Received: 10 May 2021 | Accepted: 11 January 2022

DOI: 10.1111/dme.14791

DIABETIC Medicine

RESEARCH ARTICLE

Randomized controlled study to evaluate the impact of flexible patient-controlled visits in people with type 1 diabetes: The DiabetesFlex Trial

Tinne Laurberg[1] | **Liv Marit Valen Schougaard**[2,3] | **Niels Henrik Ingvar Hjollund**[2,4,5] | **Kirsten Elisabeth Lomborg**[3,5,6] | **Troels Krarup Hansen**[1,5] | **Annesofie Lunde Jensen**[1,3,5]

[1]Steno Diabetes Centre Aarhus, Aarhus University Hospital, Aarhus, Denmark

[2]AmbuFlex, Center for Patient-Reported Outcomes, Regional Hospital West Jutland, Herning, Denmark

[3]ResCenPI – Research Centre for Patient Involvement, Aarhus University and the Central Denmark Region, Denmark

[4]Department of Clinical Epidemiology, Aarhus University Hospital, Aarhus, Denmark

[5]Department of Clinical Medicine, Aarhus University, Aarhus, Denmark

[6]Steno Diabetes Centre Copenhagen, Herlev, Denmark

Correspondence
Tinne Laurberg, Steno Diabetes Centre Aarhus, Aarhus University Hospital, Aarhus, Denmark.
Email: tinlaurb@rm.dk

Funding information
This research was funded by the Novo Nordic Foundation (reference no. NNF16OC0022382), Aarhus University Hospital, Department of Endocrinology, Internal Medicine, and Aarhus University Hospital, Steno Diabetes Center Aarhus.

Abstract

Aim: The objective of this study was to assess the impact of health care–initiated visits versus patient-controlled flexible visits on clinical and patient-reported outcomes in people with type 1 diabetes.

Methods: The DiabetesFlex trial was a randomized controlled, pragmatic non-inferiority 15-month follow-up study comparing standard care (face-to-face visits every 4 months) with DiabetesFlex (patient-controlled flexible visits using patient-reported, outcome-based telehealth follow-up). Of 343 enrolled participants, 160 in each group completed the study. The primary outcome was mean change in HbA_{1c} from baseline to 15-month follow-up. Secondary outcomes were blood pressure, lipid levels, frequency of visits, the World Health Organization score—five well-being-index (WHO-5), the Problem Areas In Diabetes (PAID) scale and experience of participation in own care (participation score).

Results: The adjusted mean difference in HbA_{1c} between standard care and DiabetesFlex was similar and below the predefined non-inferiority margin of 0.4% (−0.03% [95%CI: 0.15, 0.11]/−0.27 mmol/mol [−1.71, 1.16]). No intergroup mean changes in lipid or blood pressure were observed. Conversely, DiabetesFlex participants presented an increased mean WHO-5 index of 4.5 (1.3, 7.3), participation score of 1.1 (0.5, 2.0), and decreased PAID score of −4.8 (−7.1, −2.6) compared with standard care. During follow-up, DiabetesFlex participants actively changed 23% of face-to-face visits to telephone consultations, cancelled more visits (17% vs. 9%), and stayed away without cancellation less often (2% vs. 8%).

Conclusion: Compared with standard care, flexible patient-controlled visits combined with patient-reported outcomes in participants with metabolic controlled type 1 diabetes and good psychological well-being further improved diabetes-related well-being and decreased face-to-face visits while maintaining safe diabetes management.

KEYWORDS

diabetes mellitus type 1, disease management, patient participation, patient-initiated and patient-controlled, patient-reported outcome measures, randomized controlled trial

1 | INTRODUCTION

Globally, the number of individuals with diabetes is growing, increasing the burden on health care systems. Simultaneously, accumulating evidence indicates that a key element to achieving successful treatment requires increased involvement of the person with diabetes[1] and a focus on minimizing health care–related disruptions to people's lives,[2] prompting researchers to rethink currently employed strategies for diabetes care.

To allow for flexible patient-controlled diabetes care management, the person with diabetes should ideally have online access to their laboratory data, including glycated haemoglobin (HbA_{1c}), while also providing patient-reported outcome data to the diabetes care team at their outpatient clinic; this requires an effective telehealth setup.[3] Furthermore, the complexity of living with and managing diabetes in day-to-day life may negatively impact the well-being of the person with diabetes.[4] Hence, developing diabetes care management that strives to minimize the treatment burden remains of critical importance.[2]

Controlled studies investigating the impact of patient-initiated timing and frequency of visits for people with chronic diseases such as rheumatoid arthritis and inflammatory bowel disease have reported safe disease management, unaltered or higher satisfaction, and fewer visits compared with standard care.[4,5] However, whether this can be extrapolated to adults with type 1 diabetes remains unknown.

