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Effectiveness of a personal health coaching intervention (diabetescoach) in patients with type 2 diabetes: protocol for an open-label, pragmatic randomised controlled trial

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ABSTRACT

Introduction The widespread prevalence of type 2 diabetes (T2D) not only influences patients' daily lives but also has an economic impact on society. Increasing physical activity and a healthy diet can delay the progression of T2D. Although there are evidence-based recommendations on diet and physical activity, patients with T2D have difficulties implementing them. An appropriate lifestyle intervention can address this problem.

Methods and analysis This study is based on the need to develop an intervention that helps patients to establish behavioural changes in order to achieve glycaemic control. The intervention will be evaluated in a monocentric, open-label, pragmatic, two-arm randomised controlled trial with a sample ratio of 1:1 and a parallel design. This superiority study will be conducted in Switzerland. All enrolled patients (n=90) will receive the standard medical treatment for T2D. The intervention group will receive personal health coaching by telephone and access to a smartphone and web application for 1 year. The control group will receive access to the application for 1 year and a one-time written diet and exercise recommendation. The primary outcomes are objectively measured physical activity and glycated haemoglobin. Secondary outcomes are self-reported physical activity, nutrition, cognitive mediators of changes in sport-related behaviour, blood values, medication and nutritional supplements, anthropometric data, quality of life, neuropathy and cost-effectiveness. All outcomes will be measured at baseline, at 27 weeks after inclusion and at 54 weeks after inclusion. The recruitment of participants and the measurements will be completed after 2 years. Linear mixed-effects models will be applied for each outcome variable to analyse the intervention effects.

Ethics and dissemination This study was approved by the Ethics Committee North-western and Central Switzerland in February 2021 (ref: 2020-02755). All participants will be required to provide written informed consent. The results will be published in international peer-reviewed journals.

Trial registration number ISRCTN79457541.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Examining the effectiveness of the diabetes coach intervention through a pragmatic randomised controlled trial could determine whether it can be used in primary care settings.
⇒ The primary outcome of physical activity will be measured objectively using accelerometers, which provide a valid basis for data interpretation.
⇒ Glycated haemoglobin (HbA1c) will not be measured by the study team but by physicians during standard treatment at the points of measurement and will be forwarded to the study team.
⇒ If the control group's HbA1c levels are well controlled with medication, we nevertheless suspect that the intervention effects will be seen in parameters other than the levels of HbA1c, for example, in taking less medication.

INTRODUCTION

Type 2 diabetes mellitus (T2D) is a chronic, multifactorial metabolic disease caused by an insufficient production of insulin, which is triggered by beta cell dysfunction. Risk factors for T2D include weight gain, physical inactivity and obesity.[1] Due to the widespread prevalence of unhealthy lifestyles, the number of people worldwide suffering from T2D is steadily increasing: in 2021, more than 536.6 million people suffered from diabetes, most of them from T2D. The global prevalence of diabetes in adults is predicted to rise from 10.5% in 2021 to 12.2% in 2045.[2] The prevalence of T2D impacts mortality, with a 70% increase in T2D-related deaths worldwide between 2000 and 2019.[3] In Switzerland, more than 460 000 people (5.2% of the Swiss population) are affected by T2D, which has not only individual consequences but also far-reaching economic ones for society.[4]

Each patient in Switzerland costs the healthcare system an average of CHF 12,000 per year in direct and indirect treatment costs.[5] In view of the increasing number of patients with T2D and the associated costs for the healthcare system,[6] there is an urgent need to develop further interventions for treating T2D in addition to standard therapy.

Changing the lifestyle of patients with T2D is an essential part of treatment. Due to the individual courses of the disease and the emergence and severity of comorbidities, the treatment of T2D should be based on a tailored approach to support lifestyle change.[7] Three lifestyle change factors are crucial to positively influencing the course of the disease: increasing physical activity, establishing a healthy and balanced eating behaviour and the self-management of drug use. A healthy diet and regular physical activity are essential to treating and preventing T2D, as they allow glucose and metabolic disorders to be controlled. In addition, long-term lifestyle changes lead to weight loss and weight maintenance. A reduction of body weight by more than 5% is necessary to improve metabolic factors in a clinically relevant way.[8] Drugs should only be used to control T2D and not replace necessary changes to unhealthy lifestyles.[9] Moreover, a meta-epidemiological analysis showed that physical activity interventions in patients with pre-diabetes are comparable to drug interventions in terms of mortality.[10] If the lifestyle of patients can be positively affected in relation to the aspects mentioned, the progression of T2D can be slowed down and possible complications can be avoided.[11]

Although the promotion of physical activity and healthy eating is part of standard treatment, the recommendations are insufficiently implemented.[12 13] TPatients with T2D remain responsible for implementing diet and physical-activity recommendations,[14] but simply advising them to be more physically active is not enough to increase their level of physical activity.[15] It is difficult for patients with T2D to change health behaviours and firmly established habits.[14] Effective lifestyle interventions to support and implement changes in health behaviours in the treatment of patients with T2D are therefore essential.

In recent years, a number of interventions to change the health behaviours of patients with T2D have been developed, reviewed and implemented in the field of medical rehabilitation.[11] Some programmes have exhibited the potential to improve health-related outcomes in the prevention and treatment of T2D.[16 17] In particular, interventions that combine promoting physical activity and healthy eating promotion appear to be successful in improving blood glucose and reducing hospital days, medications and healthcare costs.[18 19] Compared with app-based interventions for patients with T2D, which have achieved positive but small effects,[20] the diabetescoach (dbcoach) intervention is based on a blended-care approach. Blended-care interventions consist of a therapist-guided component and a digital component. The individual components complement each other in their benefits, so blended-care interventions have the potential to effectively promote lifestyle changes.[21] Blended-care interventions targeting T2D have been found to be effective in multiple studies (d=0.23–0.56).[22–25] An additional distinctive characteristic of the dbcoach intervention is personal health coaching. As an intensive form of lifestyle intervention, personal health coaching has demonstrated positive effects on the clinical endpoints of T2D, for example, glycated haemoglobin (HbA1c), systolic blood pressure,[26 27] body weight and fat mass.[28] It is therefore suitable for supporting patients with T2D in implementing physical activity and diet recommendations. Furthermore, the dbcoach intervention combines current recommendations for physical activity and diet for patients with T2D from the American College of Sports Medicine (ACSM) and the American Diabetes Association (ADA)[9 17 29] with behaviour change concepts.[30 31]

