Physical therapy to improve physical activity by exercise during hospitalization

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22358

Source
Nationaal Trial Register

Brief title
FLITZ

Health condition

Elective surgery

Sponsors and support

Primary sponsor: Leiden University Medical Center, department of Physical Therapy
Source(s) of monetary or material Support: Dutch Royal Society of Physical Therapy

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

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

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

-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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	24-06-2019
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	NL7820
Other	METC LUMC : P15.026 (CCMO-number NL52321.058.15)

Study results