Accordingly, we conducted the DiabetesFlex trial, a randomized controlled trial aimed at demonstrating that among people with type 1 diabetes, patient-controlled flexible visits (DiabetesFlex) are not substantially unfavourable (non-inferior) compared with standard care (health care provider–initiated face-to-face consultation every 4 months). In our setting, participants in the DiabetesFlex arm decided whether some of their face-to-face visits should be converted to telephone consultations or cancelled altogether. We aimed to assess the impact of flexible patient-controlled diabetes management using patient-reported, outcome-based telehealth follow-up. Herein, we reported the primary outcome of HbA_{1c}, as well as blood pressure, lipid levels, diabetes-related well-being,[6] the experience of participation in own care, and the frequency of rescheduled visits after a 15-month follow-up period.

What is already known?

- Involvement of people with diabetes has been shown to be an important predictor of successful diabetes self-management.
- Patient-controlled timing of visits has been successfully implemented for other chronic diseases, but its potential in adults with type 1 diabetes remains unknown.

What this study found?

- Patient-controlled diabetes management was safe, with no negative effect on clinical outcomes (HbA1c, lipids, and blood pressure).
- Patient-controlled visits improved diabetes-related well-being and resulted in reduced face-to-face visits and non-attendance.

What are the implications of the study?

- Standard type 1 diabetes follow-up can be changed to patient-controlled visits combined with patient-reported outcomes in people with adequate metabolic control and good psychological well-being. This change of diabetes management decreases the need for face-to-face visits, increases involvement and minimizes health care disruptions to people's lives.

2 | METHODS

2.1 | Study design and participants

The DiabetesFlex study was a pragmatic randomized non-inferiority controlled trial, as previously described,[7] involving individuals diagnosed with type 1 diabetes who attended routine follow-up at a large publicly funded outpatient clinic in Denmark. The trial was registered with ClinicalTrials.gov (identifier NCT03202732), and the predefined outcomes are reported in the current paper.

From October 2017 to February 2019, individuals with type 1 diabetes who received standard diabetes care at the outpatient clinic at Aarhus University Hospital in Denmark were invited to participate in the trial. Inclusion criteria were age >18 years, diagnosis of type 1 diabetes for >1 year, internet access and ability to understand, read and write Danish. Randomization was performed using the REDCap randomization model.[8] Allocation lists were generated for the treatment groups at a 1:1 ratio using permuted blocks with randomly varying sizes of 4, 6 and 8, stratified by HbA1c <59 mmol/mol versus HbA1c >58 mmol/mol. To maintain proper concealment of randomization, allocation lists were generated and uploaded to REDCap using an external randomization service (Clinical Trial Unit, Department of Clinical Medicine, Aarhus University, Denmark). Blinding was not possible owing to the study design.

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Danish

Data Protection Agency (record no. 2012–58–006) and by the Central Denmark Regional Committee on Health Research Ethics (record no. M-2017–139–17). Written informed consent was obtained from all enrolled individuals.

2.2 | Procedure

All participants underwent a face-to-face consultation at baseline and at the end of the study (15 months). Blood samples to measure the HbA_{1c} levels were obtained and analysed prior to the consultation, whereas blood pressure and weight were registered by a nurse at the consultation. In the control arm, participants with type 1 diabetes continued to receive standard care, consisting of routine face-to-face consultations every 4 months with either a doctor or a specialist diabetes nurse. In the treatment arm, participants were assigned to DiabetesFlex care, which is a patient-reported outcome-based telehealth system designed to support individuals with diabetes, as well as health care professionals for evaluating patients' condition and care needs by substituting in-person consultations.[9,10]

Information regarding the development of DiabetesFlex care, such as questionnaire design, pilot testing and involvement of people and health care professionals in the process, has previously been reported.[7]

The first consultation in DiabetesFlex care was a face-to-face consultation with an endocrinologist and a specialist diabetes nurse. The last two consultations in the annual cycle were optional, and participants could choose to have a face-to-face consultation, change to telephone consultation, or cancel the visit. Two weeks prior to each consultation, participants completed the internet-based, AmbuFlex diabetes-specific, patient-reported outcome questionnaire. A more extensive questionnaire was used for the annual visit (45 items), and a shorter form (17 items) for the optional visits (Table S1). Based on their responses on the AmbuFlex questionnaire, a specialist diabetes nurse evaluated whether it was clinically safe to change or cancel a consultation, in accordance with the participants' request.[7]

