Effectiveness of Hospital Fit on physical activity of hospitalised patients: a stepped-wedge cluster-randomised clinical trial and process evaluation.

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Primary: to investigate the effectiveness of using Hospital Fit as part of the physiotherapy treatment on average time spent walking per day in patients hospitalised at the Medical Oncology or Cardiology Departments of the Maastricht University…

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51649

Source
ToetsingOnline

Brief title
Effectiveness of Hospital Fit

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Low physical activity; low mobility

Health condition

General cardiac disorders and malign neoplasms are addressed

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Activity monitoring, Effectiveness, Physical activity, Process evaluation

Outcome measures

Primary outcome

Primary outcome parameter: average time spent walking per day (min).

Secondary outcome

Secondary outcome parameters: average time spent standing and lying/sitting per day (min.), average number of transitions from lying/sitting to standing/walking per day, and mILAS score per day. Outcome parameters process evaluation: participation; representation; perceived efficacy; use of app; use of different functionalities; barriers and facilitators to Hospital Fit use; and expected maintenance.

Study description

Background summary

Physical inactivity is a major, underrecognised problem in patients during their hospital stay. Patients spend between 87 and 100% of their time lying or sitting. This physical inactivity has been associated with adverse outcomes such as functional decline, increased length of hospital stay and mortality. Digital health tools could be valuable to prevent negative effects of inactivity. Hospital Fit is a promising app-based intervention to stimulate physical activity by 1) continuous physical activity monitoring, 2) goalsetting, 3) providing patients insight in their functional recovery, 4)

providing patients tailored exercise programs, 5) informing patients about benefits of physical activity, 6) reminding patients to use Hospital Fit and 7) linking the data to the electronic medical record, making it available for other healthcare professionals.

Study objective

Primary: to investigate the effectiveness of using Hospital Fit as part of the physiotherapy treatment on average time spent walking per day in patients hospitalised at the Medical Oncology or Cardiology Departments of the Maastricht University Medical Center (MUMC+) and Radboud University Medical Center (Radboudumc) compared to patients who received physiotherapy before implementation of Hospital Fit. Secondary: 1) to investigate the effectiveness of using Hospital Fit as part of the physiotherapy treatment on average time spent standing per day, average time spent lying/sitting per day, average number of transitions per day and the Modified Iowa Level of Assistance scale (mILAS) scores in hospitalised patients; and 2) to investigate the reach, efficacy, adoption, and implementation of using Hospital Fit as part of the physiotherapy treatment from the perspective of both patients and healthcare professionals.

Study design

A prospective, multi-centre, stepped-wedge cluster-randomised trial (SW-CRT) will be performed to investigate the effectiveness of Hospital Fit. Additionally, a process evaluation will be performed using semi-structured interviews and questionnaires in patients and focus-group interviews in healthcare professionals. Data will be collected between April 2022 and November 2022.
The data will be collected on patient and healthcare professional level in four clusters: two academic centres in the Netherlands (MUMC+ and Radboudumc) and two departments per setting (Medical Oncology and Cardiology Departments). Hospital Fit will be implemented in a stepped-wedge manner. All clusters will begin with a non-intervention phase during which included patients will receive usual care physiotherapy treatment without using Hospital Fit. During the non-intervention phase, included patients will receive usual care physiotherapy and will additionally wear an accelerometer to measure their physical activity behaviour for a maximum of nine days. However, the patient and healthcare professionals do not gain insight in the patients* physical activity data. The non-intervention phase lasts two to five months, depending on the cluster. After two months, Hospital Fit will be implemented as part of the physiotherapy treatment in the first cluster. During the one-month implementation phase, no patients will be included in the study in this cluster. The goal of the implementation phase is to instruct physiotherapists, nurses and physician(s) assistant(s) about the use of Hospital Fit. After the implementation phase, the cluster will continue with an intervention phase

during which included patients will use Hospital Fit as part of the physiotherapy treatment. They will wear an accelerometer to measure their physical activity behaviour for a maximum of nine days, but both the patient and the treatment team will be able to view the physical activity data. Every month, a new cluster will transition from the non-intervention phase to the implementation- and subsequently intervention phase until all four clusters are in the intervention phase. Depending on the cluster, the intervention phase will last two to five months. The order in which the four participating clusters - MUMC+ Medical Oncology Department, MUMC+ Cardiology Department, Radboudumc Medical Oncology Department, and Radboudumc Cardiology Department - will transition from the non-intervention phase to the implementation phase will be randomised by using a non-block randomised model in Castoredc.

