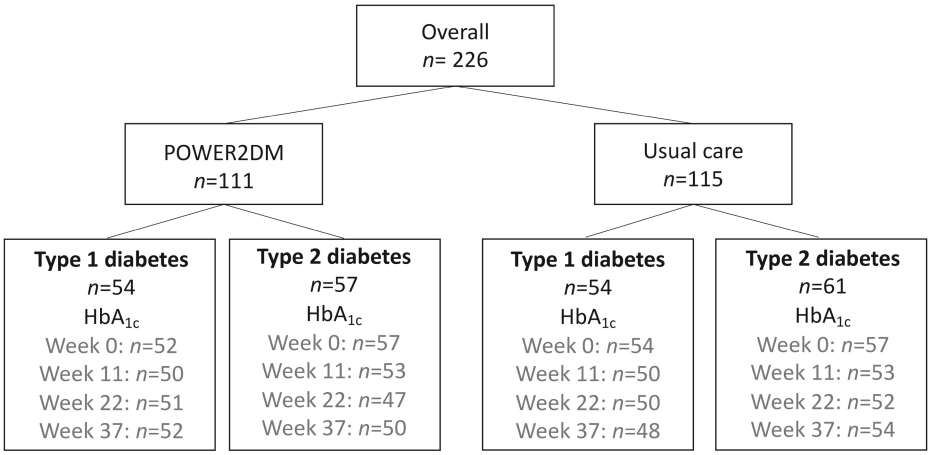

Figure 2. Flow chart showing the number of study participants in each group and the number for whom HbA1c data were available at each time point.

Participants had a mean age of 51.3±12.0 years, and 36.3% were female. In total, 25.2% were already monitoring their glucose values using (intermittently scanned) continuous glucose monitoring devices prior to the start of the study. The mean follow-up duration was 40.2±4.7 weeks. Baseline characteristics were similar in the POWER2DM and usual care groups (**table 1**).

Overall, of the 226 participants included in the study, 108 had type 1 diabetes and 118 had type 2 diabetes (**table 1**). Individuals with type 2 diabetes had a higher BMI (31.5±5.0 kg/m2) than those with type 1 diabetes (26.1±4.6 kg/m2). Individuals with type 1 diabetes had more diabetes-related complications than those with type 2 diabetes (59.3% and 36.4%, respectively). Of the participants with type 1 diabetes, 45.8% monitored their glucose values using an (intermittently scanned) continuous glucose monitoring devices, compared with 12.5% of those with type 2 diabetes.

Table 1. Baseline characteristics

	Total group		Type 1 diabetes		Type 2 diabetes	
	Control	POWER2DM	Control	POWER2DM	Control	POWER2DM
N	**115**	**111**	**54**	**54**	**61**	**57**
Age, mean (SD), years	51.1 (10.9)	51.5 (13.2)	45.3 (11.5)	44.6 (13.9)	56.2 (7.2)	57.8 (8.6)
Gender, n (%), female	42 (36.5)	40 (36.0)	25 (46.3)	19 (35.2)	17 (27.8)	21 (36.8)
BMI, mean (SD), kg/m^2	28.8 (5.0)	29.1 (5.9)	26.0 (3.8)	26.3 (5.2)	31.2 (4.7)	31.8 (5.3)
Level of education, n (%)						
Primary	21 (18)	21 (19)	2 (3.7)	1 (1.9)	19 (31)	20 (35)
Secondary / vocational	22 (19)	23 (21)	15 (28)	13 (24)	7 (10)	10 (18)
(applied sciences) University	59 (51)	55 (50)	36 (67)	35 (65)	23 (38)	20 (35)
Unknown	13 (11)	12 (11)	1 (1.9)	5 (9.3)	12 (20)	7 (12)
Smoking, n (%)	15 (13)	16 (15)	4 (7)	5 (9)	11 (18)	11 (20)
Duration of diabetes, mean (SD), years	17.9 (12.3)	16.9 (11.6)	23.3 (13.5)	21.7 (12.7)	12.1 (7.6)	11.9 (7.6)
Glucose-lowering medication, n (%)	63 (56)	54 (49)	6 (11)	2 (3.7)	57 (93)	52 (93)
Insulin	84 (73)	82 (74)	54 (100)	54 (100)	30 (49)	28 (49)
Metformin	60 (52)	40 (36)	6 (11)	2 (3.7)	54 (88)	38 (67)
GLP-1 receptor antagonist	4 (3.5)	3 (2.7)	0 (0)	0 (0)	4 (6.6)	3 (5.3)
SGLT-2 inhibitor	20 (17)	13 (12)	0 (0)	0 (0)	20 (33)	13 (23)
DPP-4 inhibitor	14 (12)	18 (16)	0 (0)	0 (0)	14 (23)	18 (32)
Sulfonylurea derivative	6 (5.2)	6 (5.4)	0 (0)	0 (0)	6 (10)	6 (11)
Pioglitazone	1 (0.8)	2 (1.8)	0 (0)	0 (0)	1 (1.6)	2 (3.5)
Other	3 (2.6)	3 (2.7)	0 (0)	0 (0)	3 (4.9)	3 (5.3)

Table 1. *(continued)*

	Total group		Type 1 diabetes		Type 2 diabetes	
	Control	POWER2DM	Control	POWER2DM	Control	POWER2DM
N	**115**	**111**	**54**	**54**	**61**	**57**
Glucose monitoring, n (%)						
None	27 (23)	27 (24)	0 (0)	0 (0)	27 (44)	27 (47)
Yes	88 (77)	84 (76)	54 (100)	54 (100)	34 (56)	30 (53)
Blood glucose monitoring only	60	54	28	33	32	21
Continuous glucose monitoring	3	8	3	2	0	6
Intermittently scanned glucose monitoring	25	21	25	19	0	2
Complications, n (%)						
None	63 (55)	56 (50)	21 (39)	23 (43)	42 (69)	33 (58)
Retinopathy	43 (37)	42 (38)	31 (57)	29 (54)	12 (20)	13 (23)
Laser coagulation	8 (6.7)	8 (7.2)	6 (11)	4 (7)	2 (3)	4 (7)
Diabetes neuropathy	16 (14)	12 (11)	9 (16)	7 (13)	7 (11)	5 (9)
Diabetes nephropathy	7 (6.1)	7 (6.3)	2 (3.7)	5 (9.3)	2 (3.3)	2 (3.5)
Macroangiopathy (peripheral vascular disorders)	11 (9.6)	19 (17)	3 (5.6)	7 (13.0)	8 (13)	12 (21)
Comorbidity, n (%)	79 (69)	65 (59)	46 (85)	36 (67)	33 (54)	29 (51)
Blood pressure, mean (SD), mmHg						
Systolic blood pressure	133 (25)	133 (18)	128 (20)	131 (16)	137 (28)	136 (20)
Diastolic blood pressure	78 (9.1)	79 (9.8)	77 (9.8)	80 (8.6)	79 (8.4)	79 (11)
LDL cholesterol, mean (SD), mg/dL	100 (32.7)	93.3 (31.5)	106 (27.4)	91.4 (24.3)	95.2 (36.4)	95.1 (34.5)
HDL cholesterol, mean (SD), mg/dL	55.8 (18.2)	54.4 (17.3)	66.7 (17.7)	64.4 (17.4)	46.1 (12.1)	45.1 (11.0)

Values are means ± SD or n (%); Information about sex (female/male) was self-reported by participants; DPP-4, dipeptidylpeptidase-4; GLP-1, glucagon-like peptide-1; SGLT-2, sodium-glucose cotransporter-2.

Glycemic control

In the POWER2DM group, HbA1c decreased from 60.6±14.7 mmol/mol (7.7±1.3%) to 56.7±12.1 mmol/mol (7.3±1.1%) during the study (p<0.001). No significant change in HbA1c was observed in the usual care group (baseline: 61.7±13.7 mmol/mol, 7.8±1.3%; end of study: 61.0±12.4 mmol/mol, 7.7±1.1%; p=0.19) (**figure 3a**).

The improvement in HbA1c in the POWER2DM group was already present at 3 months, was maintained over time and was 2.6 mmol/mol (0.24%) greater than in the usual care group (between-group difference: p=0.008). Within the POWER2DM group, the HbA1c level of participants with type 2 diabetes improved over the course of the study (baseline: 62.3±17.3 mmol/mol, 7.9±1.6%; end of study: 54.3±11.1 mmol/mol, 7.1±1.0%; p<0.001) (between-group difference: −5.2 mmol/mol (0.48%), p=0.01) (**figure 3c**), compared with no change in HbA1c level in those with type 1 diabetes in the POWER2DM group (baseline: 58.8 ± 11.2 mmol/mol, 7.5±1.0%; end of study: 59.2±12.7 mmol/mol, 7.6±1.2%; p=0.84) (between-group difference: 0.1 mmol/mol (0.01%), p=0.88) (**figure 3b**).

Glucose profiles obtained from blinded continuous glucose monitors showed no significant change in time in range (3.9–10.0 mmol/l) for the POWER2DM group (baseline: 62.8±20.5%; end of study: 68.2±19.7%; p=0.053); however, a significant improvement in time between 10.0 and 13.9 mmol/l was observed (baseline: 21.6±11.6%; end of study: 17.9±12.1%; p=0.001), together with a small but significant increase in time between 3.0 and 3.9 mmol/l (baseline: 3.7±3.8%; end of study: 6.3±6.0%, p<0.001). The percentage of time above 13.9 mmol/l and below 3.0 mmol/l did not change significantly in the POWER2DM group during the trial. The usual care group showed a similar effect, with an increase in time in range (3.9–10.0 mmol/l) (baseline: 59.3±22.4%; end of study: 64.5±21.2%; p=0.024), a decrease in both time between 10.0 and 13.9 mmol/l (baseline: 22.0±11.7%; end of study: 17.3 ± 12.3%; p=0.007) and time above 13.9 mmol/l (baseline: 14.7±17.6%; end of study: 7.4±11.0%; p=<0.001), and an increase in time between 3.0 and 3.9 mmol/l (baseline: 3.9±3.9%; end of study: 5.6±5.3%; p=0.003) and time below 3.0 mmol/l (baseline: 2.8±4.2%; end of study: 4.5±6.5%; p=0.004) (**table 2**).

In participants with type 1 diabetes, the improvements in time in range and time above range and also the slight increase in time below range were less pronounced than the differences in glucose profiles over time found in participants with type 2 diabetes (t**able 2 and ESM figure 5**).

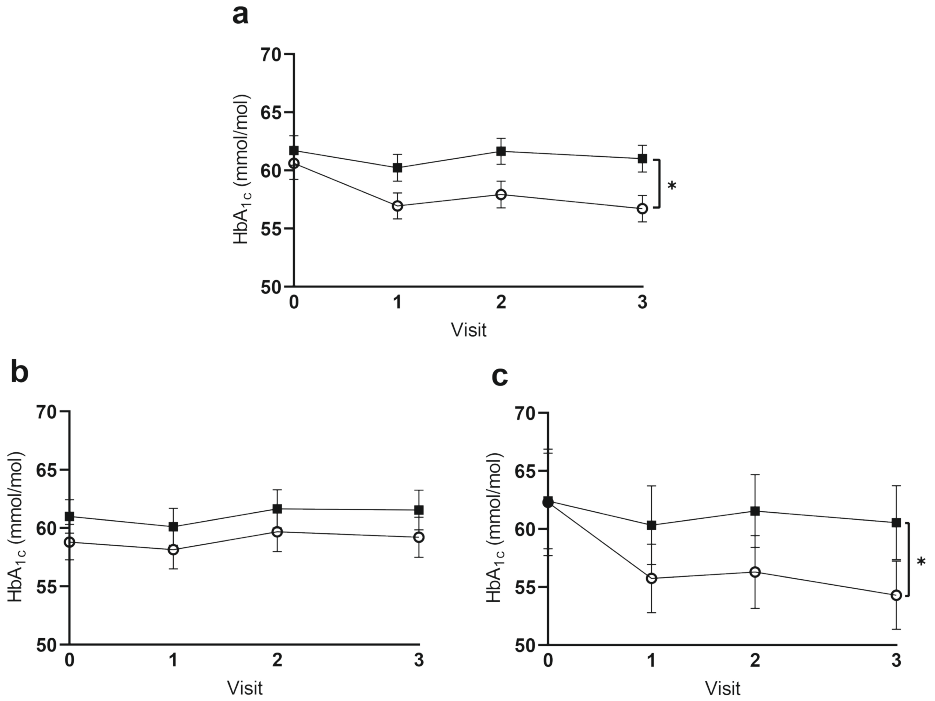

Figure 3. HbA1c values at baseline and during follow-up. (a) HbA1c values for the entire group (POWER2DM: n=111; usual care: n=115). (b) HbA1c values for participants with type 1 diabetes (POWER2DM: n=54; usual care: n=54). (c) HbA1c values for participants with type 2 diabetes (POWER2DM: n=57; usual care: n=61). Data are means and 95% CI. Open circles represent the POWER2DM group; black squares represent the usual care group. *p <0.05 between groups.

BMI

Overall, BMI did not change over time in the POWER2DM group (baseline: 29.3±5.8 kg/m2; end of study: 29.2±5.7 kg/ m2; p=0.13) or in the usual care group (baseline: 28.8±4.8 kg/m2; end of study: 28.8±4.6 kg/m2; p=0.54) (between-group difference: p=0.13). Additionally, no change in BMI was observed over time in participants with type 1 diabetes in the POWER2DM group (baseline: 26.4±5.2 kg/m2; end of study: 26.5±5.2 kg/m2; p=0.98) or the usual care group (baseline: 25.8±3.5 kg/m2; end of study: 26.2±3.5 kg/m2; p=0.10) (between-group difference: p=0.27), or in those with type 2 diabetes in the POWER2DM group (baseline: 32.1±5.0 kg/m2; end of study: 31.8±4.8) kg/m2; p=0.09) or the usual care group (baseline: 31.4±4.3 kg/m2; end of study: 31.2±4.2 kg/m2; p=0.74) (between-group difference: p=0.28).

Table 2. Outcomes of blinded continuous glucose monitoring

	Overall				Type 1 diabetes				Type 2 diabetes			
	POWER2DM		Usual care		POWER2DM		Usual care		POWER2DM		Usual care	
	Baseline	End	Baseline	End	Baseline	End	Baseline	End	Baseline	End	Baseline	End
Time below range: <3.0 mmol/L (<54 mg/dL)	2.7 (5.2)	3.4 (3.9)	2.8 (4.2)*	4.5 (6.5)*	4.7 (6.7)	4.0 (3.9)	4.5 (5.2)	4.9 (5.9)	0.9 (1.7)	2.7 (3.9)	1.3 (2.2)*	4.1 (6.9)*
Time below range: 3.0-3.8 mmol/L (54-69 mg/dL)	3.7 (3.8)*	6.3 (6.0)*	3.9 (3.9)*	5.6 (5.3)*	5.4 (4.3)	5.8 (4.0)	5.0 (3.9)	5.4 (4.2)	2.1 (2.4)*	6.7 (7.5)*	2.9 (3.7)*	5.8 (6.2)*
Time in range: 3.9-10.0 mmol/L (70-180 mg/dL)	62.8 (20.5)	68.2 (19.7)	59.3 (22.4)*	64.5 (21.2)*	55.6 (15.6)	56.6 (14.2)	52.6 (18.9)*	56.8 (16.4)*	69.6 (22.2)*	79.2 (17.9)*	65.2 (23.8)	71.3 (22.7)
Time above range: 10.1-13.9 mmol/L (181-250 mg/dL)	21.6 (11.6)*	17.9 (12.1)*	22.0 (11.7)*	17.3 (12.3)*	23.3 (9.1)	22.8 (9.4)	23.3 (10.1)*	19.6 (10.9)*	19.9 (13.4)*	13.3 (12.6)*	20.8 (12.8)*	15.3 (13.3)*
Time above range: >13.9 mmol/L (>250 mg/dL)	11.4 (12.9)†	9.1 (11.6)†	14.7 (17.6)*†	7.4 (11.0)*†	15.3 (13.5)†	12.9 (11.2)†	18.0 (16.8)*†	9.0 (11.2)*†	7.8 (11.2)	5.6 (11.0)	11.8 (17.8)*	6.1 (10.7)*

Outcomes of blinded continuous glucose monitoring during 2 weeks in participants with type 1 or type 2 diabetes receiving POWER2DM or usual care at baseline and at the end of the study. Data represent the time below range, time in range and time above range as a percentage of the total time that the sensor was worn by participants (means ± SD); *p <0.05 for change in percentage of time within each range between baseline and the end of the study within the POWER2DM or usual care groups; †p<0.05 for change in percentage of time within each range between the POWER2DM group and the usual care group.

Lipids

The changes in total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides did not differ between the POWER2DM and usual care groups (p>0.51), nor when analysed separately for participants with type 1 diabetes (p>0.15) and those with type 2 diabetes (p>0.18) **(ESM table 1**).

Safety

Overall, the time spent between 3.0 and 3.9 mmol/l increased in the POWER2DM group (from 3.7±3.8% to 6.3±6.0%; p<0.001) without a significant increase in time below 3.0 mmol/l (from 2.7±5.2% to 3.4±3.9%; p=0.43). The increase in time between 3.0 and 3.9 mmol/l was not associated with clinical symptoms reported by participants or with severe hypoglycaemic episodes, nor was it associated with an increase in impaired awareness of hypoglycaemia, as measured by the Clarke hypoglycaemia unawareness instrument (overall: −0.07, p=0.23; type 1 diabetes: −0.08, p=0.36; type 2 diabetes: 0.02, p=0.76).