2.3 | Outcome measures

The primary outcome was the mean change in HbA_{1c} from baseline to the last visit after a 15-month follow-up. The secondary clinical outcomes were the lipid and blood pressure measurements of participants. The outcomes concerning participants' use of health care resources were based on the number and type of consultations and registered non-attendance. Secondary patient-reported outcomes were scores on the World Health Organization—five well-being-index (WHO-5), the Problem Areas In Diabetes (PAID) scale and the participation score.[11]

The participants' well-being was determined using the WHO-5, and a generic measure of mental well-being comprising five questions rated on a 6-point Likert scale from 0 (at no time) to 5 (all of the time); the corresponding WHO-5 index is a percentage score ranging from 100 (the best imaginable well-being) to 0 (the worst imaginable well-being), obtained by multiplying the raw well-being score by 4.[12] In addition, emotional distress linked directly to diabetes was recorded via PAID, a 20-item questionnaire using a 5-point scale from 0 (not a problem) to 4 (a severe problem), with the corresponding PAID percentage score ranging from 0 (best) to 100 (worst) by multiplying the raw PAID score by 1.25.[13]

The experiences of participation in one's own care were assessed with a 5-item questionnaire measuring the degree of agreement with the following statements on a 6-point Likert scale from 0 (do not know) to 5 (to a very high degree): (1) The health care professionals asked questions about my experiences with the disease. (2) I talked to health care professionals about the questions and concerns that I had. (3) The health care professionals invited me to ask questions and talk about my concerns. (4) I was consulted when decisions about my plans were made. (5) I talked adequately to health care professionals about how I manage my condition. The items were summarized, and the participation scores ranged from 0 (worst) to 25 (best). The five generic questions and the derived participation score were previously validated and tested in a Danish context.[14]

2.4 | Data collection

Data from the questionnaires were collected electronically using REDCap. The participants completed an electronic questionnaire covering health outcomes either at home or at the outpatient clinic. Data regarding HbA_{1c}, lipids and resources (number of contacts and consultations) were obtained from the participant's medical records. All data were stored in REDCap.[8]

2.5 | Statistical analysis

The sample size calculation was based on an assumption of non-inferiority for the primary outcome, defined as an intergroup difference of a maximum of 0.4% in the mean HbA_{1c} change from baseline to study end. The non-inferiority margin was selected based on the use of a 0.4% margin in studies assessing individuals with type 1 diabetes,[3,15] and because it would insure a sufficiently small between-group difference to avoid a substantial clinical

impact. Given a statistical power of 90%, a significance level of 0.05%, a standard deviation (SD) of 1, and an allocation ratio of 1:1, the estimated sample size was 109 participants in each group. To examine secondary end points and account for dropouts, 344 participants were enrolled.

Statistical analyses were performed as intention-to-treat analyses based on valid available information from the participants who completed the study. All participants received initially allocated treatment. Descriptive data are presented as mean ± SD for continuous variables, proportions (*n*, %) for categorical variables, and mean difference with 95% confidence interval (CI). In addition, registered visits during the 15-month follow-up were compared using Student's *t*-test.

The association between change in HbA_{1c} level and treatment was examined using linear regression adjusted for baseline HbA_{1c} (stratification variable). Lipid, blood pressure and patient-reported outcome measurements were analysed in a similar manner. To avoid excluding participants without baseline lipid measurements, a variable indicating missing baseline data was included in the regression model; all missing values were set to the mean value of the baseline measure. This missing-indicator method has been validated in previous studies.[16,17] To assess the sensitivity of results for the missing-indicator method, the outcome measure on the treatment indicator in models without baseline measures was regressed; the results were found to be similar. Statistical analyses were performed using Stata version 16.

3 | RESULTS

In total, 344 participants with type 1 diabetes were enrolled in the present study, with 1 participant withdrawing before randomization, and 13 were excluded as COVID-19 restrictions prevented them from attending the department. The study cohort, thus, consisted of 320 participants: 160 in the standard care group and 160 in the DiabetesFlex group (Figure S1). Among the 320 participants, 47% were women, with a mean age of 48 years, and 74% had the diagnosis of type 1 diabetes for >10 years (Table 1). At the end of the study period, no significant change in diabetes treatment and use of technologies were observed within the two groups (data not shown). The response rate for answering the AmbuFlex diabetes-specific, patient-reported outcomes questionnaire was 98%.

