ISRCTN18138025 https://doi.org/10.1186/ISRCTN18138025

Treatment results and patient satisfaction: an evaluation of care for cardiovascular disease by specialized nurses (nurse practitioners) and physicians using multiple research methods

Submission date
14/02/2026

Recruitment status
Recruiting

Registration date
26/02/2026

Overall study status
Ongoing

Last Edited
23/03/2026

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Primary care in Switzerland is facing major challenges. The population is ageing, and more people are living with chronic diseases such as heart and cardiovascular conditions. At the same time, there is a growing shortage of general practitioners. Almost half of current primary care doctors are over 55 years old, and many do not yet have a successor for their practice. To meet future healthcare needs, the number of general practitioners would need to increase significantly in the coming years.

Innovative care models may help address this problem. One such model involves specially trained nurses called Nurse Practitioners (NPs). Nurse Practitioners have advanced academic training and work closely with doctors. In many countries, they already provide safe and effective care, particularly for people with long-term conditions.

However, in Switzerland there is still limited scientific evidence directly comparing care provided by Nurse Practitioners with traditional doctor-led care. This study aims to close this gap.

The main goal of the study is to evaluate whether care provided by Nurse Practitioners for patients with chronic cardiovascular diseases is as effective and safe as usual care provided by doctors. We will compare medical outcomes, healthcare use, and patient satisfaction between the two models of care.

Who can participate?
Adults (18 years and older) who are receiving care for a chronic cardiovascular condition (such as high blood pressure, coronary heart disease or heart failure) at one of the participating Medical Centers may be eligible.

People cannot take part if they are:
Under 18 years of age

In an unstable acute medical condition (e.g. acute heart problems or severe shortness of breath)
Severely cognitively impaired or unable to give informed consent
Pregnant
Living with a terminal illness
Taking part in another clinical study at the same time

What does the study involve?
The study lasts 12 months.
Participants are randomly assigned (by computer) to one of two groups:
Nurse Practitioner group: Care is mainly provided by a Nurse Practitioner, working closely with doctors.
Standard care group: Care is provided by a doctor as usual.
Random assignment means neither the patient nor the healthcare team can choose the group.
During the 12 months, participants will attend their usual medical appointments (typically two main visits as part of routine care). No extra clinic visits are required for the study.

At these visits, we will:
Measure blood pressure, pulse, height and weight
Record laboratory results (e.g. cholesterol and kidney function), taken as part of routine care
Document the number of consultations, referrals and hospital stays
After 12 months, some participants will be invited to take part in a voluntary 30-minute telephone interview to talk about their experiences and satisfaction with care.

What are the possible benefits and risks of participating?
Possible benefits:
Participants are unlikely to receive a direct personal benefit. However, the results may help improve future care for patients with cardiovascular diseases in Switzerland.
Possible risks or disadvantages:
The study does not involve new medications or experimental treatments. All care follows established medical standards. There are no additional medical risks beyond usual primary care.

Blood tests are part of routine care and may cause minor discomfort or bruising. The optional telephone interview may take around 30 minutes and could feel slightly time-consuming.

Where is the study run from?
The study is conducted at Medbase Medical Centers in:
Eglisau (ZH)
Zurich-Wiedikon (ZH)
Winterthur (ZH)
Wil (SG)
Wattwil (SG)
The study is part of a doctoral project at Paracelsus Medical Private University (PMU), Salzburg.

When is the study starting and how long is it expected to run for?
The study is planned to start in 2026. Recruitment and follow-up are expected to continue for approximately 12 months per participant. The overall study duration is expected to be several years, including data analysis and reporting.

Who is funding the study?
The study is conducted as part of a doctoral research project by Anne-Marie Schirmer at PMU Salzburg.

There is no direct external funding. Medbase AG supports the study by providing the necessary infrastructure and access to patients within its Medical Centers.