This dbcoach study is based on the need to implement physical activity and diet recommendations to establish appropriate health behaviours in patients with T2D in order to achieve glycaemic control. This leads to the following questions: Does the intervention affect behaviour, that is, objectively assessed physical activity? Does the intervention have a positive influence on the most important clinical parameter of glycaemic control as assessed through HbA1c levels? We expect the following study results:

1. The HbA1c of the intervention group (IG) will decrease after 1 year compared with the control group (CG).
2. The physical activity of the IG will increase compared with the CG.

The aim of our randomised controlled study is to evaluate this individual telephone-based intervention for promoting a physically active lifestyle and healthy-eating behaviours that positively influence HbA1c in addition to existing treatment methods.

METHODS AND ANALYSIS

Study design

This is a superiority, open-label, pragmatic randomised controlled trial (RCT) with a sample ratio of 1:1. Following Zwarenstein *et al*,[32] the pragmatic setting for the intervention will not be tested under laboratory conditions but in comparison to standard therapy for patients with T2D. The study will be conducted at the Department of Sport, Exercise, and Health at the University of Basel, so it is monocentric. The intervention can be applied flexibly in practice, the outcomes will be relevant for patients and healthcare practitioners, and the intervention will have a direct relevance to practical implementation. This study is a two-arm RCT with parallel design. Eligible patients are being screened for the inclusion criteria in cooperating clinics or through a physician network. For participation in the study, patients are referred to the project team at the University of Basel for study information

and recruitment. On inclusion, participants will be randomised into an IG or a CG. All enrolled patients will receive the standard medical treatment for T2D (treatment as usual, TAU). The IG will receive a personal health coaching by telephone and access to the dbcoach smartphone and web applications (app). The CG will receive a written physical activity and diet recommendation as well as access to the dbcoach app. All variables (see table 1) will be assessed in the study at baseline (T0), at 27 weeks after inclusion (T1), and at 54 weeks after inclusion (T2). If a measurement point is postponed, it will be documented. A range of 1 month is considered acceptable for the measurement points. Patients with T2D are involved in the study at recruitment for the first time. The study design, outcomes and recruitment strategies were coordinated with physicians and diabetologists.

The study follows the Consolidated Standards of Reporting Trials (CONSORT) statement,[33] the extension of the CONSORT Statement for pragmatic efficacy studies[32] and the current guidelines for eHealth studies.[34] The study received ethical approval from the Ethics Committee Northwestern and Central Switzerland in February 2021 (ref: 2020-02755). Before any amendments or modifications are implemented in the study design, the review and approval of the Ethics Committee Northwestern and Central Switzerland will be obtained. Potential changes will be communicated through the study registration.

Recruitment

Recruitment for the study is taking place in the German-speaking region of Switzerland. It started in May 2021 and is expected to end in September 2022. The study participants are being recruited through a physician network as well as by the University Hospital Basel, the Cantonal Hospital St. Gallen, the Cantonal Hospital Baselland, and further physicians in local medical practices in Basel and St. Gallen. Although various hospitals and physicians are assisting in recruiting study participants, the study is monocentric since it will be carried out solely at the Department of Sport, Exercise and Health at the University of Basel. Both the recruitment and the execution of the study will be performed by the study team from the University of Basel. Patients with T2D are being screened for inclusion and exclusion criteria by the cooperating physicians during standard medical examinations. If patients meet the inclusion criteria, they receive an information flyer about the study with the contact details of the study team. If patients are interested in participating in the study, they can contact the project team for a detailed informed-consent interview, which includes information about the study procedure and intervention.

Inclusion and exclusion criteria

Patients with T2D can be included in the study if they (1) are older than 18 years, (2) have an HbA1c above 7.5%, (3) have T2D as defined by the ADA, (4) have the ability to understand German at a sufficient level to comprehend instructions and information, (5) have access to ongoing management of T2D by a primary care physician or diabetologist, (6) have internet access to use the app and (7) have a physical activity level of less than 150 min of moderately intense activity or of less than 75 min of vigorously intense activity per week. The activity level of the patients will be determined using the International Physical Activity Questionnaire-Short Form.[35]

Patients with T2D will be excluded from the study if (1) they have chronic or acute contraindications to physical activity or cannot be physically active for other medical reasons, (2) have psychiatric or dependence disorders, (3) are pregnant, (4) are receiving insulin therapy or (5) have medical conditions that prevent reliably determining their levels of HbA1c (haemoglobinopathy, haemolytic anaemia, blood transfusion, HIV, hepatic renal failure or renal failure requiring dialysis). The evaluation of the exclusion criteria will be performed by medical staff during standard therapy and will be extracted from patients' medical reports.

Consent to participate

Before interested patients are informed about the study, the inclusion and exclusion criteria will be checked by telephone and in their medical reports. Patients who meet all the inclusion criteria and do not exhibit any of the exclusion criteria will be informed about the study. The study team will explain the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits, and any inconveniences that can be expected to each interested patient. Each participant will be informed that participation in the study is voluntary, that they can withdraw at any time, and that the withdrawal of consent will not affect subsequent medical care and treatment. In addition, participants will be informed that their medical data will be viewed by authorised persons in the study team but will not be disclosed to third parties and will only be published anonymously. Patients who decide to participate in the study will receive the consent form for study participation by mail (see online supplemental file 1). It describes the study and contains the information described above. This procedure will give patients sufficient time to consider the decision to participate under the conditions listed. Patients who decide to participate in the study will sign and date the consent form and mail it back to the project team.

