Physical therapy to improve physical activity by exercise during hospitalization

Gepubliceerd: 24-06-2019 Laatst bijgewerkt: 18-08-2022

Patients in the intervention group are more physically actice during and the 2nd week after hospitalisation.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22358

Bron
Nationaal Trial Register

Verkorte titel
FLITZ

Aandoening

Elective surgery

Ondersteuning

Primaire sponsor: Leiden University Medical Center, department of Physical Therapy
Overige ondersteuning: Dutch Royal Society of Physical Therapy

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the amount of daily physical activity during admission

and during the 2nd week after discharge measured with an activity monitor (the Activ8) and a questionnaire about physical activity during hospitalization (diary).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

There is increasing evidence for a beneficial effect of preoperative conditioning of physical condition in patients undergoing surgery (BIBO, Better In, Better Out). However, there is less attention to further optimize the recovery during and after hospitalization, although it is known that physical inactivity, even of short duration, can lead to significant decrease in functional ability. The hospital physiotherapist has several interventions available for physical activity during and immediately after hospitalization to promote, but a systematic selection and evaluation are lacking.

Objective of the study:

Determine the feasibility of a study on the effectiveness of an integrated physiotherapy strategy aimed at promoting healthy physical activity during and after hospitalization. If the pilot project proves to be feasible, a multicenter randomized controlled trial (RCT) set .

Study design:

This is a pilot pre/post design on two surgical wards at the LUMC. The strategy consists of : 1) electronic or paper information about physical activity around the hospitalization ; 2) twice daily exercise program through a movie (hospital television , laptop, tablet) ; 3) communication with icons around the bed of the patient to improve communication around the functional mobility of the patient; 4) pedometer to monitor their own physical activity; 5) tailored physiotherapy: a physical coach (email and phone) during hospitalization and shortly after discharge; 6) individual exercise through a digital training program and an App for patients (Physitrack) which gradually adds daily exercises and activities.
The control group consists of usual care.

Study population:

Sixty adult patients from two surgical wards undergoing elective surgical intervention, with a planned hospital stay of 3 days or more, will be enrolled. Thirty patients will be given the intervention and 30 patients forming the

control group wille receive the usual care .

Primary study parameters/outcome of the study:

Effect
The primary outcome is the amount of daily physical activity during admission and during the 2nd week after discharge measured with an activity monitor (the Activ8) and a questionnaire about physical activity during hospitalization (diary).

Feasibility
The evaluation process also involves percentage of patients meeting inclusion criteria and participates in the study, the compliance (adherence) with the different components of the intervention, and the percentage of patients > completes 80% of the measurements. In addition, care providers and patients registered with the intervention are evaluated on their the experiences (questionnaires) .

Secondary study parameters/outcome of the study (if applicable):

Secondary outcomes include quality of life (EQ5 -D, SF-36) and the demand of care in the 1st month after discharge.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

Patients taking part in the study fill in three questionnaires about their physical activity and quality of life (times: for hospitalization, at discharge and 4 weeks after discharge). During hospitalization and during the 2nd week after discharge they carry an activity monitor for 7 days. Patients who are being included in the period in which the strategy is implemented get the intervention in addition to the regular physiotherapy. The intervention focuses on structured restarting physical activities and offering therapy through innovative methods.

Doel van het onderzoek

Patients in the intervention group are more physically actice during and the 2nd week after hospitalisation.

Onderzoeksopzet

Fill in three questionnaires about their physical activity and quality of life (times: for hospitalization, at discharge and 4 weeks after discharge). During hospitalization and during the 2nd week after discharge they carry an activity monitor for 7 days.

Onderzoeksproduct en/of interventie

The strategy consists of : 1) electronic or paper information about physical activity around the hospitalization ; 2) twice daily exercise program through a movie (hospital television , laptop, tablet) ; 3) communication with icons around the bed of the patient to improve communication around the functional mobility of the patient; 4) pedometer to monitor their own physical activity; 5) tailored physiotherapy: a physical coach (email and phone) during hospitalization and shortly after discharge; 6) individual exercise through a digital training program and an App for patients (Physitrack) which gradually adds daily exercises and activities.
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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-18 years and older
-Living self-dependent
-Scheduled surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Insufficient knowledge of the Dutch language to be able to fill in a questionnaire and to understand the information strategy (Dutch movie, Dutch app and Dutch information).
-Not able to wear or control an activity monitor during 7 days and to return this by postal mail.
-Visual or hearing problems that make it impossible to use the movie and the app properly.
-Postoperative conditions preventing participation the strategy or completing the assessments.
-Cognitive problems that prevent participation the strategy or completing the assessments.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2015
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7820
Ander register	METC LUMC : P15.026 (CCMO-number NL52321.058.15)

Resultaten