Digital Cardiac Counseling Trial: DCC Trial

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Pre-operative comprehensive digital Cardiac Counseling (prehabilitation) will reduce the cumalative incidence of MACE at 1 year postoperatively in patients operated for a cardiovascular procedure.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19901

Source
Nationaal Trial Register

Brief title
DCC Trial

Health condition

Cardiovascular disease

Sponsors and support

Primary sponsor: Academic Hospital Maastricht (Academisch Ziekenhuis Maastricht)
Source(s) of monetary or material Support: Department of Cardiothoracic Surgery, Academic Hospital Maastricht

Intervention

Outcome measures

Primary outcome

-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 outcome

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 description

Background summary

Rationale: 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 an increased mortality associated with an increased waiting time for the patients on the 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 Counseling (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. 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. Study population: The patient population will include any adult patient on the waiting list for any elective cardiovascular operation in MUMC during Covid-19 pandemic. Intervention: All participants will receive at the different time intervals through our custom-made Digital Cardiac Counseling platform different questionnaires related to the different known risk factors for the perioperative cardiac care and measured outcomes. Additional to above participants in the intervention group will receive through the Digital Cardiac Counseling platform different modules with E-counseling for risk factors evaluated in the questionnaires. Additional to known risk factors a Covid-19 module will be used as well. Main study parameters/endpoints: 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.

Study objective

Pre-operative comprehensive digital Cardiac Counseling (prehabilitation) will reduce the cumalative incidence of MACE at 1 year postoperatively in patients operated for a cardiovascular procedure.

Study design

Baseline (T0), pre-operative (T1), after 3 months postoperative (T2), after 6 months postoperative (T3) and after 12 months postoperative (T4)

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. Digital counselling The digital counselling modules for intervention group are described below: -Screening for reduced physical fitness. If there are signs for a decreased physical condition we will refer the patient, after consultation, for a digital intake with our physiotherapist. The patients then get access to a digital module with information and videos of physical exercise training. The patient gets a trainings schedule and we will contact the patient after about 1 and 3 weeks to check their progression and to give additional advice when needed. -Screening for smoking. If the patient smokes and is motivated to quit smoking, we will refer, after consultation, for a digital intake with one of our stop smoking nurses. Then, a digital and telephone supported

counselling will start after an informed and shared decision making with the nurse. When needed, supportive medication can be prescribed. -Screening for malnutrition and obesity. If there are signs of malnutrition (MUST-score) or obesity (BMI >30) we will refer the patient, after consultation, for a digital intake with a dietician. The patients then get access to a digital module with information about a healthy diet. We will contact the patient ever 2 weeks in case of malnutrition and every 4 weeks in case of obesity. In the case of malnutrition the dietician can prescribe protein rich nutrition supplements when needed. -Screening for anxiety and depression. If there are signs for anxiety and depression, we will refer the patient, after consultation, for a digital intake with a psychological assistant. The patients then get access to a digital platform with information and exercises. The assistant will guide the patient and will provide digital support after 1 and 3 weeks. -Screening for elevated pulmonary risk score. When patients have an elevated risk score for adverse pulmonary complications (pulmonary risk score for cardiac surgery patients questionnaire) we will refer the patient, after consultation, for a digital intake with our physiotherapist. The patients then get access to a digital module with information and videos of pulmonary exercise training. We will send a inspiratory muscle trainer (IMT) to the patient to perform daily exercises. The patient gets a trainings schedule and we will contact the patient after about 1 and 3 weeks to check their progression and to give additional advice when needed.

Contacts

Public
Maastricht University Medical Center
Peyman Sardari Nia

0031-(0)-43-3875070
Scientific
Maastricht University Medical Center
Peyman Sardari Nia

0031-(0)-43-3875070

Eligibility criteria

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 the Covid-19 pandemic -Patients accepted for any elective cardiac operation and are older than 18 years during the 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)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-05-2020
Enrollment:	394
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-05-2020
Application type:	First submission

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
NTR-new	NL8577
CCMO	NL72754.068.20

Study results