The process evaluation will use the RE-AIM health promotion evaluation framework to assess seven constructs of the intervention: participation; representation; perceived efficacy; use of Hospital Fit; use of the different functionalities of Hospital Fit; barriers and facilitators Hospital Fit use; and expected maintenance. Qualitative data will be collected in the intervention phase using semi-structured interviews in patients, and focus group interviews in healthcare professionals. Quantitative data will be collected in the intervention phase using questionnaires in patients. In the questionnaires, patients in the intervention phase are asked to indicate whether they have used Hospital Fit (the so called *users*) or whether they have not used Hospital Fit (the so called *non-users*). This enables exploring differences in patient characteristics between users and non-users in the intervention phase.

Intervention

Physical activity will be measured in all patients with an accelerometer until discharge with a maximum of nine days. The control group will receive usual care physiotherapy (n=90), while the intervention group will use Hospital Fit additionally (n=90).

Study burden and risks

The burden and risks on patients are minimal. The control group will receive usual care physiotherapy and will wear an accelerometer. The intervention group will use Hospital Fit additionally. Wearing a small accelerometer and using Hospital Fit should not be a burden to patients. The only burden is the time it takes to prepare subjects (install app, explain study). No invasive interventions will take place. Anticipated benefits of Hospital Fit use include improved physical activity, therewith reducing the negative effects associated with low physical activity.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria patients (n=180):
In order to be eligible to participate in this study, a patient must meet all the following criteria:
• Over 18 years old.
• Receiving physiotherapy at the Medical Oncology department or the Cardiology department at the MUMC+ or Radboudumc.
• Enough understanding of the Dutch language.
• Owning a smartphone (operating system >= iOS13.0 or Android 8.0)
• Able to use a smartphone app
• Able to walk independently 2 weeks before admission, as scored on the Functional Ambulation Categories (FAC >3)

Inclusion criteria healthcare professionals (n=24):
In order to be eligible to participate in the focus group interviews of the proces-evaluation, a healthcare professional must meet all the following criteria:
• Employed as physiotherapist, nurse or physician (assistant) at the Medical Oncology Department or the Cardiology Department.
• Working at the MUMC+ or Radboudumc for at least one month.

Exclusion criteria

Exclusion criteria patients:
A potential subject who meets any of the following criteria will be excluded from participation in this study:
• A contraindication to walking (as reported by a medical specialist in the electronic medical record).
• A contraindication to wearing an activity monitor, fixed by a hypoallergenic plaster at the upper leg (such as active bilateral upper leg infection, severe oedema or bilateral transfemoral amputation).
• Admitted for cancers of the head and neck (i.e., cancer in the oral cavity, throat (pharynx), voice box (larynx), paranasal sinuses and nasal cavity, salivary glands).
• Admitted with cardiac arrhythmia and hemodynamic instability requiring medication over 48 hours (i.e., beta blockers or noradrenaline) or invasive treatment (i.e., pacemaker or defibrillator implementation).
• Mentally incapacitated subjects as reported by healthcare professionals in the medical record. When any doubt arises, the patient will be excluded.
• Impaired cognition (delirium / dementia) as reported in the medical record by a healthcare professional. When any doubt arises, the patient will be excluded.
• Unable to participate in the informed consent procedure or unable to provide written informed consent.
• A life expectancy shorter than 3 months as mentioned by the medical specialist in the medical record.
• Previous participation in this study.

Exclusion criteria healthcare professionals:
• No participation in care for patients at the Medical oncology Department or Cardiology Department during the intervention phase (e.g., absence or research employment).

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-08-2022
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Hospital Fit 2.0;HFITAPP0;release 05
Registration:	No

Ethics review

Approved WMO

Date:	05-04-2022
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
Other	-
CCMO	NL79684.068.21