Quality of life and self-management

Overall scores for QoL (WHO-5) did not change in either the POWER2DM or the usual care group (**figure 4a**). However, in participants with type 1 diabetes, there was an improvement in QoL in the POWER2DM group compared with the usual care group (between-group difference: p=0.047) (**figure 4b**). Overall diabetes self-management scores, reflected by the DSMQ-R questionnaire, improved both in the POWER2DM group (from 6.9±1.3 to 7.2±1.3; p<0.001) and in the usual care group (from 6.7±1.5 to 7.0±1.4); p=0.006) (between-group difference: p=0.21) (**ESM figure 6**). In participants with type 1 diabetes, an improvement in DSMQR scores over time was found both in the POWER2DM group (from 7.3±1.2 to 7.7±1.2; p=0.002) and in the usual care group (from 7.0±1.5 to 7.4±1.4; p=0.009).

There was no significant difference between the groups (between-group difference: p=0.55) (**ESM figure 6b**). In participants with type 2 diabetes, there was an improvement in DSMQ-R scores in the POWER2DM group (from 6.5±1.3 to 6.7±1.3; p=0.003) but not in the usual care group (from 6.4±1.4 to 6.6±1.2; p=0.15). There was no significant difference between these groups (p=0.33) (**ESM figure 6c**). Scores for self-monitoring of blood glucose values improved in participants with type 1 diabetes and those with type 2 diabetes in the POWER2DM group, but not in the usual care group (**ESM figure 7a**), but only in participants with type 2 diabetes was there a significant difference between the POWER2DM and usual care groups (between-group difference: p=0.036) (**ESM figure 7c**).

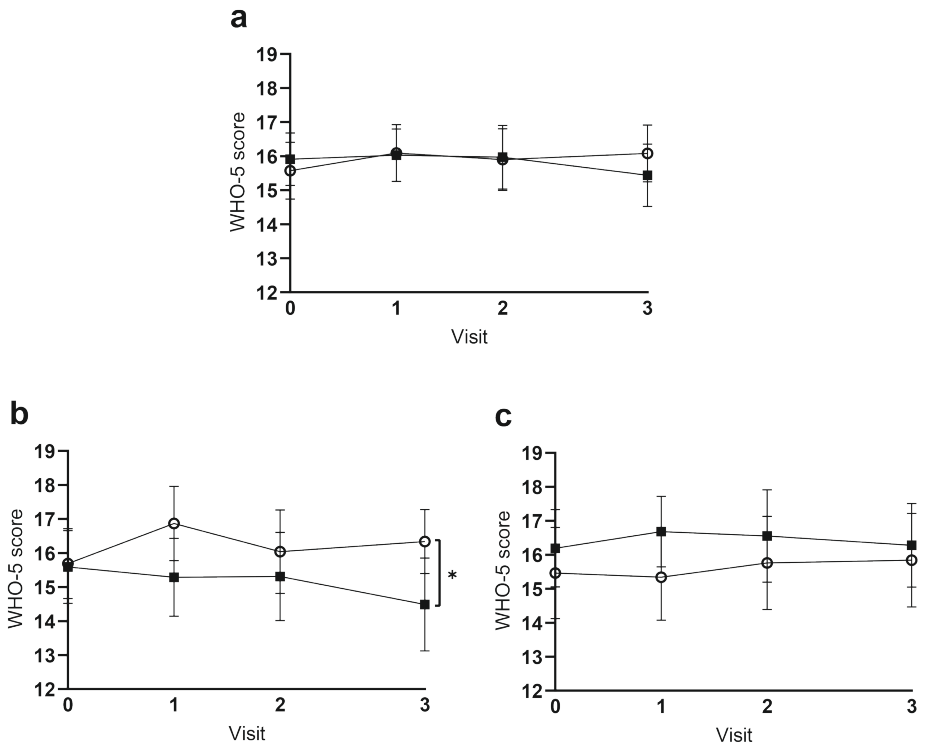

Figure 4. WHO-5 scores (possible range 0–25) for QoL over the course of the study. (a) WHO-5 scores for the entire group (POWER2DM: n=111; usual care: n=115). (b) WHO-5 scores for participants with type 1 diabetes (POWER2DM: n=54; usual care: n=54). (c) WHO-5 scores for participants with type 2 diabetes (POWER2DM: n=57; usual care: n=61). Data are means and 95% CI. Open circles represent the POWER2DM group; black squares represent the usual care group. *p <0.05 between groups.

Use of the POWER2DM system

System usage was highest in period 1 (weeks 4–15: 1.05 times per day) and gradually decreased with time towards the end of the study period (period 3, weeks 26–37: 0.41 times per day; p=0.001). Overall, system usage by participants with type 2 diabetes was significantly lower than that by participants with type 1 diabetes (between-group difference: −0.54 times per day; p<0.001). Participant satisfaction, as assessed using the Technology Acceptance Questionnaire, was high in both those with type 1 diabetes and those with type 2 diabetes, with positive scores in ten of the ten domains, indicating that the system was well accepted by participants in their daily diabetes care (**ESM figure 8**).

DISCUSSION

This RCT shows that POWER2DM integrated e-health support improved glycaemic control, QoL and self-management in people with diabetes mellitus, without increasing clinically relevant hypoglycaemia (blood glucose below 3.0 mmol/l). POWER2DM integrated e-health support was well accepted in daily life by both those with type 1 diabetes and those with type 2 diabetes.

Within the POWER2DM group, outcomes of blinded continuous glucose monitoring showed a decrease in time above range, together with a slight increase in time between 3.0 and 3.9 mmol/l, but no increase in clinically relevant hypoglycaemia (time below 3.0 mmol/l). As baseline glycaemic control was good in the POWER2DM group, with a mean HbA1c level of 60.6±14.7 mmol/mol (7.7 ±1.3%), the slight increase in time spent between 3.0 and 3.9 mmol/l may be expected. In the usual care group, a decrease in time above range, an increase in time within range and an increase in time below range were found, but no change in HbA1c. An explanation for this may be that use of the blinded continuous glucose monitor for 2 weeks resulted in a short-lived emphasis on glycaemic control that was not reflected in changes in HbA1c.

The sub-analyses in our study indicated that the improvement in HbA1c, associated with improvements in glucose monitoring outcomes, was more pronounced in those with type 2 diabetes, and was already established within the first 3 months, after which the beneficial effect was sustained. As education has been shown to be directly associated with diabetes knowledge (28) and participants with type 2 diabetes in our study had received a lower level of prior education regarding their diabetes than those with type 1 diabetes, it is likely that those with type 2 diabetes experienced a steeper learning curve. A study by Feigerlová et al also found no effect of additional e-health education on HbA1c levels in people with type 1 diabetes (29), supporting this hypothesis.

Previous studies on the effects of m-health and e-health interventions have reported similar findings of improved glycaemic control in people with type 1 diabetes (30) and type 2 diabetes (31, 32), decreased feelings of distress (30, 33) and improved QoL (33, 34). A systematic review by Pal et al found no effect of m-health interventions on behavioural, emotional or cognitive outcomes (35). However, the m-health interventions used were one-sided and were not combined with real-life clinical visits. Greenwood et al showed that the most effective strategy to support individuals is to use a two-way communication system, providing tailored support

and individualised feedback (31). Despite this evidence, m-health and e-health interventions are often one-sided, and frequently available to either the individual with diabetes (most often) or the healthcare professional, not incorporating real-life human interaction and creating a divide between diabetes care in practice and at home. This divide is not helpful when aiming for person-centred care, which requires collaboration between the individual with diabetes, as the expert on their life and living, and the clinician, as a medical expert. A helpful collaboration can only be established based on a meaningful connection, something that requires human contact, emphasising the need to combine m-health and e-health interventions with human contact and face-to-face clinical consultations.

POWER2DM integrated e-health support distinguishes itself from other m-health and e-health systems by providing multifactorial support for both individuals with diabetes and healthcare professionals. However, the incorporation of multiple electronic interfaces, several connected devices and specific goal-oriented consultations with healthcare professionals makes it difficult to determine the effect of specific components of POWER2DM. Thus the effect of POWER2DM can only be evaluated as a whole, acknowledging that both an increase in consultation frequency (36) and the use of intermittently scanned continuous glucose monitoring devices (37, 38) improve glycaemic control and also decrease diabetes distress (38) and improve QoL (36). While the additional effect of use of intermittently scanned continuous glucose monitoring devices (39) as a part of the POWER2DM intervention should be taken into account, HbA1c levels had already improved before the use of these monitoring devices, and this device was only available twice for 2 weeks, limiting the expected effect. Furthermore, the use of activity trackers such as Fitbits has shown to result in an increase in physical activity and weight loss, which may also improve glycaemic control and psychological outcomes (40). We believe the multifaceted character of the system to be one of the major strengths of this study, as it not only acknowledges the complexity of diabetes care, but also fits in with the current state-of-the-art multifactorial care approach. This care approach aims to address all factors that may affect healthcare outcomes and to support the day-to-day decision making, planning, monitoring, evaluation and problem-solving involved in diabetes self-management through a multistep model. Through the various functions, the system is able to gather information about and intervene in a broad variety of behavioural, psychological and medical aspects of an individual's self-management that ultimately determine glycaemic control and QoL.

A limitation to this study is the fact that participants were not blinded to the intervention, so expectation bias cannot be ruled out. However, we observed the

same effect size in objective outcomes such as HbA1c level and in more subjective outcomes such as diabetes self-management and QoL, aspects of diabetes that have been shown to all be connected (41). Another limitation is that the POWER2DM integrated e-health support system is less easily accessible for older people, people experiencing vision loss and people with limited technological skills or devices, and for clinical use in low-income countries or other clinical fields in which a computer is not always readily available. However, with the rapid technological advances, the group of older people who are capable of using this modern technology is growing, and the number of people owning a smartphone in low-income countries is increasing. With its adjustable character and person-centred clinical consultations focused on SDM and personal goal setting, the POWER2DM integrated e-health support system is expected to provide care that fits a broad range of people from a variety of backgrounds and socioeconomic situations, and with varying literacy and educational levels.

While implementation of the POWER2DM integrated e-health support system in standard care may initially require a financial investment in software and an investment of time spent teaching individuals how to use the system and interpret the results, we expect the system to be cost-effective in the long term. Studies have shown that educating people helps them understand the consequences of their self-management decisions and makes them feel empowered (42), thus motivating them and potentially improving therapy adherence. Furthermore, the system may help to identify and address potential barriers, which will help to overcome crucial problems hampering glycaemic control and improve QoL.

User engagement with the POWER2DM integrated e-health support system gradually declined over time, as is commonly observed for m-health systems (43). Whether this is the result of a successful and lasting change in behaviour, for which support of the system is no longer needed, or a lack of user engagement remains unclear. To our knowledge, there are no studies available about the long-term implications of declining user engagement in e-health systems. Therefore, the long-term effects of the system should be investigated further, as well as its viability and applicability in different healthcare systems, different countries and different patient populations.

In conclusion, the POWER2DM integrated e-health support system is unique in its design, aiming to bridge the gap in diabetes care between the diabetes clinic and daily life. Its multifaceted approach acknowledges the complexity of the various domains of self-management and how these domains intertwine. It automatically identifies potential barriers to self-management, and provides practical tools and psychoeducation to overcome these barriers. This study showed that the

POWER2DM system is a safe and effective tool to support patients and healthcare professionals to improve glycaemic control and self-management. The POWER2DM integrated e-health support system provides a multifaceted intervention that could be easily implemented into daily clinical practice and help both patients and clinicians, with little training required.

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SUPPLEMENTARY MATERIAL

ESM List 1: POWER2DM consortium

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ESM Methods 1: Inclusion and exclusion criteria POWER2DM study

Inclusion criteria
To be eligible to participate in this study, a subject must meet all of the following criteria:

- Age 18 or older
- Diagnosed T2DM or T1DM
- Able to self-monitor and work with computer and smart phone with internet connections (as assessed by researcher)

Exclusion criteria
A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Severe renal insufficiency (eGFR<30ml/min)
- Serious/severe comorbidity that interferes with diabetes outcomes or diabetes self-management including but not limited to: psychiatric diseases, chronic hepatopathy, active malignancy, COPD, diseases of the digestive tract, endocrine disorders, cerebrovascular disease with disability
- For female participants: pregnancy or wanting to become pregnant in the coming 9 months
- Concurrent participation in other clinical trials
- Any other situation in which the investigator identifies a potential risk of not being able to perform the study.

ESM Methods 2: Primary and secondary outcomes

Description of outcomes

In venous blood samples HbA1c, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides were measured. Anthropometrics consisted of height and body weight. Data on ethnicity and race were not analyzed, since participants were predominantly Caucasian. collected. Blood pressure measurements were performed at each visit. To assess potential barriers for self-management patients in the POWER2DM group completed questionnaires on diabetes distress (Problem Areas In Diabetes questionnaire (PAID))(1), fear of injections / fear of needles (Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ)(2)), fear of hypoglycaemic episodes (Clarke Hypoglycemia Unawareness Instrument)(3), Hypoglycaemic Fear Survey II (HFS II)(4)) and fear of complications (Fear of Complications Questionnaire (FCQ)(5)). To assess the overall effect of POWER2DM integrated e-health on quality of life and diabetes self-management all patients completed the WHO wellbeing index (WHO-5) and the Diabetes Self-Management Questionnaire (DSMQ-R). Furthermore, patients randomized to the POWER2DM group completed the technology acceptance questionnaire (TAQ)(6) (ESM Questionnaire 1) at the end of the study. Data from unblinded intermittently scanned continuous glucose monitoring devices (regular FreeStyle Libre) of patients in the POWER2DM group were not used for data analysis. Outcomes of blinded continuous glucose monitoring devices (FreeStyle Libre Pro) were defined as percentage of time <3.0 mmol/L (<54 mg/dL), percentage of time between 3.0-3.8 mmol/L (54-69 mg/dL), percentage of time in range: 3.9-10.0 mmol/L (70-180 mg/dL), percentage of time between 10.1 and 13.9 mmol/L (181-250 mg/dL) and percentage of time >13.9 mmol/L (>250 mg/dL).(7)

Complete list of secondary outcomes (as registered on clinicaltrials.gov) and considerations concerning data selection.

1. Amount hypoglycaemia [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Amount of hypoglycaemia measured by time spent in hypoglycaemia before and after treatment in the Power2DM group compared to the usual care control group

2. Hypo unawareness [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Hypo unawareness as measured by Clarke hypoglycaemia unawareness instrument, before and after treatment in the Power2DM group compared to the usual care control group

3. Incidence of adverse events [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Incidence of adverse events occurring during the study period including serious hypoglycaemic events

4. Mean blood glucose (MBG) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

5. Standard deviation of MBG (SDBG) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

6. Largest amplitude of glycaemic excursions (LAGE) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

7. Mean amplitude of glycaemic excursions (MAGE) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

8. Absolute means of daily differences (MODD) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

9. Time spent in range [0 weeks, 11 weeks, 22 weeks and 37 weeks]

As derived from continuous glucose measurements made by (intermittently scanned) continuous glucose monitoring devices

10. ADVANCE Cardiovascular risk [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The ADVANCE Cardiovascular Risk Engine, calculates the risk of major cardiovascular disease in patients with type 2 diabetes for the next 4 years (range 0-100%). This is defined as fatal or non-fatal myocardial infarction, stroke or cardiovascular death

11. ADVANCE Kidney disease Risk [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The ADVANCE Kidney Risk Engine, calculates the risk of new-onset albuminuria and major kidney-related events in patients with type 2 diabetes for the next 5 years (range 0-100%). Major kidney-related events are defined as doubling of serum creatinin to >2.26mg/dL, renal replacement therapy, or renal death

12. Major Outcomes T1D [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The Major Outcomes T1D risk score assess the 3, 5 and 7 year risk of a patient with type 1 diabetes on major outcomes (range 0-100%). These outcomes included major coronary heart disease, stroke, end-stage renal failure, amputations, blindness and all-cause death

13. UKPDS risk score [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The UKPDS risk score calculated the risk a patient with type 2 diabetes will develop coronary heart disease, fatal coronary heart disease, stroke or fatal stroke (range 0-100%)

14. Q score [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The Q score is a single metric for a continuous glucose monitoring (CGM) profile which summarizes the glucose profile using five factors: central tendency, hyperglycaemia, hypoglycaemia, intra- and inter daily variations.

15. Amount of steps [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Average amount of steps per day over a week measured by a step counter

16. Self-reported exercise time [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Exercise time per week as reported in the POWER2DM system

17. Frequency of self-monitoring of blood glucose (SMBG) measurements [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Frequency of SMBG measurements as reported by the glucose measurement device

18. Self-reported adherence to medication plan [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Self-reported adherence to medication plan as reported in the POWER2DM system

19. Weight [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Weight in kilograms measured on a scale

20. Body mass index (BMI) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

BMI in kg/m2, computed from height and weight

21. Diabetes Self-Management Questionnaire Revised (DSMQ-R) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

Subscales: glucose management, dietary control, physical activity, health care use. Transformed scale scores can vary between 0-10, with higher scores indicating more effective self-care

22. Patient utilities by EQ-5D [0 weeks, 11 weeks, 22 weeks and 37 weeks]

No subscales: EQ-5D provides a general health index with higher scores indicating better general health. QALYs will be calculated from EQ-5D scores

23. Problem Areas in Diabetes (PAID) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The PAID provides a total diabetes distress score (0-100), with higher scores (> 40) indicating more distress

24. Mood/Well-being by WHO-5 and Patient Health Questionnaire (PHQ-9) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

WHO-5 provides a total score (0-100) with higher scores indicating better wellbeing, PHQ-9 provides a total score (1-27) indicating a likelihood of depression, with higher scores indicating more depressive symptoms

25. Technology Acceptance Questionnaire (TAQ) [5 weeks and 37 weeks]

The TAQ provides scores (1-7) on the following domains: performance expectancy, effort expectancy, social influence, facilitating conditions, affect, self-efficacy, trust, motivation and behavioural intention. Higher scores indicate better acceptance of the system

26. Cost-effectiveness [Over 37 weeks]

Costs/quality adjusted life years (QALYs) Costs assessed via cost questionnaire and medication registry. QALYs based on patient utilities measured via EQ5D

27. Stress by perceived Stress Scale (PSS) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The PSS provides a total perceived stress score (0-40), with higher scores indicating more perceived stress

28. Patient Assessment of Chronic Illness Care (PACIC) [0 weeks, 11 weeks, 22 weeks and 37 weeks]

The PACIC measures the patient's perception of the care that they receive

The current manuscript focuses only on the effect of POWER2DM on glycaemic control, diabetes self-management and quality of life and therefore does only report on a selection of secondary outcomes (1, 2, 3, 9, 19, 20, 21, 24 and 25).

