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Making diabetes care fit: insights, strategies and support

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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.

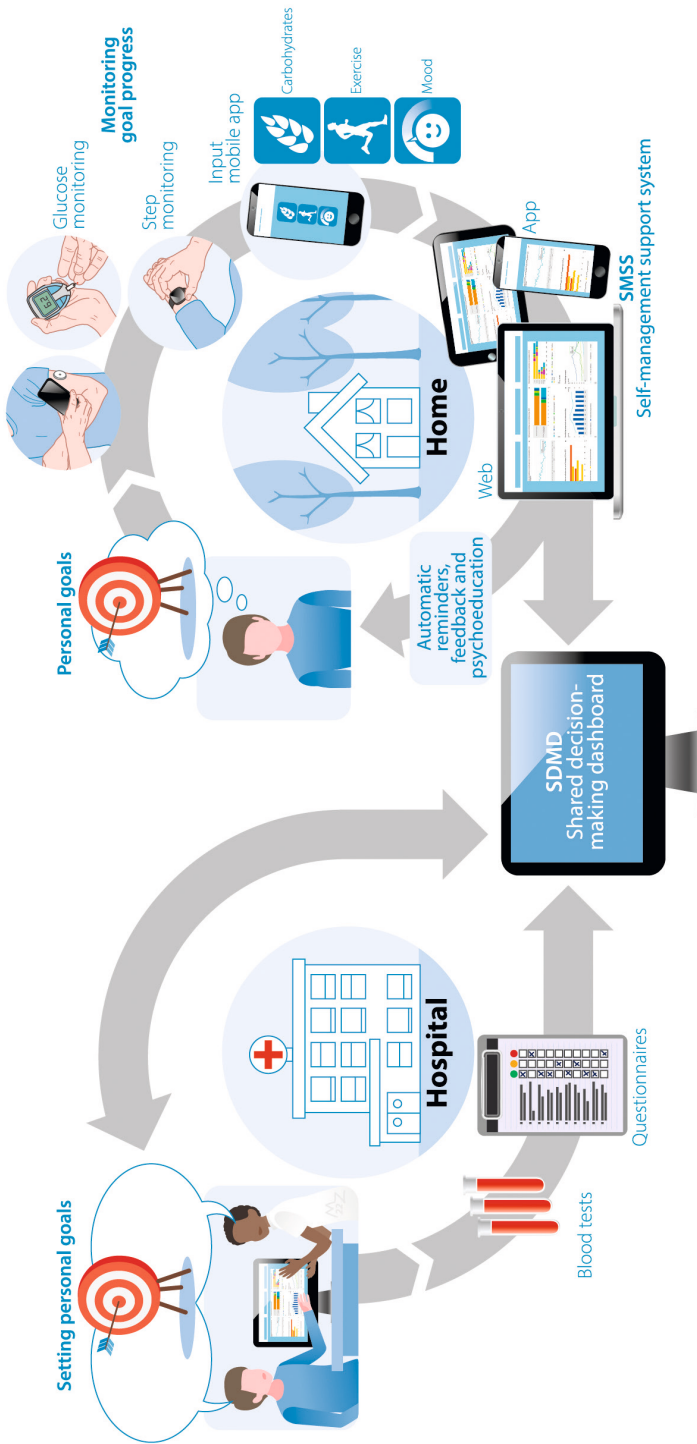


Figure 1. POWER2DM intervention. Personal goal setting is first carried out by the participant and the healthcare professional using SDM and the data from the POWER2DM SDMD during clinical consultation. The participant then tries to reach these personal goals through use of the POWER2DM SMSS and multiple 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 \geq 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 \pm 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**).

