ISRCTN11499301 https://doi.org/10.1186/ISRCTN11499301

Digital follow-up. Can well-regulated patients with type 2 diabetes have digital annual follow-up without compromising quality of care?

Submission date 09/07/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/07/2026	**Overall study status** Ongoing	
Last Edited 29/09/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Public

Contact name
Mrs Kirsten Christensen

ORCID ID
https://orcid.org/0009-0000-0726-0575

Contact details
Palle Juel-Jensens Boulevard 11, indgang A
Aarhus
Denmark
8200
+45 24600481
kichis@rm.dk

Type(s)
Principal investigator

Contact name
Prof Annelli Sandbæk

ORCID ID
https://orcid.org/0000-0003-1647-2646

Contact details
Palle Juel-Jensens Boulevard 11, indgang A
Aarhus
Denmark
8200
+45 2128 2073
anesnd@rm.dk

Additional identifiers

Study information

Scientific Title
Can well-regulated patients with type 2 diabetes followed by their general practitioner be offered digital follow-up without compromising quality of care?

Study objectives
The study will investigate whether digital annual follow-up can be implemented for patients with well-controlled type 2 diabetes (as defined by predefined indicators) without compromising treatment quality.

Furthermore the study is purposed to gain knowledge on how general practice can safely differentiate care for people with type 2 diabetes with the aim of increasing health equity. In addition, the study contributes knowledge on how digital care can support differentiation in general practice.

In this study, every second annual diabetes follow-up, is conducted remotely via email communication between the healthcare provider and the participant over a two-year intervention period.

The primary outcome is HbA1c. It is hypothesized to have non-inferiority with respect to changes in HbA1c for the participant in the intervention group compared to a matched control group receiving standard annual follow-up. Secondary outcomes are other diabetes-related clinical indicators (e.g., LDL, eGFR), morbidity and primary and secondary healthcare utilization, where the analysis compares the change in these indicators between the intervention group and the matched control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/06/2026, The Central Denmark Region Committees on Health Research Ethics (Skottenborg 26, Viborg, 8800, Denmark; +45 78410186; komite@rm.dk), ref: Sagsnr. 1-10-72-56-26

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Screening

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes (ICD-10: E11) and follow-up in general practice.

Interventions
The intervention consists of replacing annual in-person follow-up with a digital annual follow-up every second year.
In this setting, digital annual follow-up means that communication between healthcare provider and the participant is conducted remotely via email.

Blood glycated haemoglobin (HbA1c) is measured using HbA1c blood samples gained from the participants medical record. HbA1c must be sent to and analyzed at the local Department of Clinical Biochemistry. Analyses will follow the department's standardized and accredited procedures. Point-of-care HbA1c measurements conducted in the GP clinic are not acceptable.

Intervention Type
Behavioural

Primary outcome(s)
1. Blood glycated haemoglobin (HbA1c) measured using analysis of blood samples by the local Department of Clinical Biochemistry following standardized accredited procedures, with data obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 and 2 years

Key secondary outcome(s)
1. Total cholesterol level measured using analysis of blood samples by the local Department of Clinical Biochemistry following standardized accredited procedures, with data obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

2. Low-density lipoprotein (LDL) cholesterol level measured using analysis of blood samples by the local Department of Clinical Biochemistry following standardized accredited procedures, with data obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

3. Urinary albumin-to-creatinine ratio (UACR) measured using analysis of urine samples by the local Department of Clinical Biochemistry following standardized accredited procedures, with

data obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

4. Estimated glomerular filtration rate (eGFR) measured using analysis of blood samples by the local Department of Clinical Biochemistry following standardized accredited procedures, with data obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

5. Smoking status measured using participant medical records and GP records at baseline, 1 year, and 2 years

6. Weight measured using self-reported weight recorded on a personal bathroom scale or weight recorded in GP practice records at baseline, 1 year, and 2 years

7. Blood pressure measured using home arm-cuff monitoring (three measurements each morning and three each evening for three consecutive days, averaged across all measurements and recorded in Webpatient.dk) or GP practice records at baseline, 1 year, and 2 years

8. Primary healthcare utilization measured using the total number of GP consultations (face-to-face, telephone, video, or email) obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

9. Secondary healthcare utilization measured using records of contacts with secondary healthcare obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

10. Diabetes-related medication use measured using medication records obtained from medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

11. Comorbidities measured using medical records and the BI Data Warehouse for Central Region Denmark at baseline, 1 year, and 2 years

Completion date
30/11/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/09/2026:
1. eGFR >59 mL/min/1.73 m²
2. HbA1c:
2.1. ≤48 mmol/mol, or
2.2. 49–53 mmol/mol if the individual HbA1c treatment target is <53 mmol/mol
3. Urine albumin-to-creatinine ratio (UACR):
3.1. <30 mg/g, or
3.2. 30–300 mg/g with ongoing treatment with organ-protective medication: SGLT-2i or GLP1 agonist and RAS-blockade with ACE-I or ARB (ATC-code: C09, A10BK, A10BD, A10BJ)
4. LDL <2.6 mmol/L
5. Ability to use the Danish national healthcare website (www.sundhed.dk)
6. Ability to read and understand Danish

Previous inclusion criteria:
1. eGFR >59 mL/min/1.73 m²
2. HbA1c:
2.1. <48 mmol/mol, or
2.2. 48–53 mmol/mol if the individual HbA1c treatment target is <53 mmol/mol
3. Urine albumin-to-creatinine ratio (UACR):
3.1. <30 mg/g, or
3.2. 30–300 mg/g with ongoing treatment with organ-protective medication: SGLT-2i or GLP1 agonist and RAS-blockade with ACE-I or ARB (ATC-code: C09, A10BK, A10BD, A10BJ)
4. LDL <2.6 mmol/L
5. Ability to use the Danish national healthcare website (www.sundhed.dk)
6. Ability to read and understand Danish

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The following diagnosis, ICD-10 codes:
1.1. F00–F03: Dementia – all forms
1.2. F70-F79: Intellectual disability
1.3. I50: Heart failure
1.4. Z51.5: Palliative care.
1.5. Pregnancy (ICD-10 O00-O99)
2. Any diagnoses or circumstances, that by the GPs judgement, makes digital annual follow-up inadvisable or unsafe

Date of first enrolment
01/09/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment

Denmark

Sponsor information

Organisation
Steno Diabetes Centers

ROR
https://ror.org/03w7awk87

Funder(s)

Funder type

Funder Name
Steno Diabetes Center Aarhus

Alternative Name(s)
SDCA

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request to Kirsten Christensen, kichis@rm.dk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	25/06/2026	09/07/2026	No	No