Effects of Patient-Initiated Visits on Patient Satisfaction and Clinical Outcomes in a Type 1 Diabetes Outpatient Clinic: A 2-Year Randomized Controlled Study

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Diabetes Care 2021;44:2277–2285 | https://doi.org/10.2337/dc20-3083

OBJECTIVE

We investigated the effects of replacing regular outpatient follow-up through prescheduled visits with patient-initiated visits on patient satisfaction and clinical variables of type 1 diabetes (T1D).

RESEARCH DESIGN AND METHODS

A 24-month randomized controlled trial in which adults with T1D were allocated to either patient-initiated unlimited access to outpatient visits or usual care through regular prescheduled visits. The primary outcome was seven patient-reported experience measures of patient satisfaction focused on benefit of consultation and accessibility of the outpatient clinic. Secondary outcomes included clinical variables of diabetes and use of staff resources.

RESULTS

We enrolled 357 outpatients (intervention, $n = 178$; control, $n = 179$). After 24 months, participants in the intervention group experienced more benefit from consultations compared with baseline within groups ($P < 0.05$) and fewer unnecessary visits compared with control subjects ($P < 0.05$). Patient needs covered and satisfaction with the outpatient clinic were high and unchanged in both groups, and accessibility was increased (three questions, all $P < 0.05$). A calculated 7-item patient satisfaction sum score favored the intervention group over control subjects ($P < 0.001$). There were no significant changes in glycated hemoglobin (HbA_{1c}), LDL, blood pressure, and complication status. The mean number of outpatient visits over 24 months (± SD) was lower in the intervention group compared with control subjects (4.4 ± 2.8 vs. 6.3 ± 2.7; $P < 0.001$), while the number of telephone contacts was higher (3.1 ±3.4 vs. 2.5 ± 3.2; $P < 0.001$).

CONCLUSIONS

Patient satisfaction remained high or improved with patient-initiated on-demand use of the diabetes outpatient clinic, with no decline in the quality of diabetes care, and a reduction in the use of staff resources.

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Received 19 December 2020 and accepted 18 June 2021

Clinical trial reg. no. NCT03083899, clinicaltrials.gov

This article contains supplementary material online at https://doi.org/10.2337/figshare.14810130.

National guidelines define treatment goals, but standards for the organization of diabetes outpatient clinics are less well defined. Outpatient management should be proactive rather than reactive, support self-management, and be quality-oriented in its broadest sense (1). The setup of diabetes outpatient clinics in Denmark involves preplanned visits, the timing and frequency of which may not take into account patients' needs and wishes and may therefore be suboptimal from the perspectives of patients and the health care system. Giving more responsibility to patients in the management of their disease can increase treatment adherence and quality of life (2) and thereby increase patient satisfaction with the outpatient health care management. One way to increase responsibility is through patient-initiated visits, which may better address patient needs and reduce the number of nonessential visits.

Previous primary care studies of patients with diabetes examining the value of patient-requested open access have either been retrospective cohort studies (3) or based on historic controls (4–6), and none focused on type 1 diabetes (T1D) or investigated patient satisfaction. In secondary care, randomized controlled trials (RCTs) of patient-initiated visits have been conducted for other chronic diseases, such as rheumatoid arthritis (7), inflammatory bowel disease (8), chronic obstructive pulmonary disease (9), and psoriasis (10); these studies showed unchanged or improved disease status and lower frequency of visits, with no change in patient satisfaction. However, patients with diabetes may be unaware of disease progression, and placing the responsibility of arranging visits on the patients can increase the risk of undetected progression of diabetes-related complications. To date, there have been no controlled trials evaluating the effect of patient-initiated visits in secondary care diabetes outpatient clinics on patient satisfaction and clinical outcomes.

The aim of our study was to test a new model of diabetes outpatient management for T1D in which there is a higher degree of self-planning in patients' use of the clinic. We hypothesized that decisions regarding the timing and frequency of visits could safely be transferred to patients and would lead to increased patient satisfaction without compromising the quality of clinical diabetes care.

RESEARCH DESIGN AND METHODS

Study Design

A study group of physicians, nurses, and patient representatives designed and modified the protocol after 10 interviews with patients with T1D.

We conducted a 24-month RCT at two diabetes outpatient clinics of the Medical Department, Endocrinology, at Hospital South West Jutland. More than 95% of all patients with T1D living in the urban uptake area of 225,000 inhabitants visit the clinics who managed all diabetes-related health issues.

