

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

<b>Submission date</b> 01/04/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/12/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 consider their 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

**Contact name**

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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

Austria

5026

**Study participating centre**

**Gemeinnützige Salzburger Landeskliniken Betriebsgesellschaft mbH**

Müllner Hauptstraße 48

Salzburg

Austria

5020

## **Sponsor information**

**Organisation**

Salzburg University of Applied Sciences (Fachhochschule Salzburg)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.fh-salzburg.ac.at/en/>

**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