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Protocol for a mixed-methods research project to develop and test the feasibility of a virtual nursing intervention promoting engagement and self-management in diabetes: the PIAVIR study

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Abstract

***Background*:** Diabetes has far-reaching negative impacts on the biological, physiological and psychosocial health of people living with the disease and their families, placing a heavy burden on health systems worldwide. Self-management education and support have a critical role to play but are insufficiently used. Therefore, there is a need to develop and implement effective support interventions for this population.

***Methods*:** This study protocol comprises the development and feasibility testing phases of a virtual nursing intervention named PIAVIR *(Pratique infirmière avancée virtuelle – Virtual advanced nursing practice)*, using the Medical Research Council framework for developing complex interventions. PIAVIR is based on humanistic-centred theories of education: adult learning theory, experiential learning and transformative learning, as well as the results from focus group interviews with healthcare professionals and people with type 1 or type 2 diabetes. The feasibility testing will include 60 participants recruited and randomised to either the intervention group with immediate access to the intervention for 6 months or to the waiting-list control group with access to the intervention after a 6-month waiting time. Both groups will be followed-up for another 6 months post-intervention. Outcome measures will be collected at baseline, 6 months and 12 months. Findings will be evaluated against predetermined feasibility criteria and changes in metabolic and psychosocial outcomes.

***Results*:** This paper presents the study protocol and describes and discusses the development and feasibility phases of the PIAVIR virtual intervention. The results of the feasibility study cover primarily: acceptability, feasibility, recruitment and completion of the newly developed intervention, as well as metabolic and psychosocial measures.

***Conclusion*:** This study contributes to the development of effective virtual self-management education and support interventions and informs a larger randomised controlled trial to examine the effectiveness of the intervention in different populations and multiple sites.

***Ethics and dissemination*:** This study has ethical approval from the Research Ethics Committees of Canton Vaud (CER-VD-2021-01763). The results will be disseminated to professional and lay audiences.

***Trial registration number*:** International Standard Randomized Controlled Trial Number registry ISRCTN30640743.

Keywords: *virtual systems*; *advanced practice nursing*; *patient education*; *qualitative research*; *feasibility study*; *diabetes mellitus*

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Non-communicable diseases, such as diabetes mellitus, cause major burdens for those with the disease, their families, healthcare systems and societies globally.[1] Diabetes can have multiple negative impacts on a person's physiological, mental and social health and well-being.[2] Supporting people with diabetes

to engage with their condition through self-management education is a core care requirement for reducing the health hazards associated with diabetes. However, many people with diabetes do not access such support. This problem was exacerbated during the COVID-19 crisis, when many have been unable to follow their routine diabetes care, which involves different disciplines and healthcare professionals for prevention, screening and management of the disease.[3,4] An integrated approach to diabetes care is not always available, and continuity of care is often insufficient.[5] Hyperglycaemia is known to be the common feature of different heterogeneous diabetes types and their sub-phenotypes.[6] These sub-phenotypes of type 1 diabetes and type 2 diabetes can simultaneously exhibit both impaired insulin secretion and impaired insulin sensitivity and require personalised treatment strategies to address hyperglycaemia and the different risks for the development of late complications.[7] Part of this strategy is adapted patient education, which is not addressed by the standardised education and support programmes for self-management that are widely used today in type 1 or type 2 diabetes. Therefore, there is a need for easily accessible, modular interventions that can take account of personalisation in therapeutic patient education. In addition, technical advances such as continuous glucose monitoring or insulin pump therapy are also increasingly being used in type 2 diabetes in high-income healthcare systems.[8] It is therefore imperative to find new ways of improving patient support to help both people with type 1 or type 2 diabetes engage in self-management behaviour. And virtual support has great promise in that regard.