3.1 | Impact of DiabetesFlex care on clinical outcomes

At the end of the study period, the adjusted mean difference in HbA_{1c} between standard care and DiabetesFlex was similar and below the predefined non-inferiority margin of 0.4% (−0.03% [95%CI: −0.15, 0.11]/−0.27 mmol/mol [−1.71, 1.16]) (Table 2). No intergroup mean changes in lipid or blood pressure were observed, and no participants were hospitalized with severe hypoglycaemia or ketosis/ketoacidosis during the 15-month follow-up period.

3.2 | Impact of DiabetesFlex care on patient-reported outcomes

In comparison with the standard group, participants in the Flex group showed improved overall diabetes well-being at the end of the study (Table 3): the WHO-5 index (range: 0–100) increased by 4.5 points (95% CI: 1.6, 7.3) and the participation score (range: 0–25) increased by 1.1 points (0.5, 2.0), whereas the PAID score (range: 0–100) decreased by −4.8 points (−7.1, −2.6).

3.3 | Impact of DiabetesFlex on the need for visits

During follow-up, the registered mean number of visits per person was 2.9 in the standard care group and 3.0 in the DiabetesFlex. However, the DiabetesFlex group had 22% (16, 28) fewer face-to-face visits than the standard care group (Table 4), attributed to a switch from face-to-face visits to telephone contacts. Further, the proportion of face-to-face visits cancelled ahead of time was greater in the DiabetesFlex group than in the standard care group (17% vs. 8.7%; risk difference: 8.4% [4.2, 13]). In addition, staying away without cancellation occurred less frequently in the DiabetesFlex group than in the standard care group (2% vs. 8%; risk difference: −6.0% [−8.8, −3.1]). On four occasions, the specialist nurse judged that the decision by a participant in the DiabetesFlex group to switch from face-to-face to telephone or to cancellation was potentially unsafe.

3.4 | Impact of DiabetesFlex on diabetes care after study end

At the end of the study period, participants could choose to receive standard care or the DiabetesFlex plan. In the standard care group, 87 of 160 participants (54%) chose to switch to the DiabetesFlex strategy; in the DiabetesFlex group, almost all participants (151 out of 160, 94%) selected to continue with the DiabetesFlex plan (Table 4).

For each of the above-reported outcomes, a separate analysis was performed for participants who exhibited an HbA_{1c} >58 mmol/mol, and the findings were similar (data not shown).

TABLE 1 Baseline characteristics of the standard care ($N = 160$) and DiabetesFlex groups ($N = 160$)

	Standard care ($N = 160$)	DiabetesFlex ($N = 160$)	Total
Age	48 ± 14	49 ± 15	48 ± 14
Women	72 (45)	79 (49)	151 (47)
BMI (kg/m^2)	25.8 ± 4.4	25.9 ± 3.6	25.8 ± 4.0
Native language			
Danish	157 (98)	157 (98)	314 (98)
Other	3 (1.9)	3 (1.9)	6 (1.9)
Education			
Less than bachelor	38 (24)	34 (21)	72 (23)
Bachelor's degree	80 (50)	85 (53)	165 (52)
Advanced degree	33 (21)	35 (22)	68 (21)
Other	9 (5.6)	6 (3.8)	15 (4.7)
Household			
Live with others	112 (70)	110 (69)	222 (70)
Alone	47 (30)	50 (31)	97 (30)
Other chronic disease			
Yes	42 (26)	54 (34)	96 (30)
No	114 (71)	101 (63)	215 (67)
Do not know	4 (2.5)	5 (3.1)	9 (2.8)
Duration of type 1 diabetes			
Diabtes <10 year	43 (27)	39 (25)	82 (26)
Diabetes ≥10 year	117 (73)	120 (75)	237 (74)
Diabetes treatment			
Pen	105 (66)	98 (61)	203 (63)
Insulin pump	55 (34)	62 (39)	117 (37)
Diabetes technology			
Blood glucose meter	99 (62)	93 (58)	192 (60)
Continuous glucose monitoring	26 (16)	18 (11)	44 (14)
Flash glucose-sensing	35 (22)	49 (31)	84 (26)
Last HbA1c measurement			
<7.5%/59 mmol/mol	97 (61)	96 (60)	193 (60)
>7.5%/58 mmol/mol	63 (39)	64 (40)	127 (40)
Diabetes complication			
None	121 (76)	122 (76)	243 (76)
Retinopathy	9 (5.7)	6 (3.8)	15 (4.8)
Neuropathy	8 (5.1)	11 (7.0)	19 (6.0)
Nephropathy	1 (0.6)	1 (0.6)	2 (0.6)
Complication, not specified	9 (5.7)	4 (2.5)	13 (4.0)
More than one complication	9 (5.7)	14 (8.9)	23 (7.2)
Not registered	3 (1.9)	2 (1.3)	5 (1.6)

Note: Data are presented as mean ± SD or *n* (%).