ESM Methods 3: Detailed description of statistical analyses

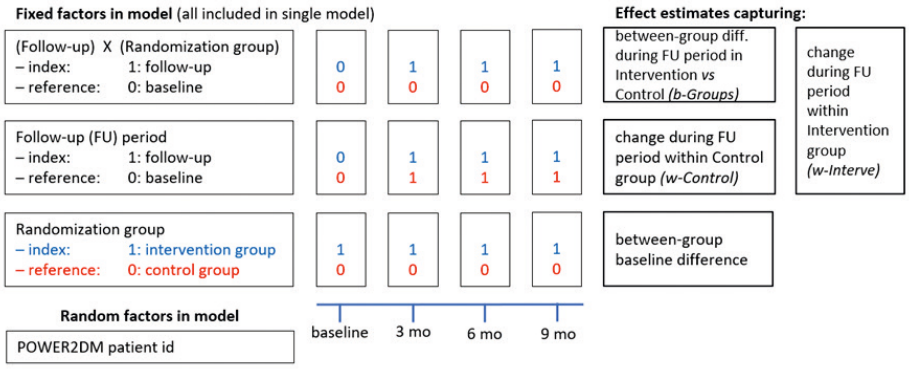
Sample size and power calculations

Sample size requirements were calculated based on a minimal detectable difference of 0.35% (SD 0.9%) (3.8 mmol/mol (SD 9.8 mmol/mol)) in the primary outcome variable HbA1c. For an alpha error of 0.05 and a power of 80%, the minimum sample size needed was 104 subjects per group. Therefore, we aimed to include a total of 115 patients with type 1 diabetes and 115 patients with type 2 diabetes. This allowed us to face a loss to follow-up of up to 9.6%. In pre-specified subgroup analyses of patients with type 1 and type 2 diabetes a difference of 0.5% (5.5 mmol/mol) in HbA1c could be detected with a sample size of 51 subjects per treatment strategy per diabetes subtype (N=57 with 11% loss to follow-up).

Statistical analyses

All outcomes were analysed using the STATA xtmixed command for multi-level linear regression. Visual inspection of outcome graphs suggested a stable intervention effect in the most important outcomes, already after 3 months. Therefore, we used the same approach for all (continuous) endpoints, by including indicators for follow-up period (3-9 months) and randomization group as fixed factors into the model to adjust for baseline differences and random factors to allow adjustment for repeated measurements within a patient (see figure below).

Mixed-model analysis



An interaction term (randomization group_X_follow-up) was included in the model to assess possible differences in outcomes between the groups during the follow-up period. For all endpoints we performed an overall analysis of all patients (patients with type 1 diabetes and type 2 diabetes combined) and two separate analyses for patients with type 1 and type 2 diabetes.

Despite not being explicitly stated on the clinicaltrials.gov website, subgroup analyses in patients with type 1 and type 2 diabetes were pre-planned. See POWER2DM deliverable D5.2.2 Evaluation of Campaign Methodology (https://www.power2dm.eu/wp-content/uploads/Power2DM-D5.3.pdf), page 19.

We used multiple imputation by chained equations (MICE) which uses a separate conditional distribution and model for each imputed variable and allows imputation of outcome data at a specific visit by including (imputed) data obtained at other visits(8). Before running MICE in STATA the data were reshaped from long format (one observation per patient per record) to wide format (a single record per patient). Missing values in the dependent variable were fitted by linear regression using all available measurements of the respective outcome at other timepoints in addition to diabetes type, center, sex, randomization group and treatment. Since MICE is an iterative process, the variable with the fewest missing values is imputed first followed by the variable with the next fewest missing values and so on for the rest of the variables. We used the default number of five datasets to be imputed. We used a random seed number (9478) in order to obtain reproducible results. After MICE this reshape procedure was reversed to obtain five imputed datasets in long format with an indicator variable for imputation set.

Most multiple imputation assumes that the data come from a multivariate normal distribution, however, the procedures are robust to moderate deviation from normality in typically sized trials(9). We therefore did not check convergence, but did check whether imputed data were within the plausible range.

ESM Technology Acceptance Questionnaire (TAQ)
We want to ask you a few questions about your current view on the Power2DM system and your expectations.

With the Power2DM system we mean the app, the web application and devices with the different applications to support your self-management.

For us it is important to know how you think about it at the moment. There are no right or wrong answers, it is your opinion.

The first question is about your motivation for using Power2DM. Please indicate to what extent you agree with the statement.

I am motivated to continue using the Power2DM system.

( ) Completely disagree
( ) Mostly disagree
( ) Somewhat disagree
( ) Neither agree nor disagree
( ) Somewhat disagree
( ) Mostly agree
( ) Completely agree
( ) Not applicable

There are several reasons for continuing to work with the Power2DM system. Below are a number of reasons. To what extent do they apply to you?

"I want to continue working with the Power2DM system, because ….

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
I find it a personal challenge	( )	( )	( )	( )	( )	( )	( )	( )
I would feel bad if I did not	( )	( )	( )	( )	( )	( )	( )	( )
I have chosen for it myself	( )	( )	( )	( )	( )	( )	( )	( )
I think I benefit from it as a patient	( )	( )	( )	( )	( )	( )	( )	( )
I want to show others that I can do this	( )	( )	( )	( )	( )	( )	( )	( )
I find this important	( )	( )	( )	( )	( )	( )	( )	( )
I do not want to disappoint my partner or someone who is important to me	( )	( )	( )	( )	( )	( )	( )	( )
I want my doctor to find me an exemplary patient	( )	( )	( )	( )	( )	( )	( )	( )
I think it is important to have insight in my condition myself	( )	( )	( )	( )	( )	( )	( )	( )
I like to have responsibilities within my treatment	( )	( )	( )	( )	( )	( )	( )	( )
I would feel guilty if I did not do it	( )	( )	( )	( )	( )	( )	( )	( )
I really think it's good to do this	( )	( )	( )	( )	( )	( )	( )	( )

The following questions are about what you think of and expect from the Power2DM system.

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
With the Power2DM system I can really keep an eye on my health	( )	( )	( )	( )	( )	( )	( )	( )
Through the Power2DM system I understand my condition and the treatment better	( )	( )	( )	( )	( )	( )	( )	( )
The Power2DM system has taught me useful things	( )	( )	( )	( )	( )	( )	( )	( )
The Power2DM system clearly provides insight into my current health	( )	( )	( )	( )	( )	( )	( )	( )
With the Power2DM system I identify problems with my condition earlier	( )	( )	( )	( )	( )	( )	( )	( )
With the Power2DM system my health runs less risk	( )	( )	( )	( )	( )	( )	( )	( )

Please indicate to what extent you agree with the statements.

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
Working with the Power2DM system takes little effort	( )	( )	( )	( )	( )	( )	( )	( )
The Power2DM system is easy in daily use	( )	( )	( )	( )	( )	( )	( )	( )
The use of the Power2DM system yields no ambiguities	( )	( )	( )	( )	( )	( )	( )	( )
Learning to deal with the Power2DM system is easy for me	( )	( )	( )	( )	( )	( )	( )	( )
I think my family believes I should continue using the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I think my friends believe I should continue using the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I think my health care providers believe I should continue using the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I think my fellow patients believe I should continue using the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )

Please indicate to what extent you agree with the statements.

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
I find it interesting to work with the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I experience working with the Power2DM system as something unpleasant	( )	( )	( )	( )	( )	( )	( )	( )
I like working with the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
Working with the Power2DM system gives me a restless feeling	( )	( )	( )	( )	( )	( )	( )	( )
I am confident that the Power2DM system is working well	( )	( )	( )	( )	( )	( )	( )	( )
I have confidence in the information provided by the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I am confident that my own measurements or questions answered by me provide sufficient insight into my health situation	( )	( )	( )	( )	( )	( )	( )	( )
I think that using the Power2DM system puts my privacy at risk	( )	( )	( )	( )	( )	( )	( )	( )

Please indicate to what extent you agree with the statements.

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
With the help of the Power2DM system, I play a greater role within my own medical care	( )	( )	( )	( )	( )	( )	( )	( )
The Power2DM system contains a lot of interesting information	( )	( )	( )	( )	( )	( )	( )	( )
I find it an advantage that changes in my condition can be quickly noticed by using the POWER2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I find it a disadvantage that I am more preoccupied about my condition by using the POWER2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I find it an advantage that I can adjust the action plan by myself	( )	( )	( )	( )	( )	( )	( )	( )
I find it an advantage that my healthcare provider has direct access to my measured values or manually entered data	( )	( )	( )	( )	( )	( )	( )	( )

Please indicate to what extent you agree with the statements.

	Completely disagree	Mostly disagree	Somewhat disagree	Not disagree/ not agree	Somewhat agree	Mostly agree	Completely agree	Not applicable
I find it a disadvantage of the Power2DM system that it takes a lot of my time	( )	( )	( )	( )	( )	( )	( )	( )
A disadvantage of Power2DM is that I have less time for other activities	( )	( )	( )	( )	( )	( )	( )	( )
An advantage of using the Power2DM system is that I have more time for other activities.	( )	( )	( )	( )	( )	( )	( )	( )

The following questions are about your computer skills and whether you have everything at home that is needed to work with the Power2DM system.

Please indicate to what extent you agree with the statements.

	Completely disagree	Mostly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Mostly agree	Completely agree	Not applicable
I use my computer daily	( )	( )	( )	( )	( )	( )	( )	( )
I find it a disadvantage that I have to use a mobile phone for the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I use the Internet daily	( )	( )	( )	( )	( )	( )	( )	( )
I have sufficient Internet skills to use the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
My computer is excellent for working with the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
My Internet connection works well	( )	( )	( )	( )	( )	( )	( )	( )
Where possible, my family helps me with the use of the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
Where possible, my friends help with the use of the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I can work well with the Power2DM system without the help of others	( )	( )	( )	( )	( )	( )	( )	( )
I can work well with the Power2DM system without the help of the Power2DM-team	( )	( )	( )	( )	( )	( )	( )	( )
I can work well with the Power2DM system as long as someone is available to help me	( )	( )	( )	( )	( )	( )	( )	( )
I can work well with the Power2DM system as long as nothing abnormal happens	( )	( )	( )	( )	( )	( )	( )	( )

The final questions are about how you intend to use the Power2DM system in the coming period.

Please indicate to what extent you agree with the statements.

	Completely disagree	**Mostly disagree**	**Somewhat disagree**	**Neither agree nor disagree**	**Somewhat agree**	**Mostly agree**	**Completely agree**	**Not applicable**
In the coming period I will again fill in the measurements in the Power2DM system at the indicated moments	( )	( )	( )	( )	( )	( )	( )	( )
In the coming period I will look at the action plan in the Power2DM system	( )	( )	( )	( )	( )	( )	( )	( )
I will look closely at the graphs on the measurement page of Power2DM	( )	( )	( )	( )	( )	( )	( )	( )
I will certainly follow the advice given by the action plan	( )	( )	( )	( )	( )	( )	( )	( )
I will consult the information modules if I have medical questions	( )	( )	( )	( )	( )	( )	( )	( )

ESM Tables

ESM Table 1a. Lipid values - overall population

	Baseline (week 0)		Week 11		Week 22		End (week 37)		P-value
	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	
Total cholesterol, mean (SD), mmol/l	4.45 (0.92)	4.65 (0.94)	4.42 (0.97)	4.63 (0.93)	4.42 (0.89)	4.71 (1.04)	4.34 (0.81)	4.55 (0.96)	0.52
LDL cholesterol, mean (SD), mmol/l	2.41 (0.77)	2.59 (0.85)	2.33 (0.78)	2.59 (0.86)	2.34 (0.75)	2.55 (0.90)	2.29 (0.67)	2.51 (0.77)	0.74
HDL cholesterol, mean (SD), mmol/l	1.41 (0.44)	1.45 (0.47)	1.40 (0.46)	1.46 (0.51)	1.49 (0.48)	1.51 (0.51)	1.46 (0.55)	1.55 (0.63)	0.91
Triglycerides, mean (SD), mmol/l	1.50 (2.13)	1.39 (1.13)	1.57 (1.83)	1.32 (0.89)	1.59 (1.99)	1.40 (0.95)	1.54 (1.54)	1.40 (0.87)	0.53

POWER2DM: n=111, usual care: n=115. P-value represents the between-group difference in effect over the study period between the POWER2DM and usual care group.
HDL: high density lipoprotein; l: liter; LDL: low density lipoprotein; mmol: millimol; SD: standard deviation.

ESM Table 1b. Lipid values – patients with type 1 diabetes

	Baseline (week 0)		Week 11		Week 22		End (week 37)		P-value
	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	
Total cholesterol, mean (SD), mmol/l	4.42 (0.81)	4.89 (0.73)	4.60 (0.89)	4.81 (0.71)	4.55 (0.86)	4.99 (0.75)	4.50 (0.80)	4.91 (0.85)	0.46
LDL cholesterol, mean (SD), mmol/l	2.37 (0.62)	2.74 (0.71)	2.40 (0.77)	2.69 (0.69)	2.33 (0.73)	2.64 (0.70)	2.36 (0.70)	2.69 (0.69)	0.37
HDL cholesterol, mean (SD), mmol/l	1.66 (0.44)	1.73 (0.45)	1.67 (0.46)	1.68 (0.45)	1.76 (0.42)	1.82 (0.50)	1.74 (0.61)	1.82 (0.55)	0.65
Triglycerides, mean (SD), mmol/l	0.83 (0.36)	0.94 (0.60)	1.03 (0.62)	0.97 (0.52)	1.09 (0.62)	1.10 (0.71)	1.05 (0.44)	1.06 (0.62)	0.15

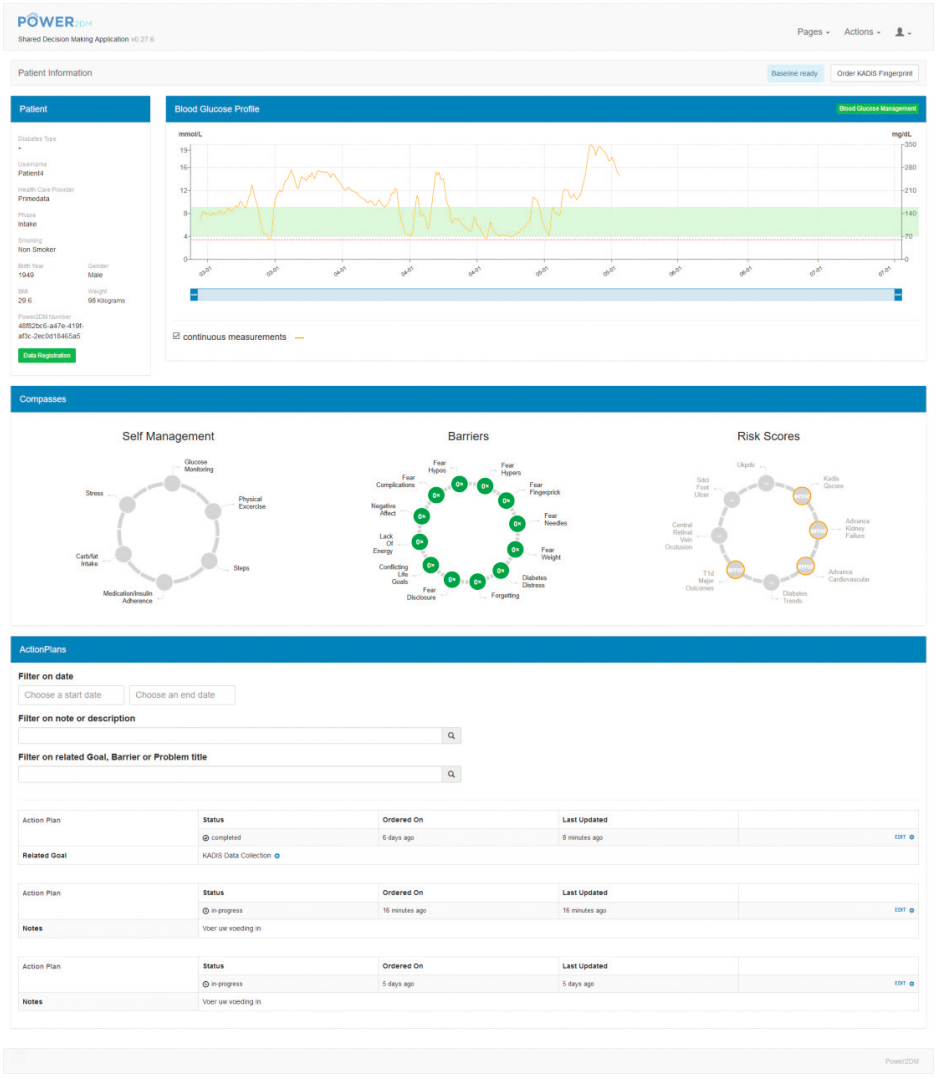
POWER2DM: n=54, usual care: n=54. P-value represents the between-group difference in effect over the study period between the POWER2DM and usual care group.
HDL: high density lipoprotein; l: liter; LDL: low density lipoprotein; mmol: millimol; SD: standard deviation.

