The effect of a smartphone app with accelerometer on patients* physical activity: a randomised controlled trial.

Published: 16-12-2020
Last updated: 08-04-2024

The primary objective of this study is to investigate if using Hospital Fit 2.0 as part of the usual care physiotherapy treatment of patients hospitalised at the department of Internal Medicine and the department of Pulmonology in MUMC+ will result...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON51887

Source
ToetsingOnline

Brief title
Hospital Fit 2.0 - RCT

Condition

- Autoimmune disorders
- Viral infectious disorders
- Respiratory disorders NEC

Synonym
Low physical activity: low mobility

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: subsidie TKI-LSH

Intervention

Keyword: activity monitoring, hospitalised patients, Physical activity

Outcome measures

Primary outcome

The primary outcome parameters is time spent walking per day (min.)

Secondary outcome

The secondary outcome parameters are:

- Average time spent walking (defined as the total number of minutes walking divided by the total number of valid measurement days in the period between inclusion and discharge, with a maximum of seven days).
- Time spent standing per day (min.)
- Average time spent standing (defined as the total number of minutes standing divided by the total number of valid measurement days in the period between inclusion and discharge, with a maximum of seven days).
- Number of transitions from a sedentary position (lying or sitting) to an active position (standing or walking) per day
- Average number of transitions from a sedentary position (lying or sitting) to an active position (standing or walking) (defined as the total number of transitions divided by the total number of valid measurement days in the period between inclusion and discharge with a maximum of seven days).

The following medical and demographic data are collected from the electronic medical record:

- Age (years)

- Gender (male/female)

- Clinical diagnosis

- Walking aid (e.g. walker, crutches)

- Length of stay (days)

- Discharge location (e.g. home, rehabilitation clinic)

- Number of physiotherapy treatment sessions received between inclusion and

discharge

Study description

Background summary

Low physical activity (PA) levels are common during hospitalisation. Patients spend between 92% and 96% of their time lying or sitting. This sedentary behaviour has been associated with adverse outcomes such as functional decline, increased length of stay, increased risk of institutionalization, loss of independency during activities of daily living, reduced quality of live and even mortality.
Physiotherapy during hospitalisation is aimed at enhancing PA levels and stimulating functional recovery of activity of daily living which are essential in order to function independently at home. Objective insight into the PA behaviour of patients and strategies aimed at stimulating PA during hospitalisation are therefore of high importance for physiotherapists. In order to advise patients effectively on their PA behaviour, continuously PA monitoring with real-time feedback should be implemented in standard care.mHealth provides a solution to this issue. mHealth has been defined by the WHO as *medical and public health practice supported by mobile devices, such as smartphones, tablets or wireless patient-monitoring sensors* . PA can be monitored by connecting external wearable devices such as accelerometers, gyroscopes or pedometers, to a smartphone or tablet via Bluetooth.
Recently, the department of Physiotherapy of Maastricht University Medical Center (MUMC+) and Maastricht Instruments B.V. developed Hospital Fit 1.0. Hospital Fit 1.0 consists of a smartphone app connected to the MOX Activity Monitor and is designed to be used in hospitalised patients. It provides patients and their physiotherapist feedback on the amount time spent upright (standing and walking) per day. Additionally, it provides patients insight into

their own recovery progress as well as a tailored exercise program supported by videos.
A recent study showed that physical activity (time standing + walking) was increased with 28 minutes in patients who were operated for a total knee/hip arthroplasty by using Hospital Fit 1.0. This study made suggestions for improvement of Hospital Fit 1.0. Based on these suggestions, improvements have been made to Hospital Fit 1.0, resulting in an updated version: Hospital Fit 2.0. Hospital Fit 2.0 contains the following improvements: 1) The algorithm of the MOX Activity Monitor is improved. It is able to differentiate walking or shuffling from standing in hospitalised patients. In addition it is able to detect the number of transitions (sit to stand). 2) A goalsetting function is added, enabling the physiotherapist to set a goal regarding the number of minutes spent walking per day. The goal is visible in the app as well as the percentage of this goal that the patient has achieved up to that moment. 3) A reminder function is added. Notification messages will be automatically generated four times per day, informing the patient on what percentage of the set goal has been achieved up to that moment. 4) Data from the PA overview and recovery assessment will be automatically sent to the electronic medical record four times per day, making the information available to nurses and physicians as well.

Study objective

The primary objective of this study is to investigate if using Hospital Fit 2.0 as part of the usual care physiotherapy treatment of patients hospitalised at the department of Internal Medicine and the department of Pulmonology in MUMC+ will result in an increase in the amount of PA performed compared to patients who did not use Hospital Fit 2.0 as part of the physiotherapy treatment.