Randomisation

An independent researcher will randomly assign patients to the IG or the CG such that they are stratified by age, sex and body mass index (BMI). We will apply a permuted-block randomisation with variable block sizes of 2, 4 and 6 (randomly arranged) in a 1:1 ratio using a web-based programme (https://www.sealedenvelope.com/). The randomisation will be conducted and transmitted by J-NK via email. The time point of the randomisation and of the study design are shown in figure 1. Due to the nature of

Table 1 Schedule for enrolment, interventions and assessments

Time point	Measurement	Evaluator	Enrolment	Allocation	T0	T1	T2
Screening			X				
Informed consent			X				
Allocation				X			
Intervention group							
TAU (medical diabetes treatment)				X	X	X	X
dbcoach (telephone coaching, app)				X	X	X	X
Control group							
TAU (medical diabetes treatment)				X	X	X	X
dbcoach-app, written recommendation				X	X	X	X
Inclusion criteria							
Age >18 years old	Screening	Study team	X				
HbA1c>7.5 %	Screening	Physician	X				
T2D according to ADA	Screening	Physician	X				
Sufficient knowledge of German language	Screening	Physician	X				
Access to ongoing diabetes care	Screening	Physician	X				
Internet access	Screening	Study team	X				
Physically inactive	Screening	Study team	X				
Primary outcomes							
HbA1c	Medical report	Physician			X	X	X
Objectively assessed physical activity	ActiGraph wGT3X-BT	Objective			X	X	X
Secondary outcomes							
Self-reported physical activity	SIMPAQ questionnaire	Self-rating			X	X	X
Cognitive mediators of behaviour change	Sport related:						
	► Goal intention				X	X	X
	► Self-concordance				X	X	X
	► Consequence experience	Self-rating			X	X	X
	► Barrier management				X	X	X
	► Action planning				X	X	X
	► Self-efficacy				X	X	X
Nutrition	Nutrition diary, Healthy Eating Index	Self-rating			X	X	X
Nutrition behaviour	SEV questionnaire	Self-rating			X	X	X
Quality of life	SF-8 questionnaire	Self-rating			X	X	X
Neuropathy	FACT questionnaire	Self-rating			X	X	X

Continued

Table 1 Continued

Time point	Measurement	Evaluator	Enrolment	Allocation	T0	T1	T2
Medication	Medical report	Physician			X	X	X
Food supplements	Medical report	Physician			X	X	X
Anthropometry	Medical report	Physician			X	X	X
Blood values	Medical report	Physician			X	X	X
Comorbidities	Medical report	Physician			X	X	X
Cost-effectiveness	Tarmed V.1.09	Study team			X	X	X
Demographic variables	Demographic questionnaire	Self-rating			X		

ADA, American Diabetes Association; FACT, Functional Assessment of Cancer Therapy; HbA1c, glycated haemoglobin; SEV, Eating Behaviour Scale; SF-8, Short Form-8 Health Survey; SIMPAQ, Simple Physical Activity Questionnaire; TAU, treatment as usual; T2D, type 2 diabetes.

the study, researchers, coaches and clinicians will not be blinded.

Content of the dbcoach intervention

Patients assigned to the IG will receive 12 months of individually tailored counselling aimed to promote physical activity and healthy eating for treating T2D. Lifestyle counselling will be provided through telephone calls in 24 sessions. The frequency of the telephone calls will depend on the time of the intervention: in the first 6 weeks, the telephone calls will occur weekly; in the following 24 weeks, every 2 weeks; and in the last 24 weeks, every 4 weeks. Each counselling call will last 40 min. Coaches will have 10 min to prepare and to review each conversation. In addition, patients will have access to an application and a website for monitoring their health behaviour and for communicating with their personal health coach. The contents of the intervention can be found in table 2.

The dbcoach programme combines knowledge from sports science, nutritional science, diabetology and sports psychology. Based on the ADA's and ACSM's recommendations for physical activity[17] and nutrition,[29] the personal health coaches will support patients in changing their lifestyles. The aim is to integrate and maintain a healthy, physically active lifestyle in patients' daily routines.

Physical activity

The dbcoach intervention adapts the ACSM's recommendations to the individual needs of patients based on comorbidities, contraindications and realistically achievable goals. Starting from patients' status quo, the goal is to progressively increase and then to maintain their physical activity. In addition, patients are encouraged in the intervention to increase their habitual daily physical activity. The dbcoach programme helps patients achieve the following ACSM activity recommendations:

- 150 min of at least moderately intense physical activity or 75 min of vigorously intense aerobic physical activity per week spread over 3 days. Physical activity sessions should be at least 10 min in duration, and the duration should increase as the patient progresses.
- Strength training on 2–3 days per week of light to moderate intensity. A slow increase is recommended. Optimally, 10–15 repetitions per exercise should be performed for each major muscle group.

According to the recommendations, patients are also supported in the intervention in undertaking other types of sports and exercise and in integrating them into their daily routines (eg, yoga, balance training, stretching).[17]

Nutrition

The ADA recommends nutrition therapy aimed at addressing glycaemic status, body weight and cardiovascular risk factors. Improvements in metabolism and body weight can be achieved using a variety of nutritional approaches and regardless of particular macronutrient distributions. Healthy diets can be implemented individually within the framework of the following nutritional