The Regional Committees on Health Research Ethics for Southern Denmark (Vejle, Denmark) found that the study was not notifiable (S-20160177). The study was approved by the Danish Data Protection Agency (RSD-SVS-16/43148–18/25680) and is registered at ClinicalTrials.gov (NCT03083899). The study is reported in accordance with the Consolidated Standards of Reporting Trials guidelines.

Study Population

Consecutive patients screened between March 2017 and December 2017 were enrolled, and the last visit of the last patient was in December 2019. Inclusion criteria were T1D (ICD-10 DE10.x) for a minimum of 6 months; visiting our outpatient clinic; treatment with insulin injection or pump therapy; aged between 18 and 80 years; and internet user. Exclusion criteria were severe psychiatric illness, dementia, or other conditions that could compromise the patient's judgment of the need to visit the clinic or otherwise posed a safety risk; unstable late-onset diabetes complications (progressive retinopathy or current foot ulcers); increase in glycated hemoglobin (HbA_{1c}) level $>$2.7% (30 mmol/mol) within 3 months or $>$3.7% (40 mmol/mol) within 6 months; and planned or current pregnancy.

A diabetes specialist nurse or a physician screened the patients for eligibility during a routine visit. Eligible patients were invited to participate, and informed consent was obtained at a separate inclusion visit with a trial-associated project manager. We also invited eligible patients who declined participation to fill out a baseline questionnaire and grant access to their medical records.

Intervention

Participants were randomized 1:1 in blocks of four, stratified for insulin administration (pump/injection) and location of the outpatient clinic using REDCap software (Vanderbilt University, Nashville, TN), and followed for 24 months.

Danish citizens have free and equal access to primary and secondary care covered by government taxes. Patients with T1D have regular preplanned visits to specialized hospital outpatient clinics that are initiated by the physician deciding visits for the upcoming year with acceptance from the patient. This typically includes once-a-year visits with a physician preceded by examination of HbA_{1c}, LDL, and creatinine levels and urine albumin-to-creatinine ratio (uACR); one or two visits with a diabetes specialist nurse preceded by HbA_{1c} sampling; and visits with a dietitian when appropriate.

In the intervention group, all visits to the outpatient clinic were patient-initiated on demand with no prescheduled visits, and the participant could determine whether the visit would be with a diabetes nurse, physician, or dietitian. The participants had unlimited access and a time guarantee to request visits with the diabetes nurse within 1 week and with the physician (endocrinologist) or dietitian within 2 weeks. By default, the contact was made through their usual personal health care provider to maintain continuity. Additionally, participants could request blood HbA_{1c} testing. HbA_{1c} was measured prior to each visit, and HbA_{1c}, LDL, and creatinine levels and uACR were measured if $>$9 months had passed since the last test.

Participants could call the nurse during daily prespecified hours and request a phone call or visit by calling a secretary or by sending a secured e-mail or message via the patient portal Diabetes Online (IntraMed A/S, Ballerup, Denmark). To ensure that participants were actively considering their needs, they received a message stating the time

since their latest visit or HbA_{1c} test via the patient portal 6 months after their last visit and HbA_{1c} test, respectively, and every 3 months thereafter. Participants who did not read the messages, and had no visits for 6 months, were contacted by phone. Participants who did not respond or could not be contacted were excluded.

Participants in the control group received usual care through physician-initiated scheduled visits. They could call a nurse during daily prespecified hours and contact the secretary by phone or secured e-mail to request a phone call or a visit—however, without the time guarantee unless it was urgent. Routine examination of the eyes continued irrespective of group assignment.

In the patient portal, all patients could track their laboratory test results, blood pressure, body weight, complication status, record notes, and time since last visits. Participants in both groups attended a final visit with the physician 24 months (± 31 days) after enrollment.

Outcomes and Data Collection

The primary outcome was patient-reported measures of patient satisfaction with use of the diabetes outpatient clinic evaluated by seven single items (statements) focused at: *1*) satisfaction with affiliation to the outpatient clinic (S1, "I am satisfied with the outpatient clinic"); *2*) benefit of consultations (three items: S2, "I am satisfied with the benefit I derive from my consultations"; S3, "I have experienced unnecessary visits at the outpatient clinic"; and S4, "The outpatient clinic meets my needs related to diabetes treatment"); and *3*) accessibility of the outpatient clinic (three items: S5, "I can contact the outpatient clinic when needed"; S6, "I can get an appointment at the outpatient clinic when needed"; and S7, "I am satisfied with the different means of contacting the outpatient clinic [visit, phone, or e-mail]"). Measures were evaluated with a five-point Likert scale (1 is "strongly agree" to 5 is "strongly disagree" and "do not know"). The seven items were part of a larger multi-item questionnaire developed by the investigators, which also included one item of patient involvement, two items of diabetes distress, and four items of patient empowerment.