ESM Table 1c. Lipid values - patients with type 2 diabetes

	Baseline (week 0)		Week 11		Week 22		End (week 37)		P-value
	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	
Total cholesterol, mean (SD), mmol/l	4.47 (1.03)	4.45 (1.06)	4.27 (1.02)	4.45 (1.06)	4.27 (0.90)	4.47 (1.20)	4.16 (0.79)	4.24 (0.95)	0.18
LDL cholesterol, mean (SD), mmol/l	2.45 (0.89)	2.46 (0.94)	2.26 (0.79)	2.49 (0.98)	2.34 (0.78)	2.48 (0.27)	2.23 (0.65)	2.34 (0.81)	0.29
HDL cholesterol, mean (SD), mmol/l	1.17 (0.28)	1.20 (0.31)	1.16 (0.29)	1.26 (0.49)	1.25 (0.40)	1.23 (0.33)	1.20 (0.31)	1.31 (0.60)	0.63
Triglycerides, mean (SD), mmol/l	2.13 (2.82)	1.78 (1.32)	2.08 (2.39)	1.63 (1.03)	2.07 (2.64)	1.67 (1.06)	2.00 (2.00)	1.69 (0.96)	0.91

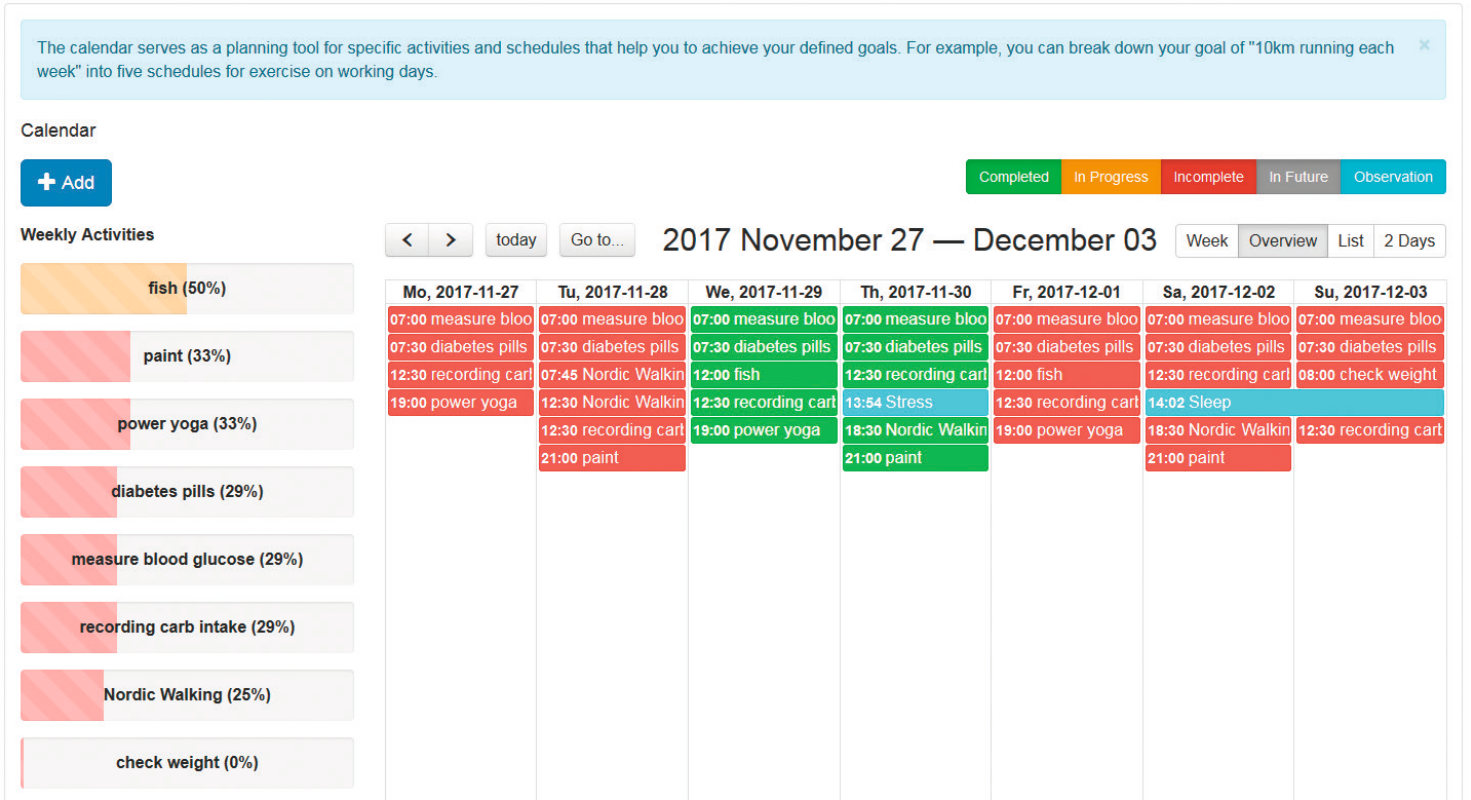
POWER2DM: n=57, usual care: n=61. P-value represents the between-group difference in effect over the study period between the POWER2DM and usual care group.
HDL: high density lipoprotein; l: liter; LDL: low density lipoprotein; mmol: millimol; SD: standard deviation.

ESM Figures

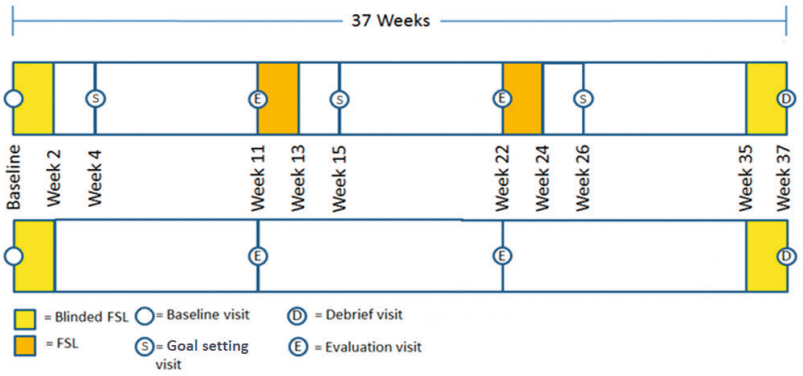


ESM Figure 1: Example of opening screen Shared Decision Making Dashboard (SDMD) application.

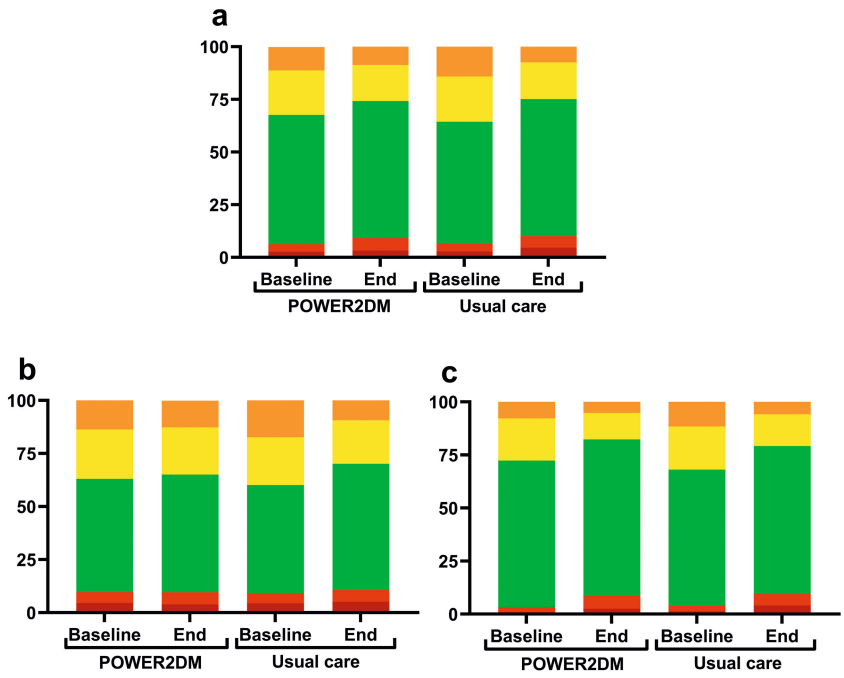
ESM Figure 2: Example of opening screen Self-Management Support System (SMSS) mobile application.



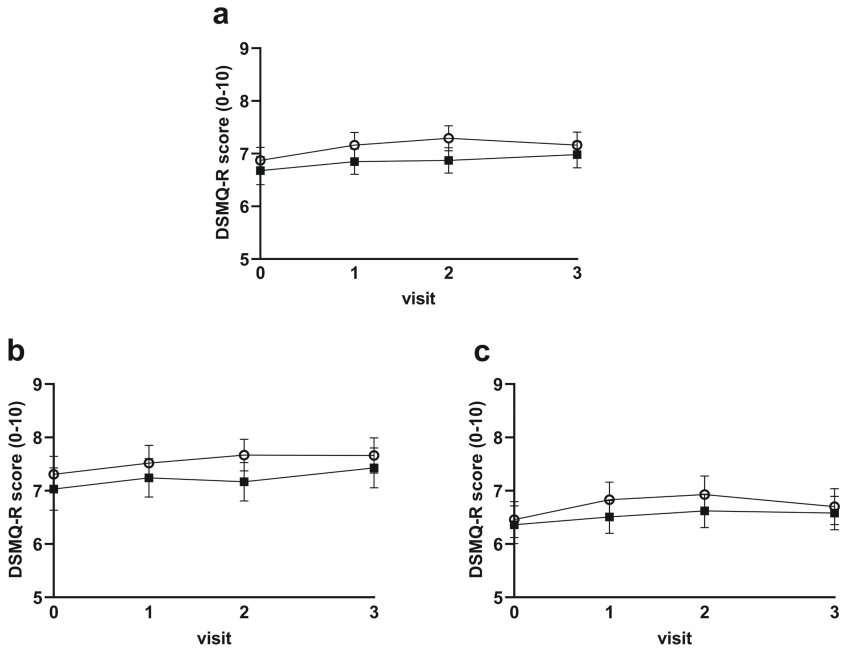
ESM Figure 3: Example of test participant calender in Self-Management Support System (SMSS) application.



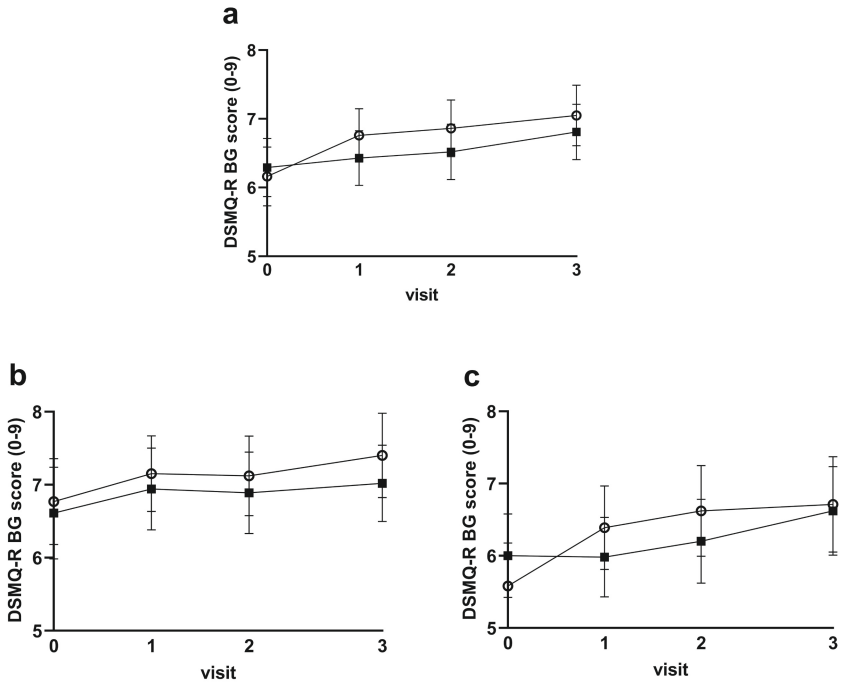
ESM Figure 4: POWER2DM study visit flow chart.
Upper bar: POWER2DM group. Lower bar: usual care group. Blinded FSL: FreeStyle Libre Pro (blinded continuous glucose monitoring device); FSL: FreeStyle Libre (non-blinded intermittently scanned continuous glucose monitoring device).



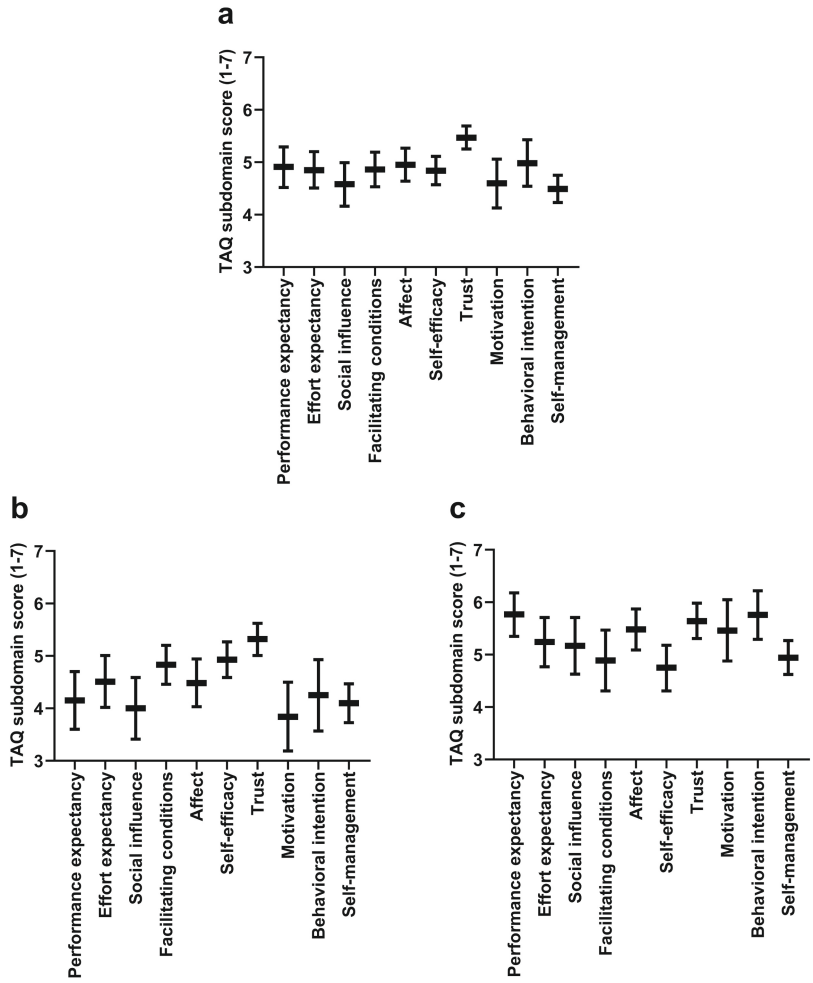
ESM Figure 5: Outcomes of blinded continuous glucose monitoring.
a. Outcomes of continuous glucose monitoring measured by a blinded glucose monitoring device (FreeStyle Libre Pro) in the POWER2DM and usual care group. b. Outcomes of blinded continuous glucose monitoring in patients with type 1 diabetes in the POWER2DM and usual care group. c. Outcomes of blinded continuous glucose monitoring in patients with type 2 diabetes in the POWER2DM and usual care group. Orange: % of time >13.9 mmol/L. Yellow: % of time 10.1-13.9 mmol/L. Green: % of time 3.9-10.0 mmol/L. Bright red: % of time 3.0-3.8 mmol/L. Dark red: % of time < 3.0 mmol/L.



ESM Figure 6: Diabetes self-management.
a. DSMQ-R score (diabetes self-management) over the course of the study (POWER2DM: n=111, usual care: n=115). b. DSMQ-R score over the course of the study in patients with type 1 diabetes (POWER2DM: n=54, usual care: n=54). c. DSMQ-R score over the course of the study in patients with type 2 diabetes (POWER2DM: n=57, usual care: n=61). Data are mean, 95% CI. White circles represent the POWER2DM group. Black squares represent the usual care group.



ESM Figure 7: Diabetes self-management of blood glucose.
a. DSMQ-R BG score (diabetes self-management of blood glucose) over the course of the study (POWER2DM: n=111, usual care: n=115). b. DSMQ-R BG score over the course of the study in patients with type 1 diabetes (POWER2DM: n=54, usual care: n=54). c. DSMQ-R BG score over the course of the study in patients with type 2 diabetes (POWER2DM: n=57, usual care: n=61). Data are mean, 95% CI. White circles represent the POWER2DM group. Black squares represent the usual care group.