4 | DISCUSSION

In the present study, we found that using patient-reported outcomes in combination with patient-controlled diabetes management in people with acceptable metabolic control and good psychological well-being further improved diabetes-related well-being and decreased the use of face-to-face visits while maintaining safe diabetes management.

TABLE 2 Clinical outcomes after a 15-month follow-up of the standard care and DiabetesFlex groups

	Standard care ($N = 160$)	DiabetesFlex ($N = 160$)	Treatment effect
Haemoglobin			
HbA1c (%)			
Start	7.36 ± 1.03	7.44 ± 1.05	−0.03 (−0.15, 0.11)
End	7.42 ± 1.00	7.47 ± 1.00	
Difference	0.06 (−0.02, 0.15)	0.04 (−0.07, 0.15)	
HbA1c (mmol/mol)			
Start	56.91 ± 11.31	57.79 ± 11.54	−0.27 (−1.71, 1.16)
End	57.57 ± 10.79	58.21 ± 10.79	
Difference	0.69 (−0.23, 1.61)	0.43 (−0.79, 1.64)	
Lipids			
Cholesterol (mmol/L)			
Start	4.58 ± 0.79	4.59 ± 1.09	0.21 (−0.17, 0.59)
End	4.33 ± 0.72	4.42 ± 1.18	
Difference	−0.20 (−0.40, 0.00)	0.01 (−0.28, 0.31)	
HDL (mmol/L)			
Start	1.70 ± 0.49	1.63 ± 0.51	0.01 (−0.08, 0.10)
End	1.68 ± 0.51	1.61 ± 0.47	
Difference	−0.05 (−0.12, 0.02)	−0.04 (−0.11, 0.02)	
LDL (mmol/L)			
Start	2.37 ± 0.70	2.41 ± 0.81	0.21 (−0.13, 0.55)
End	2.15 ± 0.56	2.28 ± 0.99	
Difference	−0.13 (−0.29, 0.03)	0.08 (−0.20, 0.36)	
Triglycerides (mmol/L)			
Start	1.07 ± 0.62	1.30 ± 0.64	−0.08 (−0.31, 0.14)
End	1.08 ± 0.52	1.23 ± 0.77	
Difference	−0.01 (−0.15, 0.13)	−0.10 (−0.27, 0.08)	
Blood pressure			
Diastolic (mmHg)			
Start	78.87 ± 8.37	78.54 ± 8.43	−1.94 (−4.26, 0.38)
End	79.19 ± 8.49	77.54 ± 8.98	
Difference	0.90 (−0.66, 2.46)	−0.91 (−2.63, 0.81)	
Systolic (mmHg)			
Start	131.76 ± 15.49	131.06 ± 14.27	0.00 (−4.10, 4.09)
End	131.41 ± 14.19	131.27 ± 14.87	
Difference	0.05 (−2.99, 3.09)	0.15 (−2.62, 2.92)	

Note: Start and end data are presented as mean ± SD.

Difference between start and end are presented as mean with 95% confidence interval.

Treatment effect with 95% confidence interval.

To the best of our knowledge, this is the first randomized controlled study investigating the impact of patient-controlled visits combined with the systematic use of patient-reported outcomes on metabolic control. The key strengths of this study include its randomized pre-registered design, large sample size, and low dropout rate. Furthermore, the well-validated, patient-reported outcome data combined with clinical data provide insights into the complexity of living with and managing diabetes on a day-to-day basis. Given the research design, it was difficult to discriminate between the influence of the patient-controlled diabetes management and the use of patient-reported outcomes.

