ISRCTN30640743 https://doi.org/10.1186/ISRCTN30640743

A virtual nursing intervention for self-management education and support versus usual care in adults with diabetes: a feasibility randomised controlled trial

Submission date
16/03/2022

Recruitment status
No longer recruiting

Registration date
31/03/2022

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Virtual interventions have beneficial effects on diabetes self-management, especially when they integrate components of patient education and support as essential parts of therapy. They are not yet widely implemented into usual patient care but have the potential to improve the delivery of continuous high-quality care. The study follows the phases of the Medical Research Council (MRC) framework for developing and evaluating complex interventions. The aim of this feasibility randomised controlled trial with a waiting-list control group is to evaluate the feasibility and acceptability of a virtual intervention of diabetes self-management education and support.

Who can participate?
Adults with type 1 or type 2 diabetes

What does the study involve?
Participants are recruited at a diabetes clinic and, after giving informed consent, are randomly assigned in a 1:1 ratio to either the intervention group or a 6-month waiting-list control group. The intervention consists of educational videos designed to support diabetes self-management between routine clinical visits. Participants are encouraged to watch at least one of the 57 short educational videos; they receive monthly reminder emails during the 6-month intervention period. The control group receives usual outpatient care for 6 months, then completes the same 6-month digital intervention as the intervention group. Sociodemographic, clinical, and psychosocial data are collected at baseline, 6 months, and 12 months; reasons for non-completion are documented. Feasibility and acceptability are assessed against predefined criteria addressing recruitment (enrolment rate), completion (retention rate), and participants' perceived acceptability and implementability, including usability of the intervention via questionnaires and interviews at 6 and 12 months.

What are the possible benefits and risks of participating?
The virtual intervention is evaluated in terms of feasibility, acceptability, recruitment and completion rates. The benefits include providing better support to people with diabetes to help them improve their self-management behaviour through a video-based virtual intervention. The study poses a slight risk of participants having to reflect on experiences that could elicit strong emotions; otherwise, there are no physical or psychological risks to the participants' health.

Where is the study run from?
University of Applied Sciences and Arts Western Switzerland

When is the study starting and how long is it expected to run for?
April 2021 to September 2024

Who is funding the study?
Swiss National Science Foundation

Who is the main contact?
Claudia Huber, PhD, claudia.huber@hefr.ch

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SNSF PT00P1_198985, SNCTP 000004677

Study information

Scientific Title
Understanding and improving patient engagement in self-management behaviour through virtual nursing interventions for diabetes in inpatient and outpatient clinics: a development and feasibility study

Acronym
PIAVIR

Study objectives
Current study hypothesis as of 05/06/2025:
It is hypothesised that a virtual intervention (PIAVIR), which uses educational videos in addition to usual care, is feasible for supporting diabetes self-management in adults, as evidenced by recruitment, retention, acceptability, and usability in a randomised controlled trial.

Previous study hypothesis:
To test the feasibility of undertaking a randomised controlled trial of a virtual nursing intervention for self-mangement education and support (PIAVIR) versus usual care in adults with diabetes in inpatient and outpatient clinics

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 16/11/2021, Cantonal Commission for Ethics in Human Research of the Canton of Vaud (Commission cantonale (VD) d'éthique de la recherche sur l'être humain (CER-VD), Av. de Chailly 23. 1012 Lausanne, Switzerland; +41 (0)21 316 18 36; secretariat.cer@vd.ch), ref: BASEC 2021-01763

Study design
Single-centre interventional open-label 6-month waiting list randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Diabetes mellitus, Type 1; diabetes mellitus, Type 2; patient education, health education; educational support of self-management in adults

Interventions
Current interventions as of 05/06/2025:
In the intervention arm, participants undertake a 6-month digital self-management intervention featuring 57 short educational videos covering topics such as: general information about diabetes, treatment with insulin, insulin injection techniques, blood glucose monitoring, hypo- and hyperglycaemia management, food choices, physical activity, living with diabetes, testimonials and coping strategies. They are encouraged to watch at least one video between regular clinic visits. Automated motivational emails are sent monthly to maintain engagement. After the 6-month active phase, participants retain access to the video library for another 6 months, but no longer receive reminder emails.

Participants assigned to the control group are placed on a 6-month waiting list, during which they continue to receive usual diabetes care, including standard clinical appointments, laboratory testing and ad-hoc telephone or email support. They do not have access to the educational videos while on the waiting list. After completing the 6-month control period, they gain access to the same intervention as the intervention group.

