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Blood pressure and blood glucose telemonitoring in seniors

Submission date	Recruitment status	[_] Prospectively registered
20/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
05/10/2021	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
24/10/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
Arterial hypertension (high blood pressure) and diabetes are a significant burden on the general health of the population. This study will examine whether the addition of smart technology in the form of telemonitoring (i.e. disease control at a distance) improves the management of these chronic conditions. The main aim is to find out whether blood pressure (BP) and blood glucose (BG) telemonitoring is better than standard care in the BP and BG reduction. The secondary aim is to evaluate whether BP and BG telemonitoring is a feasible method for patients and healthcare workers.

Who can participate?
Patients aged 65 years or over with arterial hypertension and type 2 diabetes

What does the study involve?
Participants will be randomly allocated to the telemedicine group or the control group. Participants in the telemedicine group will receive a telemedicine package which will include a smartphone, blood pressure and blood glucose monitor. They will take their blood pressure two times weekly and blood glucose once monthly. Data will be transmitted via smartphone to the telemonitoring platform. The telemedicine centre coordinator (physician) will examine transmitted values and indicate appropriate interventions (e.g., change in treatment, referral to GP, phone consultation). The control group will receive standard care only. The researchers will also sample blood for laboratory tests in both groups at the start of the study and after 12 months.

What are the possible benefits and risks of participating?
Patients in the telemedicine group will receive a telemedicine package. Measurement of blood pressure is a non-invasive and safe procedure. Blood glucose measurement may cause minimal pain in the fingers, dizziness, or inflammation at the measurement site. No significant side effects are expected.

Where is the study run from?
The Primary Healthcare Centre Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
January 2021 to September 2023

Who is funding the study?
EU H2020 - Health programme (H2020-SC1)

Who is the main contact?
Prof. Antonija Poplas Susič
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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
ScubyTel-825432

Study information

Scientific Title
Telemonitoring of patients with comorbid hypertension and type 2 diabetes mellitus: a multicentre randomised controlled pilot study

Acronym
ScubyTel

Study objectives
The goals of the study are:
1. To evaluate the effect of blood pressure (BP) and blood glucose (BG) telemonitoring (TM) on BP and BG reduction in a group of patients with comorbid arterial hypertension (AH) and type 2 diabetes mellitus (T2DM)
2. To evaluate BP and BG TM's effect on mental health (depressive and anxiety symptoms) and other behavioural risk factors (daily activity, nutrition, alcohol consumption, smoking)
3. To evaluate the effect of BP and BG TM on quality of life
4. To evaluate the acceptability of BP and BG TM for patients and healthcare workers
5. To evaluate costs associated with the intervention and perform a cost-effectiveness analysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/05/2019, Slovenian National Medical Ethics Committee (Komisija Republike Slovenije za medicinsko etiko, Štefanova ulica 5, SI-1000 Ljubljana, Slovenia; +386 (0)1 478 69 06; kme.mz@gov.si), ref: 0120-219/2019/4

Study design
Multicentre randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease in patients with diabetes and arterial hypertension

Interventions
The SCUBY telemedicine pilot study is a randomised controlled study comparing telemonitoring of blood pressure and blood glucose (intervention group) with a standard care (control group). This multicentre pilot study will run in three primary healthcare centres in Slovenia and will last for 12 months. It will include patients with hypertension and diabetes mellitus type 2 over 65 years of age who will be randomised in a 1:1 ratio to the experimental or control group. After consented to participate, patients will be randomised to either the intervention or control group. We will use a simple 1:1 randomisation. The first patient on the list will be randomised to the telemedicine group (intervention group). The second patient will be randomised to the standard care group (control group). If candidates drop out within the first week of the study, new patients will be sought. These will be randomised according to the previous randomisation list of patients. If the last patient on the list was randomised to the telemedicine group, the next patient will be randomised to the control group and vice versa.