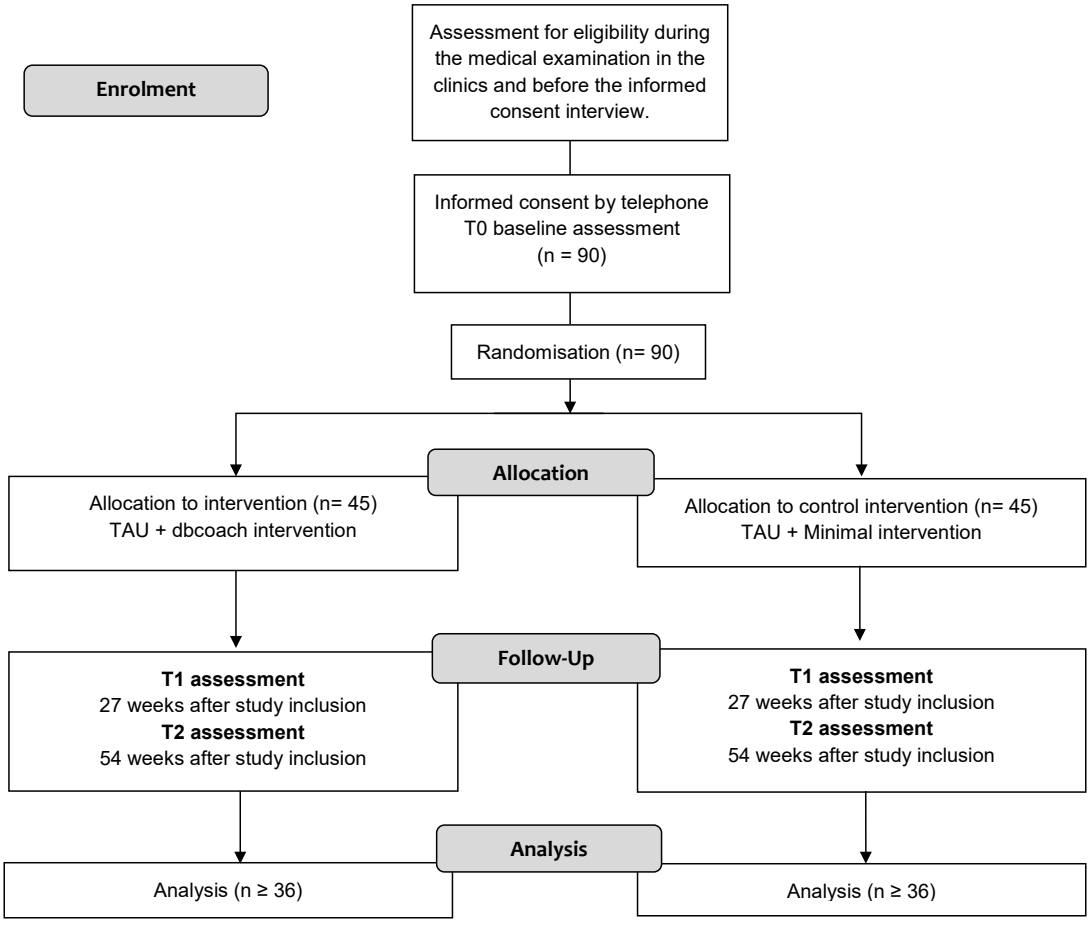

Figure 1. Study flowchart based on Consolidated Standards of Reporting Trials (CONSORT).

Figure 1 Study flow chart based on Consolidated Standards of Reporting Trials. TAU, treatment as usual.

approaches: Mediterranean diets,[36–38] low-fat diets,[39–42] low-carbohydrate diets[43–45] and Dietary Approaches to Stop Hypertension.[46 47] Detailed information on the contents of the nutrition concepts can be found in online supplemental file 2. Due to the numerous differences in the cultural backgrounds, socioeconomic environments, individual dietary preferences and comorbidities of diabetes patients and the multifactorial disease process of T2D, there is not a 'one-size-fits-all' nutritional approach for patients with T2D.[29] Thus, participants in the IG will be able to choose one of the concepts they would like to integrate into their everyday life. The coaches will be trained to teach the concepts. In addition to the counselling calls, participants can read information about the concepts in the associated coaching app. This includes the nutrient recommendations (carbohydrates, fats, proteins, fibres) for the concepts as well as the recommended amount to eat of specific food categories (fruits, vegetables, grains, nuts, dairy, oils, meat and fish). Moreover, participants can find background information on how implementing the concept can positively impact their T2D.

Motivation-volition concept

The dbcoach intervention is based on the principles of the motivation-volition (MoVo) process model and includes interventional strategies of MoVo-Lifestyle-Integrated Sporting Activity (MoVo-LISA)[48] and the multicentre organised exercise-oriented initiative for lifestyle change based on self-responsibility (MOBILIS; German: Multizentrisch organisierte bewegungsorientierte Initiative zur Lebensstiländerung in Selbstverantwortung).[49] In this context, the MoVo concept assumes that habits ingrained in everyday life over years are difficult to change for most people, especially when it comes to changing unhealthy behaviours, such as insufficient physical activity or an unhealthy eating behaviour. Even if there is a high level of motivation, many people are not able to change their lifestyle for a longer period of time. Support for the volitional implementation of their intentions is needed.[30]

The MoVo concept will mainly be implemented in the first six counselling sessions. Based on the nutrition and exercise recommendations outlined above, participants will set together with their coaches overall health goals,

Table 2 Elements of the dbcoach intervention

Component	Time of event	Duration	Content/aim	Task for participants before the next coaching
Coaching 1	Week 1	30 min	▶ Give overview of coaching process ▶ Build trust with coach ▶ Establish compliance with the programme	▶ Test functions of the app
Coaching 2	Week 2	30 min	▶ Provide information about targeted health behaviour ▶ Clarify advantages of the new health behaviour ▶ Strengthen expectations of consequences	▶ Monitor nutrition and exercise ▶ Read information on diet approaches and exercise recommendations
Coaching 3	Week 3	30 min	▶ Determine health goals ▶ Set nutrition and physical-activity goals ▶ Collect ideas for action planning	▶ Experiment with exercise and nutrition ideas
Coaching 4	Week 4	30 min	▶ Discuss implementation of nutrition ideas ▶ Concretize ideas and create nutrition plan ▶ Review nutrition plan	▶ Implement nutrition plan
Coaching 5	Week 5	30 min	▶ Discuss implementation of ideas for physical activity ▶ Concretise ideas and create physical-activity plan ▶ Review physical-activity plan	▶ Implement physical-activity plan
Coaching 6	Week 6	30 min	▶ Identify barriers to physical activity and healthy eating ▶ Create individual barrier management	▶ Use barrier management ▶ Note further barriers
Coaching 7–24	Weeks 8–54	30 min	▶ Address individual goals, needs and problems ▶ Use of individual BCTs	▶ Set individual tasks

BCTs, Behaviour change techniques.

weight-loss goals and specific nutrition and exercise goals. Furthermore, participants will create action plans for nutrition and physical activity with their personal health coaches. Participants will identify barriers to implementing the new health behaviour and create barrier management strategies to shield the new behaviour. These motivational and volitional strategies will be implemented at the beginning of the intervention and revisited throughout the process.

