Randomized controlled trial of Digital Cardiac Counseling in patients with delayed cardiac surgical treatment due to Covid-19 pandemic (DCC trial)

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Primary Objective: -What is the effect of an interactive Digital Cardiac Counseling platform with E-consulting on cumulative incidence of major adverse cardiovascular events (MACE) at 1 year after the cardiac surgery compared to the control...

Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54854

Source
ToetsingOnline

Brief title
Digital Cardiac Counseling Trial: DCC Trial

Condition

- Cardiac therapeutic procedures

Synonym
Cardiac Surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Digital Cardiac Counseling, Prehabilitation

Outcome measures

Primary outcome

The primary endpoint is cumulative incidence of MACE (Major Adverse Cardiovascular Events) at 1 year after cardiac surgery. The primary outcome is the difference in percentage of patients that experienced Mace at 1-year follow-up postoperatively. We expect that approximately 20% of patients in the control group will experience an event. We will include 197 patients per group, or 394 in total, to be able to have 80% power to detect a difference in MACE of 10% between groups in favor of the intervention group, using an alpha of 0.05.

Secondary outcome

The percentage of patients that experienced a MACE during the waiting period will be compared between groups similar to the primary outcome. We will use Kaplan-Meier plots to illustrate the cumulative incidence of overall and cardiovascular-related, and COVID-19-related mortality over the 1 year follow-up period. Cox proportional hazards regression will be used to test for differences between groups. The model will be extended with covariates (Possible confounders are Euroscore II, type of the operation, operation time, cross-clamp time and unforeseen intraoperative complications) in case of baseline imbalance.

Differences between groups in the average NYHA Class, CSS, and SF-36 at 3, 6, and 12 months will be tested using the independent-samples t-test, or linear

regression in case of baseline imbalance.

Study description

Background summary

Most patients undergoing a cardiovascular procedure need an IC-bed during the hospitalization and therefore it is possible that for the unforeseen future, because of the Covid-19 crisis, many patients will stay on the waiting list for many months to come. There are some studies showing increased mortality associated with the increased waiting time for patients on a waiting list for an elective cardiac surgery. However, there is no data on the evolution of the morbidity, the quality of life and the symptomatology of the patients waiting for an elective operation. Also it is not clear whether the period of waiting for an elective cardiovascular operation would impact the morbidity or the mortality of the planned operation at later stage. Furthermore, there is a plethora of studies on risk factors associated with the perioperative morbidity and mortality in general.
Therefore, the rationale of the current study is to evaluate whether Digital Cardiac Counselling (DCC) would improve outcomes of the patients waiting for an elective cardiac operation. At the DCC platform, there will be assessments of cardiovascular symptoms, Covid-19 prevention for cardiovascular patients, smoking cessation, anxiety relief, exercise stimulation, pulmonary rehabilitation and diet adjustments. This will be done by means of questionnaires and E-consults.
We start this project now because of two reasons. First, the prolonged waiting list due to the Covid pandemic creates the opportunity to use this period for cardiac prehabilitation. Second, it is only recently that we got the possibility to use a digital platform, which is ideal in this period of social distancing.

Study objective

Primary Objective:
-What is the effect of an interactive Digital Cardiac Counseling platform with E-consulting on cumulative incidence of major adverse cardiovascular events (MACE) at 1 year after the cardiac surgery compared to the control condition (no interactive Digital Cardiac Counseling)?

Secondary Objective(s):
- What is the effect of an interactive Digital Cardiac Counseling platform with E-consulting on patient-measured outcomes during treatment delay due to the Covid-19 pandemic measured just before, and 1 year after the cardiac surgery

compared to the control condition (no interactive Digital Cardiac Counseling)?

Study design

Randomized controlled trial
We will use random permuted block size if technically feasible otherwise with random block sizes of 4, 6, and 8. The randomization will be computer-based and will generate two groups. Both groups will get access to the Digital Cardiac Counseling platform and both groups will complete the same set of validated questionnaires at the same time intervals. The intervention groups will get additional training modules and E-consulting based on the risk assessment retrieved from the completed questionnaires. The complete workflow is depicted in Figure 1.

Intervention

All participants will receive at the different time intervals through our custom-made Digital Cardiac Counselling platform different questionnaires related to the different known risk factors for the perioperative cardiac care and measured outcomes.
Additional to above participants, the intervention group will receive through the Digital Cardiac Counselling platform different modules with E-counselling for risk factors evaluated in the questionnaires. Additional to known risk factors a Covid-19 module will be used as well.

Study burden and risks

The risk of participation is negligible to the patients and the burden of participation of the control group will be minimal. For the intervention group the burden of the participation is more pronounced as more Digital Cardiac Counselling moments are anticipated. However this increased burden is for addressing the increased perioperative risk factors and therefore we hope that patients in the intervention group will benefit from this (however this is not certain en subject of the study). Furthermore all patients will undergo the same standard of care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Patients who are on the waiting list for any elective cardiac operation and are older than 18 years old (adult cardiac surgery patients) during Covid-19 pandemic
-Patients accepted for any elective cardiac operation and are older than 18 years during Covid-19 pandemic (adult cardiac surgery patients)

Exclusion criteria

-Patients who are not able to use digital platforms for various reasons (blindness, illiteracy, neurological deficits, mental inability etc.)
-Patients who do not have an Internet connection or any digital platform and whose direct family are not able to provide that.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-06-2020
Enrollment:	394
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL73754.068.20