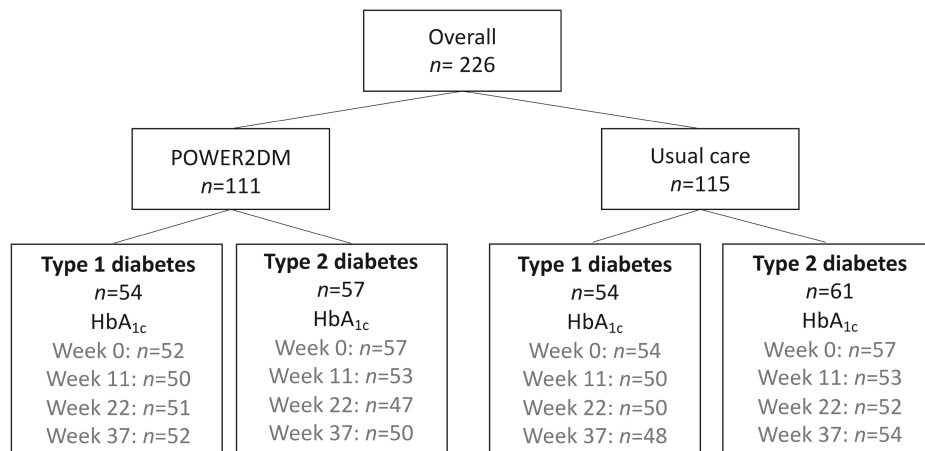


Figure 2. Flow chart showing the number of study participants in each group and the number for whom HbA1c data were available at each time point.

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

Table 1. (continued)

	Total group		Type 1 diabetes		Type 2 diabetes	
	Control	POWER2DM	Control	POWER2DM	Control	POWER2DM
	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 \pm 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 ($7.7 \pm 1.3\%$) to 56.7 ± 12.1 mmol/mol ($7.3 \pm 1.1\%$) 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, $7.8 \pm 1.3\%$; end of study: 61.0 ± 12.4 mmol/mol, $7.7 \pm 1.1\%$; $p = 0.19$) (**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, $7.9 \pm 1.6\%$; end of study: 54.3 ± 11.1 mmol/mol, $7.1 \pm 1.0\%$; $p < 0.001$) (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, $7.5 \pm 1.0\%$; end of study: 59.2 ± 12.7 mmol/mol, $7.6 \pm 1.2\%$; $p = 0.84$) (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: $62.8 \pm 20.5\%$; end of study: $68.2 \pm 19.7\%$; $p = 0.053$); however, a significant improvement in time between 10.0 and 13.9 mmol/l was observed (baseline: $21.6 \pm 11.6\%$; end of study: $17.9 \pm 12.1\%$; $p = 0.001$), together with a small but significant increase in time between 3.0 and 3.9 mmol/l (baseline: $3.7 \pm 3.8\%$; end of study: $6.3 \pm 6.0\%$, $p < 0.001$). 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: $59.3 \pm 22.4\%$; end of study: $64.5 \pm 21.2\%$; $p = 0.024$), a decrease in both time between 10.0 and 13.9 mmol/l (baseline: $22.0 \pm 11.7\%$; end of study: $17.3 \pm 12.3\%$; $p = 0.007$) and time above 13.9 mmol/l (baseline: $14.7 \pm 17.6\%$; end of study: $7.4 \pm 11.0\%$; $p < 0.001$), and an increase in time between 3.0 and 3.9 mmol/l (baseline: $3.9 \pm 3.9\%$; end of study: $5.6 \pm 5.3\%$; $p = 0.003$) and time below 3.0 mmol/l (baseline: $2.8 \pm 4.2\%$; end of study: $4.5 \pm 6.5\%$; $p = 0.004$) (**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 (**table 2 and ESM figure 5**).