As observed with most clinical controlled trials, the internal validity was high, but the study may be limited in

TABLE 3 Patient-reported outcomes for the standard care and DiabetesFlex groups

	Standard care ($N = 160$)	DiabetesFlex ($N = 160$)	Treatment effect	p-values
WHO−5 well-being index				
Start	70.0 ± 13.7	69.7 ± 15.5	4.5 (1.6, 7.3)	0.005
End	69.0 ± 14.5	73.4 ± 16.2		
Difference	−0.9 (−3.0, 1.2)	3.6 (1.3, 6.0)		
Problem areas in diabetes				
Start	16.3 ± 11.9	16.0 ± 13.2	−4.8 (−7.1, −2.6)	<0.001
End	17.0 ± 14.1	12.0 ± 12.1		
Difference	0.8 (−0.9, 2.4)	−4.1 (−5.6, −2.6)		
Participation score				
Start	18.9 ± 4.1	18.5 ± 4.5	1.1 (0.5, 2.2)	0.040
End	18.9 ± 4.1	19.6 ± 4.4		
Difference	0.1 (−0.6, 0.8)	1.2 (0.4, 2.0)		

Note: Start and end data are presented as mean ± SD.

Difference between start and end are presented as mean with 95% confidence interval.

Treatment effect with 95% confidence interval.

TABLE 4 Numbers of visits registered at the hospital during the 15-month follow-up and the patient choice of diabetes care after the end of the study

	Standard care ($N = 160$)	DiabetesFlex ($N = 160$)	Risk difference
Hospital visits during 15-month follow-up			
All registered visits	462	486	
Face-to-face visit	372 (81)	284 (58)	−22% (−28, −16)
Visit changed to telephone consultation	Not an option	90 (19)	
Visits cancelled by the patient	40 (8.7)	83 (17)	8.4% (4.2,13)
Patient stayed away	38 (8.2)	11 (2.3)	−6.0% (−8.8, −3.1)
Visits cancelled by the hospital	12 (2.6)	14 (2.9)	0.3% (−1.8,2.4)
Cancellation, unspecified	0	4 (0.8)	
Choice of care after study end			
Completed the trial	160	160	
Standard Care	73 (46)	9 (5.6)	
DiabetesFlex	87 (54)	151 (94)	

Note: Data are presented as *n* (%).

Risk differences with 95% confidence interval.

terms of external validity. The outpatient clinic at Aarhus University Hospital, Denmark, provides care to approximately 1700 individuals (> 18 years) diagnosed with type 1 diabetes, among whom 1275 (75%) met the inclusion criteria. Among the 542 invited to participate in the trial 343 (63%) agreed. The study population had a similar gender distribution as the outpatient clinic, but the proportion of individuals with an HbA_{1c} <59 mmol/mol (7.5%) was higher (60%) than that typically observed at the clinic (50%). The study was not designed to evaluate the potential savings associated with the DiabetesFlex solution; thus, data regarding this are not available. However, we believe it can be reasonably assumed that participants who changed their face-to-face visit to a telephone contact or cancelled the visit saved time and money in terms of transport to and from the hospital. A randomized study by the Telemed-Diabetes group evaluating the cost of telematic care as a replacement for face-to-face outpatient

appointments has reported that people with diabetes saved time (14 h were spent during 6 months follow-up in the face-to-face group vs. 6 h in the telehealth care group), whereas the diabetes team spent approximately 20% less time on average with the telehealth care group.[18]

Another limitation is the nature of a pragmatic randomized trial conducted in a real-life setting. Data collection concerning health care services was inaccurate, given an inconsistency in the manner in which different health care providers registered contacts to the hospital. In some cases, two different contacts (e.g. telephone and physical meetings with a doctor) were registered on the same day, and on reading the medical record, it was determined to be a telephone contact with a medical doctor. The same contact would have been registered as telephone contact by another health care professional. All cancellations of visits, as well as two registrations on the same day, were reviewed to establish a similar mode of registration. This misclassification is considered non-differential, as outcome measurements are similar across the treatment and control groups. Furthermore, the bias will underestimate the potential difference in cancelled visits/staying away between groups. Finally, participants lost to follow-up had missing outcome data, which was observed only in a few cases (7%), and was balanced between the groups (12/172 vs. 11/171). Moreover, the underlying reasons for loss to follow-up were similar and unrelated to the treatment (died, moved to another hospital, affected by COVID-19). Based on these findings, we believe that missing data were unlikely to induce bias in the obtained results.

The present study demonstrates in a randomized design, that standard diabetes care follow-up could be switched to people-initiated contacts while maintaining safe disease management, in line with similar reports concerning other chronic illnesses.[5,19-24] Although the diseases are markedly distinct, they all necessitate regular contact with the health care system and in that sense face similar issues.