ESM Figure 8: Technology Acceptance.
a. Technology Acceptance Questionnaire (TAQ) subdomain scores of patients in the POWER2DM group at the end of the study (n=84). b. Technology Acceptance Questionnaire (TAQ) subdomain scores of patients with type 1 diabetes in the POWER2DM group at the end of the study (n=45). c. Technology Acceptance Questionnaire (TAQ) subdomain scores of patients with type 2 diabetes in the POWER2DM group at the end of the study (n=39). Data are mean, 95% CI. Performance expectancy: the degree to which patients believe that using the system will help them attain gains or make losses with the performance of their health management. Effort expectancy: the degree of ease associated with the use of the system. Social influence: the degree to which patients perceive that important others believe they should use the system. Facilitating conditions: the degree to which patients believe that there are objective factors available in their environment to support their use of the system. Affect: patients' overall affective reaction towards the system. Self-efficacy: the degree to which patients judge themselves capable of using the system to manage their health. Trust: the degree to which patients believe that using the system will occur in a safe and reliable manner. Behavioral intention: the degree to which an individual intends to use the POWER2DM system for managing their health. Motivation: the degree to which an individual is motivated to continue the POWER2DM system for managing their health. Self-management: patients' opinion on conducting self-management through the system

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8

Increased stress, weight gain and less exercise in relation to glycemic control in people with type 1 and type 2 diabetes during the COVID-19 pandemic

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ABSTRACT

Introduction

Lockdown measures have a profound effect on many aspects of daily life relevant for diabetes self-management. We assessed whether lockdown measures, in the context of the COVID-19 pandemic, differentially affect perceived stress, body weight, exercise and related this to glycemic control in people with type 1 and type 2 diabetes.

Research design and methods

We performed a short-term observational cohort study at the Leiden University Medical Center. People with type 1 and type 2 diabetes ≥ 18 years were eligible to participate. Participants filled out online questionnaires, sent in blood for HbA1c analysis and shared data of their flash or continuous glucose sensors. HbA1c during the lockdown was compared to the last known HbA1c before the lockdown.

Results

In total 435 people were included (type 1 diabetes n=280, type 2 diabetes n=155). An increase in perceived stress, anxiety, weight gain and less exercise was observed in both groups. There was improvement in glycemic control in the group with the highest HbA1c tertile (type 1 diabetes:-0.39% (-4.3 mmol/mol) ($p<0.0001$ and type 2 diabetes: -0.62% (-6.8 mmol/mol) ($p=0.0036$). Perceived stress was associated to difficulty with glycemic control ($p<0.0001$).

Conclusions

An increase in perceived stress, weight gain and less exercise but no deterioration of glycemic control occurs in both people with relatively well controlled type 1 and type 2 diabetes during short-term lockdown measures. As perceived stress showed to be associated to glycemic control this provides opportunities for health care professionals to put more emphasis on psychological aspects during diabetes care consultations.

INTRODUCTION

The COVID-19 pandemic is not only a major health care crisis but also has a major impact on daily life worldwide. With currently no vaccine or treatment available, this viral pandemic results in a rapid increase in morbidity and mortality rates. So far over 63 million cases have been confirmed, resulting in almost 1.5 million deaths worldwide(1). Mortality rates from COVID-19 are highest in elderly people(2). Also people with diabetes mellitus have been identified to be at increased mortality risk(2). Often no distinction is made between type 1 diabetes and type 2 diabetes. But as other risk factors for adverse outcomes of COVID-19 such as elderly age, obesity, hypertension, and cardiovascular disease are very prevalent in type 2 diabetes, people with this diabetes subtype are considered to be at even higher risk(3).

In an attempt to control the outbreak many countries implemented lockdown measures(4). Lockdown strategies diverged from lockdown of cities, regions or countries to voluntary home curfews, travel restrictions and prohibition of public and social events(5). These measures resulted in major changes in daily life and social behavior. Such sudden and major disruptions in everyday life are known to influence both physical and mental health(6).

The alterations in behavioral patterns, daily life and exercise as well as increased feelings of stress and anxiety are all known to influence diabetes self-management and glycemic control(7-14). Also a change in diabetes care by health professionals further increased the importance of adequate self-management behavior of people with diabetes mellitus. Thus several factors coincided that challenged maintenance of glycemic control during the lockdown measure. It is unclear how the lockdown has a differential impact on people with type 1 and type 2 diabetes and whether the presence of additional risk factors for severe outcomes of COVID-19 in these people plays a role.

METHODS

People with type 1 and type 2 diabetes that were treated at the diabetes outpatient clinic of the Leiden University Medical Center were invited to participate. Other inclusion criteria were age ≥ 18 years, sufficient comprehension of the Dutch language and ability to perform fingerpricks and complete an online questionnaire. People that were pregnant, recently (≤ 6 months) diagnosed with a malignancy,

receiving immuno- or chemotherapy, or admitted to a hospital or rehabilitation center were excluded from participation.

Lockdown period and measures taken

Lockdown measures were implemented in the Netherlands on March 15, 2020 by the government. These measures included stay-at-home orders for people working in non-vital areas of society, social distancing and closures of schools, restaurants, bars and public spaces. A sudden reduction in mobility around the workplace (40%) and in the context of retail and recreation (40%) and an increase in mobility around residential grounds (20%) occurred immediately after March 15 as shown by mobility data of the Dutch population validating the effect of the lockdown measures(15). Because of the measures taken and the results of the mobility data, March 15 was considered the start of the lockdown period. Data were collected eight to eleven weeks after the start of the lockdown period. During the entire data collection period the lockdown measures were maintained.

Assessment of the impact of the lockdown period

After informed consent was provided participants received a link to the online questionnaire via e-mail. The online questionnaire consisted of multiple items to assess the impact of the lockdown on glycemic control and medication use, daily routines, physical activity and psychological stress, including the 'Perceived Stress Scale' (PSS) (**supplementary table 1**)(16).

An HbA1c fingerprick set was sent to the participant's home in order to prevent visits to the hospital. This set consists of a small tube, a lancet and return medical envelope. Via a fingerprick a small amount of capillary blood was collected in a tube by patients at home, which was then sent to the hospital laboratory by mail(17). This is a validated and well established measuring method for HbA1c analysis, providing identical results compared to HbA1c measurements in venous blood samples(18).

HbA1c 8-11 weeks (interval median (IQR) 65 (61 to 71) days) after the start of the lockdown period was compared to the last known HbA1c before March 15, 2020 (interval median (IQR) 178 (137 to 218) days before the start of the lockdown).

For people with type 1 diabetes using a continuous glucose monitor (CGM) or flash glucose monitor (FGM) data were analyzed during two weeks before the lockdown period (February 24th until March 8th) and 6 weeks after the start of the lockdown period (April 24th until May 7th). Online data sharing platforms were used to gain access to those data. If participants were on holiday during one or both of these

weeks prior to the lockdown period, they provided the data of two adjacent regular weeks prior to the lockdown period. As a recent start of FGM or CGM can improve glycemic control, people that had started CGM or FGM within two months of the start of the lockdown period were excluded from glucose sensor data and HbA1c analysis. CGM or FGM data were used to calculate time below range (% of time glucose < 4.0 mmol/L), time in range (% of time glucose 4.0-10.0 mmol/L), time above range (% of time glucose ≥ 10.0 mmol/L), the coefficient of variation (% CV), the time of active use (% of time) and the average number of scans per day (n).

This study was approved by the Medical Ethics Committee of Leiden, Den-Haag, Delft under the Medical Research Involving Human Subjects Act (WMO) prior to the start of the study (NL73778.058.20).

Statistical analysis

Differences in questionnaire outcomes between people with type 1 and type 2 diabetes were analyzed using Chi-squared tests. The change in glycemic control was analyzed by paired t-tests. Differences in change in HbA1c between people with type 1 diabetes and type 2 diabetes were analyzed using unpaired t-tests. Regression analyses were used to assess associations between glycemic parameters, BMI and outcomes on lifestyle, insulin use, glucose regulation and stress. Confidence intervals of the regression coefficients are reported. People were divided into tertiles based on their HbA1c prior to the lockdown period and associations with questionnaire outcomes were analyzed using ordinal logistical regression analysis. We performed complete case analyses. STATA 14.2 was used to perform the analyses.

RESULTS

A total of 435 participants (42% female) were included (type 1 diabetes n=280, type 2 diabetes n=155) (**table 1**). A basal-bolus regimen was used by 76.8% and basal insulin only by 8.3% of people. People with type 2 diabetes were on average 12.3 years older and had a higher BMI (**table 1**). The prevalence of cardiovascular complications, elevated systolic blood pressure and use of blood pressure lowering agents was higher in people with type 2 diabetes (**table 1**).

Table 1. Baseline characteristics

	Type 1 diabetes (n=280)	Type 2 diabetes (n=155)
Age, mean (SD), years	50.1 (±14.9)	62.5 (±11.6)
Sex, n (%), female	129 (46.1)	54 (34.8)
BMI, mean (SD), kg/m^2	25.9 (±4.3)	30.2 (±6.1)
Level of education, n (%)*		
Low	9 (3.4)	4 (3.0)
Middle	98 (37.0)	73 (54.5)
High	158 (59.6)	57 (42.5)
Living situation, n (%)		
Alone	41 (15.5)	23 (17.2)
Co-habitating	242 (84.5)	111 (82.8)
Duration of diabetes, mean (SD), years	27.5 (±15.1)	15.8 (±9.3)
Glucose-lowering medication, n (%)		
None	1 (0.4)	6 (4.0)
Metformin	11 (4.0)	105 (67.7)
SGLT-2 inhibitors	0 (0.0)	15 (9.7)
Sulfonylurea derivatives	1 (0.4)	38 (24.5)
GLP-1 receptor antagonists	1 (0.4)	25 (16.1)
Basal insulin only	8 (3.0)	25 (18.9)
Basal-bolus insulin regimen	256 (96.6)	49 (37.1)
Glucose monitoring, n (%)		
None	3 (1.1)	29 (21.6)
Blood glucose monitoring only	62 (23.4)	91 (67.9)
Flash or continuous glucose monitoring	200 (75.5)	14 (10.5)
Complications, n (%)		
None	58 (20.7)	21 (13.6)
Retinopathy	189 (68.2)	86 (56.2)
Lasercoagulation	61 (22.1)	19 (12.5)
GFR ≥G2†	120 (44.4)	92 (67.7)
Albuminuria (A1-A3)	27 (12.2)	33 (30.6)
Peripheral neuropathy	69 (25.4)	62 (40.0)
Cardiovascular complications‡	66 (23.9)	77 (49.7)

Table 1. *(continued)*

	Type 1 diabetes (n=280)	Type 2 diabetes (n=155)
Kidney transplantation, n (%)	3 (1.1)	3 (1.9)
Blood pressure, mean (SD), mmHg		
Systolic blood pressure	133 (±18)	138 (±17)
Diastolic blood pressure	78 (±8)	79 (±9)
Blood pressure lowering medication, n (%)		
None	171 (61.7)	45 (29.0)
ACE inhibitors	59 (21.3)	41 (26.5)
Angiotensin receptor blockers	25 (9.0)	43 (27.7)
Calcium antagonists	36 (13.0)	232 (20.7)
Alpha blockers	5 (1.8)	15 (9.7)
Beta blockers	30 (10.8)	50 (32.3)
Diuretics	39 (14.1)	38 (24.5)
Mineralocorticoid receptor antagonists	7 (2.5)	4 (2.6)
LDL cholesterol, mean (SD), mmol/mol	2.41 (±0.78)	2.25 (±1.01)
Lipid lowering medication, n (%)		
None	164 (59.2)	61 (39.4)
Statins	109 (39.4)	92 (59.7)
Ezetimibe	11 (4.0)	11 (7.1)
Smoking, n (%)		
No	239 (89.5)	126 (88.7)
Occasional[§]	7 (2.6)	3 (2.1)
Regular[||]	21 (7.9)	13 (9.2)
Pulmonary comorbidities, n (%)		
Asthma, COPD or lung fibrosis	16 (5.8)	20 (12.9)
Other medication, n (%)		
Immunosuppressive agents	14 (5.1)	13 (8.4)
Antidepressive agents	17 (6.2)	12 (7.7)

*Education: low (elementary school), intermediate (elementary school plus high school and practical education), high (college or university), †measure for chronic kidney function, GFR≥2 = GFR<89 ml/min/1.73m228, ‡Myocardial infarction/PCI/peripheral vascular disease/stroke/TIA/heart failure or amputation of toe/foot/leg, §Occasional smoking: ≥ 1x/week29, ||Regular smoking: ≥ 1x/day29. BMI: body mass index, COPD: chronic obstructive pulmonary disease, GFR: glomerular filtration rate, GLP-1: glucagon-like peptide-1, LDL: low-density lipoprotein, SD: standard deviation. SGLT-2: sodium-glucose co-transporter-2.

Stress, weight change and exercise

In total 399 participants completed the questionnaire on daily routines, physical activity, psychological stress and participant's glycemic control and medication use.

During self-lockdown 34.1% of all participants reported elevated stress (**figure 1**), without any difference between people with type 1 and type 2 diabetes (33.6% vs. 35.1%, Perceived Stress Score: 13.7 (±6.2) vs. 12.8 (±6.7) respectively). A change in perceived stress was associated with a change in HbA1c (CI:0.015;0.38, p=0.034). People who reported more difficult glycemic control experienced higher stress during the lockdown period (CI:0.41;0.83, p<0.0001) and needed more insulin than before the lockdown period (CI:1.35;2.08, p<0.0001). Furthermore, 27.3% of all participants reported elevated levels of anxiety (**figure 1**), without any difference between people with type 1 and type 2 diabetes (27.5% vs 26.9%). Anxiety for COVID-19 infection was not associated with the change in HbA1c.

Furthermore, 40.9% of the participants reported weight gain and 45.7% reported less exercise than before (**figure 1**). Only 12% of the participants reported a loss of weight and 10% of the participants reported more exercise. Less exercise was associated with weight gain during the period of self-lockdown (p<0.0001). The change in exercise or weight gain was not associated with the change in HbA1c (CI-0.20;0.05, p=0.25 and CI: -0.002;0.39, p=0.053, respectively).

Impact of lockdown measures on glycemic control

HbA1c was slightly lower in people with type 1 diabetes in the lockdown period (pre-lockdown 7.68%±1.2 (60.4±12.7 mmol/mol) vs. lockdown 7.52%±1.1 (58.7±12.2 mmol/mol), p<0.0001) but not in people with type 2 diabetes (**figure 2a**). Glucose monitoring data reflected this improvement in HbA1c in people with type 1 diabetes. Time in range (TIR) was higher (pre-lockdown 60.5% vs. lockdown 63.4%, p=0.0009) and time above range (TAR) was lower (pre-lockdown 34.6% vs. lockdown 32.1%, p<0.003) (**figure 2b**). Glucose variability did not change. There was more frequent active glucose monitoring with an increase in the number of FGM scans per day (pre-lockdown 9.6 (±6.5) vs. lockdown 11.8 (±8.1) scans/day, CI: -3.81;-0.58, p<0.01) in people with type 1 diabetes indicating more focus on self-management.

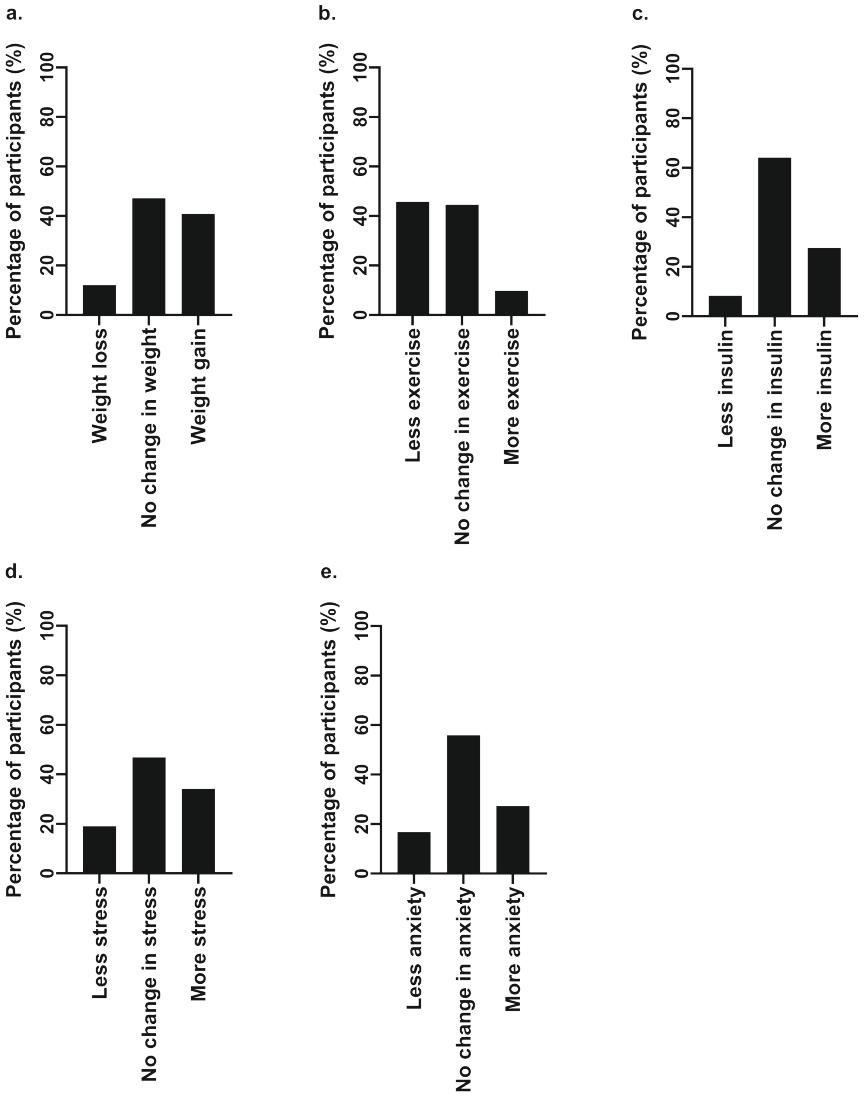

Figure 1. Change in self-reported weight (a), exercise (b), insulin use (c), perceived stress (d) and anxiety (e) during the lockdown period. a) Weight loss: sum of percentage of participants in different categories of weight loss (supplementary table 1). Weight gain: sum of percentage of participants in different categories of weight gain (supplementary table 1). c) Less insulin: sum of percentage of participants in different categories of less insulin use. More insulin: sum of percentage of participants in different categories of more insulin use. d) Less stress: sum of percentage of participants in categories of less stress. More stress: sum of percentage of participants in different categories of more stress. e) Less anxiety: sum of percentage of participants in different categories of less anxiety. More anxiety: sum of percentage of participants in different categories of more anxiety.