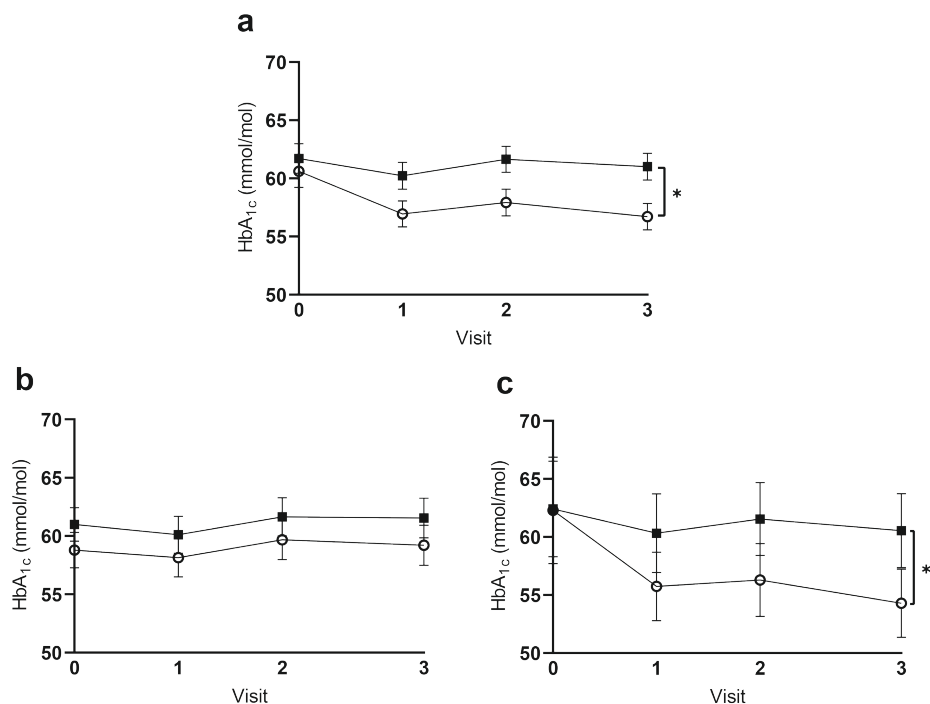


Figure 3. HbA_{1c} values at baseline and during follow-up. (a) HbA_{1c} values for the entire group (POWER2DM: n=111; usual care: n=115). (b) HbA_{1c} values for participants with type 1 diabetes (POWER2DM: n=54; usual care: n=54). (c) HbA_{1c} values for participants with type 2 diabetes (POWER2DM: 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															
	POWER2DM				Usual care				Type 1 diabetes				Type 2 diabetes			
	Baseline	End	Baseline	End	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)	4.0 (3.9)	4.5 (5.2)	4.9 (5.9)	0.9 (1.7)	0.9 (1.7)	2.7 (3.9)	2.7 (3.9)	1.3 (2.2)*	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)	5.8 (4.0)	5.0 (3.9)	5.4 (4.2)	2.1 (2.4)*	2.1 (2.4)*	6.7 (7.5)*	6.7 (7.5)*	2.9 (3.7)*	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)	56.6 (14.2)	52.6 (18.9)*	56.8 (16.4)*	69.6 (22.2)*	69.6 (22.2)*	79.2 (17.9)*	79.2 (17.9)*	65.2 (23.8)	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)	22.8 (9.4)	23.3 (10.1)*	19.6 (10.9)*	13.3 (13.4)*	13.3 (13.4)*	13.3 (12.6)*	13.3 (12.6)*	20.8 (12.8)*	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)†	12.9 (11.2)†	18.0 (16.8)*†	9.0 (11.2)*†	7.8 (11.2)	7.8 (11.2)	5.6 (11.0)	5.6 (11.0)	11.8 (17.8)*	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 $3.7\pm 3.8\%$ to $6.3\pm 6.0\%$; $p<0.001$) without a significant increase in time below 3.0 mmol/l (from $2.7\pm 5.2\%$ to $3.4\pm 3.9\%$; $p=0.43$). 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**).