The questionnaire was face validated by seven health personnel and content validated for comprehensibility, relevance, completeness, acceptability, and feasibility by pilot testing by 10 patients with T1D (40% women; mean age, 52 years) based on observation of the respondents during questionnaire completion and cognitive interviews using an interview guide with open and closed questions. The questionnaire was iteratively modified until no further changes were needed. The seven single items were also summed to an overall score of patient satisfaction with a Cronbach alpha of 0.85 (range 0.81–0.89 for individual items deleted), indicating a high correlation and supporting a high face or construct validity of the items. We explored test-retest reliability in 31 patients with T1D. The 7-item sum score showed an intraclass correlation coefficient (two-way random-effects model) of 0.89, indicating excellent agreement and scores of the individual items of S1 = 0.79, S2 = 0.85, S3 = 0.54, S4 = 0.67, S5 = 0.53, S6 = 0.39, and S7 = 0.79.

Participants responded to the questionnaire before randomization and at the 24-month follow-up. Additionally, paticipants were asked at the end of the trial about their preferences for the outpatient clinic visit setup.

Secondary clinical outcomes were obtained by review of the patients' electronic health records (Cambio COSMIC, Cambio, Stockholm, Sweden; and BCC, CGI Canada, Montréal, Quebec, Canada). The number of contacts to the outpatient clinic was electronically extracted from the health record system using SAS Enterprise Guide (SAS Institute, Cary, NC) and checked for discrepancies. All visits to physicians (including the 24-month follow-up), nurses, and dietitians; phone calls; and nonattendances after the enrollment visit were extracted. Laboratory data and body weight and blood pressure measurements were obtained at inclusion (−2 to +1 month) and at the 24-month follow-up (−2 to +1 month). We also analyzed all HbA_{1c} test results obtained during the study.

Laboratory analyses included HbA_{1c}, LDL, and creatinine levels and uACR. Estimated glomerular filtration rate (in milliliters per minute) was calculated with the Cockcroft–Gault formula. uACR was classified as normal ($<30 \times 10^{-3}$ mg/g), microalbuminuria (30–300 mg/g), or macroalbuminuria (>300 mg/g).

Information about diabetes foot and eye complications was collected at the inclusion visit (−12 to +3 months) and at the end of the trial 24 months later (−12 to +3 months). Diabetic retinopathy was graded as normal, nonproliferative, or proliferative or laser-treated and categorized as regression, unchanged, or progression. Foot complications were reported as presence or absence of foot ulcers.

Statistical Analysis

We planned to screen all patients at our outpatient clinics and invite all eligible patients to test the impact of the new model of diabetes outpatient management. We estimated that 500 patients could participate; 357 were ultimately included. A post hoc power calculation based on measurement of the primary outcome suggested a power of 80% to estimate a 14–16% difference between the intervention and control groups (11).

Data were analyzed using STATA/SE-64 (StataCorp, College Station, TX) as intention-to-treat, in which data from noncompleting participants were included for time in the trial. Two-tailed tests were used, and P values <0.05 were considered statistically significant. Descriptive data are presented as mean ± SD unless otherwise noted.

Comparisons between study groups at baseline were carried out with the χ^2 or Fisher exact test as appropriate for categorical variables, t test for normally distributed continuous data, and Wilcoxon rank sum test for nonnormally distributed continuous data. Patient satisfaction evaluated with the Likert scale and changes within and between groups were analyzed by multilevel mixed-effects ordered logistic regression. As the rate of the response "do not know" did not exceed 15% for any question, the response was not included in the analyses. Sum scores were analyzed by mixed-model multilevel mixed-effects linear regression despite a minor skewness, due to ceiling values, that could not be circumvented by transformation.

Changes in continuous variables were analyzed by mixed-model multilevel mixed-effects linear regression. HbA_{1c} and LDL levels and blood pressure were

tested for noninferiority with one-sided tests; noninferiority upper limits were defined as HbA_{1c} <0.37% (4 mmol/mol), LDL <0.15 mmol/L, systolic blood pressure <5 mmHg, and diastolic blood pressure <3 mmHg. Comparisons between randomized groups at 24 months were performed with the χ^2 test or Fisher exact test as appropriate for categorical variables. Average HbA_{1c} based on all HbA_{1c} values was analyzed by multiple linear regression weighted by the number of measurements.