Both people with type 1 and type 2 diabetes that were in the highest pre-lockdown tertile of HbA1c (type 1 diabetes: HbA1c 8.13-12.18%, type 2 diabetes: HbA1c 8.16-12.72%) showed improvement in HbA1c (type 1 diabetes:-0.39%, CI: 0.22;0.55 %, p<0.0001, type 2 diabetes:-0.62%, CI:0.22;1.03 %, p=0.0036) (**figure 2c**). Proportionally more people with type 1 diabetes in the highest HbA1c tertile group showed improvement in HbA1c compared to people with type 2 diabetes in that tertile (**figure 2d**).

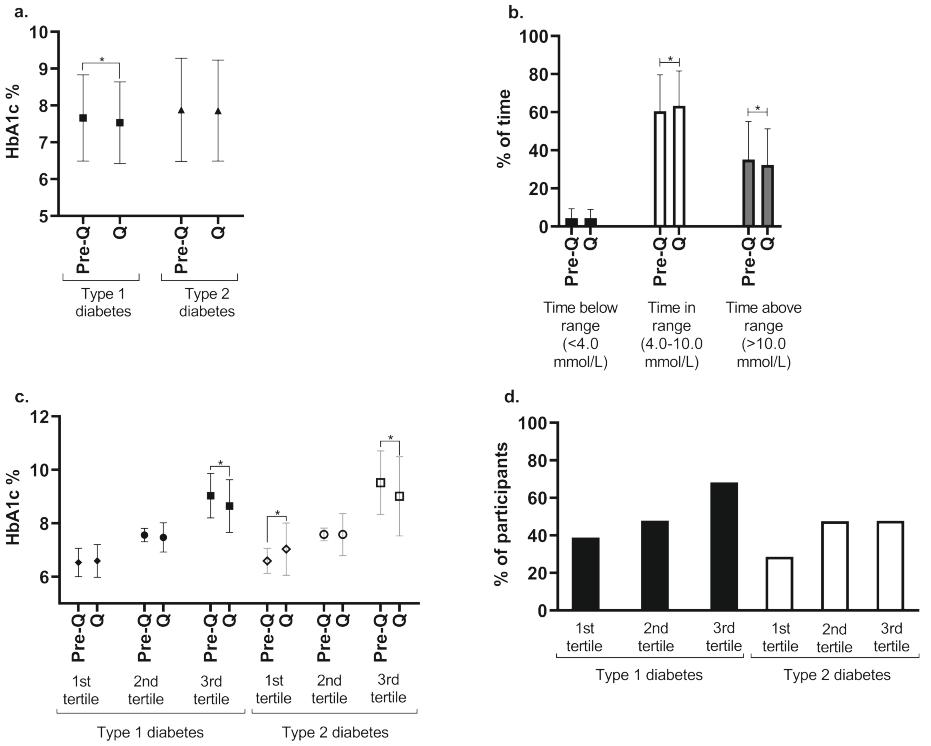

Figure 2. a) HbA1c before the lockdown period (pre-Q) and during the lockdown period (Q) in people with type 1 diabetes and type 2 diabetes. b) Ambulatory glucose profiles before and during the lockdown period in people with type 1 diabetes (n=90). c) HbA1c per tertile before (pre-Q) and after (Q) the lockdown period in people with type 1 diabetes and type 2 diabetes. 1st tertile: T1DM: HbA1c 4.92-7.22%, T2DM: 5.43-7.20%, 2nd tertile: T1DM: 7.23-8.09%, T2DM: 7.23-8.02%, 3th tertile 3: T1DM: HbA1c 8.13-12.18%, T2DM: HbA1c 8.16-12.72%. d) Percentage of people with type 1 and type 2 diabetes with improvement of HbA1c per tertile. HbA1c was available for 339 participants.

Risk factors for a more severe outcome of COVID-19

BMI, presence of cardiovascular disease, systolic blood pressure or use of blood pressure lowering agents was not associated with a change in stress or HbA1c during the lockdown period.

DISCUSSION

People with diabetes mellitus are considered a high risk population prone to a complicated course of COVID-19 and associated mortality(19). Here we show that in people with relatively well controlled type 1 and type 2 diabetes the COVID-19 pandemic and lockdown measures increased stress and resulted in weight gain and less physical exercise during this short observational period. However, despite these factors no deterioration in glycemic control was observed.

Previous research has shown a lockdown to be associated with increased levels of emotional distress and anxiety(5 6), which is in line with our findings. Distress, as well as changes in daily structures and behavior, which were inevitable due to the lockdown period, are known to influence diabetes self-management and glycemic control(7-10). Adding to this challenge of maintaining glycemic control was the increased emphasis on diabetes self-management due to a shift to COVID-19 care and social distancing rules in hospitals, which led to cancellations of face-to-face consultations, and the use of telemedicine. The small overall improvement in HbA1c in people with type 1 diabetes (-0.16%) may be statistically significant but clinically not relevant. Together with an increase in scans of glucose sensors these results indicate an increased focus on self-management. However, it should be noted that seasonal variation in glycemic control has been shown and higher temperatures are associated with lower HbA1c(20,21). Thus the small improvement in glycemic control could be due to a seasonal variation in our and other studies. Our results also indicate that the presence of more risk factors for a severe outcome of COVID-19, such as a higher BMI, cardiovascular comorbidities and hypertension, was not associated with stress, anxiety or change in HbA1c.

One of the main strengths of our study is the large study population, consisting of both people with type 1 and type 2 diabetes. We were able to assess changes in psychological stress, body weight and exercise providing important insight in participant's daily life during the lockdown period and knowledge about potential opportunities for improvement of diabetes care. The large study population allowed us to investigate these factors both in people with good and poor glycemic control, and we used both HbA1c and glucose monitoring data. For people with type 1 diabetes our findings are in line with flash glucose monitoring data in a small group of 55 people, in which a small improvement in time in range and time above range was observed(22).

A limitation of the study is the reliance on self-reported data due to restricted access to health facilities during the lockdown period. Self-reported data about weight change are often an underestimation of the actual change in weight(23). So the proportion of participants that increased in weight may be even larger. Furthermore, whilst HbA1c reflects glycemic control during the previous three months, the lockdown period had only been going on for eight to eleven weeks at the time that the HbA1c measurement was performed and may underestimate the impact of lockdown on glycemic control. It should also be noted that most of the people with diabetes that participated in the study were relatively well controlled. In addition, most participants with type 2 diabetes used insulin. Therefore, the results are not representative for all people with diabetes, especially for people with type 2 diabetes as the majority of them do not need insulin treatment and are treated in primary care.

Poor glycemic control is considered a risk factor for adverse outcomes of infections(24-26). Although no data are available, the message that poor glycemic control poses a higher risk is often conveyed to people in the context of COVID-19(27). We found a decrease of HbA1c in the group with the poorest glycemic control. People that experienced most difficulty with glycemic control also experienced more stress. Potentially people with the poorest glycemic control may have put more emphasis on glycemic control in order to cope with the increased stress levels, ultimately improving their HbA1c values during the lockdown period. However, also for this subanalysis seasonal effects in HbA1c cannot be completely excluded.

In conclusion, our short-term observational study shows that lockdown measures resulted in increased levels of perceived stress, weight gain and less exercise in both people with relatively well controlled type 1 and type 2 diabetes, however this did not negatively impact glycemic control. Additional risk factors for adverse outcomes of COVID-19, including poor glycemic control, do not appear to influence this effect. Since a third of the participants reported elevated levels of stress, associated with difficulties in glycemic control, diabetes care professionals should take these aspects into account when discussing diabetes self-management and well-being during consultations.

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SUPPLEMENTARY MATERIAL

Supplementary questionnaire 1. Questionnaire about the impact of the quarantine on patients' glycemic control and medication use, daily routines, physical activity and psychological stress and anxiety.

Since March 2020 the government has pronounced some rules and restrictions in order to halt the spreading of the coronavirus pandemic. From March 15th on all Dutch citizens were asked to stay at home and work from home as much as possible and perform social distancing. We are interested in which way these rules and restrictions have impacted the lives of patients with diabetes, a high risk population according to the RIVM.

1. Do you feel like your glucose regulation has changed during the period of self-quarantine?

☐ No, my glucose regulation remained the same
☐ Yes (chose one of the options below)
  ☐ Keeping my glucose values stable is much easier
  ☐ Keeping my glucose values stable is somewhat easier
  ☐ Keeping my glucose values stable is somewhat more difficult
  ☐ Keeping my glucose values stable is a much more difficult

2. Did the amount of insulin you use change during the period of self-quarantine? *(Only applicable for patients using insulin to regulate their diabetes)*

☐ No, I use the same amount of insulin as before
☐ Yes (chose one of the options below)
  ☐ I use much more insulin
  ☐ I use somewhat more insulin
  ☐ I use somewhat less insulin
  ☐ I use much less insulin

3. Do you feel like your weight has changed during the period of self-quarantine?

☐ No, my weight remained the same
☐ Yes (chose on of the options below)
  ☐ I gained weight
    ☐ 1-2 kilograms
    ☐ 3-4 kilograms
    ☐ ≥ 5 kilograms

- ☐ I lost weight
  - ☐ 1-2 kilograms
  - ☐ 3-4 kilograms
  - ☐ ≥ 5 kilograms

4. On a scale from 1-10, how anxious have you been to get infected with the coronavirus during the last 6 weeks?
VAS-scale 1-10

5. Have you experienced a change in stress since the start of the period of self-quarantine?
☐ No, my stress level remained the same
☐ Yes (chose one of the options below)
  - ☐ I experienced much less stress
  - ☐ I experienced somewhat less stress
  - ☐ I experienced somewhat more stress
  - ☐ I experienced much more stress

6. Have you experienced a change in anxiety since the start of the self-quarantine period?
☐ No, my anxiety level remained the same
☐ Yes (chose one of the options below)
  - ☐ I experienced much less anxiety
  - ☐ I experienced somewhat less anxiety
  - ☐ I experienced somewhat more anxiety
  - ☐ I experienced much more anxiety

7. How was your living situation prior to the period of self-quarantine? (chose one of the options below)
☐ I lived alone
☐ I lived with my partner
☐ I lived with my partner and children
☐ I lived with my children
☐ I lived with my parents
☐ I lived with my roommates

8. Did anything change regarding your exercise activities?

☐ No, my exercise activities remained the same

☐ Yes

- ☐ I exercised less than before
- ☐ I exercised more than before

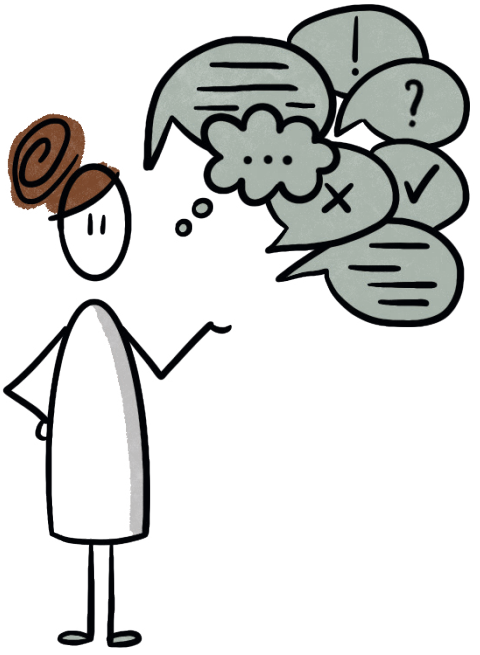
Supplementary table 1. Impact of the quarantine on participant's glycemic control and insulin use, weight, exercise, and psychological stress and anxiety

	All patients (n=399)	Type 1 diabetes (n=265)	Type 2 diabetes (n=134)	P-value
Change in ability to regulate glucose (%)				0.03
Much easier	6.5	7.9	3.7	
Somewhat easier	13.3	15.1	9.7	
No change	49.1	46.8	53.7	
Somewhat more difficult	24.1	25.3	21.6	
Much more difficult	7.0	4.9	11.2	
Change in insulin use (%)				0.07
Much less insulin	0.9	0.4	2.3	
Somewhat less insulin	7.4	8.4	4.6	
No change in insulin	64.1	61.2	72.7	
Somewhat more insulin	23.9	26.6	15.9	
Much more insulin	3.7	3.4	4.6	
Change in weight (%)				0.002
Weight loss ≥ 5 kilograms	2.0	0.4	5.2	
Weight loss 3-4 kilograms	2.5	2.3	3.0	
Weight loss 1-2 kilograms	7.5	6.8	9.0	
No change in weight	47.1	50.2	41.0	
Weight gain 1-2 kilograms	29.6	32.1	24.6	
Weight gain 3-4 kilograms	8.8	6.4	13.4	
Weight gain ≥ 5 kilograms	2.5	1.9	3.7	

Supplementary table 1. *(continued)*

	All patients (n=399)	Type 1 diabetes (n=265)	Type 2 diabetes (n=134)	P-value
Change in exercise (%)				0.46
Less exercise than before	45.7	43.4	50.0	
No change in exercise	44.5	46.9	40.2	
More exercise than before	9.7	9.7	9.8	
Change in stress (%)				0.35
Much less stress	7.0	7.9	5.2	
Somewhat less stress	12.3	14.0	8.2	
No change in stress	46.9	44.5	51.5	
Somewhat more stress	27.8	27.2	29.1	
Much more stress	6.3	6.4	6.0	
Change in anxiety (%)				0.60
Much less anxiety	5.3	5.7	4.5	
Somewhat less anxiety	11.5	12.8	9.0	
No change in anxiety	55.9	54.0	59.7	
Somewhat more anxiety	24.6	25.3	23.1	
Much more anxiety	2.8	2.3	3.7	
PSS total score (mean, SD)[a]	13.3 (±6.5)	13.7 (±6.2)	12.8 (±6.7)	0.16

[a]Perceived Stress Scale: scores ≥ 14 indicate moderate distress. P value for difference between T1DM and T2DM.



9

General discussion

GENERAL DISCUSSION

Making diabetes care fit

Diabetes care relies predominantly on the patient's diabetes self-management in daily life(1). It is therefore of major importance that the patient's care plan fits seamlessly within one's daily routines(2-5). To make care fit, patients and clinicians (a term we use capaciously to include any professional with the privilege of directly participating in the patient's care) need to collaborate and share information, knowledge, insights and preferences; a process often referred to as 'shared decision making' (SDM)(6). With the growing evidence favoring SDM and the emphasis of healthcare shifting more towards person-centered care, SDM is currently broadly advocated by major leading diabetes institutions(7).

Whilst SDM is increasingly gaining momentum, a clear consensus of what is or should be considered SDM still lacking(8), resulting in an ongoing debate. One of the most often used definitions is that SDM is a stepwise, collaborative process for preference-sensitive decision making, that is, for when multiple treatment options are available and the decision depends on the patient's preferences(9). In line with this definition, experts describe SDM to consist of four consecutive steps: 1) fostering choice awareness, 2) presenting potential treatment options together with their pros and cons, 3) clarifying the patient's preferences, and 4) reaching a final decision(10). Defined this way, researchers found SDM to be rare in clinical practice(11, 12). Clinicians, on the contrary, report to engage in SDM routinely(13). This discrepancy may (in part) be explained by a mismatch between what 'SDM' looks like in practice, and how SDM is defined and measured from a theoretical point of view. Hartasanchez et al. indeed recently showed that observer-based SDM instruments to assess the occurrence of SDM, fail to measure collaborative decisional processes other than the ones focusing on weighing alternatives(14). Furthermore, a systematic review by Kunneman, et al. found that studies assessing SDM in clinical practice are often primarily focused on measuring SDM technique – on taking the right steps in the correct sequence and at the right time – leaving the humanistic interactional features of collaboration and communication mostly unacknowledged and almost always unevaluated(15). We may therefore highly underestimate the efforts made by patients and clinicians collaborating, aiming to resolve meaningful, human problems in daily clinical practice. For SDM to be embraced by patients and clinicians, and for SDM to be a helpful strategy in trying to make care fit in real-life, it is important that the definition and construct of SDM reflect these aspects relevant to successful patient-clinician collaboration.

This thesis aimed to explore patient and clinician efforts towards **making diabetes care fit**.

In this exploration we aimed to provide *insight* in the factors driving the decision making process, discuss various *strategies* to tailor SDM to the patient's situation, needs and preferences, and explore ways to *support* the patient and the patient-clinician partnership in diabetes care.

This thesis argues that SDM is not limited to situations requiring weighing of alternatives. To our opinion, SDM is apparent in every conversation where a patient and clinician uncover or develop a shared understanding of the patient's (problematic) situation and figure out together how to improve this situation. When broadening the scope of SDM to reflect this collaborative work, and in line with recent developments in a new SDM framework called 'purposeful SDM', SDM was found to be common in clinical practice. Patient-clinician collaborations in clinical practice often consisted of a flexible dance between multiple SDM forms and SDM steps, without following a specific order. Personal factors showed to be of major importance for the decision making process. These factors may change within a conversation or within the course of life and living, especially in response to extreme conditions such as the coronavirus pandemic. Personalized, inclusive e-health systems can be helpful to create insight in the patient's unique situation and to provide diabetes self-management support that fits the individual patient. This may help ease the work of being a patient and reduce (part of) the continuous burden of disease and treatment the patient has to shoulder on a daily basis.

