PROMOTING INPATIENTS' PHYSICAL ACTIVITY From the development of a family participation intervention to the implementation of a multidimensional action plan

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Thesis, Utrecht University, with a summary in Dutch Proefschrift, Universiteit Utrecht, met een samenvatting in het Nederlands

Provided by thesis specialist Ridderprint, ridderprint.nl

Author: Lotte van Delft ISBN: 978-90-393-7429-0

Printing: Ridderprint Cover design: Rob Walter

Layout and design: Anke Muijsers | www.persoonlijkproefschrift.nl

The printing of this thesis was financially supported by the Scientific College Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF), Arjo Nederland B.V., and Levare Cura; a foundation for healthcare professionals, supplying innovative healthcare aids, therapy equipment and services.

Promoting inpatients' physical activity

From the development of a family participation intervention to the implementation of a multidimensional action plan

Het bevorderen van fysieke activiteit bij patiënten opgenomen in het ziekenhuis: van de ontwikkeling van een interventie voor familie participatie tot de implementatie van een multidimensionaal actieplan

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector magnificus, prof.dr. H.R.B.M. Kummeling, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op

donderdag 17 februari 2022 des middags te 12.15 uur

Door

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geboren op 6 december 1991 te Leiden

Promotoren:

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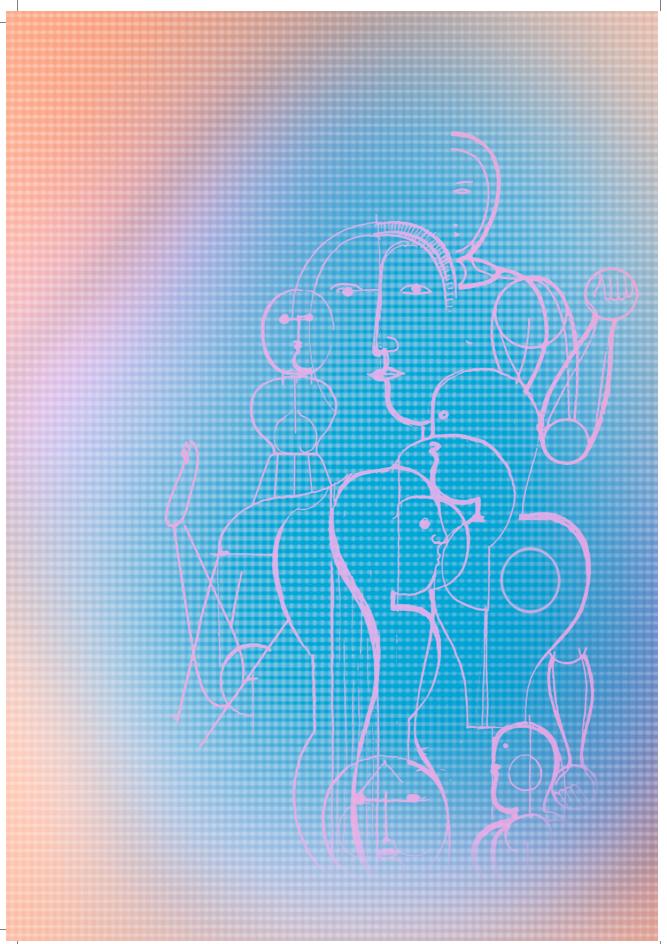
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Chapter 1

General introduction

Above 1.6 million patients are admitted to Dutch hospitals yearly [1, 2]. Of these admissions, about 80.000 patients are treated in an intensive care unit (ICU); around 53% of them have a medical diagnosis (e.g. pneumonia, sepsis or cardiac arrest), 35% have undergone planned surgery and 12% emergency surgery [3]. The average length of hospital stay in the Netherlands is approximately five to six days [1, 2]. It is well known that prolonged hospital and/or ICU admissions harmfully affect patients' physical functioning, often resulting in long term dependence in performing activities of daily living (ADL) (figure 1) [4-8]. In addition to the patients' medical situation, low levels of physical activity during hospitalization have an impact on patients' physical functioning [4-7]. In order to prevent functional decline or to restore physical functioning, it is necessary that patients remain physically active as much as possible during their hospital stay [9]. A key stakeholder in promoting physical activity is the physiotherapist. In hospitals, the physiotherapist is an indispensable member of the multidisciplinary team, aiming to preserve or improve physical function with respect to, among others, muscle strength, exercise tolerance and the performance of daily physical activities [10].

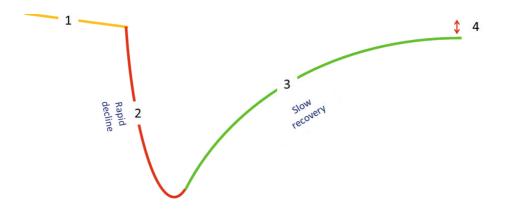


Figure 1. Timeline of patients' physical functioning, before (1), during (2) and after (3) a hospital admission

Intensive care unit

Almost 80% of all critically ill patients is admitted to the ICU for a short period (1-3 days); around 10% is treated for three to seven days, and 10% is admitted more than a week [3, 11]. This is a heterogeneous patient group with large differences in age, comorbidity and admission diagnosis [3].

Physical impairments after critical illness

One of the most commonly observed types of physical impairment of critical illness is generalized muscle weakness, named intensive care unit-acquired weakness (ICU-AW) [12]. ICU-AW is caused by dysfunction or damage of the muscles (critical illness myopathy), nerves (critical illness neuropathy), or both (critical illness neuro-myopathy). ICU-AW is diagnosed by measuring muscle strength with the Medical Research Council sum score, where a sum score of <48 indicates ICU-AW [12, 13]. ICU-AW occurs in 35% of all mechanically ventilated patients, 50% of sepsis patients, and 15% to 50% of patients who stay in the ICU for at least one week [14]. About 15% of ICU survivors with ICU-AW has a reduced muscle strength two years after discharge [12, 14]. ICU-AW is associated with a decrease in physical function during and after ICU admission, longer duration of mechanical ventilation, longer ICU and hospital stay, increased mortality and a delayed rehabilitation [12, 15, 16]. In addition to the severity of the critical illness and its necessary treatment, the duration of bedrest and physical inactivity influences ICU-AW [12, 17]. The diagnosis and co-morbidity, application of medical devices (e.g. mechanical ventilation) and the use of sedatives in the acute phase of critical illness contribute to physical inactivity. This immobilization does not only negatively add to the decline in muscle strength, but also to a reduction in cardiovascular-and respiratory condition [18, 19].

Due to improvements in care, the survival rate of critically ill patients has significantly increased over the past decades. Nevertheless, survivors of critical illness often experience long-lasting impairments in physical functioning, resulting in restrictions in daily functioning and decreased quality of life [11, 14, 20-22]. One year after discharge, more than 50% of the patients treated for more than two days in the ICU still have physical limitations in their daily functioning [11, 14, 22]. In addition to the physical impairments, survivors often experience long term problems within cognitive function and/or mental health. In 2012, the Society of Critical Care Medicine introduced the term "Post-Intensive Care Syndrome" (PICS) to describe these impairments arising after critical illness [23]. The term PICS can be applied to a survivor but also to a family member (PICS-F), since the psychological impact of an ICU admission is not limited to the patients, but appears to affect the mental health of relatives as well (figure 2) [23]. Family members are at high risk of anxiety, posttraumatic stress disorder, depression and complicated grief, which may adversely affect quality of life of the whole family [24-26].

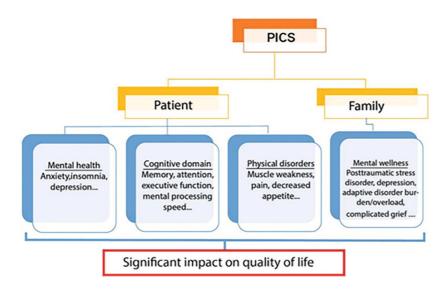


Figure 2. Post-Intensive Care Syndrome (PICS) [23]

Family participation in physiotherapy-related care of critically ill patients

For the daily care of critically ill patients it is advised to integrate elements of the ABCDEF Bundle, an inter-professional approach for symptom management during critical illness [27, 28]. The ABCDEF Bundle consists of six components (i.e. Assess, prevent, and manage pain; Both spontaneous awakening and breathing trials: Choice of Analgesia and Sedation; Delirium assess, prevent, and manage; Early Mobility and Exercise; and Family engagement) and shows significant and clinically meaningful improvements in outcomes including survival, shortening of mechanical ventilation coma, delirium, restraint-free care, decrease of ICU readmissions, and discharge to a nursing home. The greatest benefit occurs when these interventions are combined [28]. A crucial element of the bundle is Early Mobility and Exercise; it is advised to start as early as possible with mobilizing out of bed and promoting physical activity (i.e. performing exercises) [29-31]. The last 20 years, evidence accumulates on the benefits of early rehabilitation in the ICU. Studies show positive effects of early mobilization and physiotherapy-related interventions, such as passive and active physical exercises, cycling, mobilization in and out of the bed and ambulation, on muscle strength and physical functioning. In addition, early mobilization and physiotherapy-related interventions shorten the duration of mechanical ventilation, length of ICU and hospital stay, decrease delirium, and can reduce adverse psychological effects [29-34]. Another important component is Family Engagement; family engagement in the ICU is found to be beneficial for both patients and their family members [35, 36]. Studies highlighted the families' desire to have a role in the care of their critically ill relative. Family involvement in the ICU mostly involves improving communication and dissemination of information, or participation in nursing activities [35, 37]. Engaging families could humanize the patient illness and recovery experience, enhance psychological wellbeing for both patients and family, could decrease the strain of families during a crisis, and might improve family member's ability to cope with the patients' situation [35-42].

Since both early mobilization, physical exercise and family engagement are important components of the daily care of critically ill patients, family participation in physiotherapy-related tasks might be promising [36, 43]. Physiotherapists treat patients usually once a day due to constrained time, nurses often lack the time to help patients with their exercises or mobilization, and family is often not consulted to increase patients' physical activity while they may be present at the bedside. Family members can be engaged in many practical low-cost, high-value rehabilitative physical activities of critically ill patients [36]. However, limited research has been performed on the feasibility and effectiveness of this combination and there are currently no interventions developed on this topic.

General ward

Despite the well-known benefits of physical activity during hospitalization, patients admitted to general wards spent 49% to 98% of their time lying in bed and less than 6% physically active [5-7, 44]. This physical inactivity is associated with complications like pneumonia, urinary-tract infection, deep venous thrombosis and pressure ulcers, which can result in prolonged hospital stays, increased readmissions, higher mortality and increased hospital costs [19, 45, 46]. In addition, lower levels of physical activity during hospitalization lead to functional decline, which results in new disabilities in activities of daily living, which is described as the loss of ability to complete one of the basic ADLs needed to live independently without assistance (e.g. bathing, dressing, rising from bed or a chair, using the toilet, eating, or walking across a room) [47]. New disabilities lead to longer hospital length of stay, long-term care in nursing homes, increased discharges to rehabilitation centers, readmissions or even death [8, 9, 48, 49].

