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'Diabetescoach' – personal health coaching in patients with type 2 diabetes mellitus

Submission date
13/02/2021

Recruitment status
No longer recruiting

Registration date
17/02/2021

Overall study status
Completed

Last Edited
11/06/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (DT2) is a common condition that causes the level of sugar (glucose) in the blood to become too high. Risk factors for DT2 include a high-calorie diet, physical inactivity and the resulting obesity. In view of the increasing number of DT2 patients and the associated costs for the health care system, there is an urgent need to further develop interventions for the treatment of DT2 in addition to standard treatment. Due to the different course of DT2 and the emergence and severity of the associated illness, treatment of DT2 should be based on a tailored approach to support lifestyle change.
This Diabetescoach (dbcoach) study is based on the need to develop a lifestyle intervention to implement the exercise and nutrition recommendations and to establish appropriate health behavior for DT2 patients. The aim of this study is to evaluate an individual personal health coach intervention to promote an active lifestyle and healthy eating behavior in addition to the existing treatment methods. It is assumed that the investigated intervention has a positive effect on HbA1c, physical activity, nutritional and dietary behavior and other examined parameters.

Who can participate?
Patients between 18-65 years old with type 2 diabetes

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Patients assigned to the intervention group will receive a 12-month, individually-tailored counselling to promote physical activity and healthy eating during medical treatment. Lifestyle counselling is provided through telephone calls in 24 sessions. The frequency of the telephone calls depends on the time of the intervention: in the first 6 weeks the telephone calls take place weekly, in the following 24 weeks every 2 weeks and in the last 24 weeks every 4 weeks. In addition, patients have access to an application for monitoring their health behavior and for communicating with their personal health coach. The intervention is based on the MoVo-concept, behavior change techniques and physical activity and nutritional recommendations of the American College of Sports Medicine and the American Diabetes Association. The researchers expect to achieve long-term lifestyle changes in patients with type 2 diabetes through individualized, ongoing support via telephone counseling and the app.

In addition to the standard treatment of diabetes type 2, patients in the control group receive a one-time written diet and exercise recommendation. This recommendation is based on the current standard recommendation of the American College of Sports Medicine and the American Diabetes Association. The control group also gets access to the application and should follow the standard treatment.

What are the possible benefits and risks of participating?
There are no disadvantages to participating in the study. Participation is on a voluntary basis and can be stopped at any time. Medical treatment will continue even if the patient participates in the program. Therefore the standard treatment is independent of participation. There are no risks associated with participation in the study.
By participating in the study, patients have the opportunity to change their lifestyle in the long term and thus slow down the progression of DT2. The program also takes place regardless of location.

Where is the study run from?
University of Basel (Switzerland)

When is the study starting and how long is it expected to run for?
July 2019 to February 2024

Who is funding the study?
Innosuisse (Switzerland)

Who is the main contact?
1. Dr Oliver Faude
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Study website
https://www.db.coach/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
'Diabetescoach' – personal health coaching in patients with type 2 diabetes mellitus: a randomized controlled trial

Acronym
dbcoach

Study objectives
1. The HbA1c level of the intervention group can be reduced in the long term compared to the control group.
2. The physical activity of the intervention group will be increased and maintained compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/02/2021, Ethikkommission Nordwest- und Zentralschweiz (Hebelstrasse 53, 4056 Basel CH, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2020-02755

Study design
Interventional single-blind monocentric pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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
Type 2 diabetes

Interventions
Patients will be randomly assigned to the intervention group or the control group by an independent person, stratified by age, sex, and BMI. Randomization will be conducted as permuted block randomization with variable block sizes of 2, 4, and 6 (randomly arranged) in a 1: 1 ratio.

Patients assigned to the intervention group will receive 12 months of individualized counseling to promote physical activity and healthy eating in addition to standard therapy for type 2 diabetes. Lifestyle counselling is provided through telephone calls in 24 sessions. The frequency of the telephone calls depends on the time of the intervention: in the first 6 weeks the telephone calls take place weekly, in the following 24 weeks every 2 weeks and in the last 24 weeks every 4 weeks. In addition, patients have access to an app to monitor their health behaviors and communicate with their personal health coach. The intervention is based on the Movo concept, behavior change techniques, and exercise and nutrition recommendations from the American College of Sports Medicine and the American Diabetes Association. This theory- and evidence-based intervention has the potential to achieve long-term lifestyle changes in patients with type 2 diabetes through individualized, ongoing support via telephone counseling and the app.