The WHO-5 and PAID questionnaires are key components of the AmbuFlex diabetes-specific, patient-reported outcomes questionnaire; these well-being scores were improved in the DiabetesFlex group throughout the study period. Previous reports have revealed the correlation between WHO-5 and PAID, as well as the association between greater well-being and lower HbA_{1c}.[25] In the present study, we observed no effect on glycaemic control, possibly due to the low mean HbA_{1c} level at the study baseline (58 mmol/mol, 7.5%) compared with other randomized controlled studies (70–74 mmol/mol, 8.6–8.9%).[25] Furthermore, the mean WHO-5 at baseline was high and similar to that of the Danish general population,[26,27] leaving limited scope for improvement. This could explain why the observed improvement in well-being was below the threshold value considered clinically relevant.[12]

Another beneficial effect of the patient-reported outcome questionnaire is its known impact on patients' experience of involvement.[28] As expected, the study documented a positive effect on the participants' scores in the DiabetesFlex group compared with the standard care group. Overall, the participants seemed to be very satisfied with DiabetesFlex, with most participants selecting to continue with this type of diabetes management after the study concluded. Finally, participants in the DiabetesFlex group requested fewer consultations, and the proportion of those who stayed away from appointments without cancellation was low. These findings are consistent with a study by Brewster et al., which revealed a reduction in non-attendance when people were involved in their own care and when telehealth consultations were also offered.[29]

In conclusion, compared with the standard care group, flexible patient-controlled visits combined with patient-reported outcomes in individuals with metabolic well controlled type 1 diabetes and good psychological well-being further improved diabetes-related well-being and lowered the use of face-to-face visits while maintaining safe diabetes management. Therefore, the present study encourages health care providers to change some of the usual diabetes care follow-up to patient-initiated contacts for this specific profile of individuals with type 1 diabetes. This strategy could improve diabetes treatment by increasing involvement of people with type 1 diabetes and minimizing health care–related disruptions to people's lives.

ACKNOWLEDGMENTS

The authors would like to thank the study participants. In addition, the authors are grateful to the staff at Steno Diabetes Centre Aarhus for their involvement and support in implementing the new intervention. This research is funded by the Novo Nordic Foundation (reference no. NNF16OC0022382); Aarhus University Hospital, Department of Endocrinology and Internal Medicine; Aarhus University Hospital, Steno Diabetes Centre Aarhus.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

ORCID

Tinne Laurberg https://orcid.org/0000-0002-7555-2665

REFERENCES

1. Ga Y. 2019 Health care & education presidential address: it's all about access! *Diabet Care*. 2021;44(Suppl. 1):1-7.
2. Serrano V, Spencer-Bonilla G, Boehmer KR, Montori VM. Minimally disruptive medicine for patients with diabetes. *Curr Diab Rep*. 2017;17(11):104.
3. Ruiz de Adana MS, Alhambra-Expósito MR, Muñoz-Garach A, et al. Randomized study to evaluate the impact of telemedicine