Interventions promoting physical activity at general wards

Hospital processes play a role both in inhibiting recovery of functional loss that occurred shortly before admission and in accelerating additional functional decline during hospitalization. Importantly, most hospitalized patients spent

the majority of time in bed while even short periods of bedrest accelerate muscle wasting [8]. Studies targeting inactivity during hospitalization demonstrate that mobilization and physical activity is a modifiable factor that can prevent in-hospital functional decline [50, 51]. Additionally, higher physical activity levels during hospitalization lead to a reduction in length of stay and increase of discharges home [50, 52-54]. However, sedentary behavior is still deeply rooted in the hospital culture. Promoting inpatient mobilization is challenging since the traditional hospital culture seems to discourage patients to be physically active [55-58]. The environment; hospital wards are often not motivating for patients to be physically active. Patient care is usually organized around the inactivating hospital bed, with food and drinks supplied within reach. Patients indicate that they are motivated but experience various barriers, such as pain, fatigue, and limited knowledge about what they are allowed to do and can do. Health care providers (HCPs) report that they are willing to improve physical activity in hospitalized patients, but they encounter multiple barriers as well, including insufficient knowledge, resources, time/workload, responsibility and role expectations within the multidisciplinary team regarding stimulating patients to be physical active [55-58]. The entire team involved in routine medical and nursing care should be responsible for prioritizing and improving physical activity in hospitalized patients, which is often not the case [58, 59]. All together this has resulted in a culture where many patients spend most of the time in bed. To overcome this culture and create more sustainable changes integrating physical activity in usual care, there is a need for effective interventions integrating physical activity in usual care. Multicomponent interventions are preferred above single-component interventions as these seem to be more effective. It is suggested that interventions should be multidisciplinary and multidimensional, focusing on the entire team of HCPs, on the patients and on the built environment [52, 54, 59-62]. Interventions designed to address the problem of low hospital mobility should take a systems approach and consider allocation of resources, clarity around professional responsibilities, and elevation of patient and clinician expectations surrounding mobility [63].

Hospital in Motion

Programs aiming to improve inpatients movement behavior focusing on the whole system, integrating physical activity in all levels of daily hospital care by implementing multidisciplinary and multidimensional interventions tailored to local context, are still rare. Additionally, there is little knowledge about the optimal content and effectiveness of such interventions. Therefore, Hospital

in Motion, a multidimensional and multidisciplinary implementation project has been developed. The aim of Hospital in Motion is to improve inpatients' movement behavior by implementing physical activity within current daily care procedures. The project includes the development and implementation of ward specific action plans. These action plans are developed by a multidisciplinary team and contain various multidimensional interventions to stimulate inpatient physical activity in usual care, focusing on patients, HCPs and hospital environment [64].

Development, evaluation and implementation of complex interventions

To develop, evaluate and implement complex interventions in healthcare, it is advised to use an evidence based approach. The Medical Research Council (MRC) published influential guidance on developing and evaluating complex interventions, presenting a framework of four phases: development, feasibility/piloting, evaluation and implementation (figure 3) [65].

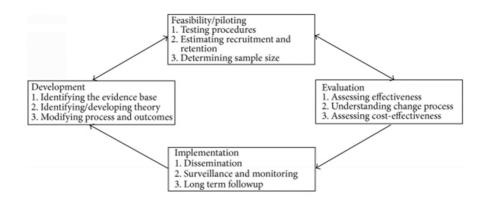


Figure 3. Key elements of development, evaluation and implementation of complex interventions [65]

Phase one, the development phase, consists of three important steps. First, identifying existing evidence about similar interventions; if there is no recent systematic review of the relevant evidence, one should be conducted. The second step is to identify and develop a theoretical understanding of the likely process of change by drawing on existing evidence, supplemented by new research. In this stage it is crucial to gain knowledge on the area of concern, to get an understanding of the prospective users and their context, and determine which values and requirements the different stakeholders deem important to include in the intervention. Last step of the development phase is modelling process and

outcomes, which can provide important information about the design of both the intervention and the evaluation. Before conducting a large scale evaluation and implementation study of the developed intervention, a pilot study is necessary [66]. Large scale evaluations are often undermined by problems of feasibility, usability, compliance and delivery of the intervention, and recruitment and retention. Therefore, a pilot study should explore the key uncertainties and possible barriers that have been identified during development. Afterwards, clinical trials can be performed for evaluating effectiveness of the intervention. The last phase of the MRC framework is large scale implementation. Successful implementation often depends on changing behavior. This requires a scientific understanding of the behavior that needs to change, the factors maintaining current behavior and barriers and facilitators to change, and the expertise to develop strategies to achieve change [65]. To create sustainable changes, not only the intervention but also the implementation approach is of high importance [65, 67]. Large scale implementation should follow a dynamic stepby-step approach using an evidence based framework. The evidence base for effective implementation remains limited, but some promising approaches have been identified, like the Implementation of Change Model_developed by Grol and Wensing. This model is developed especially for the implementation of change in clinical practices and contains seven steps. Steps one to three include the development of proposal for change, analysis of actual performance and problem analysis. Step four of the model includes the selection of interventions and measures to change practice, and step five focusses on the development, testing and execution of the implementation plan [68].

Process evaluation of complex interventions

To understand the whole range of effects, the variety and the interaction when implementing complex interventions, it is important to understand the underlying implementation processes. To maximize their benefits, insight in the factors of influence on the implementation of interventions is the key to ensure that complex interventions are adopted in clinical practice [60, 65, 69]. However, there is often information missing about these implementation processes. Studies that explore these processes and factors of influence during the implementation of interventions aiming to improve physical activity during hospitalization, are lacking.

In 2008 the MRC developed a framework for the process evaluation of complex interventions [68]. This framework exists of three key functions including implementation, mechanisms of impact, and context (figure 4). Implementation contains the goals and interventions that have been delivered

by the project, including the adaptations, dose and reach, and how the delivery had been achieved. The mechanisms of impact include the response to the interventions, the mediators, and all unexpected pathways and consequences. The context includes all other factors that may affect the implementation, interventions, and outcomes, such as barriers and facilitators [69]. In addition to evaluating the effectiveness of a complex intervention, it is suggested to execute a process evaluation, exploring these factors of influence during the implementation.

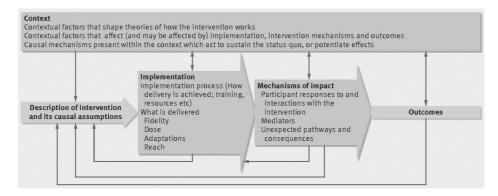


Figure 4. Framework for process evaluations of complex interventions [69]

OUTLINE OF THIS THESIS

This thesis focusses on two intervention projects aiming to increase physical activity during hospitalization. Each project focuses on different phases of the MRC framework for developing and evaluation complex interventions. **Part 1** describes the development and feasibility of an intervention for family participation in physiotherapy-related tasks of critically ill patients, phase one and two of the MRC framework. **Part 2** evaluates the effectiveness and factors of influence on the implementation of Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve inpatients' movement behavior, phase three and four of the MRC framework.

Part 1.

Family participation in physiotherapy-related tasks of critically ill patients

Chapter 2 is a mixed methods systematic review about family participation in physiotherapy- related tasks of critically ill patients, as first step of the development phase of an intervention in this field. In chapter 3, the perceptions and ideas of critically patients, their relatives and ICU staff members regarding this topic and the future intervention are investigated, using a qualitative study design, as second step of the development phase. The pilot study in chapter 4 evaluates the feasibility of the developed intervention aiming to increase family participation in physiotherapy-related tasks of critically ill patients.

Part 2.

Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve patients' physical behavior during hospitalization

Chapter 5 describes a mixed methods study protocol for the implementation and evaluation of Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve patients' physical behavior during hospitalization. The study in chapter 6 investigates the effectiveness of Hospital in Motion on inpatients' movement behavior and medical outcomes. Chapter 7 describes the experienced factors of influence on the implementation of Hospital in Motion, as part of the process evaluation.

This thesis ends with a general discussion in chapter 8, which reviews the main findings of this thesis, in combination with recommendations for future research.

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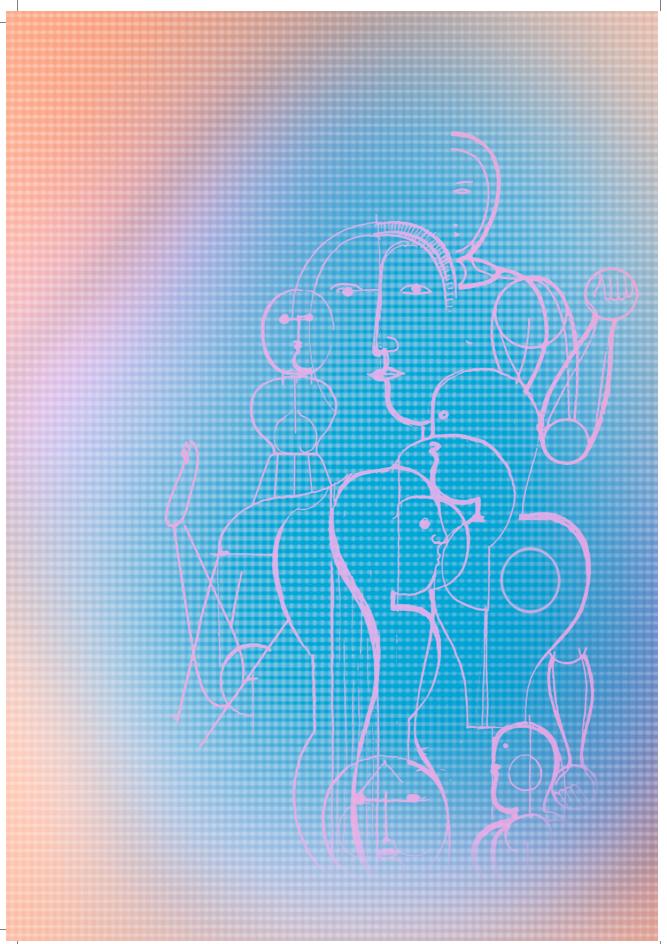
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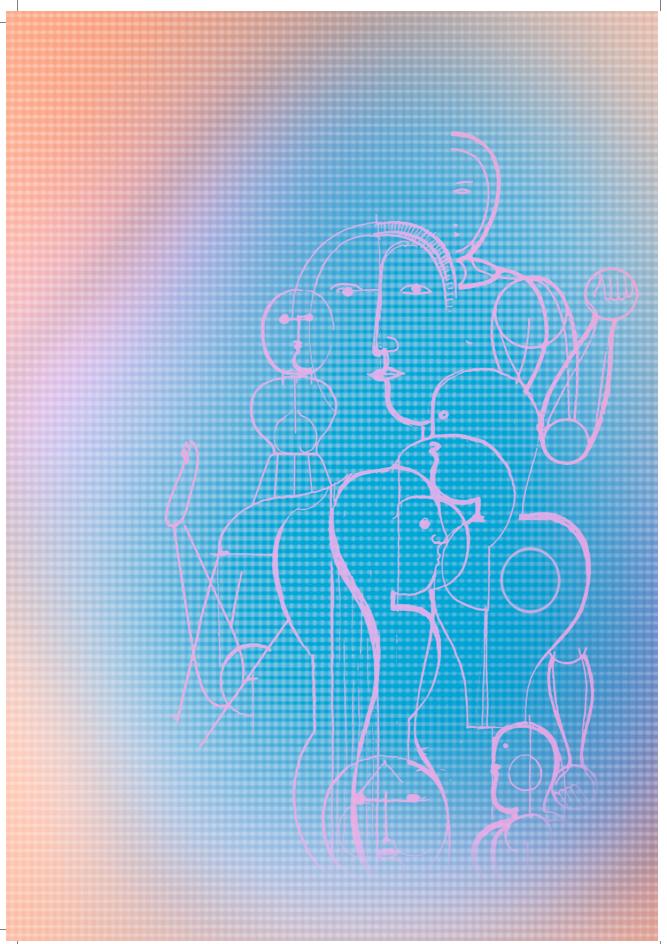
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PART 1

Family participation in physiotherapy-related tasks of critically ill patients



Chapter 2

Family participation in physiotherapyrelated tasks of critically ill patients: a mixed methods systematic review

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Published in Journal of Critical Care 2021, issue 62, pages 49-57

ABSTRACT

Purpose: Providing an overview of studies on family participation in physiotherapy-related tasks of critically ill patients, addressing two research questions (RQ): 1) What are the perceptions of patients, relatives, and staff about family participation in physiotherapy-related tasks? and 2) What are the effects of interventions of family participation in physiotherapy-related tasks?

Material and methods: Qualitative, quantitative and mixed-methods articles were identified using PubMed, Embase and CINAHL. Studies reporting on family participation in physiotherapy-related tasks of adult critically ill patients were included. A convergent segregated approach for mixed-methods reviews was used.

