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Diabetes mellitus type 2: clever assistance in everyday life - pilot study [Diabetes Mellitus Typ 2: Clevere Unterstützung im Alltag - Pilotstudie]

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
18/04/2019

Overall study status
Completed

Last Edited
01/12/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims:
Changing lifestyle is the first line of treatment in the management of type 2 diabetes. Lifestyle factors mainly include eating behavior, physical activity and mental health. In order to help newly diagnosed type 2 diabetics with the needed lifestyle modifications, outpatient clinics offer special group training courses. Unfortunately, group training courses are limited by time and resource constraints. Therefore, a smartphone app has been developed which makes use of the time between the individual group training sessions. The app provides tasks that encourage the patients to think about their lifestyle. After the final session of the group training course, the app additionally delivers diabetes-relevant tips. These tips repeat the contents discussed in the group training courses over a period of 4 weeks. The aim of this study is to evaluate whether the usage of the app increases the effects of the group training courses, especially on changes in diabetes self-management ability.

Who can participate?
Adults over the age of 18 who attend group training courses for type 2 diabetes at one of the three study centres (outpatient diabetes clinics) in Austria.

What does the study involve?
Participants are asked to join this study during the first session of a group training course for type 2 diabetes. Participants are allocated to one of two groups according to the time of participation. Those in the first group (control group) are asked to monthly complete questionnaires on their smartphones – using a specifically developed smartphone app – regarding their diabetes self-management as well as their perceived burden caused by the disease. During the study period of 3 months, the participants of the first group are additionally asked each month to give a small finger-prick blood sample to test their long-term blood sugar level. Those in the second group (intervention group) are asked to complete the same programme as the first group. In addition, they are asked to complete tasks using the specifically developed smartphone app in the time between the individual sessions of the group training

courses and to rate tips on diabetes-related topics that are received over a period of 4 weeks after their last group training course session.
This allows an evaluation whether or not mHealth supported group training sessions have a positive effect on the diabetes self-management and long-term blood sugar level of type 2 diabetics.

What are the possible benefits and risks of participating?
All participants receive additional measurements of their long-term blood sugar levels. This may be perceived as a burden, on the other hand, there is the benefit of closely monitored blood sugar levels. Participants who are assigned to the intervention group will receive prompts to considertheir diabetes-relevant behaviour. Information obtained from this study may help type 2 diabetics in adapting to a healthier lifestyle in the future. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
The DM2CUA-pilot study is being run by the University of Applied Sciences Salzburg, Austria, and takes place in three outpatient diabetes clinics across the federal state of Salzburg, Austria (Privat-Klinik Wehrle Diakonissen GmbH, Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH, Gemeinnützige Oberndorfer Krankenhausbetriebsgesellschaft mbH).

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

Who is funding the study?
Federal State of Salzburg (Austria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
Nil known

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DM2CUA-pilot-V2

Study information

Scientific Title
Effects of an mHealth support-programme within and beyond the scope of group training courses for type 2 diabetes in an open case-control cluster pilot study

Acronym
DM2CUA-pilot

Study objectives
Timepoint 0: start of group training course
Timepoint 1: end of group training course
Timepoint 2: 4 weeks after end of group training course
Timepoint 3: 8 weeks after end of group training course

Primary hypothesis:
The diabetes self-management competence (measured by means of the DSMQ questionnaire) is greater at least at one timepoint (timepoint 1, 2 or 3) in persons with type 2 diabetes mellitus who, in addition to receiving standard-of-care group training courses, are provided with a mHealth support-programme consisting of tasks administered via smartphone-app that encourage critical reflection on diabetes-relevant topics and that are discussed within the group training courses (duration: 4-5 weeks) and information on diabetes-relevant topics delivered via smartphone-app over a period of 4 weeks subsequent to the completed group training course (intervention group), than in persons with type 2 diabetes mellitus who participate in standard-of-care group training courses (control group).

