A randomized intervention study on the effects of telemonitoring in the aftercare of patients after cardiac surgery. A pilot

Published: 04-01-2011
Last updated: 03-05-2024

Four weeks after discharge what are the effects of telemonitoring with patients after cardiac surgery on: 1. Quality of life (SF-36)2. The number of readmissions within four weeks3. The number of relevant complications:atrial fibrillationrelapse...

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

Summary

ID

NL-OMON34146

Source
ToetsingOnline

Brief title
Effects of telemonitoring after cardiac surgery.

Condition

- Cardiac therapeutic procedures

Synonym
bypass surgery, coronary artery bypass grafing, valve surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Keyword: Aftercare, Cardiac surgery, Telemonitoring

Outcome measures

Primary outcome

Quality of life - measured with the SF-36 (Aaronson et al., 1998)

Secondary outcome

Number of complications and readmissions within four weeks

Study description

Background summary

The average time of hospital admission after cardiac surgery, without a patient being transferred to another hospital, is seven days, but depends on the post-operative course. Once returned to their home situation, patients* recovery is not always well. Questions and concerns may develop, which, if they remain unanswered, hinder the process of recovery. Furthermore, the recognition of symptons and complications is difficult for patients (Mistiaen, Francke & Poot, 2007). The first weeks after discharge, especially with elderly people, problems occur (Mistiaen & Poot, 2006).
A number of problems can lead to readmission within thirty days after discharge, like: arrythmia, angina-pectoris, pleural fluid, pulmonary problems and wound infections (Lahey, Campos, Jennings, Pawlow, Stokes & Levitsky, 1999; Sun et al., 2008; Hannan et al., 2003; Theobald & McMurray, 2004). These readmissions are burdensome for patients and their family, but also for the health services. The percentage of readmission after a bypass surgery within thirty days after discharge is between 6.3% and 12.9% (Sun et al., 2008; Hannan et al., 2003).
Other problems that occur in the home situation are: sleep disorder, fatigue, pain problems, shortness of breath and gastro-intestinal problems including vomiting and constipation (Hartford, 2005; Theobald & McMurray, 2004). These problems may affect the quality of life after cardiac surgery.
Within the Thoraxcentrum the patient is prepared for the surgery by the Polyclinical pre-operative screening (PPOS). During PPOS the patient receives information of different disciplines in a group and individually during a part of a day. Following surgery the patient receives aftercare up to discharge from a multidisciplinary team. After discharge the patient leaves this safe, supported and intense controlled environment and goes home with limited control

and support up to the first check up with the cardiologist, approximately four weeks after discharge.
Current aftercare consists of the advice to the patient to contact the general practitioner in the case of problems. Commonly mentioned problems are: pain, wound problems, cardiac arrythmia, re-admisisons connected to pleural fluid, fatigue and lack of appetite. These complaints are also mentioned in the literature.
Because of new developments in the area of information and communication technology (ICT) the possibilities to monitor and support patients at a distance by means of telemonitoring have risen. Studies up to now have emphasized on patients with chronic illnesses such as cardiac dysfuntion, Chronic Obstructive Pulmonary Disease (COPD) and diabetes mellitus (DM). However, Tjalsma states that also patients suffering from non-chronic diseases may profit from telemonitoring (Tjalsma, 2007).
The articles below are all related to patients with heart faillure. No research has been done to the effects of telemonitoring with patients after cardiac surgery.
In 2005 the TEN-HMS (The Trans-European Network-Home-care Management System) study investigated the differences in effects of telemonitoring, contact by telephone with a nurse and the usual aftercare with patients who recently were discharged from hospital. Telemonitoring and contact by telephone seem to have a decreasing effect on mortality, but do not contribute to a reduction of the number of readmissions. However, in case of readmission a decreasing length of stay is observed in comparison to the regular treatment (Cleland, Louis, Rigby, Janssens & Balk, 2005). Schwarz, Mion, Hudock and Litman (2007) do not find an improvement in quality of life or reduction of the number of readmissions. This study only measured weight, but measuring only started maximum ten days after discharge. The study proved to be safe, though (Schwarz, Mion, Hudock en Litman, 2007). A randomized study with a population of 57 patients describes a significant drop in the mortality and the number of re-admissions. However, it did not find an improvement in the quality of life (Antonicelli et al.,2008).
Other studies, however, mention that telemonitoring directly after hospital discharge do lead to a reduction of the number of re-admissions and improvement if the quality of life (Cardozo & Steinberg, 2010; Polisena et al., 2010; Woodend, Sherrard, Fraser, Stuewe, Cheung & Struthers, 2008). Not only is this valid for patients with cardiac dysfunction, but also for patients with angina pectoris complaints (Woodend et al.). Next to this, a high degree of patient satisfaction is found in the use of telemonitoring, together with a greater feeling of solidarity with health care (Cardozo et al.). Also Woodend et al., endorse the high degree of patient satisfaction. Even the patient group with elderly people can in general easily operate the equipment (Woodend et al.).
The number of visits to a general practitioner and/or specialist increases, however. The researchers attribute this to the more active role patients have in their treatment with telemonitoring (Polisena et al.). Companies Achmea and Philips tested the use of the Motiva telemonitoring system in a multicenter study on patients with serious cardiac dysfunctions. The study shows that patients are better informed about their illness, but does not show that the