Results: Eighteen articles were included; 13 for RQ1, and 5 for RQ2. The included studies were quantitative, qualitative and mixed-method, including between 8 and 452 participants. The descriptive studies exhibit a general appreciation for involvement of relatives in physiotherapy-related tasks, although most of the studies reported on family involvement in general care and incorporated diverse physiotherapy-related tasks. One study explored the effectiveness of family participation on a rehabilitation outcome and showed that the percentage of patients mobilizing three times a day increased.

Conclusion: Positive attitudes were observed among patients, their relatives and staff towards family participation in physiotherapy-related tasks of critically ill patients. However, limited research has been done into the effect of interventions containing family participation in physiotherapy-related tasks.

INTRODUCTION

An admission to the Intensive Care Unit (ICU) can be associated with various complications, including ICU acquired weakness (ICU-AW) and delirium (1-3). These complications are related to the duration of mechanical ventilation and forced immobility. Prolonged immobility in the ICU can trigger ICU-AW due to various mechanisms including functional denervation resulting from nerve injury caused by sepsis-induced release of cytokines, and disuse atrophy (1, 2). Up to 40% of muscle strength can be lost within the first week of immobilization (4). Survivors of critical illness often experience long-lasting impairments in physical, cognitive and/or mental health (1, 5-7). Fortunately, several lines of evidence confirmed the benefit of early physiotherapy-related of critically ill patients. Physiotherapy-related interventions (e.g. physiotherapy and mobilization) in the ICU can improve patients' physical function, shorten ICU length of stay, decrease medical complications and might reduce some adverse psychological effects (1, 3, 6, 8, 9). However, the psychological impact of an ICU admission is not limited to the patients, but appears to affect the mental health of relatives as well. Family members are at high risk of anxiety, posttraumatic stress disorder, depression and complicated grief, which adversely effects quality of life of the whole family (10-17).

The ICU Liberation Bundle is often used in the daily care of critically ill patients; both early mobilization/exercise and family engagement are elements of this bundle (18, 19). There is evidence that involvement of relatives could be beneficial for patients their relatives, and staff (20, 21). Previous studies on family involvement have primarily focused on family needs, involvement and experiences in the broad sense (13, 20, 22-24). These studies highlighted the families' desire to be involved in the care of their loved one and their wish that staff considers to give family members a role in the care of their critically ill relative. Family involvement in the ICU mostly involves improving communication and dissemination of information (e.g. physician-family conversations and shared decision making), open family visiting hours, or interventions including family participation in nursing care activities (23, 25, 26). Engaging families may enhance psychological wellbeing for both patient and relatives, may decrease the strain of families during a crisis, and may possibly improve family member's ability to cope with the patient's situation (16, 23, 27, 28). However, it is not clear what the added values are of family participation at an early stage in the physiotherapyrelated process (e.g. early mobilization, exercises). Family involvement in physiotherapy-related tasks could optimize patients' physical function by increasing the frequency and thereby impact of physical activity (24), in addition to the psychological benefits. Physical therapists generally treat patients once per day, between 15 to 45 minutes, which is fairly short and intense ^(3, 8, 29). In addition, nurses often lack the time to help patients with their exercises or mobilisation ^(30, 31). Since family is not often consulted to assist during physiotherapy while they are present at the bedside, it can be valuable when relatives are involved in physiotherapy-related tasks, resulting in a win-win situation.

Before developing and evaluating the feasibility of an intervention on family participation in physiotherapy-related tasks, it is important to gain insight into possible tasks, and the opinions of patients, their relatives and ICU staff concerning the involvement of family in the physiotherapy care of critically ill patients. Therefore, the aim of this systematic review is to identify, describe, and summarize evidence from studies reporting on family participation in physiotherapy-related tasks in ICU patients. The following two research questions (RQ) were formulated:

- RQ 1: What are the perceptions of patients, their relatives and staff on family participation in physiotherapy-related tasks of critically ill patients?
- RQ 2: What are the effects of interventions involving ICU family participation in physiotherapy-related tasks on patient outcomes, their relatives and/or staff?

MATERIAL AND METHODS

Design

This mixed methods systematic review included qualitative, quantitative, and mixed method studies reporting on family participation in physiotherapy-related tasks in the ICU. The review was guided by the steps of the PRISMA statement and the method for mixed methods review of the Joanna Briggs Institute (32, 33). To ensure transparency of the methods employed, this review was registered at the International Prospective Register of Systematic Reviews (PROSPERO) database (number CRD42020146739) .

Search strategy, eligibility criteria and study selection

Up to 5 November 2020 eligible qualitative, quantitative and mixed methods articles were identified using the electronic databases PubMed, Embase and CINAHL. The search strategy for the electronic databases included the terms and keywords within the following domains "family" or "relatives" or "visitors

to patients" AND "participation" or "involvement" or "empowerment" AND "Intensive Care (Unit)" or "critical care" or "critical(ly) ill". In the search strategy were also some excluding terms included: neonatal ICU, paediatric ICU and palliative care. The search was limited to full text studies published in English in the last twenty years (1999-2020), as family participation is fairly new and ICU physiotherapy increased in recent years. The complete search strategy can be found in Appendix 1 (online supplemented materials).

Articles were eligible for inclusion if they concerned family participation on the ICU, contained one or more physiotherapy-related tasks (i.e. passive/active exercises such as range of motion, foot flexion, limb exercises, positioning, mobilization/transfer/ambulation, or respiratory techniques/breathing training) as part of their family participation intervention and/or reported results on relative involvement in physiotherapist-related tasks (see Appendix 1, online supplemented materials, for all included physical rehabilitation activities). Relatives were not necessarily limited to family members, but could also be other persons with a close relationship to the patient. Studies solely focusing on family involvement in conversations, medical decisions, ICU rounds, nursing tasks (e.g. washing, bathing, feeding), occupational tasks, or studies on family visiting hours, were excluded. Other exclusion criteria were articles focusing on end-of-life care, palliative care or terminal care; and reviews, theses, letters to the editor, editorials and opinion articles.

For the selection of articles, the steps of the PRISMA statement were followed ⁽³³⁾. The search strategy was used to obtain possible eligible articles. In addition, reference tracking was performed by the primary author based on previously published reviews and all finally included articles. Further, articles were screened for eligibility on title and abstract independently by two researchers (LvD and CV). When one or both authors estimated that the article was eligible for inclusion, a full paper copy of the article was obtained. The eligibility of these full text articles were discussed until consensus was reached between the researchers.

Assessment of methodological quality

The methodological quality of the included articles was assessed independently by two researchers (LvD and KV). The ratings were then compared and discussed in a quality appraisal meeting. The methodological quality was assessed using the Mixed Method Appraisal Tool (MMAT), a universally utilized, validated tool for mixed methods systematic reviews (34-36). The MMAT has been designed to appraise the methodological quality of studies for a complex systematic review that contains mixed, qualitative, and quantitative (subdivided into

three subdomains: randomized controlled, nonrandomized, and descriptive) studies. Methodological quality was assessed using the relevant criterion for each method of investigation. For this study the user guide Version 2018 was followed (35) and therefore an overall quality score was not reported. However, higher quality studies were those that satisfied more criteria. Studies were included in this review regardless of their methodological quality to minimize the risk of study selection bias.

Data extraction

Data was extracted from included studies by the primary author. The included articles were divided per research question. Per research question a table with extracted data and quality assessment results was made. Data extraction included the objective, design and setting, participants, intervention, main findings of significance to the review questions and methodological quality.

Data Syntheses and Integration

This review followed the convergent segregated approach to synthesis and integration, according to the Joanna Briggs Institute methodology for mixed methods systematic reviews (32). In this study the findings were analysed separately for the two research questions. Per research question a separate quantitative and qualitative analysis was done, where the aim was to synthesize the results where possible. Both quantitative and quantitative findings are presented in narrative form, including tables to aid in data presentation. For the final integration of the resulting quantitative evidence and qualitative evidence a narrative summary was used.

RESULTS

Study inclusion

Searching the electronic databases yielded a total of 2811 articles. After removal of duplicates, title and abstracts were screened, resulting in 56 studies which were assessed in full text. Additionally, three articles were identified from hand searching. Finally, of the 59 full text articles, 18 studies were included in the review: 13 articles for RQ 1 on the perspectives of patients, relatives and staff (11, 21, 37-47), and five articles for RQ 2 on the effectiveness of family participation in physiotherapy-related tasks (48-52). See Figure 1 for the PRISMA Flow Diagram.

Characteristics of included studies

The included studies were quantitative studies (11, 39, 48, 49, 51, 52), mixed methods investigations (21, 37, 50, 53) and qualitative studies (38, 40, 41, 44-47, 54). Most of the studies were conducted in the United States (38-40, 47, 48, 50-52). Studies considered staff only (21, 39, 40, 47, 53, 54), family only (38, 44, 49-52), or both family and staff (37, 41, 46). Two investigations also included patients (11, 45), next to family and staff, and one other study focused on patients only (48). The number of participants included in each study varied between 8 and 452. Studies included for RQ 1 were all descriptive (n=13). Of the intervention studies included for RQ 2, there were four pre-post studies (48, 49, 51, 52) and one mixed methods observational study (50). An overview of the characteristics of the included publications is presented in Appendix 2 (online supplemented materials).

Methodological quality

The overall methodological quality of the included studies varied widely. Of the studies included for RQ1, the majority satisfied all applicable MMAT quality criteria, indicating strong study quality (11, 38-40, 44-47, 54). Three studies had a 'no' response to just one criterion; they had high risk of nonresponse bias (37, 53) or provided insufficient information about their results (interpretation) and discussion of findings (41). Only one investigation (21) for RQ 1 had multiple 'no' or 'not reported' responses to the quality criteria; there was insufficient detail in the used method and interpretation and integration of the results. Of the included articles for RQ 2, none of the studies satisfied all criteria. There were issues with the chosen measurements (48, 50), samples that were not fully representative of the target population (48, 51), risks of nonresponse bias (48, 50, 51), statistical analysis that were not always appropriate to answer the research question (48, 50, 51), cofounders which were not accounted for in the analysis (49) and suboptimal integration of the qualitative and quantitative results (50). Only the studies of Mitchell et al. (49) and Amass et al. (52) met almost all MMAT criteria. The remaining three studies (48, 50, 51) had many 'no' or 'not reported' responses, and one of these studies even satisfied none of the quality criteria (48). The individual results of the quality appraisal are reported in Appendix 3 (online supplemented materials).

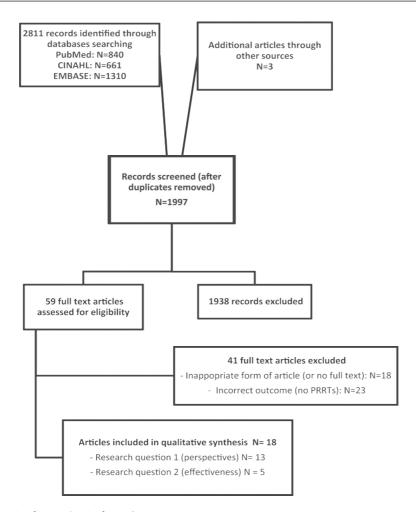


Figure 1. The PRISMA Flow Diagram

Main findings

Most of the included studies described family involvement in (hands-on) bedside care and incorporated physiotherapy-related tasks in their intervention, survey or interviews. Diverse physiotherapy-related activities were reported in the included studies: Range of Motion/passive foot flexion (21, 40, 50, 51), (limb) exercises (passive/active) (21, 37, 41, 44, 49), turning/positioning the patient (11, 37-39, 44, 52, 53) and/or mobilization/ambulation/transfer (11, 39, 45-48, 54). Two studies reported family participation in breathing exercises as a possible task (44, 54). In addition to these physiotherapy-related tasks, massage was mentioned very often as activity that families could perform (11, 38-40, 44, 45, 49-53). See Figure 2 for an overview of all reported activities (total and per research question).