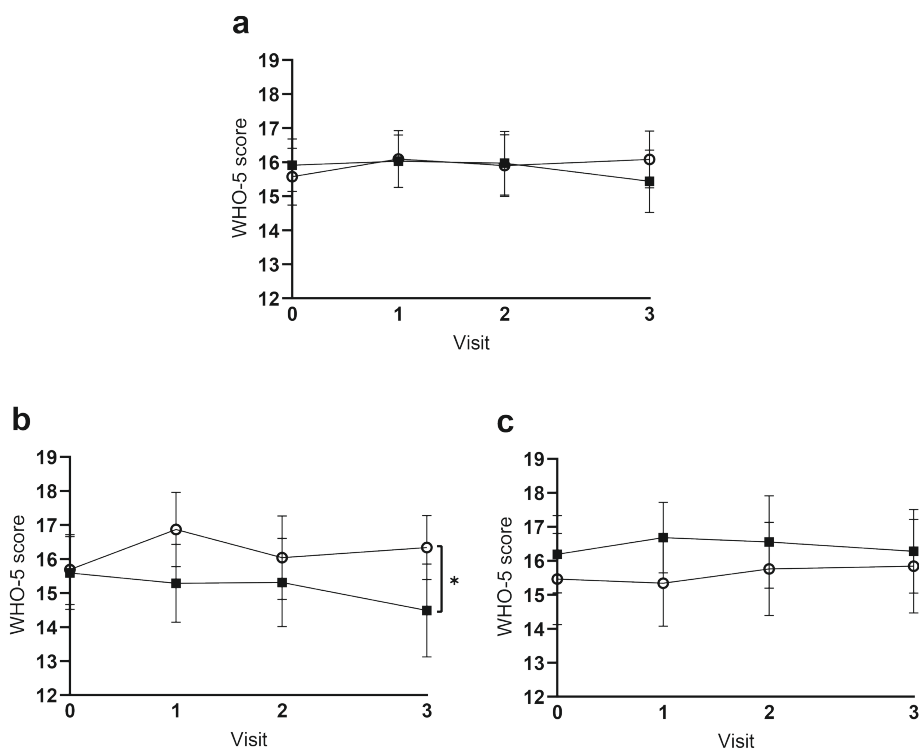


Figure 4. WHO-5 scores (possible range 0–25) for QoL over the course of the study. (a) WHO-5 scores for the entire group (POWER2DM: $n=111$; usual care: $n=115$). (b) WHO-5 scores for participants with type 1 diabetes (POWER2DM: $n=54$; usual care: $n=54$). (c) WHO-5 scores for participants with type 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 ($7.7 \pm 1.3\%$), 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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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

