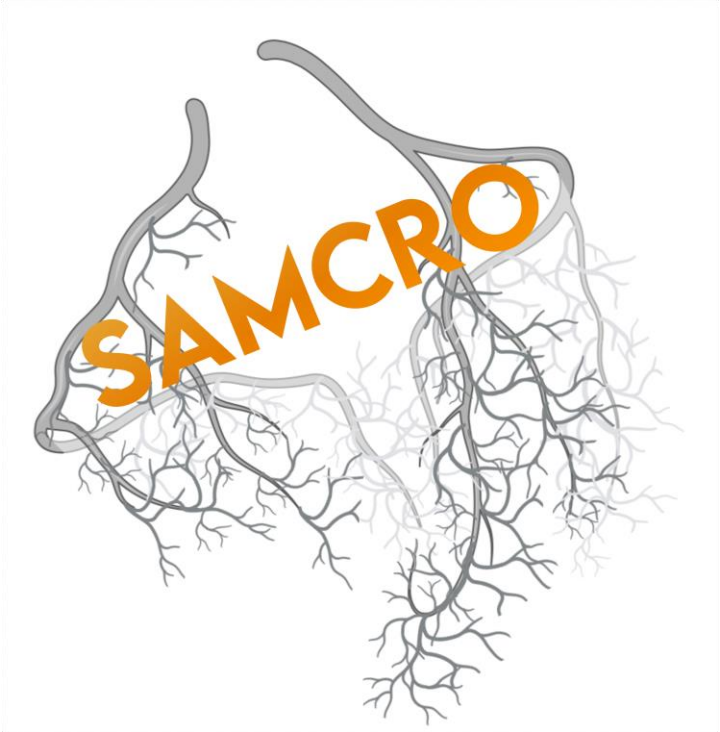
StAndardizing the Management of patients with coronary microvascular dysfunction



The SAMCRO trial

Background

- **Nearly half of of patients with angina have no obstructive coronary artery disease (CAD)**
- **This subgroup of patients is defined with the term angina with no obstructive CAD (ANOCA)**
- **In ANOCA patients is of paramount importance to evaluate for the presence of CMD and/or coronary vasomotor disorders**

Background

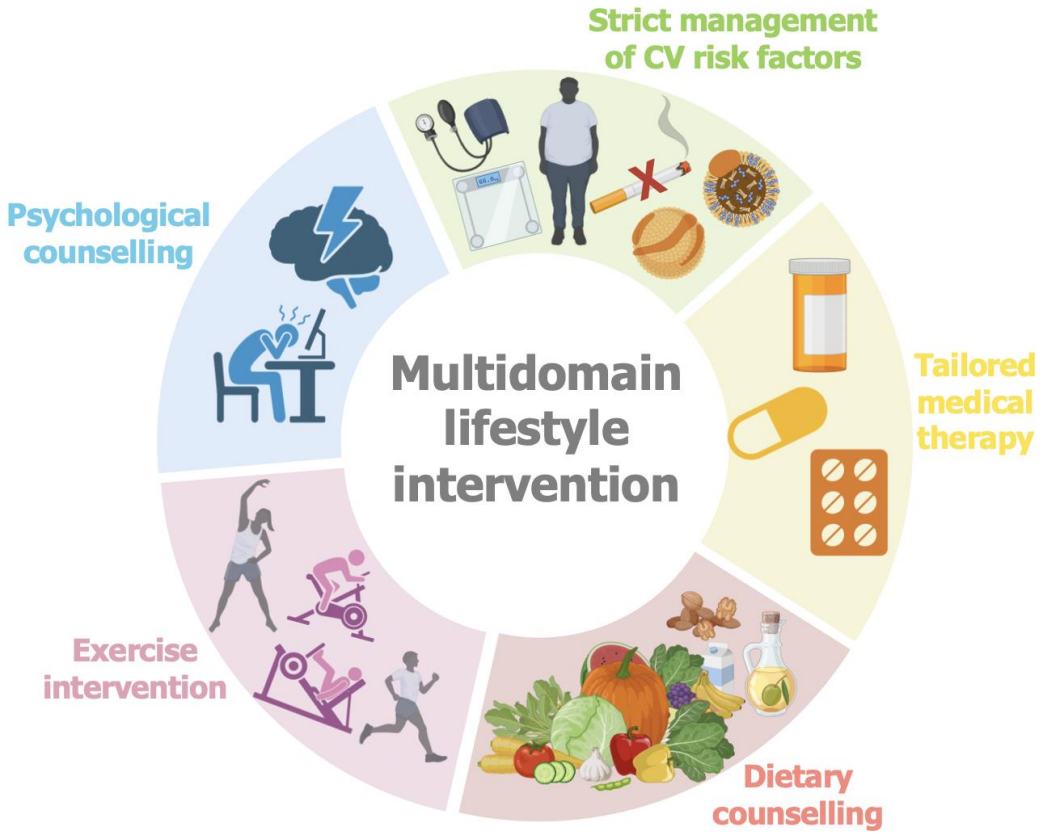
- **ANOCA patients have higher MACE compared with normal subjects and poor quality of life (QoL) with functional disability and limitations in activities of daily living**