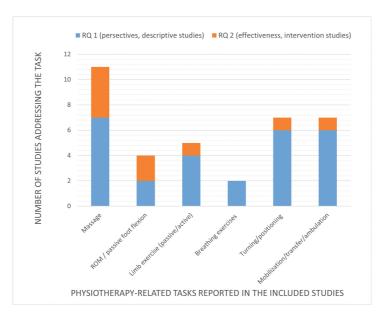


Figure 2. Number of studies addressing types of Physiotherapy-related tasks

Perspectives of patients, their relatives and staff on family participation in physiotherapy-related related tasks

Qualitative evidence

Qualitative evidence about the perceptions of patients, their relatives and staff on family participation in physiotherapy-related tasks was reported in nine studies (21, 38, 40, 41, 44-47, 54). Diverse major and minor themes were identified in these studies. Due to the many different themes regarding physiotherapyrelated tasks, the qualitative findings could not be synthesized. An overview of the individual data is outlined in Table 1. Most of the studies mentioned passive tasks (i.e. massage, passive exercises, range of motion) as an optional activity for relatives to participate in (21, 38, 40, 41, 44, 45). More active activities that were named as acceptable for relatives to be involved in were helping with turning/repositioning of the patient (38,44), assisting with mobilization, walking and transfers (45-47, 54), breathing exercises (44, 54), and active limb exercises (44). In addition to the content of family participation, two studies addressed why family participation in physiotherapy-related tasks can be of added value; reducing workload, and reassuring and comfort the patient (21, 44). One study reported factors which nurses have to take into account when they involve relatives in activities; functional factors (e.g. physical strength), psychological and emotional factors (e.g. willingness and emotional stability), knowledge (e.g. learning ability)(40) (see Table 1).

Table 1. Qualitative evidence: major themes, minor themes and quotations

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Study	Major theme(s)	Minor theme(s)	Quotations
Hetland et al. 2018 [40]	Assessment for involving family in patient care	1. Extent to which nurses encourage families to participate in care 2. Determining which family caregivers should be involved in patient care - Functional factors (e.g. physical strength) - Psychological and emotional factors (e.g. willingness, emotional stability) - Knowledge (e.g. learning ability) 5. Choosing methods of family involvement - Basic care activities such as range of motion	Not applicable
Kean et al. 2014 [21]	Workload	Not applicable	"Performing cares such ROM (range of movement), exercises, enabled me more time to attend other duties"
Beer, de et al. 2017 [41]	Togetherness & Partnership	Doing things together, involving families in care	"We allow them to do passive exercises, touch, to do thing that can stimulate the patient"
McAdam et al. 2008 [38]	Voluntary caregiver	Actual care that families want to provide: massaging, repositioning and assisting with turning	Not applicable

Table 1. [Continued]

Study	Major theme(s)	Minor theme(s)	Quotations
Engström et al. 2011 [42]	Engström Realising the significance of relatives' et al. involvement 2011 [42]	Relatives participated by helping the staff and being of practical use in care: such as helping the patient with breathing training , transfer or mobilisation .	Not applicable
Wong et al. 2019 [44]	Families as part of the team	Wanting the best: families performed some care tasks because they believed the staff may have been unavailable; massage, repositioning Providing psychosocial and emotional care: activities as massage were used to reassure and comfort the patient	Not applicable
	Family roles during recovery	• Supporting the patient's treatment: participation in massage, repositioning and helping with passive limb exercises. their breathing exercises and active limb exercises to maintain muscle strength	
Kydonaki et al. 2019 [45]	Perceived factors for enacting patient and family centered care	Care activities that families, patients and nurses found acceptable for relatives to be involved in: - Massage - Assist with mobilization when extubated	Not applicable

Table 1. [Continued]

Study	Major theme(s)	Minor theme(s)	Quotations
Jafarpoor et al. 2020 [46]	afarpoor Non-Agreed Involvement in Clinical et al. Care 2020 [46]	Family Willingness to Participate	"If you ask me, the nurse did a big favor and called me, inviting me to come in to help the patient walk I think it is really great if they let us do some things for our patients. In this way, patients get better and we ourselves also feel good."
		Compulsory Care Assignment	"When I am examining patients or performing physiotherapy, family members stand next to me. They can thus learn such procedures. As I provide care for another patient, family members can also do and repeat the same on their patients for 10 minutes and I have the chance and also more time to take care of other patients this means using resources at hand."

Table 1. [Continued]

Quotations	"Involving relatives in developing written material about treatment in the ICU. Relatives take care in daily procedures, e.g. mobilization, shaving, brushing teeth etc."	"Involving the family to actively participate in patient care, especially with mobilization and physiotherapy. Speaking and counselling family members in addition to the daily briefing at any time possible when they are with the patient".
Minor theme(s)	Family engagement	
Major theme(s)	Hamilton Engagement et al. 2020 [47]	
Study	Hamilton et al. 2020 [47]	

Quantitative evidence

Quantitative findings from surveys, presented from the perspective of patients, relatives and staff could be merged and are presented in Table 2. The overall findings demonstrates a general appreciation for the value of family participation in physiotherapy care of critically ill patients; in total, 77% of the patients favoured participation of their family in their care (11). The other 23% of the patients who were not favourable to participation of their family in their care gave diverse reasons (see table 2). In addition, 85 to 97% of the family members were willing to participate (11, 37), and between 90 to 100% of the staff agreed with the concept (10, 18, 33). One study (11) demonstrated that, of 97 family members who were willing to participate in care, only 14 (13.8%) relatives spontaneously provided or asked staff to help them participate.

Concerning physiotherapy-related tasks especially, four studies showed that passive activities (e.g. passive exercises and massage) were the most favourable tasks by both patients, their relatives and staff $^{(11,37,39,53)}$; between 70 to 90% of all patients, relatives and staff were favourable to family participation in these activities. More active activities, i.e. changing a patients' position, mobilization out of bed and ambulation, were received less positive. In total, 66% of the patients $^{(11)}$ and 71 to 77% of the relatives $^{(11,37)}$ agreed with family participating in changing the patients' position or in the transfer to a chair. Besides, between 40% (nurses) to 81% (physicians) of the staff were favourable for families helping in these activities $^{(11,37,39,53)}$.

Table 2. Quantitative evidence: engagement of relatives in rehabilitation related tasks

	ICU staff	Relatives	Patients
Overall	 It was generally believed by nurses that family participation can benefit both the patient and relatives, if relatives can sometimes assist in selected minor caring activities: the majority ranked 10 or 11 (out of 11) (45) 96% of the staff agreed with concept of involving families in physical care (37) 98% of the nurses considered the concept of inviting family members to be a part of the patients' care should be part of usual care (21) ICU staff were favourable to family participation in at least one activity was 100% for physicians, 90% for nurses, and 94% for nursing assistants (11) 81% of the nurses considered having family provide some patient care had minimal effect on their workload (21) 	 85% of the relatives wanted to be involved in physical care of the patient (37) 97% of the family members were willing to participate in care (11) 15.8% of the family members spontaneously provided patient care or askes the ICU staff to help them participate in care (11) 	• 77% of the patients were favourable to participation in care of family members. Reasons of the 23% of the patients not wanting care from their families were: desire to preserve their image (70%), unwillingness to be assisted (50%), unwillingness to cause embarrassment (70%), nurses are better skilled (60%), safety (40%), physical modesty (50%) (11)
Passive exercises	• 88.8% of the nurses agreed with passive limb exercises (37)	• 88.2% of the relatives agreed with passive limb exercises (37)	

Table 2. [Continued]

	ICU staff	Relatives	Patients
Massage	• Rehabilitation care activities offered to families: around 70% of the nurses offered massages (36) • 70% (physician) to 90% (nursing assistant) of the staff were favourable to family participation by preventing pressure sores by featuring massages (11)	• 75% was favourable to family participation by preventing pressure sores by featuring massages (11) • Of the 15.8% of the family members spontaneously provided care, they all (100%) participated in massages (11)	• 70% of the patients was favourable to family participation by preventing pressure sores by featuring massages (11)
	• Massage the hands, feet, arms and legs of the patient: the majority of nurses raked 9 or more (out of 11) (43)		
Positioning, turning	• 55.5% of the nurses agreed with helping with turning and positioning the patient (37) • Rehabilitation care activities offered to families: turning (>50% of the nurses) (39) • 50% (nurse) to 81% (physician) of the staff were favourable of families helping staff change the position in bed or transfer to a chair (11) bed or transfer to a chair (11) efamily assisting the nurse in positioning of the patient: most of the nurses ranked 6 or more (out of 11) (43)	• 70.6 % of the relatives agreed with helping with turning and positioning the patient (37) • 77% was favourable of families helping change the position in bed or transfer to a chair (11) • Of the 13.8% of the family members spontaneously provided care, they participated in helping staff change the patients position (64%) (11)	• 66% of the patients was favourable of families helping staff change the position in bed or transfer to a chair (11)

Table 2. [Continued]

	ICU staff	Relatives	Patients
Mobilization, transfer, ambulation	Mobilization, Rehabilitation care activities offered ransfer, to families: ambulation of nurses (39) • 50% (nurse) to 81% (physician) of the staff were favourable of families helping staff change the position in the staff change th	• 77% was favourable of families helping staff change the position in bed or transfer to a chair (11)	• 66% of the patients was favourable of families helping staff change the position in bed or transfer to a chair (11)
	bed or transfer to a chair (11)		

The effects of interventions reporting family participation in physiotherapy-related tasks on patients, their relatives, or staff

Quantitative evidence

Five intervention studies were included for this research question (see Table 3) (48-52). Four studies implemented and evaluated an intervention which existed of a combination of activities for family participation including some, mostly passive, physiotherapy-related tasks (i.e. passive foot flexion, range of motion, massage and/or assist with turning/positioning), using diverse clinical outcomes, all targeting relatives (psychological outcomes) (49-52). One study investigated the effect of family participation in an early mobilization protocol, with the amount of patients' daily mobilization sessions as clinical outcome (48). None of the studies included clinical outcomes of patients' physical functioning. In addition, most studies did not demonstrate any process outcomes. Only the study of Mitchell et al. (49) provided some process data; they showed that physical care was provided by 81 (82%) family members. Of the provided tasks, massage was the most common activity provided by relatives; 29% of all activities done. The clinical outcomes showed that relatives who participated in the intervention group experienced more family centered care; they reported higher scores on the family-centered care scale (p<.001) than the control group. Another comparable intervention study (52) showed that relatives symptoms of PTSD were significantly less frequent, 90 days after ICU discharge, after implementation of the intervention. In addition, the nurses were positive about the intervention; they reported that the quality of care improved, that the intervention did not interfere with care of the patient and that it improved communication with family. However, this study did also not report information about the effect of the physiotherapy-related tasks specifically. Furthermore, the study of Skoog et al. (51) demonstrated that the overall mean state anxiety levels of 56 relatives decreased after the intervention (p=.001). However, this study did not use a control group and no results were reported on the effect of the physiotherapy related outcomes specifically. Lastly, the study of Rukstele et al. (48) showed that the proportion of patients receiving three mobilization sessions per day changed from 66% to 94% following the initiative to involve family in this task (48).