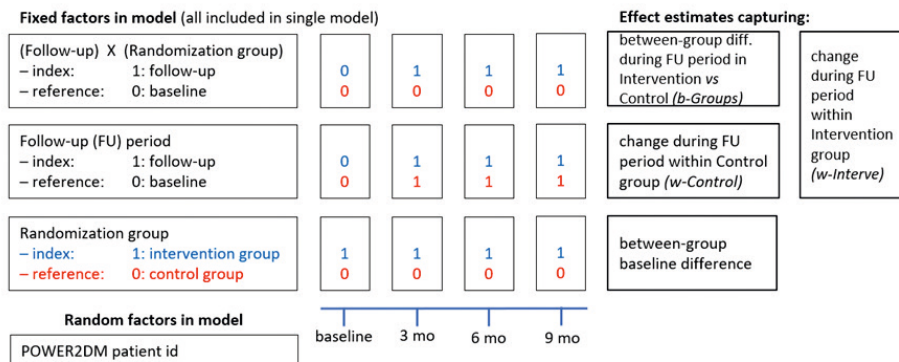
Sample size and power calculations

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

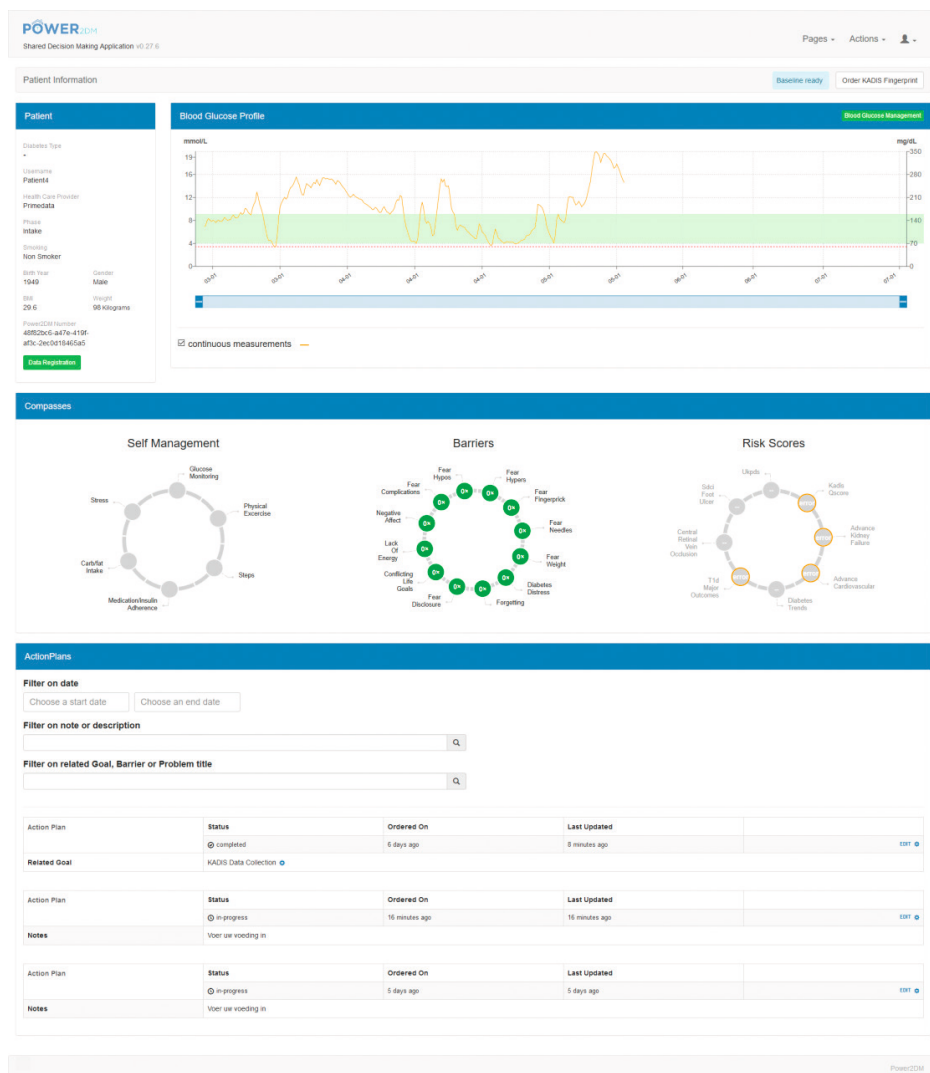
POWER2DM: n=54, usual care: n=54. P-value represents the between-group difference in effect over the study period between the POWER2DM and usual care group.
HDL: high density lipoprotein; l: liter; LDL: low density lipoprotein; mmol: millimol; SD: standard deviation.