Who is the main contact?
Anne-Marie Schirmer, Nurse Practitioner, PhD candidate
anne-marie.schirmer@stud.pmu.ac.at
annemarie.schirmer@medbase.ch
anne.schirmer95@gmail.com

Contact information

Type(s)
Principal investigator, Public

Contact name
Mrs Anne-Marie Schirmer

ORCID ID
https://orcid.org/0009-0005-0150-183X

Contact details
Greifenseestrasse 31
Zürich
Switzerland
8050
+41 764966382
anne-marie.schirmer@stud.pmu.ac.at

Type(s)
Scientific

Contact name
Mrs Nestler Nadja

Contact details
Strubergasse 21
Salzburg
Austria
5020
+43 662 2420
nadja.nestler@pmu.ac.at

Additional identifiers

Study information

Scientific Title
Treatment outcomes and patient satisfaction in cardiovascular disease – a clinical evaluation of primary care by nurse practitioners and physicians – a mixed-methods study

Study objectives

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Health services research

Study type(s)

Health condition(s) or problem(s) studied
Cardiovascular patients

Interventions
The research project follows an explanatory sequential mixed-method design (Creswell & Plano Clark, 2018). This means that quantitative data are collected first and subsequently deepened and explained through qualitative insights.

Phase 1: Quantitative sub-study (RCT)
A randomized controlled trial will be conducted over a period of 12 months. Patients with chronic cardiovascular diseases will be randomly assigned to one of two groups via software:
Intervention group (NP model): Patients are primarily managed by a Nurse Practitioner.
Control group (standard model): Patients remain in conventional physician-led care.

Parameters assessed:
Clinical outcomes: Blood pressure (systolic/diastolic), lipid levels (LDL-C), renal function (eGFR /creatinine), height, weight, BMI.
Process indicators: Number of consultations (consultation frequency), frequency of referrals to cardiology, as well as number and duration of hospitalizations.

Phase 2: Qualitative sub-study
Subsequently, semi-structured interviews will be conducted with patients to further explore and

contextualize the statistical findings. The focus will be on subjective satisfaction and the quality of the therapeutic relationship (Lincoln & Guba, 1985).

Intervention Type
Mixed

Primary outcome(s)
1. Systolic blood pressure (mmHg) measured using Routine blood pressure measurement according to standard clinical practice in participating Medical Centers; measured by MPA, Nurse Practitioner or physician and documented in the electronic health record (EHR) at baseline (first consultation after randomisation) and 12 months after randomisation

Key secondary outcome(s))
1. Diastolic blood pressure (mmHg) measured using routine blood pressure measurement documented in the EHR at baseline and 12 months

2. Heart rate (beats per minute) measured using routine pulse measurement during consultation documented in the EHR at baseline and 12 months

3. Lipid profile (LDL, HDL, total cholesterol, triglycerides; mmol/L) measured using routine laboratory blood analysis documented in the EHR at baseline and 12 months

4. Body Mass Index (BMI; kg/m²) measured using calculated from routinely measured weight and height, documented in the EHR at baseline and 12 months

5. Renal parameters (serum creatinine, urine albumin, albumin- creatinine ratio) measured using routine laboratory blood and urine analysis documented in the EHR at baseline and 12 months

6. HbA1c (%) measured using routine laboratory blood analysis documented in the EHR at baseline and 12 months

7. AGLA/ARIBA cardiovascular risk score measured using calculated cardiovascular risk score based on routinely collected clinical and laboratory data, documented in the EHR at baseline and 12 months

8. Consultation frequency (number of contacts) measured using retrospective extraction from electronic health records (EHR review) at cumulative over 12 months after randomisation

9. Referrals to cardiology specialists measured using retrospective extraction from EHR at cumulative over 12 months after randomisation

10. Cardiovascular-related hospitalisations measured using retrospective extraction from EHR at cumulative over 12 months after randomisation

11. Patient satisfaction, perceived quality of care and communication measured using semi-structured telephone interviews (~30 minutes); qualitative content analysis at completion of 12-month follow-up

Completion date
10/05/2029

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Diagnosed or suspected cardiovascular disease
3. Confirmed cardiovascular diagnosis (ICD-10 I10–I15, I20–I25, I50, E78) and/or
3.1. Documented medical history and/or use of cardiovascular-related medication (e.g., antihypertensive agents, statins) and/or
3.2. Clinically justified suspicion of cardiovascular disease with an indication for cardiological evaluation, particularly in the presence of:
Self-measured blood pressure values ≥ 135/85 mmHg
Exertional dyspnea
Stable chest tightness

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unstable acute conditions (e.g., cardiac decompensation, acute angina pectoris, or dyspnea)
2. Severe cognitive impairment
3. Inability to provide informed consent
4. Terminal illness
5. Current pregnancy
6. Concurrent participation in another clinical trial
7. Age under 18 years

Date of first enrolment
31/03/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment

Switzerland

Sponsor information

Organisation
PMU Salzburg

Funder(s)

Funder type

Funder Name
Medbase AG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available