Behaviour change techniques

Behaviour change techniques (BCTs) are the smallest identifiable components of an intervention that have the potential to change people's behaviour.[31] After the implementation of the MoVo concept in the first six coaching sessions, coaches will individually address the goals, needs and problems of the participants with selected BCTs. The focus will be on integrating diet and exercise recommendations into participants' daily lives.

The internationally recognised BCT Taxonomy V.1[31] has been used to capture strategies for behaviour changes in the dbcoach intervention. The category system includes 16 categories, each of which contains 3–11 behaviour change strategies for a total of 93 strategies. Based on studies, reviews and meta-analyses of BCTs for promoting physical activity and healthy eating,[50–53] the predecessor studies PACINPAT[54] and Movingcall,[55] and coaches' experiences, the taxonomy for the dbcoach study is limited to 41 BCTs. Coaches will be required to document the topics, goals and BCTs used in the coaching calls with each participant.

dbcoach APP

The individual telephone coaching will be supplemented with a digital intervention. This digital intervention consists of an app that was developed to support patients in making behaviour changes and to complement telephone counselling. The app will be available to participants as a web application and as a smartphone app. The goal of the app is to support participants in planning and self-monitoring physical activity and nutrition behaviours.

Participants will have the opportunity to communicate with the coach via a chat module in the data-protected app. Additionally, they can note behavioural goals, barriers and barrier management strategies in the app. Participants will have access to information on the nutrition concepts with corresponding recommendations and can use questionnaires to check their level of compliance with the nutrition concepts. They can also find information on the topic of physical activity with recommendations on how to implement it. Moreover, it is possible to set and change the outcome-related nutrition goals according to the concepts and individual conditions (macronutrients, vegetable and fruit intake, fibres). The same principle applies to the outcome-related physical activity goals: the number of minutes of activity per day and per week can be changed and adjusted. Participants can use the app to document their nutrition and physical activity behaviours as well as selected data (blood glucose, fat levels, weight, BMI, waist and hip circumference, hip-to-waist ratio, body fat, blood pressure, inflammation levels, kidney and liver values). If these values are

documented, the data can be viewed graphically in the app for an overview.

The coaches will have access to the app via an expert account, which allows them to view their patients' entries and documentation, plan activities and meals, and chat with their patients. Expert access is only available via the web app.

Control condition

Study participants assigned to the CG will receive a one-time written diet and exercise letter based on the recommendations of the ADA and ACSM. The CG will be given access to the app and website and receive the standard T2D treatment but without support from a personal health coach. This will include commonly prescribed treatments such as medications, diabetes counselling, nutrition therapy and other health services.

Training of the personal health coaches

The telephone-based personal health coaching will be provided by seven experts with a master's degree in sports science, psychology, or nutritional science. In addition, the coaches have completed training as a personal health coach as part of a standardised training programme at the University of Basel. They have been trained primarily in the areas of behavioural change, motivational techniques and interviewing as well as in specific content on nutrition, exercise and health. For implementing the dbcoach intervention, the coaches will receive further training comprising five 3-hour classes on medical, physical activity and dietary information relevant to the study. In addition, the coaches will be informed about the MoVo concept, BCTs and the intervention. The coaches will receive a detailed coaching manual in addition to the training. They will be supervised on a monthly basis.

Treatment as usual

The standard therapy for T2D in Switzerland consists of the following topics: nutrition, physical activity, medication and insulin, education, and self-control. T2D is treated on an outpatient basis by primary care physicians or diabetologists. Initially, individual therapy goals are set together with the patient with regard to lifestyle, glucose metabolism, lipid status, body weight and blood pressure. Non-pharmacological approaches in the form of diabetes and diet counselling and lifestyle interventions are used as basic therapies. If glycaemic control cannot be achieved through basic therapy, drug therapy is used. Medication adjustments forpatients with T2D depend on glycaemic control, acute and chronic complications, and comorbidities. Before any oral diabetes medication or insulin is prescribed, lifestyle modifications are supposed to be attempted. Drug and non-drug treatments can also be given simultaneously. The administration of medication can be increased if glycaemic control is not achieved with the administration of insulin.[56] Since the establishment of a healthy lifestyle has an impact on further treatment, physicians will be informed about patients' participation in the study and also about whether they are in the IG or the CG.

Primary outcomes

Objectively measured physical activity

One of two primary endpoints is objectively measured physical activity. This outcome has been selected to prove the hypothesis that the physical activity of the IG will increase in comparison to that of the CG. For the objective measurement of physical activity, a triaxial accelerometer (ActiGraph wGT3X-BT, Actigraph, Pensacola, USA) will be used. It provides information on the duration and intensity of daily physical activity based on measurements of acceleration. This accelerometer has been used as a successful measurement method in previous studies[57 58] and is considered a reliable measurement tool.[59] Study participants will receive the accelerometer by regular post and will be asked to wear it around their waist during the daytime for seven consecutive days. Wearing the accelerometer around the waist represents a standardised procedure, is widely used as a method, and is therefore comparable in terms of data.[60] In order to qualify as a valid measurement, participants have to wear the Actigraph for at least 5 days, including a least four valid weekdays and one valid weekend day.[61] Only days with at least 10 hours of wear time will be rated as valid days.[62] If they are unable to wear the Actigraph for a period, participants can fill in a form for activities undertaken during that time. Physical activities listed on the sheet for non-wear time will be included as moderate to vigorous physical activities based on the intensity levels defined in the Compendium of Physical Activities.[63] The accelerometer data are digitised using a 12-bit A/D converter and a band-pass filter is applied (0.25–4.0 Hz). The data will be analysed using the manufacturer's software (ActiLife, Actigraph, Pensacola, USA). The raw data will be divided into 60 s segments (60 s epoch time), and the counts of the accelerometers will be converted to parameters for physical activity (energy expenditure or time in certain intensity zones). Time spent in moderate to vigorous physical activity (>1952 counts per minute, >3 MET) per day will be measured. The measurements will be based on the raw accelerometer counts and will be corrected for wear time.