use of this system prevents readmissions (Hartmotief studie, 2006). Health insurance company Menzis investigated with KOALA (Kijken op Afstand, logisch alternatief (Monitoring at Distance, logical alternative)) the possibilities of another telecare system on the same group of patients in the north of Nederland in 2006. This study does not measure quality of life. However, patients experience a great degree of safety (Boonstra, Broekhuis, Offenbeek, Westerman, Wijngaard & Wortmann, 2008).
To offer a patient optimum care, support and safety during the first four weeks after discharge after cardiac surgery, a possibility lies in the use of telemonitoring. This can be achieved by introducing telemonitoring in the aftercare of patients who underwent cardiac surgery. Through telemonitoring it can be recorded if quality of life improves and if complications are detected early. Up to now, no study has been done in the support of patients after cardiac surgery.

Study objective

Four weeks after discharge what are the effects of telemonitoring with patients after cardiac surgery on:
1. Quality of life (SF-36)

2. The number of readmissions within four weeks
3. The number of relevant complications:
atrial fibrillation
relapse angina pectoris
pneumonia
hypertension
dyspnoea
sternalwound infection/dehischention
leg- of arminfection/hematoma

Study design

The study method is a randomized intervention study. It concerns open randomization with a parallel design. The study is a pilot study which will take approximately 2 to 3 months.
Patients in the intervention group receive aftercare by means of telemonitoring. The control group receives the normal aftercare.
The study is coordinated by Thoraxcentrum Twente, a division of Medisch Spectrum Twente.

Intervention

Patients in the intervention group receive aftercare by means of telemonitoring. The control group receives the normal aftercare.
For telemonitoring patients measure their blood pressure and weight daily and

make an ECG weekly.
Current aftercare consists of the advice to the patient to contact the general practitioner or the ward. After one month patients are called by the nurse of the ward to be informed on their well-being.

Study burden and risks

Burden for the group with telemonitoring:
Measure blood pressure and weight daily and make an ECG weekly. With deviating measurement results the patient is asked questions by the health monitor. Daily burden: 10 minutes.
The control group does not have this burden.
Both groups are asked to fill out questionnaires.
Quality of life (SF-36):
The patients of the control group and the intervention group independently fill out the quality of life (SF-36) questionnaire. First time at baseline (hospital admission), second time four weeks after discharge. Burden: 9 minutes each time.
Complications and readmissions:
Four weeks after discharge during a phone call patients are interviewed if there have been readmissions and/or complications. Results are recorded in a list. Burden: 10 minutes.
Participation in the study has a negligible risk. It does not concern invasive or medicinal intervention

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

all patients with CABG, valve surgery and a combination of CABG/valve surgery
Age 55-85 year
Capable to use the equipment

Exclusion criteria

No comprehension of dutch language
Bad mobility
Patients outside the clinical pathway
Patients transferred to other hospitals

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2011

Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	telemonitoring - weight and blood pressure measuring and ECG
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-01-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
Other	in behandeling
CCMO	NL34828.044.10