- **The main investigations in this field were focused on prevalence of ANOCA condition, contributing factors and its impact on QoL, ANOCA diagnostic workflow and medical treatment**

- **Data regarding how to improve physical limitation, depression and overall QoL beyond the medical treatment are lacking**

Aim

The aim of the SAMCRO trial is to investigate if a multidomain lifestyle intervention, based on 5 different domains, improves angina status and quality of life in ANOCA patients as compared to current standard of care



Endpoints

Primary

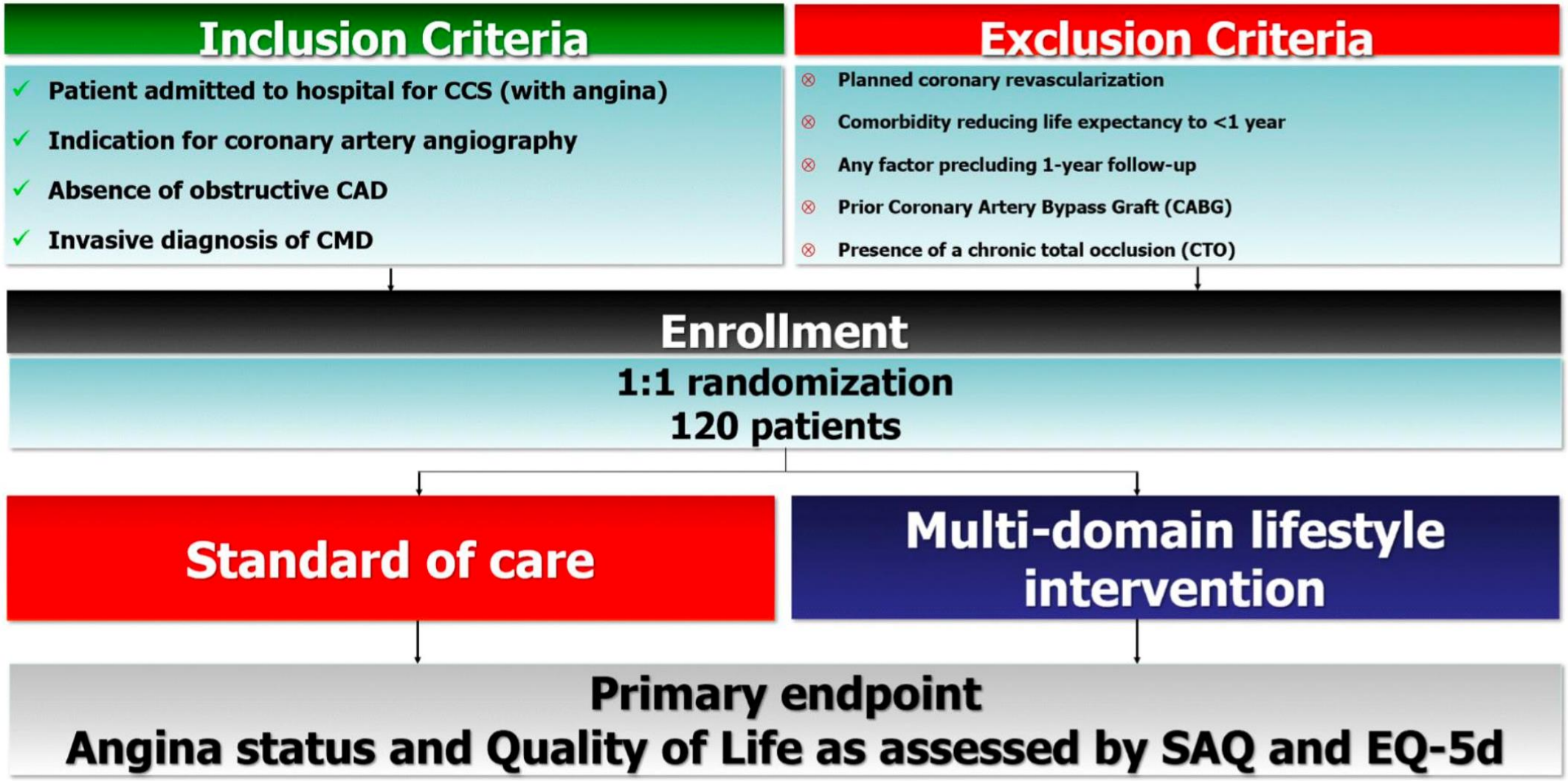
Seattle Angina Questionnaire (SAQ) summary score at 1 year