Glycated haemoglobin

With regard to the second study question, we chose HbA1c as the second primary outcome. HbA1c is a blood marker that reflects chronic glycaemic control over the past 2–3 months and is used as an essential endpoint to measure the progression of T2D. In addition, HbA1c is superior to other parameters, such as fasting plasma glucose, because it has a very low biological variability.[64] HbA1c indicates the percentage of total haemoglobin that glucose is bound to.[65] T2D is present when HbA1c is above 6.5% (values between 5.7% and 6.4% indicate pre-diabetes).[64] HbA1c can be measured at medical examinations using appropriate equipment.[66–68] It is measured every 3 months by

physicians as part of the standard treatment. With participants' consent forms, the study team will be allowed to request the values from physicians. Medications, food supplements and comorbidities will be considered as possible contributing factors in the statistical analyses. To determine whether the dbcoach intervention positively affects glycaemic control compared with the CG, HbA1c will be used as the primary outcome. HbA1c represents the most relevant parameter for assessing the effectiveness of the intervention on the course of T2D.

Secondary outcomes

Self-reported physical activity

Self-reported physical activity will be assessed using the Simple Physical Activity Questionnaire (SIMPAQ).[69] The SIMPAQ is a short, reliable and validated five-item questionnaire developed for clinically assessing physical activity in inactive individuals.[69 70] The questionnaire can be completed during a structured interview lasting between 10 and 15 min. In this study, the SIMPAQ interview will be conducted by telephone. It will involve determining the time spent sitting or lying down, walking, doing sports or doing other physical activities. In addition, the time participants spend standing will be surveyed to complement the SIMPAQ interview. Information on the frequency, intensity, duration and type of activities will thus be obtained. For this purpose, the respondents will have to remember their activity behaviour in the last 7 days.[70]

Cognitive mediators of behaviour changes related to physical activity

Cognitive mediators for behaviour changes will be measured to determine changes in study participants' health behaviours related to physical activity. We assume that initiating and maintaining health behaviours is largely dependent on a strong goal intention,[71] high self-concordance with this goal intention,[72 73] realistic action plans,[74 75] effective barrier-management strategies,[76] and, finally, positive experiences of consequences of the new behaviour.[77] Table 3 summarises the cognitive mediators of behaviour changes related to physical activity. Online supplemental file 3 contains a detailed description of the measurements of the cognitive mediators of behaviour changes related to physical activity. All cognitive mediators of behaviour changes related to physical activity will be collected with an online questionnaire. A web link to the questionnaire will be sent to participants by e-mail at particular points in time for measurement. The questionnaire was created with the web-based programme Sosci-Survey. The programme offers the possibility of downloading and analysing the data in the requested format.

Nutrition

Participants will be asked to create nutrition protocols for 1 week at the specified measurement times using Nutriguide V.4.6 (Nutri Science, Hausach, Germany). Based on these 7-day protocols, nutritional values will be assessed at baseline (T0), during the intervention (T1) and at the end of the intervention (T2). The nutritional data will encompass changes in caloric intake and macronutrients and will make it possible to calculate the Healthy Eating Index 2015 (HEI-2015), which provides an objective measure of nutritional quality across varying dietary concepts. The HEI-2015 uses a scoring system to assess food. Total HEI-2015 scores are made up of 13 components that reflect the different food groups and key recommendations of the Dietary Guidelines for Americans. Scores range from 0 to 100, with a total score of 100 reflecting an ideally balanced diet.[78] For the use of the index in this study, a metric transformation is planned.

Nutrition behaviour

The Eating Behaviour Scale (SEV)[79] will be used to evaluate eating behaviour. This scale serves to assess the outcomes of dietary behaviour in interventions related to physical activity and weight-loss. The questionnaire was created as an extension of the eating-style questionnaire[80] and assesses behavioural eating and phenomenological

Table 3 Description of the measured cognitive mediators of behaviour changes related to physical activity

Cognitive mediators of behaviour changes related to physical activity	Description
Goal intention	Goal intentions are the result of motivational processes of considering and choosing processes between the different simultaneously existing needs of a person.[30]
Self-concordance	Self-concordance expresses the degree to which goal intention is consistent with a person's other individual interests and values.[72 73]
Self-efficacy	Self-efficacy is the belief in performing a physical activity programme over a longer period of time.[106]
Action planning	In action planning, a person determines when, where and how to begin or continue an intended action.[107]
Barriers and barrier management	Situational barriers describe physical, social and psychological conditions that can impede or jeopardise the implementation of a behavioural intention. activity.[108]
Consequence experience	As a construct, consequence experience related to physical activity represent experiences with physical activity, exercise and sports.[77]

eating behaviours with 27 items. The SEV will be sent as an online questionnaire at the relevant measurement time points in the same fashion as the questionnaire on cognitive mediators for behaviour changes related to physical activity.

Blood values

In addition to HbA1c values, other blood values will be collected. As part of the blood analysis in the course of the standard treatment of patients with T2D, additional values and parameters are collected for other established risk factors for cardiovascular diseases, such as chronic inflammation. These include data on lipoproteins (high-density lipoprotein and low-density lipoprotein) and total cholesterol levels, which are predictors of atherosclerotic changes, insulin resistance and the development of late complications in patients with T2D.[81–83] In addition, the C reactive protein will be assessed, as the increase in C reactive protein is associated with insulin resistance and thus represents an essential endpoint for the progression of T2D.[84]

Medications and nutritional supplements

Information on medications and nutritional supplements that participants are taking will be collected in addition to the blood values from the submitted medical reports. It will thus be possible to determine whether any medications or dietary supplements are having a potential influence on glycaemic control.

