STEPWISE

Published: 25-02-2025
Last updated: 22-05-2025

Primary Objective: To investigate the change of objectively measured physical activity over time, from preoperative, to being placed on the waiting list for cardiac surgery, to postoperative. Secondary Objective(s): To...

Ethical review	Not available
Status	Pending
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON57482

Source
Onderzoeksportaal

Brief title
STEPWISE

Condition

- Cardiac therapeutic procedures

Synonym
Cardiac surgery, heart surgery, heart operation, coronary artery bypass graft, mitral vavle replacement, transcatheter aortic valve replacement, ablation

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

- Surigical procedure

Explanation

N.a.

Outcome measures

Primary outcome

The difference in physical activity pattern in steps/day assessed between several time points during the regular health care trajectory of a cardiac surgery (1 month preoperatively, when being placed on the waiting list, 1 and 3 months postoperatively).

Secondary outcome

The difference in psychological burden between several time points during the health care trajectory of a cardiac surgery. The relation between physical activity and psychological burden over time. The difference in self-reported physical activity patterns over time.

Study description

Background summary

Research on physical activity patterns in patients undergoing cardiac surgery has highlighted significant differences in preoperative and postoperative activity levels, as well as the implications of these patterns for recovery and long-term health outcomes. Postoperatively, the transition to increased physical activity is crucial for recovery. The amount of physical activity after cardiac surgery has been related to the incidence of cardiovascular events and the rate of readmission (Takahashi et al., 2015). Therefore, evaluating postoperative physical activity patterns may be an important indicator for the prognosis.

Preoperatively, many patients exhibit low levels of physical activity, often due to the chronic nature of their cardiac conditions and comorbidities, which can lead to frailty and decreased muscle mass (sarcopenia) (Yuenyongchaiwat et al., 2020). In the Netherlands, only about 44% of the adults met the activity guidelines in 2022 (CBS and RIVM, 2022). This is concerning, since a sedentary lifestyle is associated with worse outcomes after cardiac surgery (Nery et al., 2007; Noyez et al., 2013). However, others have found that an active lifestyle prior to cardiac surgery is associated with improved outcomes as survival (Giaccardi et al., 2011; Nery et al., 2007; Rengo et al., 2010).

Furthermore, being placed on a waiting list places a psychological burden on the patient and can significantly alter physical activity patterns. The longer a patient stays on the waiting list for cardiac surgery, the more it leads to stress, anxiety and even depression, causing patients to reduce their leisure activities (Rosenfeldt et al., 2011; Underwood et al., 1993). Elevated depressive and anxiety symptoms also lead to worse health related quality of life and increased mortality following cardiac surgery (Tully et al., 2008; Tully et al., 2009), possibly mediated by a reduction in physical activity. Additionally, patients are often told to cease exercise while waiting for their surgery to prevent severe coronary and valvular lesions ("Guidelines for rehabilitation in patients with cardiovascular disease (JCS 2012)," 2014), even though there is rising evidence that patients with severe cardiac conditions can safely undergo exercise (Argunova et al., 2022; Boidin et al., 2019; Tueller et al., 2010).

Taken together, the physical activity patterns and change hereof related to psychological distress in patients undergoing cardiac surgery could provide relevant information for prognosis. However, this has currently not been investigated yet. Therefore, the aim of the current study is to investigate the change of the physical activity and psychological burden over time, from preoperative, to being placed on the waiting list, to postoperative in patients undergoing elective cardiac surgery.

Study objective

Primary Objective: To investigate the change of objectively measured physical activity over time, from preoperative, to being placed on the waiting list for cardiac surgery, to postoperative.

Secondary Objective(s): To investigate the change of the psychological burden over time and assess the relation with changes in physical activity over time. Furthermore, the difference in self-reported physical activity over time will be assessed.

Study design

This will be an observational longitudinal study where physical activity patterns and psychological burden will be assessed at four time points: 1 month preoperatively (in retrospect), when being placed on the waiting list, 1 and 3 months postoperatively.

Intervention

Participants will undergo cardiac surgery following regular care.

Study burden and risks

This will take only a limited time for the participants. There are no other burdens or risks associated with the participation.

Contacts

Scientific
Radboud Universitair Medisch Centrum
M.P.F. van de Ven
Geert Grooteplein Zuid 10
Nijmegen 6525 GA
Netherlands
024-3613650
Public
Radboud Universitair Medisch Centrum
M.P.F. van de Ven
Geert Grooteplein Zuid 10
Nijmegen 6525 GA
Netherlands
024-3613650

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

- Be placed on the waiting list for elective cardiac surgery (e.g. CABG, TAVR, MVR, ablation);
- Have a device that tracks the number of steps per day, such as a smartwatch, smartphone or other type of fitness tracker.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- Any severe disease or disabililty that limits physical activity (other than cardiovascular disease (CVD)).

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	63
Duration:	3 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data worden opgeslagen volgens de FAIR principes. Het delen van gepseudonimiseerde ruwe data kan op redelijk verzoek worden overwogen voor relevant en gerelateerd onderzoek. Het

delen van meta data is altijd mogelijk. Gegevens kunnen via de RDR of de DRE van het Radboud worden opgevraagd en gedeeld.

Ethics review

Not available

Date:	04-03-2025
Application type:	First submission
Review commission:	CCMO

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Research portal	NL-009506