In addition to the standard treatment of type 2 diabetes, patients in the control group receive a one-time written diet and exercise recommendation. This recommendation is based on the current standard recommendation of the American College of Sports Medicine and the American Diabetes Association. The control group also gets access to the application and should follow the standard therapy.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline (T0), after study inclusion, 6 months after study inclusion (T1), and 12 months after study inclusion (T2):
1. Chronic glycemic control over the last 3 months measured using HbA1c blood marker
2. Duration and intensity of daily physical activity measured using a triaxial accelerometer (ActiGraph wGT3X-BT) around the waist for 7 days

Secondary outcome measures
Measured at baseline (T0), after study inclusion, 6 months after study inclusion (T1), and 12 months after study inclusion (T2):
1. Subjective physical activity measured using SIMPAQ questionnaire
2. Nutrition and dietary behavior measured using Nutrition Diary, SEV questionnaire
3. Sport-related cognitive mediators of behavior change measured using questionnaires
4. Quality of life measured using SF-8 questionnaire
5. Neuropathy measured using FACT questionnaire
6. Medication measured using medical report
7. Food supplements measured using medical report
8. Anthropometry (abdominal circumference, hip circumference, height, weight) measured using medical report
9. Blood levels (cholesterol, LDL, non-HDL, Chol/HDL, CRP, IFG) measured using medical report
10. Comorbidities measured using medical report
11. Demographic variables measured using a demographic questionnaire
12. Cost-effectiveness measured using Swiss Medical Association, Tarmed V.1.09 at the end of the study

Overall study start date
01/07/2019

Completion date
29/02/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/06/2021:
Type 2 diabetes patients will be included in the study if they:
1. Have an HbA1c value above 7.5
2. Have type 2 diabetes as defined by the American Diabetes Association
3. Are able to understand German at a sufficient level to comprehend instructions and information
4. Have access to ongoing treatment for type 2 diabetes by a primary care physician or diabetologist
5. Have an Internet connection
6. Have an activity level of less than 150 minutes of moderate or 75 minutes of intensive physical activity per week

Previous inclusion criteria:
Type 2 diabetes patients will be included in the study if they:
1. Are between 18-65 years old
2. Have an HbA1c value above 7.5
3. Have type 2 diabetes as defined by the American Diabetes Association

4. Are able to understand German at a sufficient level to comprehend instructions and information
5. Have access to ongoing treatment for type 2 diabetes by a primary care physician or diabetologist
6. Have an Internet connection
7. Have an activity level of less than 150 minutes of moderate or 75 minutes of intensive physical activity per week

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
Patients with type 2 diabetes must 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. They suffer from psychiatric or addiction disorders
3. They are pregnant
4. Insulin therapy is being used
5. If the HbA1c value cannot be reliably determined due to medical conditions (in the case of hemoglobinopathy, hemolytic anemia, blood transfusion, HIV, liver or kidney failure requiring dialysis)

Date of first enrolment
01/05/2021

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Basel
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Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www.unibas.ch/de

ROR
https://ror.org/02s6k3f65

Funder(s)

Funder type
Government

Funder Name
Innosuisse - Schweizerische Agentur für Innovationsförderung

Alternative Name(s)
Innosuisse - Swiss Innovation Agency, Innosuisse - Agence suisse pour l’encouragement de l’ innovation, Innosuisse - Agenzia svizzera per la promozione dell’innovazione, Swiss Innovation Agency, Innosuisse, Innosuisse

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Switzerland

Results and Publications

Publication and dissemination plan
The study protocol will be published as an additional document. The dissemination of the results will take place in a peer-reviewed journal and will be coordinated by the principal investigator.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 04/01/2022:
The statistical analysis code as well as the final data will be provided by the corresponding author in a scientific repository. The final data set does not contain any demographic or personal information that could lead to the identification of the study participants.

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Previous IPD sharing statement:
The data-sharing plans for the current study are unknown and will be made available at a later date. The researchers would like to publish the data-sharing plans with the study protocol.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/06/2022	08/06/2022	Yes	No