In this chapter, we will discuss our main findings, reflect on the methods we have used and highlight implications for research and clinical practice.

The patient-clinician collaboration

When consulting a clinician, most patients do not seek help in making a decision, but rather seek care, compassion and help to resolve their (problematic) situation(6). In the viewpoint in **chapter 2** we argue for the collaboration between patients and clinicians to be a flexible dance with multiple possible methods and foci, such as SDM and minimal disruptive medicine (MDM). During this conversational dance, patients and clinicians aim to clarify or uncover the (problematic) situation of the patient, and co-create a fitting, sensible and kind response. Patients and clinicians serve as two complimentary experts: the patient as the expert in terms of the impact of care decisions on their life and living and the clinician as the medical expert(16). Technological advances, self-management support tools and patient

communities may help ease the work of being a patient. However, these should be used in a mindful way, taking into account the patient's capacities to use and incorporate these technologies, in order to create a fitting response.

Factors in decision making

To help patients and clinicians engage in SDM and increase the likelihood that care plans fit the individual needs, values and preferences of the patient(17), understanding and eliciting the factors that drive care decisions is of major importance(18, 19).

In **chapter 3** we showed that, according to clinicians, for patients with type 1 and type 2 diabetes in secondary care, personal factors like quality of life, motivation, diabetes self-management skills, knowledge and opportunities and the patient's preferences were most likely to drive care decisions. This is not unexpected, given that diabetes care relies mostly on the patient's diabetes self-management and treatment adherence; aspects of care that are mainly affected by personal factors.

In line with our findings, Lutfey et al. showed already in 2008 that, in patients with (pre-) diabetes, clinicians predominantly considered the patient's cognitive, psychological and emotional functioning and its influence on health behavior, of importance for the decisional process(18). Lutfey et al. also reported that biological factors like age, gender and race were noted by clinicians, however these were only used to assess the patient's capacity to cope and self-manage their diabetes. Whilst the results of both studies suggest the importance of discussing personal factors during clinical consultations, these results should be interpreted with caution. Both Lutfey et al. as well as our study reported in chapter 3 of this thesis, report on pivotal factors as mentioned by clinicians, not by patients themselves. Whether these results accurately reflect the patient's viewpoint needs to be evaluated further. However, since personal factors, such as quality of life, are likely to be of major importance during the decision making process, measuring the quality of care merely by biomedical targets and success rates should be avoided. Biological targets will not reflect the true, meaningful contribution of the care provided to the life of the patient, nor do they acknowledge the efforts of patients and clinicians made during clinical encounters to make care fit. In addition, when focusing on biological targets, it is important to acknowledge that some patients will only be able to reach acceptable biological targets at the expense of those things in life that give them joy, and what makes life worth living in the first place(20, 21).

Problem-based shared decision making

In **chapter 4** we aimed to assess the prevalence and use of the multiple forms of problem-based SDM as proposed by Hargraves et al.(22) in clinical practice (**figure 1**). Problem-based SDM assumes that the most appropriate form of SDM depends on the problematic situation of the patient. It distinguishes four different forms of SDM: 1) providing alternatives from which one can be chosen, 2) negotiating about conflicting desires or views, 3) finding potential solutions for the problematic situation or 4) trying to gain a better understanding of the existential desires and needs of a patient(22). In a secondary analysis of a study conducted in the United States, we found that after broadening the scope of SDM to this spectrum of collaborative decision making processes, SDM was actually very common in primary diabetes care, with a prevalence rate of 86%. SDM used for weighing treatment alternatives, the form usually focused on when assessing SDM, accounted for only one third of the forms of SDM used. This study demonstrated that SDM processes other than those focusing on weighing alternatives are common in clinical practice. Furthermore, we found that patients and clinicians often applied multiple forms in one conversation; switching from one form of SDM to another during a clinical encounter.

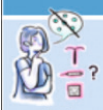
Example	Purpose: To resolve	SDM Method	Situation
 Birth control alternatives	Which alternative is best?	**Weighing**	It is uncertain what the harmful and beneficial **outcomes of alternative interventions** will be for a patient and their preferences
 How to give birth	What do we want, and can agree on?	**Negotiating**	**Desires** are ambiguous or in conflict between or **within** parties
 Complex or chronic care	How do we manage and resolve the current situation?	**Problem solving**	The **problematic human situation** and what to do about it is **intellectually, practically, and emotionally** fraught
 End of life	What ultimately matters?	**Developing insight**	The **humanity** of an individual or community is compromised or in existential transition

Figure 1. Situations that require patients/family and their clinicians to make decisions together and methods of SDM. (www.carethatfits.org, based on Hargraves, et al. Patient Education and Counseling, 2019(22)) Reprinted with permission from the author and publisher.

Since this study was performed in a population of patients with type 2 diabetes in primary care in the United States, it is however unclear whether these results can be translated to other populations or health care systems. It is likely that the type of health care setting, as well as the patient population treated, will affect to which extent each different form of SDM is used. For example, the form of SDM focused on gaining a better understanding of the existential desires and needs of a patient, is expected to be particularly prevalent in the context of life threatening or high-risk situations, such as at the intensive care unit. Further research is needed to explore how problem-based SDM is used in different clinical settings and across different patient populations.

To be meaningful, SDM needs to reflect the work that patients and clinicians do on a daily basis to collaborate, solving problems together and make care plans fit. This calls for a more inclusive approach towards SDM, something that was already advocated by Entwistle and Watt in 2016(23). With this, we do not plead against the construct of SDM as most often mentioned in literature, but rather in favor of broadening the scope of SDM to better reflect the variety of forms of SDM used in the real-life variability of clinical care.

It also should be emphasized that 'canonical SDM' and 'problem-based SDM' are not separate entities. Both make use of specific conversational elements to establish a collaboration. In **chapter 5** we show how the forms of problem-based SDM relate to the four steps of canonical SDM. We found all four SDM steps to be prevalent in each form of problem-based SDM. However, the emphasis on the different SDM steps differed per form of problem-based SDM. At the same time, the steps of SDM did not differentiate between the different forms of problem-based SDM. Additionally, in less than one in five conversations the normative order of SDM steps was followed; most often these were preceded or followed by other SDM steps. In the majority of encounters patients and clinicians went back and forth between different SDM steps within the conversation, as also observed for the forms of problem-based SDM. We hypothesize that these switches, this dance across SDM forms and steps, indicate patients and clinicians responding in a sensible way to the changing apparent situation, or needs or preferences of the patient, which are often dynamic and may arise and evolve as a response to information, options and considerations during deliberation(6, 24, 25). Newly voiced or changed preferences may require patients and clinicians to reevaluate and potentially adjust the form of SDM used, to better fit the situation. In **chapter 4** we indeed showed that preferences, desires or opinions voiced by patients or clinicians, often preceded a switch in the form of SDM used.

Supporting diabetes self-management in daily life

In **chapter 7** we assessed the effect of an integrated, personalized e-health support system (POWER2DM) on glycemic control, quality of life and diabetes self-management. This system combined two different interfaces: 1) a medical dashboard that could be used by the patient and clinician together, to support SDM and personal goal-setting, and 2) a self-management support system, that could be used by the patient at home, with connected wearables (pedometer, glucometer and intermittent use of a flash glucose sensor), automatic detection of potential barriers for self-management and automated, individualized reminders, feedback and psychoeducation. We found that POWER2DM improved glycemic control in patients with type 2 diabetes, improved quality of life in patients with type 1 diabetes, and improved diabetes self-management in both patients with type 1 and type 2 diabetes. Furthermore, the system was well accepted by patients, which is of major importance when aiming for meaningful and practice-relevant support.

The results of this study are in line with the findings of other studies investigating the effects of e- or m-health support for patients with diabetes(26-28). However, while e-health interventions have the ability to support patients in a meaningful way, most systems lack a personalized approach and fail to acknowledge the complex interaction of medical, psychological and behavioral factors that play a role in diabetes self-management(29-32), despite their clear linkage(33-37). POWER2DM aimed to bridge this gap by providing multifactorial, personalized e-health support for patients at home and patients and clinicians together in clinical practice.

Whilst our results are promising, our personal, integrated e-health support system can only be evaluated as a whole, acknowledging not only the benefits of the e-health support system, but also the impact of personal attention, psychological support and the effect of wearables like flash glucose monitoring and pedometers. However, to our opinion the inclusive character of the POWER2DM integrated e-health support system is the major strength of this intervention, as it reflects the realities of living with diabetes.

Globally, the COVID-19 pandemic has been one of the most challenging times of recent decades. During this pandemic, patients with diabetes, who often rely heavily on routines when managing their diabetes, were majorly affected by the measures taken to prevent the spread of the virus. Altogether, the disruptions in routines, increased feelings of stress and anxiety (especially being considered a high-risk population for a severe course of COVID-19 and mortality(38)), lack of social (peer)

support and changed access to diabetes care, increased the burden posed upon the patient even further, and challenged their coping skills and flexibility.

In **chapter 8** we assessed the effect of the COVID-19 pandemic on glycemic control, physical exercise, body weight, stress and anxiety in patients with type 1 and type 2 diabetes. We found that, whilst glycemic control remained stable, patients exercised less, their body weight increased and patients experienced more stress and anxiety. Perceived stress showed to be associated with difficulty in glycemic control.

Whilst being a surprise, especially with the increase in body weight, the finding that glycemic control was not negatively affected by the pandemic, was in line with the results of studies from e.g. Capaldo et al.(39), Fernandez et al.(40) and Beato-Víbora(41). The amount of psychological stress that patients experienced, however, was significantly increased. This increase in stress is an understandable, but worrisome development, since studies have shown that acute exposure to psychological stressors, such as social isolation and quarantine, often has a prolonged impact on psychological wellbeing(42). Whether the perceived stress found in our study may lead to a prolonged negative impact on wellbeing, would have to be assessed in future research.

Potentially limiting the generalizability of our results, is the fact that our study population consists of patients with well-regulated diabetes and who are motivated to invest in study participation. However, we believe that disruptions in daily life and changes in healthcare access, as seen during the COVID-19 pandemic, will affect patients with diabetes regardless of their glycemic control. Therefore identifying, addressing and caring for (psychological) issues that a patient may be facing, and supporting them in daily life while they navigate through this process, is of major importance when aiming for care that truly advances the patient's situation.

Making care fit as the golden standard

Creating space and time for patients and clinicians to engage in SDM and collaborate to form a fitting care plan should not be a luxury, but should be innate to clinical care. Whilst the amount of preferred involvement in the decision making process may vary between patients, studies have shown that the majority of patients prefer to participate in the decision making process(43-45). A study from Légare et al. has shown that patients who prefer a more passive role are often the most vulnerable patients, such as patients with low literacy(46) or low education(47). However, the reluctance of these patients to engage in the decision making process may mainly be driven by the fear of not making the 'right decision'. Especially in these populations,

explaining what SDM embodies and fostering SDM in clinical consultations is of major importance, since engaging in SDM has shown to be associated to an improved quality of life and better healthcare outcomes(48). Moreover, Légare et al. state that, restricting SDM to those individuals that most easily make and share decisions, often the patients that received the highest education, increases inequity in healthcare(13). SDM, therefore, should not be a luxury, but should be offered to *all patients* in a way that fits the patient's situation and preferences, to increase the chance of providing well-fitting care.

Main implications

Clinicians, patients, researchers, educators and policy makers all play a role in advocating for and working towards well-fitting healthcare that is meaningful and kind.

Policy and practice

Clinical care and initiatives to improve care, such as clinical guidelines(49), are often primarily focused on caring for *patients like this,* instead of caring for *this particular patient*(6). Whilst this may advance care on a group level, this might not be true for the individual patient. When aiming to advance the situation of *this particular patient*, care plans should be carefully crafted to fit the individual patient, acknowledging the complex interweaving of a person's biography, biology and context.

SDM can be a helpful tool to tailor care plans to the individual patient and should therefore be part of daily practice. In **chapter 6** we proposed a simple, four-step method to help implement SDM in clinical practice. This method consists of four elements: 1) fostering conversation, 2) personally select and adapt the decision making process, 3) support SDM, and 4) evaluate and learn SDM. Within this process decision aids, guiding the patient through the information, usually in preparation of the encounter, (50, 51) or conversation aids, guiding the patient and clinician through the conversational steps of SDM, can be helpful.

Chapter 6, however, also emphasizes that, whilst SDM may be a helpful tool for patients and clinicians to engage in meaningful conversations, SDM alone is not sufficient when aiming for meaningful care(5). Meaningful care requires patients and clinicians to humanly connect, mindfully listen and sensibly respond to the situation(19). To allow patients and clinicians to create this human connection and create space for silence and emotions, they need to be given time for unhurried conversations. For unhurried conversations to take place, the allocation of meaningful time for patient-clinician conversations should be prioritized over efficiency and cost-effectiveness(52). This means that practice should prevent the

overscheduling and overburdening of both patients and clinicians, whilst clinicians should be aware of and invest in creating a space of trust and understanding. Policy, in turn, should shift away from imperatives that lead to the acceleration of consultations and should refrain itself from measuring the quality of care merely by targets and biomedical endpoints. In doing so, care can flourish, increasing the chance that the care delivered is meaningful, makes sense and fits the individual patient.

Education

The modern clinician is not only required to be a medical expert, but also an expert in communication. During the consultation, the clinician should be able to craft both the content of the SDM conversation as well as the form of SDM used, to the individual needs and situation of the patient. This requires a flexible, responsive and iterative conversational process of feeling the situation and mindfully responding; a conversational dance based on mutual respect, curiosity, humanity and empathy(53). Education and training should help clinicians to develop the analytic and communicative skills that are needed to do so. These educational and training programs should be embedded within the medical studies, but should also be provided throughout one's medical career, to help maintain communicative skills and awareness.

Research

We have shown that making care fit in clinical practice is often a messy process, requiring patients and clinicians to go back and forth between different SDM steps and SDM forms. This messiness is currently not sufficiently accounted for in SDM theories and measurement instruments. The current measurements for SDM, are mostly focused on the correct use of SDM technique(14, 15), measuring the occurrence, sequence and timing of the SDM steps. Measuring SDM in this way does not reflect the true efforts made by patients and clinicians towards meaningful SDM(15). It overemphasizes the importance of 'SDM technique' and is blind to the flexibility and rich forms of collaboration that patients and clinicians use within clinical practice to design care plans(15).

To further advance and support person-centered, well-fitting care, research should be focused on gaining a deeper understanding of the human process of collaboration and co-creation in care(15) and create new measuring instruments that account for the humanism and flexibility that characterizes patient-clinician collaboration in clinical practice.

It is only when research, methodology, education, policy and practice all align and reflect each other, that efforts towards improving healthcare communication, collaboration and SDM will be successful and fully integrated in care routines.

Conclusion

To advance healthcare, we must work towards a reality in which the patient is acknowledged to be a complex and unique individual; a person facing a human problematic situation, seeking help and understanding, instead of an object or diagnosis. To resolve the problematic situation, patients and clinicians need to elicit what matters to the patient and search for a sensible, well-fitting solution, taking into account the best available evidence.

Caring, therefore, is an art. It is not merely taking the steps of SDM, following guidelines and discussing evidence. Care is the art of humanly connecting, sensibly responding, mindfully listening and gauging the situation. A flexible dance between patients and clinicians, and a meaningful partnership. It is then, and only then, that personal care can flourish and can truly contribute to people's meaningful lives.

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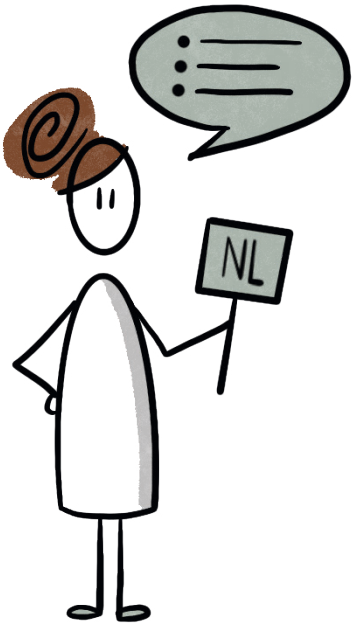
NL

Summary in Dutch
Nederlandse samenvatting

NEDERLANDSE SAMENVATTING

Hoofdstuk 1

Diabetes mellitus is een ziekte die wereldwijd veel voorkomt(1) en die zich kenmerkt door hoge bloedsuikerwaarden(2). Diabetes mellitus dient behandeld te worden, om schade aan zenuwen en bloedvaten te voorkomen. Deze behandeling vereist het continue afstemmen van medicatie, voeding en fysieke inspanning en het regelmatig meten van de bloedsuikerwaarden. Dit wordt diabetes zelfmanagement genoemd. Diabetes zelfmanagement vraagt veel tijd en discipline van de patiënt en interfereert vaak met de dagelijkse bezigheden(3, 4). Dit kan leiden tot een hoge zorglast(5), een vermindering van de kwaliteit van leven(6-8) en psychische problemen(9). De laatste decennia is op velerlei manieren gepoogd deze zorglast te verminderen. Voorbeelden hiervan zijn de inzet van technologische hulpmiddelen, zoals glucose sensoren en geautomatiseerde insulinepompen, nieuwe typen medicijnen en ondersteuning middels e-health en m-health (mobile health) systemen(10-12). Om effectief te zijn, is het echter belangrijk dat de zorg en ondersteuning aansluit bij de wensen en behoeften van de patiënt, oftewel passend is.

Passende zorg is zorg die inspeelt in op de unieke situatie van de patiënt. Het is zorg die past in het dagelijks leven van de patiënt, diens wensen en voorkeuren respecteert, en de patiënt niet overvraagt(13, 14). Het richt zich hiermee op het individu, niet op de zorg 'en masse'.