This study protocol describes the development and feasibility testing phases of a virtual nursing intervention for diabetes in inpatient and outpatient clinics (*Pratique infirmière avancée virtuelle – Virtual advanced nursing practice* [PIAVIR]) that follows the Medical Research Council (MRC) framework for developing and evaluating complex interventions.[9]

Diabetes and self-management

A crucial component of any diabetes management – shown to be effective and recommended in many national and international guidelines – is to provide educational support to people with diabetes.[10] Such interventions help them acquire and maintain the skills needed to make informed treatment decisions, to better handle the demands of living with diabetes and to make the necessary changes to improve their health outcomes.[11]

Although there is awareness of these needs, research consistently shows that self-management support is insufficiently integrated in the often fragmented healthcare delivery systems[12]; the overall uptake of self-management education and support programmes – mostly delivered by nurses – is low, with only about one third of people with diabetes participating.[13] Systematic reviews have shown the benefits of virtual interventions that support lifestyle modifications, as measured in glycated haemoglobin (HbA1c) levels, particularly in the short term.[14–20] Based on this evidence, virtual interventions would have a beneficial effect on diabetes self-management; however, they are rarely part of usual patient care delivery and would benefit from a better understanding of their theoretical underpinnings, especially with involving users in the design process to improve the acceptance and implementability of virtual interventions.

This study involves people with diabetes, nurses and other healthcare professionals in the design process and feasibility testing of the PIAVIR intervention which will include videos. In the first phase, a qualitative approach is used to develop the intervention. In the second phase, a feasibility randomised controlled trial with a waiting-list control group tests the feasibility and acceptability of the intervention (see Figure 1).

The rationale for PIAVIR

The virtual nursing intervention (PIAVIR) is a novel educational intervention to support adults with diabetes to become more actively engaged in self-management by improving their learning experience, facilitated by healthcare professionals. The intervention is based on adult learning theory,[21] experiential learning[22] and transformative learning.[23] These well-established educational theories have humanistic-centred roots and support the perspective of self-directed lifelong learning

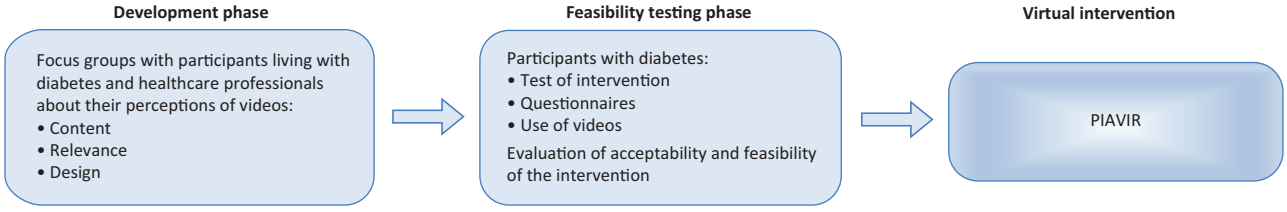

Figure 1. Overview of the development and feasibility testing phases of the PIAVIR intervention, according to the Medical Research Council framework for developing and evaluating complex interventions. PIAVIR: Pratique infirmière avancée virtuelle – Virtual advanced nursing practice.

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towards individual growth and development in adults.[24] Knowles's adult learning theory assumes that adults focus on developing learning processes related to their self-concept, prior experiences, readiness to learn, social role, problem-solving orientation, intrinsic motivation and understanding of underlying reasons. In experiential learning cycles, knowledge is created by transforming concrete experiences through reflective processing and meaning-making generalisation into the active transfer of the new understanding to future experiences in one's own lived reality.[25] Transformative learning, in this context, uses cognitive and critical perspectives to help people make more informed choices about their treatment and is very much embedded in life experience.

Internet-based interventions

People with fewer occasions to visit healthcare professionals or an unwillingness to participate in diabetes self-management education and support programmes also have the choice to follow internet-based interventions that provide information, education and support to complement their usual care.[26] However, internet-based interventions can be challenging to use because they have many different components that are provided indirectly and should reflect the needs of people with diabetes.[27]

This virtual intervention comprises at least seven video blocks, and further blocks will be developed as needed. Each video contains a brief introduction by a healthcare professional with animated illustrations and graphics on the main themes of diabetes care (see Table 1). It is envisaged to add 3–5 short questions at the end of each video for users to self-check their comprehension, in addition to exchanges with healthcare professionals and peers, if requested.

The videos are integrated into the virtual intervention provided in the form of an adaptive software application accessible via platform as a service (PaaS), which is developed in collaboration with an institute of informatics. During the PIAVIR development phase, the Scrum process framework of agile software development is used, which is a commonly followed process model in product development management involving cross-functional team collaboration.[28]

Aims

The aims of the study are to develop a virtual intervention together with nurses, other healthcare professionals and people with diabetes, and to identify their support needs (phase 1), to test the feasibility of the intervention (acceptance, implementability, recruitment and completion) and to estimate its efficacy in relation to metabolic and psychosocial outcomes (phase 2).