The number of contacts and HbA_{1c} tests were not normally distributed and were analyzed by Poisson regression controlled for exposure time in the trial. Descriptive data are presented as weighted means based on time in the trial. All regression analyses were adjusted for age, sex, diabetes duration (<5 or ≥5 years), and use of pump or injection therapy. Subgroup analyses by sex and age group (<50 or ≥50 years) were performed when relevant and tested for interactions.

RESULTS

We screened 848 of ∼900 patients with T1D. A total of 597 patients (70.4%) were found eligible; 240 declined participation and 357 agreed to participate (178 in the intervention group and 179 in the control group) (Fig. 1).

Screened patients had a mean age of 50 ± 17 years, and 40% were female (Supplementary Table 1). Almost all participants were Caucasian. The participants were slightly younger (48 ± 14 years) than noneligible patients (52 ± 20 years; $P < 0.001$) and eligible patients who declined participation (51 ± 16 years; $P < 0.05$); they also had a shorter history of diabetes than patients who declined participation, and 88% had had diabetes for >5 years. There were no differences between the two randomized groups in baseline characteristics (Table 1). In total, 25 participants in the intervention group and 10 in the control group dropped out of the trial; the most frequent reasons for discontinuation in the former were withdrawal of consent, pregnancy, and lack of response (Supplementary Table 2).

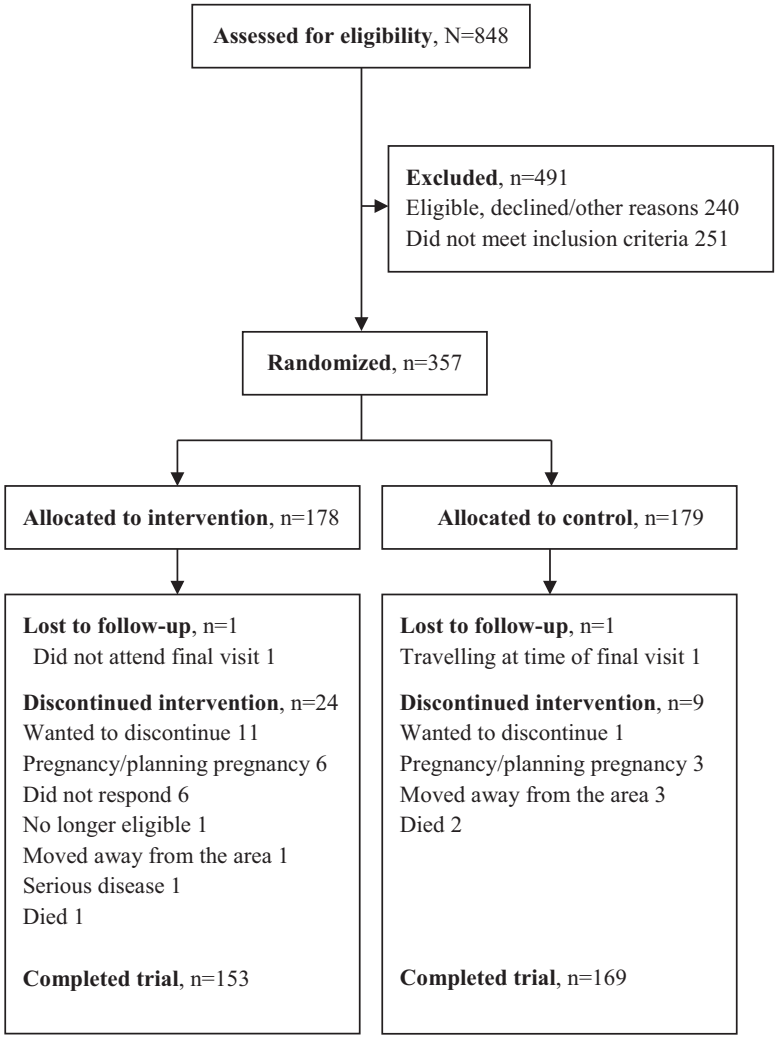

Figure 1—Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the study.

Patient Satisfaction and Preferences

Without any change during the trial within or between groups, >95% of participants agreed or strongly agreed that they were satisfied with the outpatient clinic (Item S1) (Table 2). The intervention group reported increased benefit from the consultations (Item S2, $P < 0.05$ [within group]) and had fewer unnecessary visits (Item S3, $P < 0.05$ [between groups]), while there were no differences in the patients' reports on needs in treatment met by the outpatient clinic (Item S4). Additionally, the intervention group reported greater accessibility of the outpatient clinic (Items S5–S7). The calculated seven-item sum scores were similar at baseline, but increased in the intervention group at end of trial ($P < 0.001$). Upon completion of the trial, 58% (82 of 142 questionnaire respondents) in the intervention group preferred the patient-initiated setup to preplanned regular visits. In the control group, only 20% (27 of 136) expressed a preference for the patient-initiated setup ($P < 0.001$) (Supplementary Table 3). The results did not differ between sex or age groups except for a more pronounced preference for the physician-initiated routine setup in patients ≥50 years of age in the control group (Supplementary Tables 3 and 4).