Secondary

- SAQ angina frequency, angina stability, treatment satisfaction, physical limitation, quality of life domain
- EQ-5D descriptive system: mobility, self-care, usual activities, pain/discomfort, anxiety/depression
- EQ visual analogue scale (EQ-VAS)
- Beck Depression Inventory (BDI)
- Compliance to the multidomain lifestyle intervention
- All-cause death
- Cardiovascular death
- Hospital admission for any cause

Study Design

All comers, prospective, randomized, multicenter, open-label study with blinded adjudicated evaluation of outcomes (PROBE)



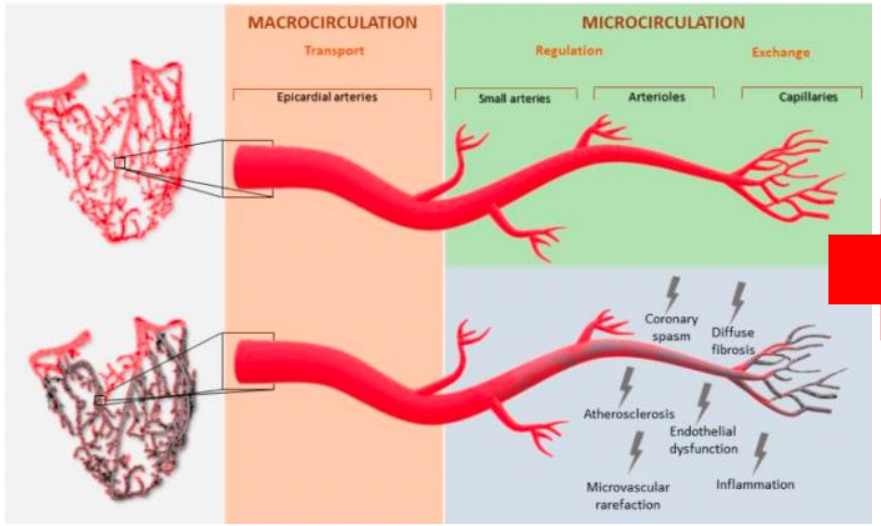
CMD

Inclusion Criteria

- ✓ Patient admitted to hospital for CCS (with angina)
- ✓ Indication for coronary artery angiography
- ✓ Absence of obstructive CAD
- ✓ Invasive diagnosis of CMD