Methods and analysis

Study design

The development and feasibility testing phases of the PIAVIR intervention use a sequential mixed-methods multiphase study design.[29]

Phase 1: This development phase consists of validating, adapting and developing videos for diabetes education by people with diabetes, nurses and other healthcare professionals using focus groups with individuals of the respective groups. An existing set of 46 videos (see Table 1) is validated for the use in people with type 1 diabetes. The videos are, if necessary, adapted, and new ones will be developed for people with type 2 diabetes. The videos (from 1 min 18 s to 5 min 55 s in duration) will be integrated into the PIAVIR platform.

Phase 2: This feasibility testing phase uses a waiting list randomised controlled trial design with a 6-month exposure to the intervention and a 6-month follow-up post-intervention (see the Consort Flowchart in Figure 2). Sixty participants will be randomised either to the intervention group (n = 30) or to a 6-month waiting-list control group (n = 30). The intervention group is exposed to the intervention over 6 months immediately following allocation; after the 6-month waiting period, the control group is also exposed to the intervention over 6 months. Both groups are followed up for 6 months after the intervention to explore the intervention effects over time.

Study setting, participants and procedures in phases 1 and 2

Study setting

The study is conducted at a single diabetes centre in Switzerland, which provides ~17,000 appointments for people with diabetes annually. Three-quarters of these appointments are delivered by nurses trained in diabetes care. The core interdisciplinary diabetes treatment team consists of endocrinologists-diabetologists (n = 2), assistant physicians (n = 2), diabetes specialist nurses (n = 9), registered nurses (n = 2), dieticians (n = 2) and the head doctor/chief resident (n = 1).

Participant samples and procedures

The participants consist of (1) people with diabetes attending the diabetes clinic (see Table 2) and (2) nurses and other healthcare professionals currently working in the diabetes inpatient and outpatient clinics (in phase 1).

Participants meeting the inclusion criteria are recruited in the clinics by referral from the clinical team, by e-mailing them and by advertising inside the diabetes ward. The participants receive the study information and are invited to participate in the study. If participants agree after at least 72 h to decide whether to participate or not, they are

Table 1. Main themes and videos of the virtual intervention

Learning blocks	Themes	Videos
1	General information about diabetes	• What is diabetes? • Different types of diabetes • What is type 1 diabetes? • Type 1 diabetes, who and why?
2	Treatment with insulin	• Treatment of type 1 diabetes • Function of insulin in the human body • Function of insulin in type 1 diabetes • Different types of insulin: long and fast acting • Different types of insulin: endogen and exogen • Determining basal insulin dosage • Determination of correction insulin • Determining mealtime insulin • Determine mealtime insulin dose based on carbohydrate intake, blood glucose and circumstances. Using calculation aids.
3	Insulin injection techniques	• Insulin delivery techniques • Insulin delivery systems and storage • Insulin delivery systems: the syringe • Insulin delivery systems: pens • Insulin delivery systems: pumps • Complication of insulin injection: lipodystrophy • Hypoglycemia: glucagon injection
4	Blood glucose	• Daily diabetes control: blood glucose • Continuous glucose monitoring systems: practical management and safety • Types of continuous glucose sensors • Diabetes control: ketonuria/acetonemia • Control targets: number of hypoglycaemia, blood glucose targets and glycosylated haemoglobin
5	Hypo- and hyperglycaemia	• Hypoglycaemia: definition • Hypoglycaemia: symptoms • Hypoglycaemia: what to do? • Hypoglycaemia: Prevention and experience • Hyperglycaemia: Definition and symptoms • Hyperglycaemia – a life-threatening condition: ketonuria/acetonemia • Hyperglycaemia: long-term complications
6	Food	• Transformation of food into nutrients • Food groups and dietary balance • Different types of carbohydrates: recommendations • Carbohydrate absorption: recommendations • Glycaemic index and sweeteners • How to calculate the carbohydrates in a meal? • How to use 'Dia10'? • Re-sugaring without insulin
7	Living with diabetes	• Managing physical activity • Diabetes in women: menstruation and pregnancy • Type 1 diabetes: driving a car • Type 1 diabetes and travel • Type 1 diabetes and alcohol • Type 1 diabetes in daily life, the timeline: decisions to make: fatigue, stress/distress

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asked for oral and written informed consent. No payment is offered for study participation.