Patients in the intervention group reported feeling more involved in the management of their diabetes compared with the control group ($P < 0.05$). There were no between-groups differences in patient empowerment and diabetes distress (Supplementary Table 5).

Clinical Outcomes

HbA_{1c} and LDL levels and blood pressure were similar at baseline, unchanged throughout the trial (Table 3), and within noninferiority limits. At the

Table 1—Baseline demographic and clinical characteristics of the study population

	Total (n = 357)	Intervention (n = 178)	Control (n = 179)	P value*
Age, years	48 ± 14	47 ± 14	49 ± 14	NS
<50 years, n (%)	183 (51)	99 (56)	84 (47)	NS
Female sex, n (%)	131 (37)	69 (39)	62 (35)	NS†
Disease duration, years	22.5 ± 14.4	22.0 ± 13.7	22.9 ± 14.8	NS‡
≤5 years, n (%)	43 (12)	19 (11)	24 (13)	NS
Insulin pump use, n (%)	62 (17)	31 (17)	31 (17)	NS†
HbA_{1c}				
%	7.6 ± 0.9	7.6 ± 1.0	7.6 ± 0.9	NS
mmol/mol	59.7 ± 10.2	59.7 ± 10.5	59.7 ± 9.8	
LDL, mmol/L	2.5 ± 0.7	2.5 ± 0.7	2.5 ± 0.8	NS
eGFR, mL/min	121 ± 43	123 ± 40	119 ± 45	NS
Blood pressure, mmHg				
Systolic	132 ± 14	132 ± 13	132 ± 15	NS
Diastolic	76 ± 9	76 ± 9	76 ± 8	NS
Body weight, kg	83 ± 16	84 ± 16	83 ± 16	NS
BMI, kg/m^2	27.2 ± 4.6	27.4 ± 4.6	27.0 ± 4.7	NS
uACR, n (%)				NS†
Normoalbuminuria	286 (84)	143 (83)	143 (84)	
Microalbuminuria	42 (12)	22 (13)	20 (12)	
Macroalbuminuria	14 (4)	7 (4)	7 (4)	
Retinopathy, n (%)				NS†
Normal	163 (46)	78 (44)	85 (48)	
Nonproliferative	138 (39)	78 (44)	60 (34)	
Proliferative or laser-treated	54 (15)	22 (12)	32 (18)	

Data are mean ± SD unless otherwise indicated and were analyzed with the t test. eGFR, estimated glomerular filtration rate. *Intervention vs. control. †χ^2 test. ‡Wilcoxon rank sum test (Mann-Whitney).

24-month follow-up, HbA_{1c} levels were unchanged within and between groups (7.7% ± 1.0% [60.5 ± 11.4 mmol/mol] in the intervention group and 7.6% ± 0.9% [59.4 ± 10.2 mmol/mol] in the control group). There was no difference between sex or age groups (Supplementary Table 6). Noninferiority of the intervention was supported by analyzing the mean HbA_{1c} values over the 24 months, which were comparable between groups (Supplementary Table 7). There were no differences between groups in the incidences of HbA_{1c} level >8.6% (70 mmol/mol), 9.5% (80 mmol/mol), and 10.4% (90 mmol/mol). The number of HbA_{1c} tests requested by participants was slightly lower in the intervention group (5.8 ± 2.1) than in the control group (6.5 ± 1.8) ($P < 0.05$). There were no differences between groups in the incidence and progression of diabetic retinopathy, kidney disease (Table 3), and foot ulcers. One patient in the intervention group and two in the control group died of reasons unrelated to study procedures.

Patient Contact With the Outpatient Diabetes Clinic

During 24 months, participants in the intervention group visited the outpatient clinic less frequently than control subjects (4.4 ± 2.8 and 6.3 ± 2.7 visits respectively; $P < 0.001$) (Supplementary Table 8); this applied to visits with the physician (intervention: 1.7 ± 1.0 and control: 2.6 ± 0.6; $P < 0.001$) and with the diabetes specialist nurse (intervention: 2.3 ± 2.2 and control: 3.2 ± 2.0; $P < 0.001$). While there were no differences between age groups, participants of both sexes had significantly fewer visits with a larger difference for males. Nineteen participants (12%) in the intervention group had no visits other than the final visit (Supplementary Table 9). The number of lost appointments was lower in the intervention group ($P < 0.05$) (Supplementary Table 8); this was mainly attributable to the male participants ($P < 0.001$) and younger age group ($P < 0.001$). The intervention group made more telephone calls to the clinic than the control group (3.1 ± 3.4 vs. 2.5 ± 3.2; $P < 0.01$), with a greater intergroup difference observed in females.