Anthropometric data

Anthropometric data will be collected by the medical staff in the course of treating T2D. These include height and weight but also the hip-to-waist ratio as an important marker for fat distribution. The anthropometric data will be measured in a standardised way. A stadiometer will be used to measure size. During the measurement, patients with T2D will not wear shoes. A digital scale will be used to measure body weight. For this purpose, patients will not wear shoes and will be lightly clothed. Based on WHO standards,[85] BMI will be calculated using the formula weight (kg)/(standing height (m))^2. Waist circumference will be measured with a measuring tape at the lower edge of the last palpable rib and the edge of the iliac crest. Hip circumference will be measured with a measuring tape at the widest part of the buttocks.[86] These data will be reported by the medical staff to the study team in a medical report for evaluation.

Quality of life

The Short Form-8 Health Survey (SF-8) will be used to assess health-related quality of life. It is a short form of the SF-36 Health Survey, a frequently used international instrument for assessing health-related quality of life. With the SF-8, participants can rate their health-related quality of life on eight items.[87 88] The SF-8 will be sent as an online questionnaire at the specific measurement time points.

Neuropathy

Subjective impairment due to symptoms of peripheral neuropathy will be assessed using the reduced (11 items) Functional Assessment of Cancer Therapy questionnaire (FACT). Since the FACT questionnaire queries neuropathic symptoms, it is not only useable in cancer therapy but also suitable for identifying neuropathy resulting from T2D. The FACT questionnaire is reliable and has been validated.[89] It will be sent as an online questionnaire at the particular measurement time points.

Cost-effectiveness

At the measurement points (T0, T1, T2), information on medications and therapy will be collected from the participants and their physicians. In addition, the costs and the extent of the intervention will be documented. Under the guidelines of the Swiss Medical Association (Tarmed V.1.09), direct medical costs can be calculated in a standardised way. The analysis of cost-effectiveness will follow the CHEERS statement[90] and will be performed according to an adapted procedure.[91] Information on the medications participants are taking will be forwarded by the clinicians in the case report form and documented by the participants in the app. Intervention costs and the work time of the coaches will be documented by the cooperation partner Salutacoach.

Data management and monitoring

All personal data of the participants will be encrypted with an anonymised participant ID. The data will be collectively entered into a file and stored with the coding list to patient data in a secure location. A list will be maintained to verify the completeness of the patient data. The analysis of the interim results and the publication of the results in the national and international community through conferences and peer-reviewed journals, will be decided by the sponsor and the monitoring committee of the study team. The monitoring committee will also coordinate who, in addition to the coauthors, will have access to the study data set. The detailed data management system has been reviewed and approved by the responsible ethics committee. The sponsor conducted a visit to each recruitment site before initiation to ensure the standardisation of recruitment and the efficient transmission of patient medical data. VH is making additional visits to recruitment sites at least quarterly. The recruitment sites will be visited more frequently if needed, for example, if there are questions or difficulties regarding recruitment. Any discrepancies observed will be documented and further action discussed. All consent forms and source documents will also be checked by the study team. The consent forms for study participation must be formally signed by the study participant and an investigator prior to the start of the study. In addition, FS will receive a report every fourth months on the recruitment rate, the number of counselling sessions conducted, the status of T1 and T2 data analyses, and the drop-out rate. In case of insufficient study progress, an agreement on

possible countermeasures will be discussed within the study team.

Proposed sample size/power calculations

The calculation of sample size was based on the main outcomes of HbA1c levels and physical activity. An a priori statistical-power analysis using sample size *N* as a function of power level 1 − β, significance level α and the selected effect size for the population was used for calculation. Based on the findings of Guo and colleagues,[92] the power analyses of multivariate models for sample-size calculation can be used for certain mixed models that fulfil conditions such as no missing or mistimed data, balance within independent sampling units, and no changes to the treatment assignment over time.[93] Since the requirements are met in this study, an analysis of variance fixed-effect, omnibus one-way has been selected as the statistical test. Given the intensive 1-year intervention phase and based on the given literature, we expect a medium to large effect size (*f*=0.33) regarding the parameters HbA1c[64 94] and physical activity.[23 95 96] With a power of 80%, an α level of 5%, and medium-to-large effect sizes, and considering an estimated drop-out rate of 20%, the necessary total sample size of the dbcoach study is *N*=90 (IG=45, CG=45). Including the drop-out rate, n≥36 per group should be analysed. The estimate of the drop-out rate refers to the predecessor project Movingcall,[57] the sample size estimation was done with the software G*Power (V.3.1.9.2, Kiel Germany).

Statistical analyses

The primary outcomes, HbA1c values and objective physical activity, will be analysed at time T2 (12 months after baseline measurement) as dependent variables with the baseline values as covariates. Statistical analysis of intervention effects will be based on linear mixed models with a restricted maximum-likelihood estimation to account for missing data. The measurement time points (T0–T2) will represent the within-subject factor, while the intervention (dbcoach, TAU) and the control intervention (dbcoach app, TAU) represent the between-subject factor. Interactions in both directions will be taken into account, and main effects and interaction will be estimated for time points T1 and T2. Baseline HbA1c and baseline minutes of objective physical activity will be included as covariates in the analyses, along with age, sex, demographic and clinical characteristics (eg, comorbidities). The model will enable multilevel analysis, and fixed effects will be defined as time, the interaction between group and time, and baseline measurements; subjects will be defined as random effects. Changes in participants' treatments for lowering glucose, like medications and food supplements, will be considered as possible contributing factors in the analyses as covariates. Comorbidities will be considered as well.

Nutrition behaviour, quality of life, neuropathy, anthropometry and blood values will be analysed as dependent variables with the values of the measurement time points T1 and T2, which represent the covariates. Linear mixed models will be used for statistical analysis of the listed secondary outcomes. Within-subject factors will be the measurement time points, and between-subject factors will be the IG and the CG. Demographic variables may be included in the analysis as covariates.