Patients in the intervention group will receive a telemedicine package (blood glucose monitor, blood pressure monitor, smartphone) and take blood pressure twice weekly and blood glucose once monthly according to the protocol. Data will be transmitted via smartphone to the telemonitoring platform, where the telemedicine centre coordinator (physician) will examine transmitted values and indicate appropriate interventions (e.g., change in protocol regimen, referral to GP, phone consultation). The control group will receive standard care only.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Systolic blood pressure measured with standardised BP monitors at baseline, 6 months, and 12 months
2. Glycated haemoglobin assessed with laboratory testing at baseline and 12 months.

Secondary outcome measures
1. Diastolic blood pressure measured with standardised BP monitors at baseline, 6 months, and 12 months
2. Lipid profile assessed with laboratory testing at baseline and 12 months
3. Glomerular filtration rate assessed with laboratory testing at baseline and 12 months
4. Body mass index assessed with standardised scales at baseline and 12 months
5. Appraisal of diabetes measured with the Appraisal of Diabetes scale at baseline and 12 months
6. Depressive symptoms measured with the Patient Health Questionnaire-9 at baseline and 12 months

7. Anxiety symptoms measured with the General Anxiety Disorder-7 questionnaire at baseline and 12 months

Overall study start date
01/01/2021

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. ≥65 years of age
2. AH and T2DM
3. Diagnosis of AH and T2DM for at least 1 year
4. Capability of smartphone use

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
120

Total final enrolment
128

Key exclusion criteria
1. <65 years of age
2. T2DM on insulin treatment
3. Type 1 diabetes or gestational diabetes
4. Cognitive impairment

Date of first enrolment
15/03/2021

Date of final enrolment
01/06/2022

Locations

Countries of recruitment

Slovenia

Study participating centre
Zdravstveni dom Ljubljana
Metelkova ulica 9
Ljubljana
Slovenia
1000

Study participating centre
Zdravstveni dom Trebnje
Goliev trg 9
Trebnje
Slovenia
8210

Study participating centre
Zdravstveni dom Slovenj Gradec
Partizanska pot 16
Slovenj Gradec
Slovenia
2380

Sponsor information

Organisation
Community Health Centre Ljubljana

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Sponsor type
Hospital/treatment centre

Website
http://www.zd-lj.si/en/

ROR
https://ror.org/04fx4vz25

Funder(s)

Funder type
Government

Funder Name
H2020 Health - Health programme (H2020-SC1) contract number 825432 - SCUBY

Alternative Name(s)
H2020 Societal Challenges - Health, Demographic Change and Well-being, H2020 DÉFIS DE SOCIÉTÉ - Santé, évolution démographique et bien-être, H2020 GESELLSCHAFTLICHE HERAUSFORDERUNGEN - Gesundheit, demografischer Wandel und Wohlergehen, H2020 RETOS DE LA SOCIEDAD - Salud, cambio demográfico y bienestar, H2020 SFIDE PER LA SOCIETÀ - Salute, evoluzione demografica e benessere, H2020 WYZWANIA SPOŁECZNE - Zdrowie, zmiany demograficzne i dobrostan, HEALTH, SOCIETAL CHALLENGES - Health, demographic change and well-being, RETOS DE LA SOCIEDAD - Salud, cambio demográfico y bienestar, DÉFIS DE SOCIÉTÉ - Santé, évolution démographique et bien-être, SFIDE PER LA SOCIETÀ - Salute, evoluzione demografica e benessere, WYZWANIA SPOŁECZNE - Zdrowie, zmiany demograficzne i dobrostan, GESELLSCHAFTLICHE HERAUSFORDERUNGEN - Gesundheit, demografischer Wandel und Wohlergehen

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication of the results in a high-impact peer-reviewed journal. The researchers also plan to publish a detailed clinical protocol and statistical analysis plan in a peer-reviewed journal.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the principal investigator Prof. Antonija Poplas Susič (antonija.poplas-susic@zd-lj.si) (e.g., for meta-analyses).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/09/2021	No	Yes
Protocol article		28/09/2022	07/03/2023	Yes	No
Statistical Analysis Plan	see section 2.13	28/09/2022	07/03/2023	No	No
Dataset			24/10/2024	No	No
Results article		15/05/2024	24/10/2024	Yes	No
Results article		01/03/2024	24/10/2024	Yes	No