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

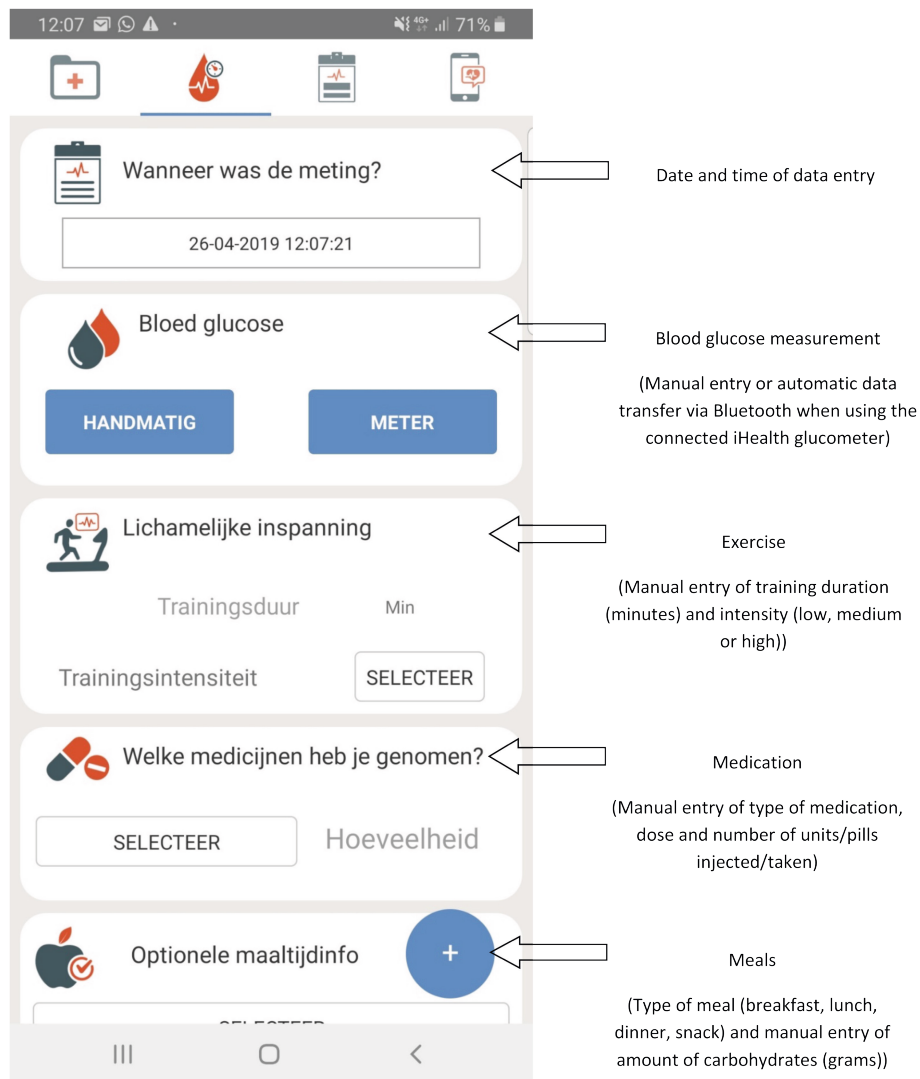
	Baseline (week 0)		Week 11		Week 22		End (week 37)		P-value
	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	Power2DM	Usual care	
Total cholesterol, mean (SD), mmol/l	4.47 (1.03)	4.45 (1.06)	4.27 (1.02)	4.45 (1.06)	4.27 (0.90)	4.47 (1.20)	4.16 (0.79)	4.24 (0.95)	0.18
LDL cholesterol, mean (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



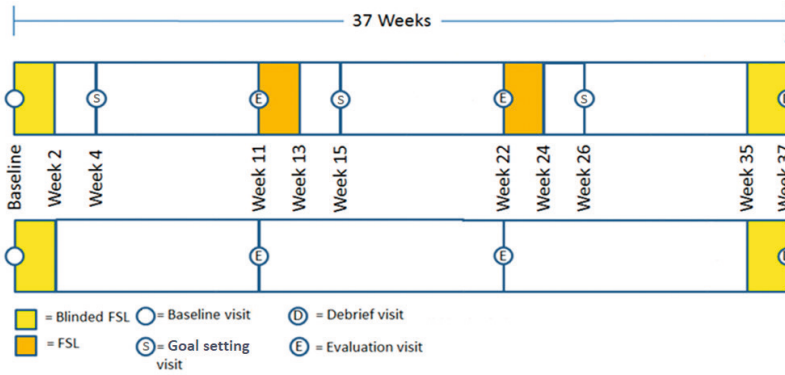
ESM Figure 1: Example of opening screen Shared Decision Making Dashboard (SDMD) application.