Om passende zorg te kunnen leveren zijn effectieve communicatie en een waardevolle connectie tussen de patiënt en zorgverlener essentieel. Gedeelde besluitvorming is een vorm van communicatie waarin de patiënt en zorgverlener beide participeren in het besluitvormingsproces (15, 16). Gedeelde besluitvorming kan patiënten en zorgverleners ondersteunen in het streven naar passende zorg.

Het belang van gedeelde besluitvorming en passende zorg is gedurende de afgelopen decennia breed onderkent en opgenomen in de richtlijnen omtrent diabeteszorg in Europa en de Verenigde Staten(17). Echter zijn vele vraagstukken omtrent de communicatie tussen patiënten en zorgverleners in de klinische praktijk tot op heden nog onbeantwoord gebleven. Inzicht in de communicatie tussen patiënten en zorgverleners en de mogelijkheden tot ondersteuning van het besluitvormingsproces, zullen de implementatie van persoonlijke, passende zorg in de klinische praktijk bevorderen, alsook het onderzoek, onderwijs en de beleidsvoering.

Het doel van dit proefschrift is het exploreren van de inspanningen van patiënten en artsen in het passend maken van zorg. Hierbij wilden we inzicht creëren in de factoren die belangrijk zijn in het besluitvormingsproces, verschillende strategieën bespreken om de vorm van gedeelde besluitvorming te laten aansluiten bij de patiënt, diens situatie en de wensen en voorkeuren van de patiënt, en verschillende manieren onderzoeken om de patiënt en de patiënt en arts samen bij de diabeteszorg te ondersteunen.

Hoofdstuk 2

Hoofdstuk 2 geeft een uiteenzetting van de ontwikkelingen in de communicatie tussen patiënt en zorgverlener over de tijd. Waar vroeger de zorgverlener bepaalde welke behandeling zou worden ingezet, bepalen de patiënt en zorgverlener heden meestal samen wat de beste behandelkeuze is voor de patiënt. Dit wordt ook wel gedeelde besluitvorming genoemd. Gedeelde besluitvorming kan gebruikt worden om de situatie, wensen en voorkeuren van de patiënt in kaart te brengen en samen met de patiënt een passend zorgplan op te stellen. Dit zorgplan dient gericht te zijn op de individuele patiënt en zo min mogelijk negatieve impact te hebben op het leven van de patiënt. Hoofdstuk 2 beschrijft verder welke barrières in het huidige zorgsysteem het leveren van passende zorg in de weg staan en geeft een duidelijke visie op de rol van effectieve arts-patiënt communicatie, een persoonlijke benadering, en het bieden van passende zorg, in het verbeteren van de kwaliteit van zorg.

Hoofdstuk 3

In hoofdstuk 3 wordt beschreven welke factoren een rol spelen in het maken van beslissingen over zorg. Om passende zorg te kunnen leveren, is het van belang om te weten welke factoren belangrijk zijn om te bespreken tijdens het consult. Zorgverleners rapporteerden dat, waar de zorg vaak primair gericht is op zorg gerelateerde factoren, zoals het behalen van doelen omtrent bloedsuikers of het voorkomen van de ontwikkeling of progressie van complicaties, voor patiënten juist persoonlijke factoren een belangrijke rol lijken te spelen in hun beslissingen over zorg. Met name de impact van de behandeling op de kwaliteit van leven, de voorkeur van de patiënt voor een specifieke behandeloptie, de gevolgen voor het diabetes zelfmanagement en de mate van motivatie van patiënten voor een bepaalde behandeling werden belangrijk geacht. Het is cruciaal dat zorgverleners aandacht hebben voor de rol van persoonlijke factoren van patiënten in het besluitvormingsproces, om de kans te vergroten dat de uiteindelijk gekozen behandelstrategie past bij de wensen, voorkeuren en verwachtingen van de patiënt.

Hoofdstuk 4

Gedeelde besluitvorming focust zich doorgaans op situaties waar meerdere, even goede behandelopties mogelijk zijn, en de voor- en nadelen van deze opties worden afgewogen. Wanneer gedeelde besluitvorming wordt gemeten, is dit dan ook vaak de enige vorm van gedeelde besluitvorming die wordt gemeten. Echter, maken patiënten en artsen in de dagelijkse praktijk in vele verschillende situaties samen beslissingen; situaties die zich niet beperken tot het wegen van meerdere, even goed geachte behandelopties. Het probleem waarmee de patiënt de arts consulteert, bepaalt hoe patiënten en artsen samenwerken om tot een oplossing te komen die het beste past binnen het leven van de patiënt. Hargraves et al. beschreven vier verschillende typen situaties waar gedeelde besluitvorming kan worden gebruikt om tot een oplossing te komen: 1) het wegen van verschillende, even goede behandelopties, 2) het onderhandelen bij niet overeenkomende wensen of verwachtingen, 3) het oplossen van een problematische situatie, en 4) het verkrijgen van existentiële inzichten. Hoofdstuk 4 beschrijft de prevalentie van deze verschillende vormen van gedeelde besluitvorming in de praktijk. Gedeelde besluitvorming kwam voor in 86% van de consulten. Het oplossen van een problematische situatie bleek in ons onderzoek de meest voorkomende vorm van gedeelde besluitvorming in eerstelijns diabeteszorg in de Verenigde Staten. Tevens toonde ons onderzoek dat artsen en patiënt vaak meerdere vormen van gedeelde besluitvorming in één consult gebruiken. Om van aanvullende waarde te zijn voor wetenschappelijk onderzoek, educatie, beleidsvorming en de medische praktijk, zou de definitie van gedeelde besluitvorming ons inziens een inclusieve reflectie moeten vormen van de samenwerking tussen patiënten en artsen.

Hoofdstuk 5

Hoofdstuk 5 focust zich op de relatie tussen de vier verschillende typen probleemgerichte gedeelde besluitvorming, zoals hierboven beschreven, en de vier stappen van gedeelde besluitvorming. Deze stappen omvatten: 1) het creëren van keuzebewustzijn, 2) het informeren over de verschillende behandelopties en hun voor- en nadelen, 3) het bespreken van de voorkeuren en overwegingen van de patiënt, en 4) het samen maken van de beslissing. In dit hoofdstuk laten we zien dat deze vier stappen van besluitvorming in elke vorm van probleemgerichte gedeelde besluitvorming tot uiting komen. De stappen differentiëren niet tussen deze verschillende vormen van besluitvorming. Tevens laten we zien dat de stappen van gedeelde besluitvorming in consultvoering zelden een vaste volgorde kennen en dat vaak niet alle vier de stappen onderdeel zijn van het consult.

Hoofdstuk 6

Hoofdstuk 6 betreft een opiniestuk waarin onze visie op de rol van gedeelde besluitvorming in de klinische praktijk wordt beschreven; elke vorm van samenwerking tussen patiënten en zorgverleners, waarin de zorgvraag wordt verduidelijkt en mogelijke passende reacties hierop worden geformuleerd. In het hoofdstuk beschrijven we de belangrijke rol van de patiënt in het formuleren van het probleem, waarvoor hulp wordt gezocht, en het exploreren van eventuele oplossingen in het licht van de unieke situatie en persoonlijke wensen en voorkeuren van de patiënt. Het hoofdstuk beschrijft handvatten en praktische adviezen voor zowel patiënten als zorgverleners om gedeelde besluitvorming onderdeel te maken van het regulier klinisch proces.

Hoofdstuk 7

In hoofdstuk 7 onderzoeken we het effect van een 'e-health' interventie (POWER2DM) als ondersteuning in de zorg voor patiënten met diabetes. Deze interventie bestaat uit een applicatie voor patiënten en zorgverleners, waarin biomedische, gedragsmatige en psychologische data worden gebruikt om inzicht te krijgen in de unieke situatie van de patiënt, doelen te stellen voor de toekomst en de progressie omtrent deze doelen te volgen. POWER2DM onderscheidt zich van andere applicaties door de verzamelde informatie niet alleen inzichtelijk te maken voor patiënten, maar ook voor hun zorgverleners, hetgeen de samenwerking en gedeelde besluitvorming kan ondersteunen. Tevens speelt POWER2DM in op de complexiteit van diabetes zorg en zelfmanagement, door zowel psychische, gedragsmatige en biomedische data te combineren, en levert het geautomatiseerde, doch persoonlijke herinneringen en feedback.

Het gebruik van POWER2DM leidde tot een verbetering in HbA1c (een maat voor de glucoseregulatie over de afgelopen 3 maanden) in patiënten met type 2 diabetes, een verbetering van de kwaliteit van leven in patiënten met type 1 diabetes, en een verbetering van het diabetes zelfmanagement in zowel patiënten met type 1 als type 2 diabetes. Het gebruik van POWER2DM was veilig en patiënten waren positief over het gebruik van POWER2DM in het dagelijks leven.

E-health kan een waardevolle bijdrage vormen aan de zorg voor patiënten, mits de geboden ondersteuning aansluit bij de wensen en behoeften van de patiënt en de complexiteit van het leven met een (chronische) ziekte reflecteert.

Hoofdstuk 8

Hoofdstuk 8 is een studie uitgevoerd in een unieke tijd: de coronavirus pandemie. In dit hoofdstuk beschrijven we het effect van de maatregelen ter preventie van de verspreiding van het coronavirus op de glucoseregulatie, stress, angst, het lichaamsgewicht en de fysieke inspanning bij patiënten met type 1 en type 2 diabetes. We vonden geen verslechtering van de glucoseregulatie 8 tot 11 weken na het ingaan van de maatregelen. Echter werd wel een toename gezien in angst, stress en lichaamsgewicht, alsook een vermindering van de fysieke inspanning. Verder bleek de stress die patiënten ervaarden, geassocieerd te zijn met een verslechtering van de glucoseregulatie.

Het bespreken van persoonlijke factoren zoals stress en angst en het bieden van passende zorg is van essentieel belang in tijden van verandering en onzekerheid, zoals de coronavirus pandemie.

Hoofdstuk 9

In deze discussie zetten we de studies opgenomen in dit proefschrift in perspectief en keren we terug naar het doel van dit proefschrift. Het leveren van zorg is complex. Om effectief te zijn, dient de geleverde zorg en ondersteuning aan te sluiten bij het probleem van de patiënt en de unieke situatie, diens voorkeuren en grenzen in acht houdende. Zorg dient passend en persoonlijk te zijn. Gedeelde besluitvorming kan helpen om de kans te op passende zorg te vergroten. Gedeelde besluitvorming is een samenspel tussen de patiënt en de zorgverlener; een samenwerking, waarin het probleem van de patiënt wordt verduidelijkt en samen gezocht wordt naar een passende oplossing. Essentieel voor deze samenwerking zijn het creëren van verbinding en vertrouwen, wederzijdse nieuwsgierigheid, het creëren van ruimte en tijd voor een ongehaast gesprek en luisteren met aandacht.

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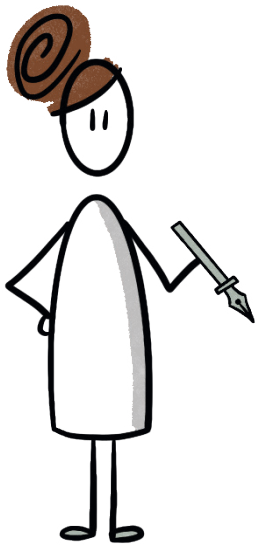


About the author

ABOUT THE AUTHOR

Merel Ruissen was born on September 6th 1992 in Eindhoven, the Netherlands. After completing the gymnasium at the 'Van Maerlant Lyceum' in Eindhoven, she moved to Leiden to study Medicine at Leiden University. During her study she participated in various student committees and, as part of the Leiden Student Counsel, won a grant for an initiative to support the integration of international students in Leiden (Leiden United Program). In 2016 Merel started her Master's in Medicine. She became interested in medical research and took a position as a student-researcher at the department of Internal Medicine, in the field of pancreatic islet transplantation.

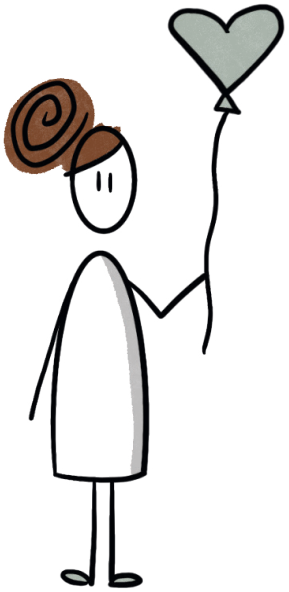
After obtaining her Master's degree in 2017, Merel continued her research to pursue a PhD at the department of Internal Medicine, division of Endocrinology, in collaboration with the department of Biomedical Data sciences, section of Medical Decision Making, supervised by Prof. Dr. Eelco de Koning, Dr. Jacob Sont and Dr. Marleen Kunneman. She conducted multiple large, (inter)national, multicenter, (randomized controlled) trials, and was part of the Leiden Islet Isolation (LEI) team, conducting pancreatic islet isolations and transplantations for people with type 1 diabetes.

In 2019, Merel was invited to work as a research collaborator at Mayo Clinic's Knowledge and Evaluation Research (KER) Unit. Under mentorship of Dr. Marleen Kunneman and Prof. Victor Montori, she further explored the concept of shared decision making, questioning pre-set rules, and eventually developed her own vision on healthcare communication and shared decision making.

To broaden her horizon, in 2020 Merel started collaborating with the department of Gastroenterology to assess the effect of fecal microbiota transplantation on liver fat accumulation and associated beta cell functionality. As part of this collaboration, she conducted a double-blinded randomized controlled trial in a cohort of patients with non-alcoholic fatty liver disease (NAFLD), under supervision of Dr. Maarten Tushuizen.

Mid 2022, Merel finished up her research and returned to the clinic as a physician at the department of Internal Medicine at the Alrijne Hospital (Leiderdorp). In 2023 she decided to change careers and started working as a physician at Basalt Rehabilitation Leiden. The holistic approach of Rehabilitation Medicine aligned with her own vision on medical care and sparked her enthusiasm. In 2023 she was accepted for the residency program in Rehabilitation Medicine. She will start her residency in March

2024. Merel aims to use the experience gained during her research to be a better, more human and mindful physician, a respectful collaborator that leaves sufficient room for patients to voice their thoughts, needs and preferences, and a competent doctor that helps to make evidence-based, well-fitting care plans.



Acknowledgements in Dutch

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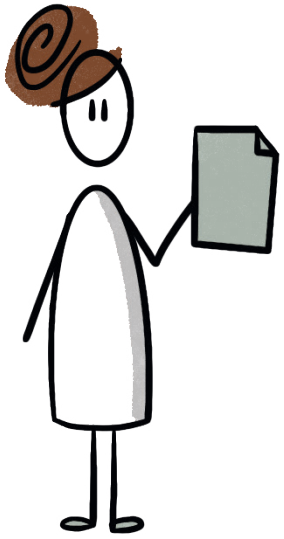

Appendix

LIST OF PUBLICATIONS

Ruissen MM, Torres-Peña JD, Uitbeijerse BS, Arenas de Larriva AP, Huisman SD, Namli T, Salzsieder E, Vogt L, Ploessnig M, van der Putte B, Merle A, Serra G, Rodríguez G, de Graaf AA, de Koning EJP, Delgado-Lista J, Sont JK; POWER2DM Consortium
Clinical impact of an integrated e-health system for diabetes self-management support and shared decision making (POWER2DM): a randomised controlled trial.
Diabetologia (2023)

Ruissen MM, Sont JK, van Vugt HA, Kunneman M, Rutten GEHM, de Koning EJP
Key Factors Relevant for Healthcare Decisions of Patients with Type 1 and Type 2 Diabetes in Secondary Care According to Healthcare Professionals.
Patient preference and Adherence (2022)

Ruissen MM, Montori VM, Hargraves IG, Branda ME, Léon García M, de Koning EJP, Kunneman M
Problem-based shared decision making in diabetes care: a secondary analysis of videorecorded encounters.
BMJ Evidence-Based Medicine (2022)

Ruissen MM, Rodriguez-Gutierrez R, Montori VM, Kunneman M
Making diabetes care fit – are we making progress?
Frontiers in Clinical Diabetes and Healthcare (2021)

Ruissen MM, Regeer H, Landstra CP, Schroijen MA, Jazet IM, Nijhoff MF, Pijl H, Ballieux BEPB, Dekkers O, Huisman SD, de Koning EJP
Increased stress, weight gain and less exercise in relation to glycemic control in people with type 1 and type 2 diabetes during the COVID-19 pandemic.
BMJ Open Diabetes Research and Care (2021)

Ruissen MM*, Mak AL*, Beuers U, Tushuizen ME, Holleboom AG
Non-alcoholic fatty liver disease: a multidisciplinary approach towards a cardio-metabolicliver disease.
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Montori VM, **Ruissen MM**, Branda ME, Hargraves IG, Kunneman M
Problem-based shared decision making: The role of canonical SDM steps.
Health Expectations (2023)

Montori VM, **Ruissen MM**, Hargraves IG, Brito JP, Kunneman M
Shared decision-making as a method of care.
BMJ Evidence Based Medicine (2022)

Perez-Corral I, Gomez-Delgado F, **Ruissen MM**, Torres-Peña JD, Arenas-de Larriva AP, Sont JK, de Graaf AA, Uitbeijerse BS, de Koning EJP, Delgado-Lista J
Sleep duration and lipid metabolism in patients with diabetes mellitus: from the POWER2DM study.
Sleep and Biological Rhythms (2022)

Ruissen MM, Keller JJ, Tushuizen ME
Interventions: 'Fecal Transplant'.
Chapter in: Visceral and ectopic fat (2022) Elsevier

*Shared first authorship.