Table 3. Quantitative evidence of intervention studies

Study	Intervention	Participants	Participants Overall results: process and clinical outcomes	Results on physiotherapyrelated tasks
Rukstele et al. 2013 [48]	Involving family in the early mobilization protocol (daily nursing mobilization): invite, educate, support	Patients	Process outcomes: N.A. Clinical outcomes: At baseline 66% of patients received 3 activity/ mobilization sessions per day. After the intervention period, this increased to 94%	See overall results
Mitchell et al. 2009 [49]	Combination of activities for family participation, tailored to the family, nurses helped family to participate in care (e.g. massage and limb exercises)	Relatives	<i>Process outcomes</i> : Care was provided by 82% of the family members <i>Clinical outcomes</i> : Family in the intervention group perceived higher scores on the overall family-centered care scale (p < 0.001), and for the subscales respect, support and collaboration (p<0.001)	Process outcomes: • Most common care activity provided by families was massage, 29% of all activities • Limb exercises was done 1% of all activities
Davidson et al. 2010 [50]	Family Support Program: personalized instructions on helpful visiting activities and provision of family visiting kits (including description of activities to perform at the bedside as desired; e.g. cognitive activities, passive foot flexion, range of motion, massage)	Relatives	Process outcomes: N.A. Clinical outcomes: N.A. Other: the Family Support Program evaluation showed that all items offered within the intervention were found helpful to some family members, however exact numbers and activities were not demonstrated.	N.A.

Table 3. [Continued]

Study	Intervention	Participants	Participants Overall results: process and clinical outcomes	Results on physiotherapyrelated tasks
Skoog et al. 2016 [51]	Facilitated Sense Making intervention card (FSM): teach and assist family in activities they can perform for their ill loved one (e.g. passive foot flexion, range of motion, hand massage)	Relatives	Process outcomes: N.A. Clinical outcomes: The overall mean state anxiety levels decreased significantly after FSM ($P = 0.001$). The overall mean trait anxiety levels before and after FSM did not differ significantly ($P = 0.46$)	N.A.
Amass et al. 2020 [52]	Family Care Rituals (FRC); information booklet containing 7 domains in which relatives may participate: e.g. massage and assist with turning and positioning.	Multiple: relatives and nurses	Process outcomes: N.A. Clinical outcomes: • Relatives: Symptoms of PTSD, 90 days after ICU discharge, were significant higher preintervention than post-intervention (39.2% vs 27.1%, p=0.046). No significant difference in symptoms of depression, anxiety or satisfaction score. • Nurses: Statement quality of care was improved; post intervention scored 3.98 out of 5, statement that the intervention did not interfere with care of the patient scored 4.42 out of 5, statement that intervention improved communication with family scored 4 out of 5.	N.A.

Integration of evidence

Most of the included studies described family involvement in general handson bedside care and incorporated diverse aspects of physiotherapy care, which varied from passive activities to more active activities (see figure 2). The results exhibit a general appreciation for involvement of relatives in physiotherapyrelated tasks, however information about the effectiveness of physiotherapyrelated tasks specifically is very limited.

Passive physiotherapy-related tasks (massage, range of motion/passive foot flexion, passive exercises)

The results of the syntheses support family participation in massage and range of motion (or passive foot flexion), as this was found feasible by most patients, relatives and staff (11, 38-40, 44, 45, 50, 51, 53). In addition, massage was the most common activity of the intervention provided by families (49). However, no results were reported on the effect of these activities specifically, and none of the intervention studies satisfied all MMAT quality criteria. Passive (limb) exercises was also often reported to be feasible (21, 37, 41, 44); one study (37) demonstrated that more than 88% of the nurses and relatives agreed with passive limb exercises. However, in an intervention study, only 1% of all performed activities concerned limb exercises (49), and no results were reported about the effect of these exercises.

Active physiotherapy-related tasks (active exercises, positioning, mobilization, transfer and ambulation)

Active physiotherapy-related tasks that were only named in descriptive studies as possible tasks for relatives were active limb exercises (to maintain strength) (44) and breathing exercises (44,54). The activities helping with repositioning in bed and mobilization out of bed were, in addition to positive descriptive results (11, 37-39, 44, 46, 47, 53), also part of interventions for family participation. Repositioning was included in one intervention study, but no results were reported about this task (52). Regarding mobilization, one study (48) investigated the effect of families participating in early mobilization, showing a change from 66 to 94% in the amount of patients receiving three mobilization sessions a day, however, this article met none of the MMAT quality criteria.

DISCUSSION

We evaluated the evidence for family participation in physiotherapy-related tasks of critically ill patients. In summary, this review supports that positive attitudes exist among patients, relatives and staff towards the participation of family members in physiotherapy-related care. However, limited research has been done to the feasibility and effectiveness of interventions focusing on participation in (active) physiotherapy-related tasks.

Concerning the perceptions of patients, their relatives and staff about family participation in physiotherapy-related tasks, studies mostly focussed on the opinion of ICU staff and families of critically ill patients. In 2001, the Institute of Medicine strongly recommended that healthcare delivery systems should become patient-centered rather than clinician- or disease-centered, with treatment recommendations and decision making tailored to patients' preferences and beliefs (55). Patient-centered care is the practice of caring for patients in ways that are meaningful and valuable to the individual patient. It includes listening to, informing and involving patients in their care (55-57). Since patients-centered care is becoming more important on ICU's as well (56, 57), patients' opinions about family involvement in the ICU care are crucial and should be investigated in more detail before developing an intervention in this field.

Interesting is that most relatives are willing to participate in care, while only a few spontaneously provide or ask staff to help them participate (11). This result emphasizes the potential of interventions to offer family participation in a structured way. Also interesting is the difference between nurses and physicians concerning family helping with mobilization out of bed; overall nurses are less positive towards it. Possibly, nurses limit family participation in mobilization care because of their concern about patient safety like the possible occurrence of adverse events such as removal of invasive devices during mobilization, but also lack of time or concern about interacting with families may play a role (11, 40,58). This could also explain why more passive activities (e.g. massage, range of motion, passive exercises) are more favourable than mobilization. In addition to the safety of these tasks, a reason might be the fact that the passive tasks could be performed in all (awake, sedated and intubated) critically ill patients.

Unfortunately involving families in physiotherapy-related tasks raises a number of concerns and possible barriers for the feasibility. Barriers reported in studies focusing on family participation in ICU patient care are patient safety, family competence, and responsibility (40, 44, 55, 56). Involving relatives in physical activities may increase the risk for adverse events (55). Not all relatives

are capable of participating because their emotional, psychological or physical capacity. Staff members must assess this properly and families should receive structured information, training before participation, and evaluation moments (40, 44, 45, 55, 56). Staff members believe it is important to maintain control over the situation and patient, since they are ultimately responsible, which is challenging in clinical practice (40, 45). Besides patients' safety, patients' privacy have to be taken seriously, since ICU patients are often not wearing clothes (56). However, this may be more a barrier when relatives are participating in nursing tasks such as washing. In addition, sometimes relatives and/or patients may want to maintain their normal relationship as partners. Not everyone wants to participate in the care. Type of relationship, younger age, non-European descent and previous ICU admission may influence the willingness to participate (40, 55, 56).

Evidence on the feasibility and effectiveness of interventions focussing on family participation in physiotherapy-related tasks is still low. Physiotherapy-related tasks are not often included, and active tasks even less, in interventions towards ICU family participation. The intervention studies included in this review (RQ 2) were all pre-post or observational designs, no randomized trails, and did not satisfy all criteria for methodological quality. In addition, none of the studies included outcomes of patients' physical functioning, most studies focused on relatives. Besides, most of them did not demonstrate any process outcomes (e.g. how many times did relatives participate), which makes the interpretation of the clinical outcomes difficult.

Since both early mobilization, exercise and family engagement are part of the ICU Liberation Bundle, the combination is an important and promising topic, resulting in need for further research in this area. To increase the impact of patients' physical therapy by family participation, it is important to investigate the feasibility of more active physiotherapy-related tasks. Involving relatives in interventions such as active limb exercises, and thereby increase the frequency of physical activity during the day, may promote patients' physical recovery. If the aim is reducing adverse psychological effects only (patient or family), then tasks such as massage or passive range of motion, which are interventions without direct evidence on improving patient physical performance, may be sufficient.

The goal of the intervention, and clinical outcomes, should be clearly defined before selecting the activities for relatives to participate in. To improve patients' physical functioning during and after critical illness, relatives should be willing to participate in helping with active exercises and/or mobilization. Therefore, it is of high importance that future studies should collect process outcomes in addition to clinical outcomes: do relatives want to participate in (active)

physiotherapy-related tasks, and if yes, how many times are they participating (e.g. amount of moments that they are doing exercises with the patient), and what tasks are they participating in? Since there is not much literature focusing on this specific topic, a proper pilot study is needed to thoroughly evaluate the feasibility before conducting a large-scale implementation and effectiveness study. When family participation in (active) physiotherapy-related tasks of critically ill patients seems feasible, the effectiveness need to be evaluated on clinical outcomes such as patient's physical functioning.

A strength of this review is that it is first review regarding family participation in physiotherapy-related care of critically ill patients. Previous reviews on ICU family participation focussed on family involvement in the broad way (e.g. nursing tasks, medical decisions, communication) (20, 22-24). Another strength is that it included both qualitative, quantitative and mixed-method studies, and involved patients, relatives and staff to provide new evidence about family participation in physiotherapy-related tasks. Since the included studies did not focus purely on physiotherapy-related tasks, it was difficult to extract physiotherapy-related results specifically, which might be seen as a limitation of this review.

CONCLUSIONS

In conclusion, the findings of this review support our hypothesis that it is worth investigating if it is feasible to involve family in physiotherapy-related tasks. Patients, relatives and staff appear to have a positive view towards the participation of relatives in the physiotherapy care of critically ill patients, but currently limited research has been done to the feasibility and effectiveness of interventions focusing on family participation in physiotherapy-related tasks. Before conducting a proper pilot study, it is important to listen carefully to the needs of staff, family and patients, to develop the intervention accordingly.

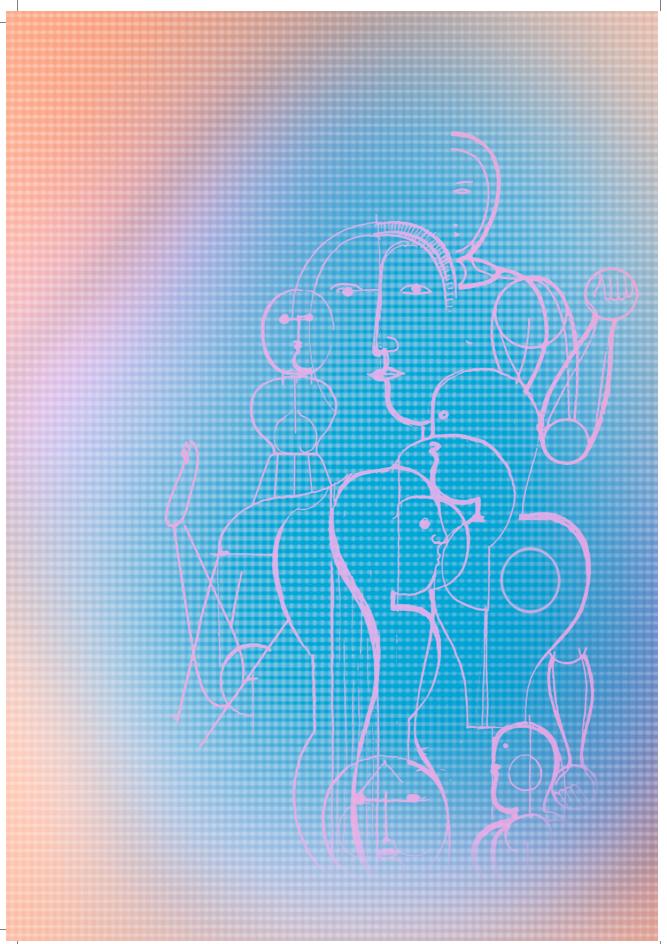
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Chapter 3

Perceptions and ideas of critically ill patients, their family and staff members regarding family participation in the physiotherapyrelated care of critically ill patients: a qualitative study

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Published in Physiotherapy Theory and Practice 2021, online ahead of print

ABSTRACT

Background: Involvement of family in physiotherapy-related tasks of critically ill patients could be beneficial for both patients and their family. Before designing an intervention regarding family participation in the physiotherapy-related care of critically ill patients, there is a need to investigate the opinions of critically ill patients, their family and staff members in detail.