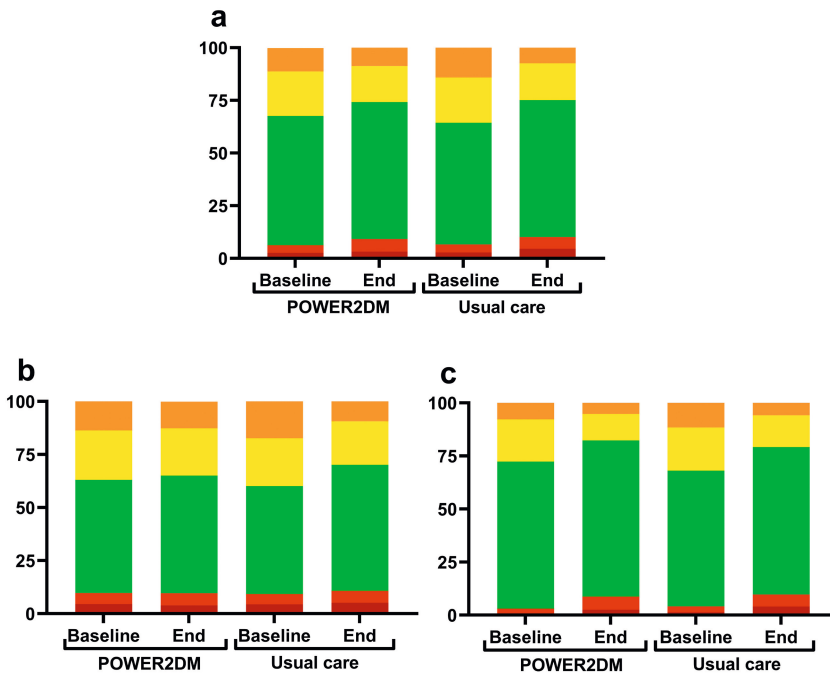
ESM Figure 2: Example of opening screen Self-Management Support System (SMSS) mobile application.



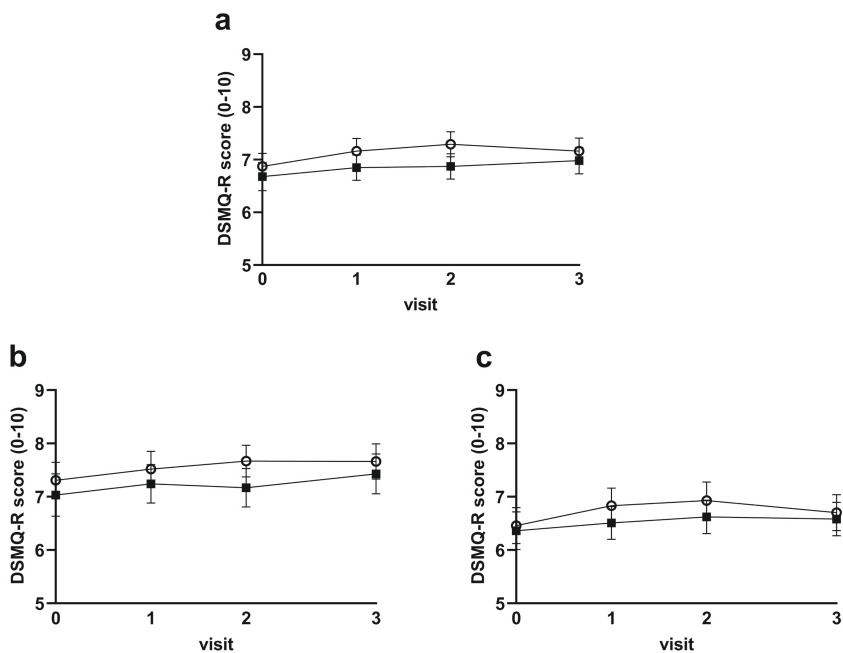
ESM Figure 3: Example of test participant calendar in Self-Management Support System (SMSS) application.



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).