Procedures in phase 1

Qualitative data are collected over a period of at least 4 months through focus group interviews with people with diabetes, nurses and other healthcare professionals discussing the content of the virtual intervention and the use of the videos. The focus groups are conducted over about 60 min by two researchers in a separate meeting room at the diabetes clinic, following a semi-structured interview guide that explores the participants' needs and expectations towards virtual interventions and helps them evaluate the videos regarding: ease of understanding, ease of use and usefulness, as well as the effort and time that it takes nurses and other healthcare professionals to use the videos in patient consultations. The interviews are digitally recorded, verbatim transcribed and thematically analysed.[30] The data are coded and pseudonymised. Digital records are destroyed immediately after data transcription.

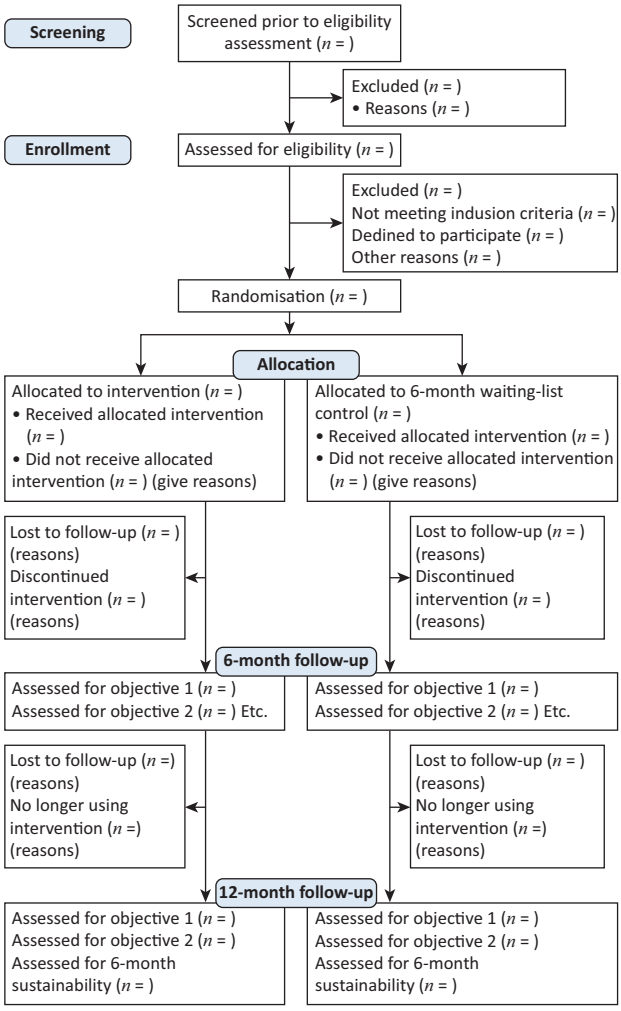

Figure 2. Consort diagram for the PIAVIR intervention feasibility study. PIAVIR: Pratique infirmière avancée virtuelle – Virtual advanced nursing practice.

The focus groups are moderated by one researcher, whilst the other keeps a logbook to take notes on methodological, theoretical and personal observations. Each focus group will bring together 4–12 participants. We expect at least 3 focus groups; however, the exact number cannot be fixed in advance as they will be conducted until data saturation is reached.[31,32] For data management, the NVivo qualitative analysis software package is used.[33]

Data analysis in phase 1

In the qualitative study phase, self-reported sociodemographic variables are collected, and descriptive statistics will depict the sample. The qualitative data will be analysed using thematic analysis.[30] The recursive process contains six distinct steps (see Table 3).

Reflective journaling, field note-taking and researcher triangulation are used in each of the above-mentioned steps to increase the trustworthiness of the qualitative study phase.[34]

The outcomes in phase 1 are the co-designed virtual intervention, and the user needs identification (e.g. in using intervention, in providing person-centred support through virtual education materials and in training for the communication skills needed to translate and share the information).