Objective: Exploring the perceptions of critically ill patients, their family and staff members regarding family participation in physiotherapy-related tasks of critically ill patients and the future intervention.

Methods: Multicenter study with a qualitative design. Semi-structured interviews were conducted with critically ill patients, family and intensive care staff members, until theoretical saturation was reached. The conventional content method was used for data analyses.

Results: Altogether 18 interviews were conducted between May 2019 and February 2020. In total 22 participants were interviewed; Four patients, five family members, and 13 ICU staff members. Six themes emerged: i) prerequisites for family participation (e.g. permission and capability), ii) timing and interactive aspects of engaging family (e.g. communication), iii) eligibility of patients and family (first-degree relatives and spouses, long stay patients), iv) suitability of physiotherapy-related tasks for family (e.g. passive, active and breathing exercises), v) expected effects (e.g. physical recovery, psychological wellbeing), and vi) barriers and facilitators which may affect the feasibility (e.g. safety, privacy, and responsibility).

Conclusion: Both patients, family members and staff members supported the idea of increased family participation in physiotherapy-related tasks, and suggested components of an intervention. These findings are necessary to further design and investigate family participation in physiotherapy-related tasks.

INTRODUCTION

An admission to an Intensive Care Unit (ICU) is often associated with a decrease in physical function and the emergence of ICU acquired weakness (ICU-AW) (Hermans and Van den Berghe, 2015; Parry and Puthucheary, 2015; Piva, Fagoni and Latronico, 2019). Survivors of critical illness can experience new or worsening impairments in physical, cognitive and/or mental health (Rawal, Yadav and Kumar, 2017). Early physical rehabilitation in the ICU can improve patients' physical function, shorten ICU length of stay, and may reduce adverse psychological effects (Needham et al., 2010; Pandharipande et al., 2017; Parker, Sricharoenchai and Needham, 2013). The psychological impact of an ICU admission is not limited to the patients, but may affect the mental health of their family members as well (Alfheim et al., 2018;, Alfheim et al., 2019; Davidson, Jones and Bienvenu, 2012; Garrouste-Orgeas et al., 2010; McAdam, Fontaine, White and Dracup, 2012; Pochard et al., 2001).

Involvement of family in the ICU has the potential to optimize diverse outcomes. It can be beneficial for patients, family members and staff members (Al-Mutair, Plummer, O'Brien and Clerehan, 2013; Haines, 2018; Kean and Mitchell, 2014; Kynoch, Chang, Coyer and McArdle, 2019; Liput, Kane-Gill, Seybert and Smithburger, 2016; McKiernan and McCarthy, 2010; Olding et al., 2016). It has been suggested that engaging families could humanize the patient illness and recovery experience, might enhance psychological wellbeing for both patients and family, could decrease the strain of families during a crisis, and might improve family member's ability to cope with the patients' situation by giving them a purposeful role (Al-Mutair, Plummer, O'Brien and Clerehan, 2013; Haines, 2018; Kean and Mitchell, 2014; Kynoch, Chang, Coyer and McArdle, 2019; Liput, Kane-Gill, Seybert and Smithburger, 2016; McKiernan and McCarthy, 2010; Olding et al., 2016). In addition, active involvement can support staff by utilizing relatives as a supporting resource to deliver care outside of constrained time staff members have (Haines, 2018). Since both early mobilization, physical exercise and family engagement were found to be beneficial in the daily care of critically ill patients (Pun et al., 2019), family participation in physiotherapy-related tasks could be promising (van Delft, Valkenet, Slooter and Veenhof, 2021). Physiotherapists treat patients usually once a day due to constrained time, nurses often lack the time to help patients with their exercises or mobilisation, and family is often not consulted to assist during the exercises while they may be present at the bedside (Haines, 2018). Interventions aiming to increase family participation in physiotherapyrelated tasks could, in addition to the previous mentioned benefits, optimize

patients physical function by increasing the frequency and thereby impact of physical rehabilitation. A recent review (van Delft, Valkenet, Slooter and Veenhof, 2021) and viewpoint (Haines, 2018) demonstrate that there are positive attitudes among patients, family members and staff members towards family participation in physiotherapy-related tasks with critically ill patients. Haines thinks that family members can be engaged in many practical low-cost, high-value rehabilitative activities of critically ill patients (Haines, 2018). However, limited research has been done to the development, feasibility and effectiveness of interventions regarding family participation in physiotherapy-related tasks (van Delft, Valkenet, Slooter and Veenhof, 2021).

The Medical Research Council (MRC) framework can be used for developing and implementing complex interventions (Craig et al., 2008). The first phase of this framework is the development phase. The first step of this phase was to identify what is already known about family participation physiotherapyrelated tasks (van Delft, Valkenet, Slooter and Veenhof, 2021). The next step is to identify and develop a theoretical understanding of the likely process of change. In this stage it is crucial to gain knowledge on the area of concern, to get an understanding of the prospective users and their context, and determine which values and requirements the different stakeholders deem important to include in the further design of the intervention (Craig et al., 2008). Before further designing an intervention regarding family participation in the physiotherapyrelated care of critically ill patients, there is a need to investigate the opinions of ICU patients, their family and staff members in detail. It is important to examine when, how and in which physiotherapy-related activities family could and would like to be involved. Therefore, to assess the feasibility of an intervention for family participation in physiotherapy-related tasks of critically ill patients, the aim of this study was to explore the perceptions and ideas of patients, their family and staff members regarding this topic and the future intervention.

MATERIALS AND METHODS

Design

This is a multicenter study, using a descriptive qualitative design. This study is the second step in the development phase of the MRC framework (Craig et al., 2008). The first step in the development phase was a systematic review to summarize the existing evidence about family participation in physiotherapy-related tasks of critically ill patients (van Delft, Valkenet, Slooter and Veenhof, 2021). The method of this study is based on the qualitative content method (Hsieh and Shannon, 2005), using individual semi-structured interviews with

open ended questions. For reporting this study the consolidated criteria for reporting qualitative research (COREQ) checklist (Tong, Sainsbury and Craig, 2007) was used; see Appendix 1 (online supplemented materials).

Setting

To provide diversity allowing generalisability in terms of patient profiles, family experience and staff member opinions, this study was performed in an academic hospital, University Medical Center Utrecht (UMC Utrecht), and a non-academic community hospital, Diakonessenhuis (DH), which are both mixed medical-surgical adult ICUs. Unit one (UMC Utrecht) is a 36-bed medical-surgical-, cardio-, neuro- transplant- and trauma centre. Unit two (DH) is a 12-bed medical- surgical community ICU. The study protocol was assessed and approved by the local Medical Ethics Committee (study protocol number 18-842). Written informed consent was obtained from all participants of this study.

Participants

For this study, critically ill patients, family members, and ICU staff members were included for semi-structured interviews. Overall inclusion criteria for participation were the ability to speak Dutch and an age of 18 years or older. Patients had to be admitted to the ICU for more than 72 hours and be both verbally and cognitively capable to talk for 30 minutes, as assessed by the treating physicians. Regarding family members, only first-degree relatives and spouses (partners) of patients admitted at the ICU for more than 72 hours were included. Involved staff members were ICU nurses (formal relevant postgraduate training completed), ICU physicians (formal relevant postgraduate training completed), physiotherapists, occupational therapists and managers, working in the ICU for at least 4 months. Staff members were purposively sampled for semistructured interviews, based on discipline and years of work experience. The inclusion of patients, family and/or staff members continued until nothing new was heard in two consecutive interviews and theoretical saturation, described as the point where no new themes other than the one already existing obtained from the data, was reached.

Study procedures

Patients and family

Eligible patients and family members received verbal and written information about the study. At study unit one (UMC Utrecht), the primary researcher (LvD, MSc) approached potential participants face-to-face, provided information,

answered questions, and asked for participation. At study unit 2 (DH), the enrolment was performed ditto by a research assistant (PT, BSc). Both researchers were female and also work as physiotherapists in the ICU, resulting in the possibility that there was a prior relationship to the patient and/or family as part of clinical care. The interviews with patients and/or family members were conducted at the end of the patients ICU stay, or within the first two days after discharge from the ICU. The interviews had a maximum of 30 minutes, and took place in a quiet room according to the participants' wishes: i.e. family room or meeting room in the ICU, or in the patient room.

Staff members

All ICU staff members that met the inclusion criteria received an email from the primary researcher (LvD) with information about the study and the question to participate in this study. Responses were selected on discipline and years of work experience, and subsequently an interview date and time was set by email. Since the primary researcher also works as physiotherapist at UMC Utrecht, it is possible that there was a professional relationship with staff members established prior to study commencement. The interviews had a maximum of 30 minutes, and took place in an office in the ICU, privately.

Data collection

The semi-structured interviews were guided by a topic list with open-ended questions; one for the patients, one for family and one for staff members (Appendix 2, online supplemented materials). The topic lists were developed by the first author (LvD), who had done a course for qualitative research and conducting interviews, and reviewed by the research team. All interviews were conducted by the first author (LvD), and were audio-recorded and transcribed verbatim (LvD). Participants were interviewed in random order. In addition to the interview data, the following data were collected for patients: age, sex, reason for ICU admission, length of ICU stay (at the moment of the interview), and cause of ICU admission. Data collected for the family members were age, sex, relationship to the patient, and cause of ICU admission of the patient (his/ her family member). For staff members age, sex, profession and the number of years of working experience on the ICU were collected. To warrant the quality and consistency of the interviews, a second investigator (CV) listened back the first three interviews, and evaluated and discussed these finding before continuing with the interviews.

Data analyses and trustworthiness

The conventional content approach was used for analysis (Hsieh and Shannon, 2005). The objective of this method is to systematically transform a large amount of text into a highly organized and concise summary of key results. Text was read verbatim to interpret its meaning and to start dividing up the text into smaller parts, called meaning units, before starting with coding. Coding involved assigning a 'label' to a segment of text (the meaning units) to represent the meaning derived from that text. After this initial coding phase, common codes were sorted for the identification of (sub)categories. Using the process of abstraction, all the codes were categorized and categories were combined until all interview data was reduced to a few main categories, which are in this study labelled as major themes. The final analytical phase resulted in a narrative story line that accounted for the major themes and explained the research question. NVivo version 12 (2018, QSR International Pty Ltd, Melbourne, Australia) was used for all analyses.

The following strategies were incorporated to enhance credibility. The first three interviews were independently coded by two researchers (LvD and KV). To create consistency and equality in the data analysis, codes were discussed, subsequently categorized and themes were selected. After creating consensus about the codes, categories and major themes, the following interviews were analysed by one researcher (LvD), and when found, appropriate new codes, categories and major themes were formulated until no new themes obtained. To assure rigor and trustworthiness, finalized analyses were checked and suggestions were provided by a second researcher (KV) before the final thematic analysis of all qualitative data was produced. Consecutively a consensus meeting was organized with two other researchers (CV and AS) to discuss the final categories and themes. In order to assure participant validation, a member check was performed at the end of each interview by providing a verbal summary of the findings, and by performing a member check of the final findings with two interviewed staff members.

FINDINGS

Sample characteristics

Altogether 18 interviews were conducted between May 2019 and February 2020 of which four were with a patient and their family member simultaneously. In total 22 participants were interviewed; Four patients, five family members, and 13 ICU staff members (Table 1). The patients were mostly female (75%) with a mean age of 61 (Standard Deviation (SD) 6). Most family members were male

(60%) and partner (80%) of the patient, with a mean age of 57 (SD 12) years old. The majority of the interviewed ICU staff members were female (77%) and nurse (46%), with a mean age of 44 (SD 12). Table 1 provides detailed information of the participant characteristics. In one interview the recording equipment failed, so field notes were made.