Research question:
Does using Hospital Fit 2.0 as part of the physiotherapy treatment of patients hospitalised at the department of Internal Medicine and the department of Pulmonology in MUMC+ result in an increase in the amount of PA performed compared to patients who do not use Hospital Fit 2.0 as part of the physiotherapy treatment?

Study design

This study is an assessor-blinded randomized controlled trial (RCT) performed at the department of Physiotherapy of the Maastricht University Medical Center (MUMC+).

Intervention

All subjects eligible for inclusion in this study receive usual care physiotherapy as prescribed by the physician and receive an accelerometer,

measuring PA, which is attached by the physiotherapist during the first treatment.

The control group receives no other additional intervention. The intervention group additionally use Hospital Fit 2.0. Hospital Fit 2.0 consisting of a smartphone app combined to an accelerometer. The app contains a separate interface for patients and physiotherapists, enabling extensive options for physiotherapists. During the first treatment after having signed informed consent (IC), the physiotherapist will apply the accelerometer and will assist the patient with installing the app on the patients* smartphone. The physiotherapist will subsequently initiate a connection between the accelerometer and the app by starting a new measurement in the physiotherapist interface. The physiotherapist will then explain the main functionalities of Hospital Fit 2.0 and will give the patient a written user manual additionally. Hospital Fit 2.0 provides patients and their physiotherapists direct feedback on the number of minutes spent lying/sitting, standing, and walking per day and an overview per week. The number of transitions from a sedentary (lying/sitting) to active (standing or walking) position per day, the number of bouts walking *5 minutes per day and the number of bouts lying/sitting *30 minutes per day are provided as well. A weekly overview can be provided per parameter if preferred. Individual goals regarding the number of minutes per day spent walking can be set by the physiotherapist based on the patient*s abilities and needs. Hospital Fit 2.0 also gives patients the option of gaining insight into their own recovery progress. During every treatment, the physiotherapist will evaluate the extent of functional recovery based on the modified Iowa Level of Assistance Scale (mILAS). The physiotherapist will subsequently report the extent of functional recovery in the app, therewith enabling the information to be seen by patients. In addition, Hospital Fit will give physiotherapists the option of creating a patient-specific exercise program supported by videos. The patients are free to use the app during the day. At the end of the last treatment session before discharge, with a maximum of seven days, the physiotherapist will remove the accelerometer and participation in this study will end.

Study burden and risks

The burden and risks of participation in this study are minimal. Participation in the study will take up approximately 25 minutes for patients in the control group and 60 minutes for patients in the intervention group. Time spent on coming to a well-informed decision on whether to participate in the study or not should be added as well and will differ between patients.

The risk of wearing an accelerometer is minimal. The accelerometer is small and does not restrict the patient in his daily activities or choice of clothing. Patients are informed that they are allowed to remove the accelerometer in case

they are bothered in any way. In addition, patients, nurses and physiotherapists are instructed to take the accelerometer and hypoallergenic plaster off in case of an MRI or skin irritation. Low risk, minimal burden.

The risks of using Hospital Fit 2.0 are minimal. The activities promoted in Hospital Fit 2.0 are also performed during the usual care physiotherapy. Hospital Fit 2.0 aims to improve the amount of PA and improve the self-management of patients, it does not stimulate patients to do other exercises than already performed during the physiotherapy treatment. The physiotherapist creates a tailored exercise program, in which the safety of the exercises performed is considered.

In conclusion, Hospital Fit use will result in a minimal burden and minimal risk to the patient.

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

• Aged 18 to 75 years.
• Receiving physiotherapy while hospitalised at the department of Internal Medicine department or the department of Pulmonology at the Maastricht University Medical Centre (MUMC+)
• Sufficient understanding of the Dutch language
• Having access to a smartphone
• Able to walk independently 2 weeks before admission, as scored on the Functional Ambulation Categories (FAC >3)

Exclusion criteria

• A contraindication to walking (as reported by the attending medical specialists in the medical record)
• A contraindication to wearing an accelerometer, fixed by a hypoallergenic plaster at the upper leg (such as active bilateral upper leg infection, severe edema or bilateral transfemoral amputation)
• Admission at the intensive care department
• Impaired cognition (delirium / dementia) as reported by the attending doctor
• Incapacitated subjects as reported by the attending medical specialist in the medical record. When any doubt arises, the patient will not be considered eligible
• A life expectancy shorter than 3 months as mentioned by the attending medical specialist in the medical record
• Previous participation in this study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2021
Enrollment:	78
Type:	Actual

Medical products/devices used

Generic name:	Hospital Fit
Registration:	No

Ethics review

Approved WMO Date:	16-12-2020
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	NL75126.068.20
Other	wordt ingevuld na goedkeuring METC