care in patients with type 1 diabetes with multiple doses of insulin and suboptimal HbA1c in Andalusia (Spain): PLATEDIAN study. *Diabet Care*. 2020;43(2):337-342.
4. Taneja A, Su'a B, Hill AG. Efficacy of patient-initiated follow-up clinics in secondary care: a systematic review. *Int Med J*. 2014;44(12a):1156-1160.
5. Thurah A, Stengaard-Pedersen K, Axelsen M, et al. Telehealth follow-up strategy for tight control of disease activity in rheumatoid arthritis: results of the non-inferiority randomised controlled trail (the TeRA study). *Arthritis Care Res (Hoboken)*. 2018;70(3):353-360.
6. Speight J, Reaney MD, Barnard KD. Not all roads lead to Rome-a review of quality of life measurement in adults with diabetes. *Diabet Med*. 2009;26(4):315-327.
7. Jensen A, Lomborg K, Hjollund N, et al. DiabetesFlex™ – the effect of PRO-based telehealth and user involvement in care management of patients with type 1 diabetes: trial protocol for a non-inferiority randomised controlled study. *Med Res Arch*. 2020;8(7):1–16.
8. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.
9. Hjollund NHI, Larsen LP, Biering K, Johnsen SP, Riiskjær E, Schougaard LM. Use of patient-reported outcome (PRO) measures at group and patient levels: experiences from the generic integrated PRO system, WestChronic. *Interact J Med Res*. 2014;3(1):e5.
10. Schougaard LMV, Larsen LP, Jessen A, et al. AmbuFlex: telepatient-reported outcomes (telePRO) as the basis for follow-up in chronic and malignant diseases. *Qual Life Res*. 2016;25(3):525-534.
11. Hjollund NHI. Fifteen years' use of patient-reported outcome measures at the group and patient levels: Trend analysis. *J Med Internet Res*. 2019;21(9):e15856.
12. Topp CW, Østergaard SD, Søndergaard S, Bech P. The WHO-5 Well-Being Index: a systematic review of the literature. *Psychother Psychosom*. 2015;84(3):167-176.
13. Welch GW, Jacobson AM, Polonsky WH. The problem areas in diabetes scale. An evaluation of its clinical utility. *Diabet Care*. 1997;20(5):760-766.
14. DEFACTUM®. Udvælgelse af inddragelsesspørgsmål til patienter Denmark 2016 [updated 24 nov 2020. Available from: http://www.defactum.dk/
15. Davies MJ, Gross JL, Ono Y, et al. Efficacy and safety of insulin degludec given as part of basal-bolus treatment with mealtime insulin as part in type 1 diabetes: a 26-week randomized, open-label, treat-to-target non-inferiority trial. *Diabetes Obes Metab*. 2014;16(10):922-930.
16. Groenwold RH, White IR, Donders AR, Carpenter JR, Altman DG, Moons KG. Missing covariate data in clinical research: when and when not to use the missing-indicator method for analysis. *CMAJ*. 2012;184(11):1265-1269.
17. White IR, Thompson SG. Adjusting for partially missing baseline measurements in randomized trials. *Stat Med*. 2005;24(7):993-1007.
18. Esmatjes E, Jansà M, Roca D, et al. The efficiency of telemedicine to optimize metabolic control in patients with type 1 diabetes mellitus: telemed study. *Diabet Technol Therap*. 2014;16(7):435-441.
19. Schougaard LMV, Mejdahl CT, Christensen J, et al. Patient-initiated versus fixed-interval patient-reported outcome-based follow-up in outpatients with epilepsy: a pragmatic randomized controlled trial. *J Patient Rep Outcomes*. 2019;3(1):61.
20. Hewlett S, Kirwan J, Pollock J, et al. Patient initiated outpatient follow up in rheumatoid arthritis: six year randomised controlled trial. *BMJ*. 2005;330(7484):171.
21. Kennedy A, Nelson E, Reeves D, et al. A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease. *Health Technol Assess*. 2003;7(28):1-113.
22. Berkhof FF, Hesselink AM, Vaessen DLC, Uil SM, Kerstjens HAM, Van Den Berg JWK. The effect of an outpatient care on-demand-system on health status and costs in patients with COPD. A randomized trial. *Respiratory Med*. 2014;108(8):1163-1170.
23. Williams JG, Cheung WY, Russell IT, Cohen DR, Longo M, Lervy B. Open access follow up for inflammatory bowel disease: pragmatic randomised trial and cost effectiveness study. *BMJ*. 2000;320(7234):544-548.
24. Khoury LR, Møller T, Zachariae C, Skov L. A prospective 52-week randomized controlled trial of patient-initiated care consultations for patients with psoriasis. *Br J Dermatol*. 2018;179(2):301-308.
25. Schmidt CB, van Loon BJP, Vergouwen ACM, Snoek FJ, Honig A. Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress. *Diabet Med*. 2018;35(9):1157-1172.
26. Ellervik C, Kvetny J, Christensen KS, Vestergaard M, Bech P. Prevalence of depression, quality of life and antidepressant treatment in the Danish General Suburban Population Study. *Nord J Psychiatr*. 2014;68(7):507-512.
27. Bech P, Olsen LR, Kjoller M, Rasmussen NK. Measuring well-being rather than the absence of distress symptoms: A comparison of the SF-36 Mental Health subscale and the WHO-five Well-Being Scale. *Int J Methods Psychiatr Res*. 2003;12(2):85-91.
28. Mejdahl CT, Nielsen BK, Hjøllund NHI, Lomborg K. Use of patient-reported outcomes in outpatient settings as a means of patient involvement and self-management support: a qualitative study of the patient perspective. *Eur J Person Centered Healthcare*. 2016;4(2):359-367.
29. Brewster S, Bartholomew J, Holt RIG, Price H. Non-attendance at diabetes outpatient appointments: a systematic review. *Diabet Med*. 2020;37(9):1427-1442.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Laurberg T, Schougaard LMV, Hjollund NHI, Lomborg KE, Hansen TK, Jensen AL. Randomized controlled study to evaluate the impact of flexible patient-controlled visits in people with type 1 diabetes: The DiabetesFlex Trial. *Diabet Med*. 2022;00:e14791. doi:10.1111/dme.14791