Table 2. The inclusion and exclusion criteria for people with diabetes in phases 1 and 2

Inclusion criteria	• Written and signed informed consent
	• Age ≥18 years
	• Diagnosed with diabetes type 1 or type 2
	• French or German speaking (sufficient comprehension for participating in focus groups and complete questionnaires)
	• No current or planned attendance at any other structured diabetes education initiative
	• Being interested and accustomed to the use of technology (e.g. smartphone, tablets and internet)
Exclusion criteria	• Severe physical/mental illness
	• Significant learning difficulties
	• Unable to give informed consent
	• Relatives of study team (spouse, children, parents and siblings)

Table 3. Thematic analysis with six distinct steps according to Braun and Clarke[30]

Step 1	• Transcribing data, reading and re-reading the data, noting down initial analytical observations.
Step 2	• Generating initial codes: coding important features of the data in a systematic way across the entire data set, collating data relevant to each code.
Step 3	• Searching for themes: collating codes into potential themes, gathering all data relevant to each potential theme.
Step 4	• Reviewing themes: checking if the themes work in relation to the coded extracts (level 1) and the entire data set (level 2), generating a thematic map of the analysis.
Step 5	• Defining and naming themes: ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
Step 6	• Producing the report: the final opportunity for analysis. Selection of vivid and compelling extract examples, final analysis of selected extracts, comparison of the analysis results to the research objectives and the literature, producing a report of the analysis.

Procedures in phase 2

Sixty people with diabetes attending the diabetes clinic are randomly allocated 1:1 to the intervention and control groups. As this is an open intervention, blinding of participants is not possible. Data (sociodemographic variables, clinical data and patient-reported psychosocial outcomes) are collected at baseline, 6 months and 12 months; it takes about 40 min to complete the questionnaires.

The data collection consists of (1) a self-developed questionnaire on sociodemographic and clinical data, as well as (2) a combination of 7 validated questionnaires on patient-reported psychosocial outcomes. The self-developed questionnaire collects variables on: (a) age, gender, language, nationality, level of education, life situation, social support and attendance at therapeutic education courses; and (b) clinical data on type of diabetes, duration of disease, diabetes treatment, presence of complications and most recent HbA1c-values. The clinical data are checked against the patient records (HbA1c, diabetes treatment and the presence of complications and emergency events) and complemented, if necessary. The data on eventual emergency events will be collected from patient records.

The combined questionnaire measures self-efficacy, diabetes self-care activities, problem areas of diabetes, chronic illness care, functional health literacy, e-health literacy and perceived level of deprivation. The psychometric scales are:

- The Chronic Disease Self-Efficacy Scale (CDSES) by Lorig et al.[35] to evaluate self-efficacy related to self-care.
- The Summary of Diabetes Self-Care Activities (SDSCA) by Toobert et al.[36] to assess the frequency of diabetes self-care activities over the last 7 days.
- The Problem Areas in Diabetes Scale (PAID) by Welch et al.[37] to measure diabetes-related emotional distress.
- The Patient-Assessed Chronic Illness Care (PACIC) by Glasgow et al.[38] to measure the extent to which participants receive care, aligned with the 5 dimensions of the Chronic Care Model.[39]
- The European Health Literacy Survey Questionnaire (HLS-EU-Q) by Sorensen et al.[40] to measure the perceived ease of finding, understanding, evaluating and applying health information.
- The eHealth Literacy Scale (eHEALS) by Norman et al.[41] to evaluate the perceived participants' skills for using web-based resources to search for health information, understanding the information found and relating it to the individuals' context.
- The Deprivation in Primary Care Questionnaire (DiPCare-Q) by Vaucher et al.[42] to assess the perceived level of deprivation in the dimensions of material, social and health care.

The psychosocial outcome measures are translated and validated in French and German and were used before in a Swiss population with diabetes.[13,43]

Study intervention

The intervention in study phase 2 is the use of a virtual nursing intervention that incorporates at least one of the videos for type 1 or type 2 diabetes. The videos are used between regularly scheduled clinical visits and, if requested, are complemented by a chat room where questions arising from individual experiences with the intervention can be discussed with peers. In addition, participants have the option of contacting their nurse or other healthcare professionals via text message or by phone if there is any need for clarification or further assistance. The participants may withdraw from the study at any time without giving any reasons and without fear of repercussions.