In addition, we will examine how the effects of the individual lifestyle intervention on physical activity behaviour were mediated by cognitive variables. For this purpose, the cognitive mediators for behaviour change related to physical activity and objective physical activity will be analysed in the course of a structural equation model.

Analyses will not consider cluster effects with respect to different recruitment sites because all participants will receive the standard treatment for T2D, and the intervention will use a tailored but standardised approach.

Standardised mean differences and 95% CIs will be calculated to measure the size of the effect between groups at T1 and T2. All analyses will be conducted on an intention-to-treat basis. Supplemental analyses (per protocol) will be conducted to examine how participants who do not meet the study protocols influence the study outcomes. In addition, the extent to which participants' activity and nutrition are consistent with ADA and ACSM recommendations will be assessed.

Source of monetary or material support

The study is funded by Innosuisse as well as Meconex AG, Swica, Sympany and EGK.

The supporting companies and organisations covers research costs, staff salaries and material costs.

Patient and public involvement

No patient involved.

ETHICS AND DISSEMINATION

The study is being conducted in accordance with the protocol and principles of the current version of the Declaration of Helsinki,[97] the ICH Good Clinical Practice guidelines,[98] Swiss law, and the requirements of the Swiss regulatory authority. Permission to conduct the study was granted by the Ethics Committee North-western and Central Switzerland on February 10, 2021 (ref: 2020-02755). Interested patients will be informed about the study and give their written informed consent to participate. Furthermore, the study will be conducted under the principle of participants' right to privacy. This means that applicable data protection laws will be respected and that participants' anonymity will be guaranteed when the data is presented at scientific conferences or published in scientific journals. Medical information about individual subjects obtained in the course of this study will be considered confidential. Disclosure to third parties is prohibited. Confidentiality is further guaranteed by the use of participant identification numbers. Physical activity and dietary recommendations will be individually tailored to participants. Participants will receive tailored advice on

gradually increasing activities adapted to their ages and abilities and on healthy eating. The risk of adverse events related to physical activity or nutrition, such as musculoskeletal injuries or food intolerances, are equal to independent participation in the programme. However, if (serious) adverse events should occur during or after the study, these will be monitored by the study team and by the physicians as part of standard therapy. All serious adverse events will be documented and reported immediately (within a maximum of 24 hours) to the principal investigator of the study.

At the end of the study, the results will be published in peer-reviewed international journals. The research team will coordinate the international dissemination of the study results through presentations at national and international conferences and publications in peer-reviewed journals (primarily open access). It has been agreed with the federal institution Innosuisse that the study results will be published by the study team at the University of Basel in the form of scientific publications.

DISCUSSION

Since a healthy lifestyle has a positive impact on glycaemic control, effective lifestyle interventions to support and implement changes in health behaviour should be investigated. This study protocol describes the design of an RCT for evaluating the dbcoach intervention. The focus of the study is to examine the primary outcomes of HbA1c, in order to classify the course of TD2 in participants, and of physical activity, to evaluate their changes in lifestyle.

In recent years, a number of interventions for changing health behaviour have been developed, reviewed and implemented in the field of T2D rehabilitation. These programmes have demonstrated the potential to have a positive impact on HbA1c levels through lifestyle modification.[99 100] Digitalisation and the accompanying advent of modern information and communication technologies have created the opportunity to implement digital and location-independent interventions to promote health behaviours.[101] Recent reviews and meta-analyses have demonstrated the positive impact of web and smartphone apps on increasing physical activity and healthy eating.[102–104] However, using digital interventions exclusively (eg, 'stand-alone' apps) is assumed to be less effective than combining digital interventions with therapist-guided interventions (eg, phone coaching).[105] The dbcoach programme employs such a blended-care approach to promote physical activity and healthy eating in order to positively influence glycaemic control. For this purpose, the intervention combines ADA and ACSM nutrition and physical activity recommendations, the MoVo concept and BCTs.

Despite promising prospects for the effectiveness of the intervention, limitations should be discussed.

The CG will receive the standard treatment for T2D, as will the IG. It is reasonable to assume that the CG's HbA1c will be well controlled with medication. We will therefore include medication as a covariate in the statistical analysis, so that we can identify its impact. We nevertheless suspect that the intervention effects will be seen in other outcomes, for example, in physical activity, diet and medication.

As the intervention will be evaluated as an additional treatment to TAU and because of considerations of feasibility, no target was set for starting medication. The physicians are not blinded to the intervention allocation of the participants, which could lead to a bias in medication prescribing. Since lifestyle changes in patients with T2D are recommended and requested by physicians in the course of TAU, this aspect could be neglected.

With regard to the power of the sample calculation, we assume a medium to high effect size for the primary outcomes. In HbA1c small but clinically important changes could be missed.

In addition, there is a possibility that the participants will be prescribed insulin during their participation in the study. Once they start insulin therapy, these patients' data will not be included in the analyses. Since an HbA1c value of 7.5% is an inclusion criteria and insulin therapy is an exclusion criteria, we hope for noticeable effects of the intervention on one of the primary outcomes. However, due to the study criteria, it is possible that a substantial number of patients with T2D are not eligible for the study.

Another potential limitation of the study is that the dates of the standard examination may not coincide with the measurement dates specified in the study. That might be the case if an appointment is cancelled or postponed. We, therefore, expect a range in the time points when HbA1c is measured, which we will document.

In spite of these limitations, the dbcoach programme represents a holistic, innovative location-independent complement to standard treatment that has a high potential to positively impact the progression of T2D in the long term and to improve health behaviours in a sustainable way. If the intervention proves to be effective in terms of glycaemic control, lifestyle-behaviour changes and cost-effectiveness, it has great potential to be offered by health insurers as an adjunct to existing treatments, which would reduce economic costs for individuals and society.

TRIAL STATUS

The study started screening and recruiting of study participants in May 2021. Assuming a recruitment rate of approximately 5–15 patients per month, recruitment will be completed in September 2022.

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