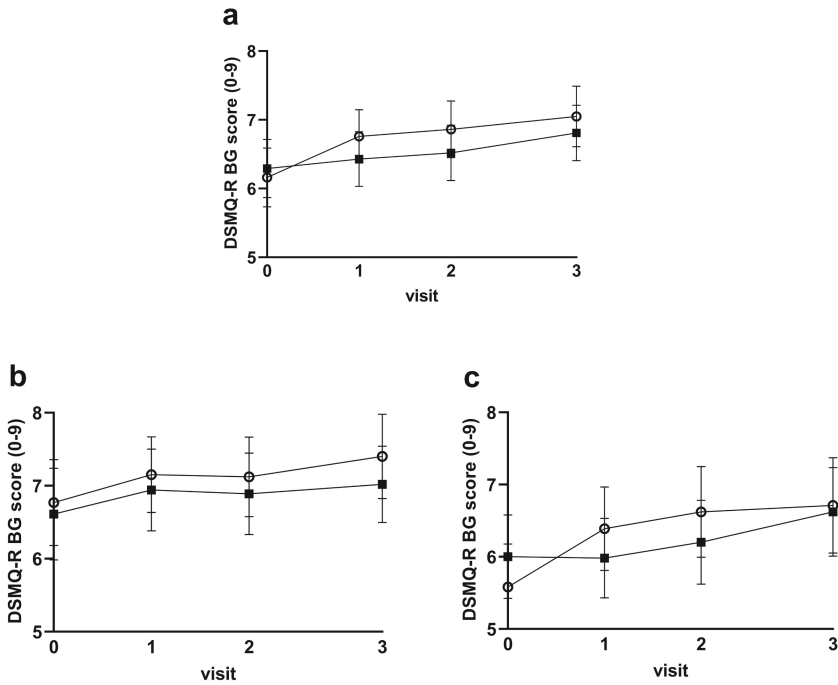


ESM Figure 5: Outcomes of blinded continuous glucose monitoring. a. Outcomes of continuous glucose monitoring measured by a blinded glucose monitoring device (FreeStyle Libre Pro) in the POWER2DM and usual care group. b. Outcomes of blinded continuous glucose monitoring in patients with type 1 diabetes 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.



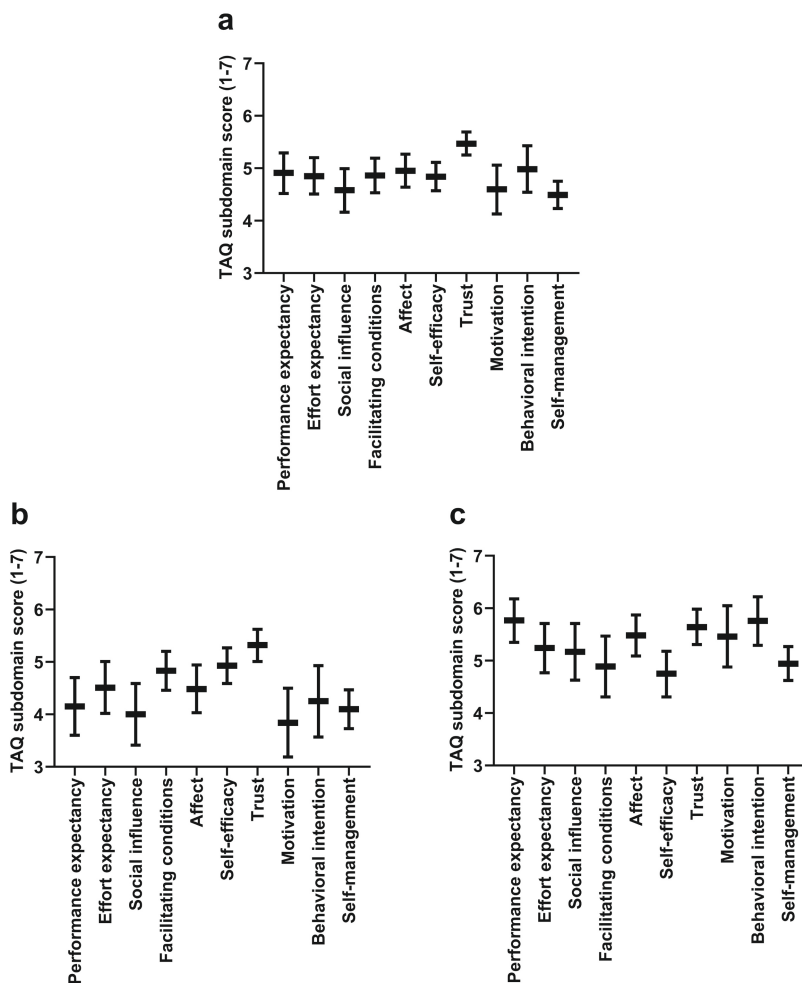
ESM Figure 6: Diabetes self-management.

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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