Intervention and control conditions

The intervention condition is participation in the virtual nursing intervention or the 6-month waiting-list control group. Participants in the waiting-list control group receive usual care following randomisation. Usual care involves outpatient consultations until exposure to the intervention at 6 months. To minimise potential external contamination, other educational interactions will be monitored in both groups.

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Data analysis in phase 2

The data in the feasibility testing phase will be analysed in relation to the recruitment rate (maximum of 30% early attrition rate of eligible participants[44]), completion rate (≥ 40% completion of final follow-up[45]) and improved level of engagement in self-management behaviour, improved psychosocial functioning and glycaemic control to assess the intervention impact. The acceptability of the intervention will be assessed with a self-developed user evaluation questionnaire and focus group interviews with a purposively selected subsample of participants (n = 12). Drop outs and non-completers will be followed-up by the researchers with a phone call to explore their reasons for this in a constructive and positive way.

The extracted data will be analysed using IBM SPSS Statistics (Version 27) software.[46] The primary clinical outcome is HbA1c to estimate the potential clinical effect because this is the most commonly used measure for determining the short- to medium-term impacts of interventions with respect to future diabetes complications.[47] The proportion of participants achieving their target range of HbA1c from baseline to follow-up (6 and 12 months) will be estimated in both intervention and control groups. The standard deviations of the mean difference between the HbA1c values of the intervention group and the control group will be estimated at 6 and 12 months of exposure to intervention and pre-exposure. Missing data will be imputed using the response function method.[48] The main outcome measures relate to the implementability of the intervention and the study procedures for the nurses and other healthcare professionals and to the suitability of the intervention for the participants with diabetes: the enrolment rate, the retention rate, adherence to the intervention, and the participants' perceived acceptability and usability of the intervention.[49]

Discussion/conclusion

This paper describes the protocol for the development and feasibility testing phases to evaluate a virtual intervention to improve active engagement in self-management behaviours for people with diabetes. The virtual intervention developed in this study differs in its humanistic-centred educational approach from other interventions that mainly focus on behaviour change theories and provide psychological support. This study will explore how this approach can be integrated into a virtual self-management intervention to create an environment that promotes self-directed, continuous learning about managing and living with diabetes.

The feasibility analysis will be used to optimise the components of intervention and the outcome measures. These aspects are important to understanding how the intervention can be effectively implemented and which framework conditions are necessary to achieve this. The barriers and facilitators will be assessed in relation to the feasibility outcomes. These findings are needed for the ongoing design of further studies based on the PIAVIR intervention. The evaluation will also provide important information on how the intervention can be transferred to other contexts.

When conducting a clinical trial in a busy clinical environment where staff resources are scarce, issues of trial feasibility, including recruitment and completeness of data, are important. The trial evaluation will consider the trial design, in particular whether the use of a waiting list model is favourable. The waiting-list design provides all eligible participants with the opportunity to benefit from the intervention whilst keeping a controlled structure to investigate differences between groups. In some conditions, however, the group allocation may influence the willingness to participate in the study and thus the intervention effect.[50]

The modular structure of the intervention enables it to be used on a larger scale and adapted to different age groups, environments and other chronic diseases. The study is conducted in a bilingual German-French region of Switzerland where most people use one of the two languages for communication. The intervention is not being tested in another language within the scope of this feasibility study. When transferring an intervention to a different setting, it is necessary to distinguish between implementation and treatment effectiveness. When such efforts are delayed or fail, which is often the case, it is important to know whether the failure is because the intervention was ineffective in the setting (failure of intervention) or because a good intervention was misapplied (failure of implementation). Current knowledge about implementation is limited because of a lack of theoretical understanding of the processes involved.[51] By conceptualising implementation outcomes, the feasibility testing phase of this study will contribute to a better understanding of the implementation processes of virtual interventions. With this understanding, effective implementation strategies can be developed. The results of this study will be used to inform a larger randomised controlled trial that will examine the effectiveness of the intervention in several clinical centres and different settings.

Ethics and dissemination

The protocol has ethical approval from the Cantonal Commission for Ethics in Human Research of the Canton of Vaud (CER-VD-2021-01763). Study results will be published in peer-reviewed scientific journals and professional journals, presented to patient organisations and professional organisations and submitted to national and international conferences. Authorship will be credited according to standard authorship eligibility guidelines.[52]

Conflict of interests and funding

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