Table 1. Characteristics of the interviewed participants

Characteristic	Critically ill patients n = 4	Family members n =5	Staff members n = 13
Sex; N (%)			
- Female	3 (75)	2 (40)	10 (77)
- Male	1 (25)	3 (60)	3 (23)
Age; mean (SD)	61 (6)	57 (12)	44 (12)
Relationship to the patient; N (%)	`,		
- Partner	NA	4 (80)	NA
- Daughter	NA	1 (20)	NA
Days admitted to ICU; mean (SD)	33 (19)	30 (18)	NA
First ICU admission; N (%)			
- Yes	3 (75)	4 (80)	NA
- No	1 (25)	1 (20)	NA
Hospital location; (N%)			
- UMC Utrecht	4 (100)	4 (80)	8 (62)
- Diakonessenhuis	NÁ	1 (20)	5 (38)
Admission diagnosis; N (%)			
- Lung transplant	2 (50)	NA	NA
- Heart failure	1 (25)	NA	NA
- Left ventricle assist device	1 (25)	NA	NA
Years of critical care experience; N (%)			
- 1-5 years	NA	NA	6 (46)
- 6-15 years	NA	NA	2 (15)
- Over 15 years	NA	NA	5 (38)
Profession; N (%)			
- Nurse	NA	NA	6 (46)
- Physician	NA	NA	3 (23)
- Physical therapist	NA	NA	2 (15)
 Occupational therapist 	NA	NA	1 (8)
- Team manager	NA	NA	1 (8)
Duration of the interviews - minutes; mean (SD)	20 (2)	20 (2)	26 (5)

Main findings

Both patients, family members and ICU staff members supported the idea of increased family participation in ICU physiotherapy-related care, and contributed in suggesting relevant components of an intervention. Six major themes emerged: i) prerequisites for family participation, ii) timing and interactive aspects of engaging family, iii) eligibility of patients and family, iv) suitability of physiotherapy-related tasks for family members, v) expected effects, and vi) barriers and facilitators which may affect the feasibility (Figure 1). See Appendix 2 for a summary of quotations divided per major theme and Appendix 3 for a full overview of the major themes and (sub)categories (online supplemented materials).



Figure 1. Major themes brought up by the semi-structured interviews, regarding family participating in the physiotherapy-related care of ICU patients

i. Prerequisites for family participation

The most frequently mentioned was that participation should be voluntarily; family members must really want to get involved in the care of their loved ones.

"Yes and therefore what is important, I think you should tell family that it is not a must! That it is allowed, but if you don't want to, you don't have to. And if you say later I don't want it anymore, then that's okay too."

[ID 3, nurse]

In addition, the minority of staff members stated that also patients should agree, whenever possible. All staff members agreed that the ultimate responsibility regarding family participation should lie with the bedside nurse and/or physician. However, deciding which physiotherapy-related activities could be done by the family member should be decided by the physiotherapists, based on the patients physical condition. One team manager and nurse mentioned that, to guarantee continuity, it is important that most nurses support the program. Other prerequisites which were often stated, were that family participation should always be an addition to normal physiotherapy care and that it must be tailored per patient, per family member, and per day.

"But I think that it can differ greatly per patient or per case. And per day perhaps. But then I think as physio and nurse you have to communicate very good about it." [ID 16, nurse]

ii. Timing and interactive aspects of engaging family

Staff members talked about the right time to appoint, offer and involve family. Most of them stated that family members should be allowed to participate when the patient is medically stable. Creating awareness about the possibility for family participation should start earlier, by naming the options for participation already the first days of ICU admission. Furthermore, they thought family participation may change over time. During the first phase of admission family is likely to stay on the background more as they may be overwhelmed by the ICU environment and medical situation of their critically ill loved one. When patients become medically stable and the ICU environment becomes more familiar for family members, the readiness for family participation may increase.

Staff members find it challenging how to involve family, and two concepts were often discussed: the communication with family members and the way of offering. In the interviews staff members agreed that the first contact with family members is best done by the nurses since they see them most often. It

was suggested that if a family member wants to participate, the physiotherapist can subsequently approach them for further explanation and training.

"I think that nurses are good point to start because they see the family members more often, even in the evenings when we are not there. So I think it is certainly useful but the nurses are also busy enough, so I think it is a nice task for physiotherapist to explain it to the family afterwards. But it is nice if nurses take the first step and the first contact and information"

[ID 6, occupational therapist]

All staff members decided that guidance of family is very important; it starts with clarification and clear instructions, followed by practicing the physiotherapy-related tasks together. In addition, they agreed that interim evaluation, supervision and feedback is crucial.

"So that the physiotherapist really should do it the 1st time together, and maybe also evaluate regularly with family and how they are doing or if they have questions. I don't think you can just give a booklet about family participation, what can you do yourself, get started"

[ID 16, nurse]

Regarding the activities one offers to the family to participate in, staff members think that it is important to set boundaries in advance and predefine activities in which family can participate. The majority of nurses mentioned the option where family members can choose tasks they feel comfortable with.

Various options were mentioned about how to offer it (in which form) to the family. Participants agreed with something tangible instead of only verbally. Examples of forms that were named are a folder/booklet, a list/poster with activities, and notes in a patient dairy.

iii. Eligibility of patients and family

Participants had a clear opinion concerning the eligible patients, in terms of patient groups where family is allowed to participate in physiotherapy-related tasks or not. Most staff members mentioned patients with a long duration of ICU admission (e.g. admitted more than a week) and/or weak (e.g. ICU-AW) patients who will enter a rehabilitation process after ICU discharge as target groups. A few nurses stated that family of all patients receiving physiotherapy should be involved. Staff members agreed that patients who should be excluded are hemodynamic unstable, septic patients and patients with 'no touch policy'

due to increased intracranial pressure. Staff members also mentioned the protocolled short-stay surgery patients for exclusion because they already have strict mobilization and physiotherapy protocols. In addition, some participants had doubts about sedated patients since they cannot give permission and are mostly still medically unstable.

"Well I would like it if we do offer that, that it does not only have to be patients' with a rehabilitation process, but also ordinary patients who are here longer, the long-stayers, e.g. people after neuro trauma or people after, whatever, you know them also, there it can really be an advantage."

[ID 7, physician]

Regarding eligible family members, the interviewed participants mainly thought first-degree relatives (i.e. parents, children, brothers and sisters) and spouses/partners. Most frequently mentioned by patients, family and staff members, was the relationship between the family member and the patient. Not all family members should participate in physiotherapy-related tasks, since they may have objections to become a caregiver. Difference between sons and daughters was mentioned by a patient, where her daughters wanted to help and her sons not. In addition, one physician stated that young people are more used to participate ("doing it together") than the older generation (i.e. 70 and older).

"Yes, I think that they see their mother mainly as a mother, and not, because as soon as something will happen here, my sons will also leave. My daughters-in-law stay, they don't mind, but the kids, boys, are leaving."

[ID 11, patient]

iv. Suitability of physiotherapy-related tasks for family members

Many different activities were named by staff members, patients and family members themselves. Staff members thought that suitable physiotherapy-related tasks can vary daily, due to the changing situation and physical functioning of the patient. Concerning physiotherapy-related tasks, passive exercises / passive range of motion (ROM) for the prevention of contractures, active exercises to increase or maintain muscle function/strength, and breathing exercises (e.g. incentive spirometer) were mentioned most.

"If people are good enough that you give them an incentive spirometer something where people often don't think of themselves to practice. That you say to the family, let them practice with that incentive spirometer, even if they only say it

once, then it is already kind of, you already have a profit there. I don't think about it every hour either ... "

[ID 3, nurse]

In addition, nurses often considered massage as a possible task for family. Regarding mobilization out of bed, opinions were divided. Family members indicated that they would like to help with this activity, but most staff members consented as not all family members may be skilled to help. Letting them help will then result in more workload for the nurse of physiotherapist, and possible patient unsafety. In addition, staff members think that mobilization should not be performed by family alone, but always together with staff, ensuring safety.

"That may also depend on how it goes and how the family member helps. Someone can of course really help with mobilizing, but someone can of course also be too much on top of it, and then working against you."

[ID 5, physiotherapist]

v. Expected Effects

Several potential effects were identified. Often cited was the expectation that involvement of family members might reduce stress and anxiety for both patients and family members.

"I think for the group thinking it's too scary, who thinks everything is exciting/ stressful, that you can lower the threshold (when they participate). If you notice gosh there is still just the one you love, there in bed, touching him, movements are possible. You can really mean something to him, that it is also very nice for their psyche, certainly."

[ID 1, nurse]

Staff members (i.e. nurses, physiotherapist, physician and team manager) mentioned that for patients it might also improve their physical recovery, and even facilitate discharge, when the frequency of physical exercise moments would increase.

"Well maybe it is, in transferring a patient earlier (discharge ICU). I think that in the end, it might perhaps advance in the speed of the patient's physical recovery." [ID4, team manager] In addition, a few long-term effects were mentioned. Staff members expected the program to be valuable to mentally and physically prepare family and patients for the rehabilitation phase after ICU admission: for example, the next ward, rehabilitation center or at home.

Regarding the potential effects for staff members, opinions were divided. The majority of nurses indicated that it may save them time, but that they would only benefit from this in a later stage of the patients' admission and that this would depend on the family member. The minority of nurses stated that they expected that family participation has no direct added value for them, in the sense of they don't have to do anything less when family is participating in physiotherapy-related tasks.

There were also negative effects mentioned. Half of the nurses named the fear of family members participating too much which might interfere with the patient or nurses wishes. Involving family too much could be counterproductive because patients might be going to rebel against their family member. Another unwanted consequence which was indicated by nurses, is that family members could become overconfident, start doing things themselves they are not skilled in, resulting in unsafe situations.

vi. Barriers and facilitators which may affect the feasibility

The relationship between the family member and the patient could be a factor of influence. Not all family members would be willing to participate in physiotherapy-related tasks and patients may not appreciate help of a family member. The most important facilitator for family participation during ICU admission was considered caregiver by the family member before ICU admission.

Staff members often mentioned that family may find it scary to perform physiotherapy-related tasks with the patient because of the many lines, equipment and alarms in the room. However, the interviewed family members did not name that.

"Sometimes you are a bit afraid that you are touching the wrong line, but it is not that I really have the feeling that it is very scary, no."

[ID 11, partner]

Besides, staff members agreed that not all family members are capable (physically and/or emotionally) to participate. Since patients' safety is essential, they think it is necessary to criticize family members' capability before they start participating in physiotherapy-related tasks. As for patients, they usually wear few clothes during their ICU admission jeopardizing patients' privacy.

However, this was mostly mentioned by staff members and not by patients themselves.

"You have some family members who understand it very well, know exactly when you tell them what to do and stick to that, and you have families who are there and the moment an alarm starts they drop everything. Because then there will be a beep and then all at once "oh shit there is something going on", then it is of no use to you, then you are actually guiding that family more than you monitoring your patient."

[ID 3, nurse]

Finally, there were diverse barriers for staff members. Nurses stated that it could increase the workload of staff members, because the assessment (for capability), instructions and personal training may take time. Responsibility was also indicated by the majority of staff members, since staff members are ultimately responsible for complications. One ICU team manager mentioned behavioral change as possible barrier in the beginning, because there is often resistance against something new.

"I think the privacy of the patient and the safety. And especially with mobilization, that you can do that well, that safety can be guaranteed. If you had to do it normally with two nurses (transfer bed-chair), then not!"

[ID 16, nurse]

DISCUSSION

This qualitative study on family participation in the physiotherapy-related care of ICU patients can be considered as an important step of the development phase of the MRC framework for developing and implementing a complex intervention (Craig et al., 2008). Findings of this current study demonstrate that both patients, their family members and ICU staff members support the idea of increased family participation in the physiotherapy-related care of critically ill patients, but believe that diverse important requirements must be included in the further design and investigation of an intervention in this field.

The most important prerequisite seems to be that family participation should always be voluntarily, since not everyone wants to participate in the care. Current study results correspond to earlier studies reporting on family participation in ICU care, which also mentioned that the kind of relationship, younger age, non-European descent and previous ICU admission for their family

member may influence the willingness to participate in patient care (Azoulay et al., 2003; Engström and Uusitalo, 2011; Hetland, McAndrew, Perazzo and Hickman, 2018.)