CONCLUSIONS

We found that routine prescheduled visits could be safely replaced with patient-initiated visits in the 70% of eligible patients at the outpatient clinics. Furthermore, the intervention was associated with an increased or unchanged patient-reported benefit and satisfaction, increased accessibility, and lower number of visits to the clinic. This is the first RCT of patient-initiated (outpatient) visits in a population with diabetes (12,13).

Previous nonrandomized studies of primary care investigating the effect of patient-requested open access and same-day visits for a mixed population with T1D and type 2 diabetes (3–6,14) showed improved or unchanged HbA_{1c} and LDL levels (3,5,6), while one study found an increase in blood pressure (3). Additionally, the studies reported fewer visits (3,6) or an unchanged or higher number of visits (4,5). None of the primary care studies addressed patient satisfaction. However, RCTs of the effects of patient-initiated visits have been conducted in secondary care of other chronic diseases, with results similar to ours. A 6-year study showed that patients with rheumatoid arthritis had fewer visits, with unchanged clinical disease status and increased patient satisfaction (7). In studies of inflammatory bowel disease (8) and psoriasis (10), disease status was unchanged or improved and the frequency of visits was lower, while patient satisfaction was unchanged; moreover, patient-initiated visits were preferred over prescheduled routine visits (8,15,16).

We found that all measures related to accessibility improved, which was expected due to the time guarantees and easy access via the patient portal. For the items focusing on benefits, patients in the intervention group had fewer self-rated unnecessary visits compared with control subjects and

Table 2—Patient-reported experience measures for patient satisfaction at baseline and at the end of the trial*†

Item‡	Intervention			Control			*P* value (between groups)
	Baseline	End of trial	*P* value (within group)	Baseline	End of trial	*P* value (within group)	
Satisfaction with the outpatient clinic (S1)	4.57 ± 0.58	4.59 ± 0.55	NS	4.48 ± 0.66	4.49 ± 0.58	NS	NS
Benefit							
Benefit consultation (S2)	4.23 ± 0.75	4.39 ± 0.64	<0.05	4.25 ± 0.74	4.27 ± 0.71	NS	NS
Unnecessary visits (S3)	2.79 ± 1.20	2.54 ± 1.26	0.05	2.85 ± 1.21	2.81 ± 1.26	NS	<0.05
Needs covered (S4)	4.47 ± 0.60	4.52 ± 0.60	NS	4.35 ± 0.76	4.40 ± 0.64	NS	NS
Accessibility							
Contact when needed (S5)	4.25 ± 0.84	4.52 ± 0.66	<0.05	4.23 ± 0.79	4.26 ± 0.76	NS	<0.05
Appointment when needed (S6)	3.91 ± 0.91	4.48 ± 0.64	<0.001	4.01 ± 0.82	4.09 ± 0.82	NS	<0.001
Means of contact (S7)	4.09 ± 0.84	4.41 ± 0.67	<0.001	4.09 ± 0.80	4.22 ± 0.74	NS	<0.05
Overall 7-item satisfaction sum score§	28.8 ± 3.7	30.4 ± 3.5	<0.001	28.5 ± 4.0	28.9 ± 3.7	NS	<0.001

Data are mean ± SD. *Number of patients replying to the questionnaires at baseline/end of trial: intervention group, 177/152; control group, 179/165. †Patient-reported experiences were measured on a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree); single-item scores were analyzed by multilevel mixed-effects ordered logistic regression. ‡S1, I am satisfied with the outpatient clinic; S2, I am satisfied with the benefit I derive from my consultations; S3, I have experienced unnecessary visits at the outpatient clinic; S4, The outpatient clinic meets my needs related to diabetes treatment; S5, I can contact the outpatient clinic when needed; S6, I can get an appointment at the outpatient clinic when needed; and S7, I am satisfied with the different means of contacting the outpatient clinic (visit, phone, or e-mail). §Scores of item S3 were reversed prior to calculation of the 7-item sum score; the sum score was analyzed by mixed-model multilevel mixed-effects linear regression.

experienced a within-group increase in the benefit of consultations. This indicates that the possibility for the patient to choose time and form of the visit in accordance with needs and wishes may lead to increased experienced relevance and focus of the consultation and may be driven by an active process by the patient of clarifying the purpose of the visit. The intervention did not include initiatives targeted to enhance empowerment, nor did we find changes between groups related to either perceived empowerment or diabetes distress.