Based on invasive coronary physiology and defined as:

- **FFR > 0.80**
  and
- **CFR < 2**
  and/or
- **IMR>25**
  and/or
- **Positive vasoreactivity test with Ach**



Three ANOCA endotypes:

1.Coronary microvascular dysfunction

2.coronary vasospasm (epicardial and/or microvascular)

3.mixed forms

Experimental arm

Multi-domain lifestyle intervention with 5 different kinds of interventions:

i) strict management of CV and metabolic risk factors

ii) tailoring of medical therapy on the basis of the assessment of CMD endotype

iii) dietary counselling
[two visits within the first one month with a nutritionist where personal dietary goals and patient's daily diet will be agreed]

iv) psychological counselling
[two/three sessions of individual supportive-expressive psychotherapy focused on four areas related to depression in CAD: coping with illness, dealing with emotions, change of lifestyle, shaping of social relationship]

Experimental arm

v) exercise intervention

[early, tailored mixed program with six supervised physical activity sessions (at 1, 2, 3, 6, 9 and 12 months) and a series of exercises to be performed at home from the Otago Exercise Program, along with recommending at least 20 minutes of moderate walking]

First supervised session	Home-based sessions	Subsequent supervised session
Pre-test: • measure of blood pressure • positioning RS100 Polar heart rate monitor to constantly evaluate heart rate • Calisthenics exercises	• 30 to 60 min of continuous moderate walking a day, at least 3 to 4 and preferably 7 days a week • Calisthenics exercises[b]	Pre-test: • Measure of blood pressure • Positioning RS100 Polar heart rate monitor to constantly evaluate heart rate. • Calisthenics exercises[b]
Start: walking on the level at 2.0 km/h		Start: walking at an updated intensity estabilished according to reached results in the previous activity session
Every 30 s: increases of 0.3 km/h up to reach a walking speed corresponding to a perceived exertion of 11–13 on the Borg scale for 1 km[a].		Every 30 s: increases of 0.3 km/h up to reach a walking speed corresponding to a perceived exertion of 11–13 on the Borg scale for 1 km[a].
Post-test: • Measure of blood pressure. • Counselling on physical activity and daily activities, such as gardening, or household work.		Post-test: • Measure of blood pressure • Counselling on physical activity and daily activities, such as gardening, or household work.

Study Timeline

BASELINE	From 0 to 6 months	6-MONTH	From 6 to 12 months	1, 2, 3, 4, 5-YEAR
ALL: Assessment of inc/exc criteria	EXPERIMENTAL INTERVENTION: Medical therapy optimization	ALL: Clinical visit and assessment of compliance with therapy. Medical Therapy optimization	EXPERIMENTAL INTERVENTION: Exercise intervention	ALL: Clinical visit and assessment of compliance with therapy. Medical Therapy optimization
ALL: Signature of the informed consent	EXPERIMENTAL INTERVENTION: Dietary counselling	ALL: Seattle Angina Questionnaire (SAQ)		ALL: Seattle Angina Questionnaire (SAQ)
ALL: Assessment of baseline characteristics	EXPERIMENTAL INTERVENTION: Psychotherapy counselling	ALL : EQ-5D-5L questionnaire		ALL : EQ-5D-5L questionnaire
ALL: Seattle Angina Questionnaire (SAQ)	EXPERIMENTAL INTERVENTION: Exercise intervention	ALL: Beck Depression Inventory (BDI)		ALL: Beck Depression Inventory (BDI)
ALL : EQ-5D-5L questionnaire	EXPERIMENTAL INTERVENTION: Strict CV risk factor control			
ALL: Beck Depression Inventory (BDI)				
ALL: RANDOMIZATION				
CONTROL ARM: face-to-face session to promote a heart-healthy lifestyle in terms of diet, smoking cessation, stress management and physical activity. Medical therapy optimization				