Previous interventions:
We aim to evaluate the feasibility of the PIAVIR intervention which is a virtual nursing intervention that incorporates at least one of the 48 video capsules for diabetes education of

type 1 or type 2 diabetes. The virtual support of video capsules will be added between regularly scheduled clinical visits and complemented with options of direct exchange via text message or phone call if there is any uncertainty. Usual care involves out-patient consultations until exposure to the intervention at 6 months. To minimise potential external contamination, other educational interactions will be monitored in both groups.
Computerised block randomisation with 1:1 allocation rate will be used.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 05/06/2025:
1. Recruitment rate is measured using the proportion of eligible participants who consent to participate. Data sourced from the study recruitment log at baseline
2. Completion rate is measured using the proportion of participants who complete the intervention and follow-up assessments. Data recorded in the study database at 6 and 12 months
3. Acceptability of the intervention is measured using a participant feedback questionnaire developed based on the Technology Acceptance Model (TAM), covering perceived usefulness, ease of use, attitude toward use, and intention to use at 6 and 12 months
4. Usability of the intervention is measured using the same TAM-based participant feedback questionnaire, including Likert-scale items on orientation, clarity, and overall system satisfaction at 6 and 12 months

Previous primary outcome measures:
Feasibility outcomes:
1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 6 months
2. Retention/attrition rates recorded as the number of participants remaining in the study at 0, 6 and 12 months
3. Adherence to data collection plan recorded as the percentage of completed study measures
4. Adherence to the intervention recorded as the number of recommended and participants' actual use of the virtual intervention
5. Participants perceived acceptability recorded as the level of appropriateness and usefulness of the intervention using questionnaires and interviews

Primary clinical outcome:
6. HbA1c recorded as the number of patients achieving HbA1c values in the set target range and the mean differences between groups at 6 and 12 months

Secondary outcome measures
Current secondary outcome measures as of 05/06/2025:
1. Glycaemic control is measured using self-reported HbA1c values, verified with patient medical records, at baseline, 6 and 12 months
2. Diabetes self-efficacy is measured using the Diabetes Management Self-Efficacy Scale (CDSES) at baseline, 6 and 12 months
3. Chronic illness care experience is measured using the Patient Assessment of Chronic Illness Care (PACIC) questionnaire at baseline, 6 and 12 months
4. Diabetes-related emotional distress is measured using the Problem Areas in Diabetes Scale (PAID) at baseline, 6 and 12 months
5. Socioeconomic deprivation is measured using the Deprivation in Primary Care Questionnaire (DiPCare-Q) at baseline, 6 and 12 months

6. Digital health literacy is measured using the eHealth Literacy Scale (eHEALS) at baseline, 6 and 12 months.
7. General health literacy is measured using the European Health Literacy Survey Questionnaire (HLS-EU-Q) at baseline, 6 and 12 months
8. Diabetes self-management behaviors are measured using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire at baseline, 6 and 12 months
9. Emergency treatment events are measured as the number of emergency treatment episodes (severe hypoglycaemia, diabetic ketoacidosis, unplanned hospitalisation) based on patient records at baseline, 6 and 12 months

Previous secondary outcome measures:
1. Self-efficacy measured using the Chronic Disease Self-Efficacy Scales (CDSES) at baseline, 6 and 12 months
2. Self-care management behaviour measured using the Summary of Diabetes Self-Care Activities (SDSCA) at baseline, 6 and 12 months
3. Diabetes-related emotional distress measured using the Problem Areas in Diabetes Scale (PAID) at baseline, 6 and 12 months
4. Patient reports of received care measured using Patient-Assessed Chronic Illness Care (PACIC) at baseline, 6 and 12 months
5. Health literacy measured using the European Health Literacy Survey Questionnaire (HLS-EU-Q) at baseline, 6 and 12 months
6. Ability in using information technology for health measured using the eHealth literacy scale (eHEALS) at baseline, 6 and 12 months
7. Perceived level of deprivation measured using the Deprivation in Primary Care Questionnaire (DiPCare-Q) at baseline, 6 and 12 months
8. Emergency care events recorded as the number of emergency care events (severe hypoglycaemia, diabetic ketoacidosis, unplanned hospitalisations) throughout the study

Overall study start date
01/04/2021

Completion date
10/09/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/06/2025:
1. Written and signed informed consent
2. Aged ≥18 years
3. Diagnosed with diabetes type 1 or type 2
4. French- or German-speaking (with sufficient comprehension to participate in focus groups and complete questionnaires)
5. No current or planned attendance at any other structured diabetes education initiative
6. Being interested and accustomed to the use of technology (e.g., smartphone, tablets and internet)

Previous inclusion criteria:
1. Aged ≥18 years

2. Diagnosed with diabetes type 1 or type 2
3. No current or planned attendance at any other structured diabetes education initiative
4. Being interested and accustomed to the use of technology

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 60

Total final enrolment
54

Key exclusion criteria
Current exclusion criteria as of 05/06/2025:
1. Severe physical/mental illness
2. Significant learning difficulties
3. Unable to give informed consent
4. Relatives of the study team (spouse, children, parents or siblings)

Previous exclusion criteria:
1. Severe physical/mental illness
2. Significant learning difficulties
3. Unable to give informed consent

Date of first enrolment
01/08/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Diabetology and Endocrinology of Hôpital fribourgeois (HFR)
Chemin des Pensionnats 2-6
Fribourg

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Sponsor information

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University of Applied Sciences and Arts Western Switzerland

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http://www.hes-so.ch/en/homepage-hes-so-1679.html

ROR
https://ror.org/01xkakk17

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 05/06/2025:
Planned publication in peer-reviewed journals and international conferences.

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 05/06/2025:
De-identified and aggregated datasets will be made available upon reasonable request and after publication at a later date in accordance with the study's data management plan. The researchers will add the details at a later date.

Previous IPD sharing plan:
The definitive data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request