Due to a ceiling effect of the item responses, it is difficult to demonstrate increases in satisfaction, as reported by others (17–19). Patients in Denmark generally have very high satisfaction with outpatient clinics, reporting a mean national score of 4.43 on a scale of 1 to 5 (20). However, increased patient satisfaction in the intervention group was supported by the calculated 7-item sum score.

At trial completion, participants in the intervention group showed a preference for the patient-initiated setup, while the control group preferred routine visits. Although patients in the control group can only express their preferences from assumptions, responses are in line with other studies (8,15,16). While the preference for patient-initiated visits was larger in the age group <50 years, patients with a long disease duration were also seen to be willing to change their approach.

An increase in HbA_{1c} is a risk factor for late diabetic complications (21,22), and higher HbA_{1c} testing frequency is associated with greater success in metabolic control (23–25). Reduced glycemic control is usually asymptomatic and therefore not recognized by the patient. Despite fewer visits and a marginally lower frequency of HbA_{1c} testing in the intervention group, HbA_{1c} levels did not change within groups or differ between groups. There were no changes in the rate of late diabetes complications or any clinical diabetes outcomes beside an increase in body weight in the intervention group. As overweight is a health problem in T1D, this is an issue to be aware of.

Our results demonstrated that the lower number of visits in the intervention group was more prominent among

Table 3—Clinical status at baseline and at the end of the trial*

	Intervention			Control			
	Baseline	End of trial	Within-group difference	Baseline	End of trial	Within-group difference	Between-group difference
HbA_{1c}							
%	7.6 ± 1.0	7.7 ± 1.0	NS	7.6 ± 0.9	7.6 ± 0.9	NS	NS
mmol/mol	59.7 ± 10.5	60.5 ± 11.4		59.7 ± 9.8	59.4 ± 10.2		
LDL, mmol/L	2.5 ± 0.7	2.5 ± 0.8	NS	2.5 ± 0.8	2.4 ± 0.8	$P < 0.05$	NS
eGFR, mL/min	123 ± 40	120 ± 42	NS	119 ± 45	120 ± 43	NS	NS
Blood pressure, mmHg							
Systolic	132 ± 13	133 ± 11	NS	132 ± 15	135 ± 12	$P < 0.05$	NS
Diastolic	76 ± 9	75 ± 9	NS	76 ± 8	75 ± 9	NS	NS
Body weight, kg	84 ± 16	86 ± 17	$P < 0.001$	83 ± 16	84 ± 15	NS	NS
BMI, kg/m^2	27.4 ± 4.6	28.1 ± 5.1	$P < 0.001$	27.0 ± 4.7	27.3 ± 4.4	NS	NS
uACR, *n* (%)			NS			NS	NS†
Normoalbuminuria	143 (83)	120 (81)		143 (84)	144 (87)		
Microalbuminuria	22 (13)	26 (17)		20 (12)	17 (10)		
Macroalbuminuria	7 (4)	3 (2)		7 (4)	4 (2)		
uACR change, *n* (%)							NS
Regression		10 (7)			14 (9)		
No change		122 (85)			137 (86)		
Progression		12 (8)			8 (5)		
Retinopathy, *n* (%)			NS			NS	NS†
Normal	78 (44)	67 (44)		85 (48)	75 (45)		
Nonproliferative	78 (44)	64 (42)		60 (34)	62 (37)		
Proliferative or laser-treated	22 (12)	21 (14)		32 (18)	31 (18)		
Retinopathy change, *n* (%)							NS
Regression		13 (9)			10 (6)		
No change		126 (83)			142 (85)		
Progression		13 (9)			16 (10)		

Data are presented as mean ± SD unless otherwise indicated. eGFR, estimated glomerular filtration rate. *Changes in continuous variables were analyzed by mixed-model multilevel mixed-effects linear regression; uACR and retinopathy variables were analyzed with Fisher exact or χ^2 test as appropriate. †Calculated at baseline and at the end of the trial, with no significant differences found between groups.

men than women. Surprisingly, 12% of patients in the intervention group had no visits during the 24-month study period other than the end-of-trial visit, which was especially true for male participants. Similar results have been reported for rheumatoid arthritis (7,26). In general, females use the health care system more than males (27–29). We found no difference between sexes in requests for HbA_{1c} testing, but the higher number of phone consultations in the intervention group was attributable to higher use by females. The majority of the phone consultations were performed by nurses (>90%) and are of shorter duration than a visit. Overall, we found a lower use of staff resources by the intervention group.