Secondary hypotheses:
1. The (clinically positive) change from timepoint 0 to timepoint 2 in diabetes self-management competence is greater in the intervention group than in the control group.
2. The diabetes self-management competence in the intervention group is sustainably higher (timepoint 2 to timepoint 3) than in the control group.
3. The (clinically positive) change from timepoint 0 to timepoint 3 in the long-term blood sugar level (HbA1c) is greater in the intervention group than in the control group.
4. There is a measurable correlation between smartphone usage data and smartphone sensor data and the subjective rating of information value by intervention group participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2019, Province Ethics Committee of Salzburg [Ethikkommission für das Bundesland Salzburg] (Michael-Pacher-Str 36, Postfach 427, 5010 Salzburg; +43 662 8042-2375; ethikkommission@salzburg.gv.at), ref: 415-E/2438/5-2019

Study design
Open-label case-controlled cluster-randomized multicentre pilot study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Internet/virtual

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 mellitus

Interventions
Intervention: participation in standard-of-care group training courses supplemented with a mHealth support programme consisting of:
1. Tasks administered via smartphone app that encourage critical reflection on diabetes-relevant topics and that are discussed within the group training courses (duration: 4-5 weeks)
2. Information on diabetes-relevant topics delivered via smartphone app over a period of 4 weeks subsequent to the completed group training course
Control: participation in standard-of-care group training courses
Cluster-randomization: allocation to intervention or control group as well as study centre (cluster) according to time and location of participation in group training courses.

Intervention Type
Behavioural

Primary outcome measure
Self-care relevant to glycaemic control assessed using the Diabetes Self Management Questionnaire (DSMQ) at T0 (start of group training course), T1 (end of group training course), T2 (4 weeks after end of group training course) and T3 (8 weeks after end of group training course)

Secondary outcome measures

1. Diabetes-related emotional distress assessed using the Diabetes Distress Scale (DDS) T0 (start of group training course), T1 (end of group training course), T2 (4 weeks after end of group training course) and T3 (8 weeks after end of group training course)
2. Impact of health education assessed using the Health Education Impact Questionnaire (heiQ) at T0 and T1
3. Long-term blood glucose concentration assessed by HbA1c measurement at T0, T1, T2 and T3
4. Personal environmental factors assessed using smartphone background data between T1 and T2
5. Subjective rating of information value of intervention between T1 and T2

Overall study start date
01/10/2018

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Any gender
3. Diagnosed with type 2 diabetes mellitus
4. Able to use a smartphone independently
5. Knowledge of the German language in speaking and writing (independent use of language)
6. Able and willing to participate in a group training course for type 2 diabetes mellitus at one of the three study centres

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
73 (3 clusters; 20-27 participants per cluster)

Total final enrolment
15

Key exclusion criteria
1. Diagnosed with type 1 diabetes mellitus
2. Diagnosed with gestational diabetes mellitus
3. Visual impairments that adversely affect the use of the smartphone application

Date of first enrolment
01/02/2019

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Austria

Study participating centre
Gemeinnützige Oberndorfer Krankenhausbetriebsgesellschaft m.b.H.
Paracelsusstraße 37
Oberndorf bei Salzburg
Austria
5110

Study participating centre
Diakonissen & Wehrle Privatklinik GmbH
Guggenbichlerstraße 20
Salzburg
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5026

Study participating centre
Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH
Müllner Hauptstraße 48
Salzburg
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5020

Sponsor information

Organisation
Salzburg University of Applied Sciences (Fachhochschule Salzburg)

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Sponsor type
University/education

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ROR
https://ror.org/0072dxg89

Funder(s)

Funder type
Government

Funder Name
Salzburger Landesregierung

Alternative Name(s)
Federal State of Salzburg

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 01/12/2023:
The investigators plan to publish all results from the study distributed over approximately one publication in relevant discipline-specific (e.g. diabetic medicine, mobile health, health education) peer-reviewed journals until 06/2024.

Previous publication and dissemination plan:
The investigators plan to publish all results from the study distributed over approximately four publications in relevant discipline-specific (e.g. diabetic medicine, mobile health, health education) peer-reviewed journals until 12/2020.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the approved ethics committee proposal and corresponding informed consent letters for the participants, which also correspond to the data protection strategy of the Salzburg University of Applied Sciences for this study, do not allow the publication of participant level data.

IPD sharing plan summary
Not expected to be made available