The limited decrease in HbA_{1c} testing and higher number of phone contacts in the intervention group indicates that the participants may have replaced some of the physical visits with HbA_{1c} testing or phone consultations. This finding is in accordance with a study of patients with inflammatory bowel disease that reported a patient preference for blood sampling and follow-up phone calls over annual routine visits (30).

Our study has some limitations. Firstly, the screening procedure allowed health care personnel to evaluate the patient as noneligible if they found that the study setup posed a risk to the patient. During the trial, we held regular meetings for all personnel to strive for a uniform screening practice and to empathize a neutral approach to the intervention, but a potential bias cannot be completely ruled out. Accordingly, caution should be exercised when generalizing the present findings to the entire population with T1D. In particularly, fragile patients could be at risk, and a patient-initiated model might require a customized approach for this group. Secondly, 40% of the eligible patients declined participation. In other studies of patient-initiated visits, 5–31% declined participation, which may be influenced by age, the way the study is presented, and the study design (7,8, 16). Patients declining participation in this study were older and had longer diabetes duration and may have more fixed habits of diabetes control or being uncomfortable with use of the patient portal. In addition, 14% of the participants in the intervention group did not complete the study, compared with 6% in the control group, which may have reflected lower treatment satisfaction, potentially biasing the results. Thirdly, we did not find a validated questionnaire measuring experienced satisfaction with organizational structures of diabetes care and designed our own questionnaire. Data are reported as

single-item measures that may be less reliable than multi-items; however, data from all items show the same direction, indicating the measures to be reliable and unambiguous. A 7-item sum score supported this analysis. Fourthly, we examined late-onset complications, but a 2-year follow-up is relatively short to identify long-term adverse outcomes. However, the observation that HbA_{1c} was stable over time suggests that long-term negative effects are unlikely. Finally, as our study was conducted at a single hospital in Denmark, and access to primary and secondary care is free of charge and equal for all Danish citizens, extrapolation to other health care systems must take local organization into account.

In conclusion, the results of this study showed that patient-initiated visits instead of prescheduled visits were associated with unchanged or increased patient-reported satisfaction and benefit with consultations and increased accessibility, fewer visits to the clinic, and no changes in HbA_{1c} or other clinical variables of diabetes. Accordingly, the transfer of responsibility to patients is safe and can potentially free resources at outpatient clinics for more fragile, deteriorating, and dysregulated patients. This is particularly important because of the aging population with chronic diseases that is likely to place increasing pressure on the health care system in the future (31,32).

Acknowledgments. The authors thank the participants and all personnel and the Head of Department at Medical Department, Endocrinology, Hospital of South West Jutland, University Hospital of Southern Denmark, Esbjerg and Grindsted, for the contributions to this research. The authors also thank Prof. Gabriele Berg-Beckhoff (Unit for Health Promotion Research, Department of Public Health, University of Southern Denmark) for assistance with statistics and power calculation, Odense Patient data Explorative Network (OPEN), Odense University Hospital for assistance with statistics and REDCap, and The Danish Knowledge Center for User Involvement in Health Care (ViBIS) for advice regarding the development of the questionnaire.

Funding. This study was supported by the Medical Department, Hospital South West Jutland, University Hospital of Southern Denmark, Department of Regional Health Research, University of Southern Denmark, STENO Diabetes Center Odense, and the Karola Jørgensen Research Foundation.

The funders were not involved in the design or conduct of the study, collection, management, analysis, or interpretation of the data, preparation, review, or approval of the manuscript, or decision to submit the manuscript for publication.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. J.G. and C.B.J. conceived the study. N.D.R., J.G., and C.B.J. designed the study and statistical analyses. N.D.R. carried out data collection, project and data handling, and statistical data analysis in collaboration with C.B.J. M.H. collected and scored the retinopathy data. N.D.R., J.G., and C.B.J. were responsible for data interpretation. N.D.R. wrote the first draft of the manuscript. All authors were involved in the revision of the manuscript and approved the final version. C.B.J. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Prior Presentation. A portion of this study with the main findings was presented at the Annual Meeting of the Danish Endocrine Society, Nyborg, Denmark, 17–18 January 2020 and the 56th Annual Meeting of the European Association for the Study of Diabetes, 21–25 September 2020. The study was presented using the acronym DIATAST (the DIAbetes patient TAkes reSponsibiliTy).

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