Involving families in physiotherapy-related tasks raises a number of concerns and possible barriers for the feasibility, which are comparable with barriers reported in previous studies focusing on family participation in ICU care; patient safety and privacy, family capability, and responsibility were often mentioned (Azoulay et al., 2003; Engström and Uusitalo, 2011; Hetland, McAndrew, Perazzo and Hickman, 2018; Wong et al., 2019). Involving family in physical activities may risk adverse events such as accidental extubating or catheter removal (Wong et al., 2019). Therefore it is of high importance that family receives structured information, training before participation, and evaluation moments (Azoulay et al., 2003; Hetland, McAndrew, Perazzo and Hickman, 2018; Kydonaki, Kean and Tocher, 2019; Wong et al., 2019). In addition, family members anxiety to participate were also cited as possible barriers in previous studies (Hetland, McAndrew, Perazzo and Hickman, 2018; Wong et al., 2019). Besides patients' safety, patients' privacy has to be taken into account as well. However, this may be more important when family is participating in nursing tasks such as washing (Engström and Uusitalo, 2011), which might have higher thresholds for family and patients than rehabilitation related tasks. In addition, not all family members are likely to be capable of participating (Hetland, McAndrew, Perazzo and Hickman, 2018; Kydonaki, Kean and Tocher, 2019; Wong et al., 2019). This includes both personal qualities of the family member, such as functional factors (e.g. physical strength), psychological and emotional factors (e.g. willingness to be involved, emotional stability), knowledge (e.g. disease, learning ability), but also the relationship between the family member and the patient (Hetland, McAndrew, Perazzo and Hickman, 2018). Staff members believe it is important to maintain control over the situation and patient, since they are ultimately responsible (Hetland, McAndrew, Perazzo and Hickman, 2018; Kydonaki, Kean and Tocher, 2019). It can differ per patient, per family member and even per day, whether participation, and which activities, are possible to execute. Therefore, there is a need for effective communication about rules and expectations (Hetland, McAndrew, Perazzo and Hickman, 2018; Kydonaki, Kean and Tocher, 2019; Wong et al., 2019).

Multiple possible beneficial effects were mentioned in this study. Participation in physiotherapy-related tasks may generate a feeling of usefulness for family members, may decrease stress and anxiety for both patients and family, and may feel patients more safe. These expectations are consistent with previous research investigating the effects of involving family in different types of care of

critically ill patients (Amass et al., 2020; Black, Boore and Parahoo, 2011; Skoog, Milner, Gatti-Petito and Dintyala, 2016). Just as important, it may also promote physical recovery by increasing the frequency and thereby impact of physical rehabilitation, although this has not yet been investigated before. Many possible physiotherapy-related activities were indicated in the interviews, from relatively passive (e.g. PROM, massage) to active (e.g. active limb exercises, breathing training, mobilization). Before developing an intervention and deciding which activities family members are allowed to perform, the goal of the intervention (and clinical outcomes) must be well-defined. If the intention is to increase physical functioning and promote physical recovery, then the emphasis should be on active physiotherapy-related tasks: active (limb) exercises, breathing exercises and/or mobilization. If the goal is only to reduce anxiety of families and patients or to make family feel useful, then passive physiotherapy-related tasks (e.g. massage or range of motion) may already be sufficient.

A major strength is that this is the first study focusing on physiotherapyrelated care only. Another strength is the diversity of participants, since most of the previous qualitative exploration studies focusing on family participation in ICU care included staff members and/or family members only (Azoulay et al., 2003; Engström and Uusitalo, 2011; Hetland, McAndrew, Perazzo and Hickman, 2018; Smithburger, Korenoski, Alexander and Kane-Gill, 2017; Wong et al., 2019). In this present study both critically ill patients, their family members and staff members were interviewed, resulting in valuable information from all stakeholders to be involved in family participation in physiotherapyrelated tasks. This enables a better understanding of experiences, concerns and motivations, which is part of the first steps of the development phase of the MRC framework for developing and implementing a complex intervention (Craig et al., 2008). A limitation of this present study is that it was conducted right before the COVID-19 pandemic. Due to the current pandemic parts of the ICU care have been changed. For example, at this moment the visitation of loved ones in critical care has been minimized, resulting in less possibilities for family involvement. Additionally, the perceptions regarding family participation in the ICU may have changed due to the pandemic, whereby the findings of this study might be less applicable in the current pandemic and post-pandemic world. Future studies must take this into account and will experience the possible consequences. In addition, due to the COVID-19 crisis, the interviews had to stop early, therefore less interviews could be done with patients and family members in study center two. To improve the distribution between the two hospitals and participants, a few more interviews were planned in center two, but these were redundant because theoretical saturation had already been reached in center

one. Another limitation is the fact that the researchers who approached the participants also worked as physiotherapists in the ICU, resulting in the risk of selection bias. Besides, for the sample inclusion of patients and their family, no prior selections in characteristics (e.g. gender, diagnosis, admission duration) were made. This lack of purposive sampling could have influenced the credibility of this sample and generalizability of the results.

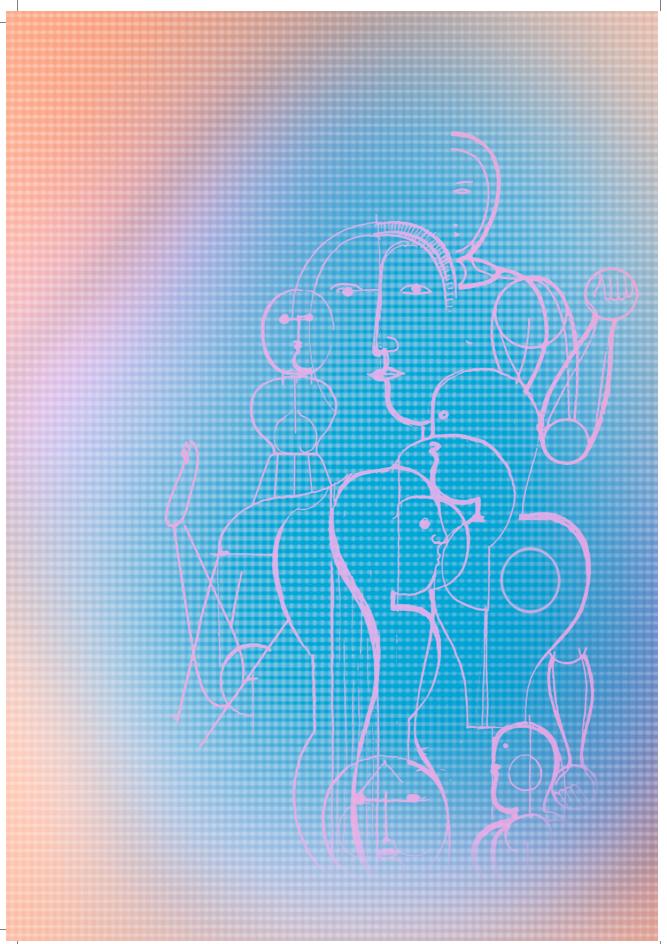
In conclusion, both patients, their family and staff members were found to have a positive attitude towards family participation in physiotherapyrelated tasks and to recognize the added value of an intervention. However, the development of an intervention in this field is of high complexity and diverse requirements should be taken into consideration in the design and implementation. The goal of the intervention must be clearly defined before selecting the activities for family to participate in. Besides, the practical approach is challenging, and influenced by diverse possible barriers and facilitators to keep in mind. Following steps are to merge these results, and produce and test prototype(s). Since this is the first study focusing on this specific topic, a proper pilot study is needed to thoroughly evaluate the feasibility of an intervention to increase family participation in (active) physiotherapyrelated tasks. Following the MRC framework, a pilot study is necessary to collect input to further design the final intervention before conducting a large-scale implementation and effectiveness study (Craig et al., 2008). When family participation in physiotherapy-related tasks of critically ill patients seems feasible, even in the post-pandemic world, the effectiveness must be evaluated on relevant clinical outcomes.

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Chapter 4

Increasing family participation in physiotherapy-related tasks of critically ill patients: a pilot study on the feasibility of an intervention

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Under review

ABSTRACT

Objective: To investigate the feasibility of an intervention for family participation in physiotherapy-related tasks of critically ill patients. The intervention contained three components: 1) brochure with: a) activities to calm the patient and b) physiotherapy-related tasks; 2) poster in the patient room; and 3) real-life instruction.

Design: Pilot study with a non-equivalent control group design, conducted within a mixed adult Intensive Care Unit (ICU). Included were relatives of patients who were admitted to the ICU for more than three days.

Study parameters: The primary outcome was feasibility, based on 1) recruitment rate; 2) percentage of relatives who chose physiotherapy-related tasks; 3) usage of physiotherapy-related tasks; 4) usability of the intervention; and 5) number of adverse events.

Results: Between March and June 2021, 34 family members (19 intervention group, 15 control group) of 27 critically ill patients were included. The recruitment rate was 75.6% (34 out of 45). The percentage relatives who chose physiotherapy-related tasks at baseline was 94.7% (18 out of 19). The average percentage of days that these family members performed physiotherapy-related tasks was 56.7%. The mean System Usability Scale score was 77.1. No adverse events occurred.

Conclusion: Family participation in physiotherapy-related tasks of critically ill patients seems feasible.

INTRODUCTION

Admission to an Intensive Care Unit (ICU) is often accompanied by the emergence of ICU acquired weakness [1]. One year after discharge, more than 50% of the patients treated for more than two days in the ICU still have physical limitations in their daily functioning [2-4]. Additionally, survivors of critical illness often experience long-term impairments in cognitive function and/or mental health [4-7]. In 2012, the Society of Critical Care Medicine introduced the term "Post-Intensive Care Syndrome" (PICS) to describe these impairments arising after critical illness [7]. The term PICS can be applied to an ICU survivor but also to a family member of a patient who had been admitted to an ICU (PICS-F), since the psychological impact of an ICU admission is not limited to the patients, but appears to affect the mental health of relatives as well [7]. Family members are at high risk of anxiety, depression, a posttraumatic stress disorder (PTSD), and complicated grief, which adversely effects quality of life of the whole family [8-10].

A crucial element of daily ICU care is early mobilization and exercise [11-13]. The last 20 years evidence confirmed the benefits of ICU early rehabilitation, which can improve patients' physical function, shorten length of stay, and reduce adverse psychological effects [11, 13-15]. Another important component in ICU care is family engagement; family engagement can be beneficial for both patients and their family members [16, 17]. Engaging families could humanize ICU care, may enhance psychological wellbeing for both patients and family and improve family members' ability to cope with the patients' situation by having a purposeful role [16, 18]. Since physical therapists treat patients mostly once a day and nurses often lack time to help patients with their exercises, active family involvement may support staff by utilizing family members as a supporting resource to deliver additional care [17]. Currently, family involvement in the ICU mostly involves improving communication and dissemination of information, or participation in nursing activities. However, family members may also be engaged in many practical low-cost, high-value rehabilitative physical activities of critically ill patients [16-20]. At this moment, limited research has been performed on the feasibility and benefits of family participation in physiotherapy-related tasks, and there are currently no interventions developed on this topic [20].

For that reason, a multidisciplinary team of experts developed a new intervention, aiming to increase family participation in physiotherapy-related care of critically ill patients with the goal of improving patients' physical functioning and reducing stress-related symptoms in family members. For

the development of this intervention, the Medical Research Council (MRC) framework for developing and evaluating complex interventions was used [21]. After designing a new complex intervention, a feasibility study is necessary before conducting large scale effectiveness evaluations because these are often undermined by problems of feasibility, usability, and recruitment [21, 22]. Therefore, the aim of this study was to investigate the feasibility of family participation in physiotherapy-related tasks of critically ill patients. The secondary aim was to determine between group differences in patients' physical functioning and symptoms of anxiety, depression and PTSD in family members, after the intervention period.

METHODS

Design, setting and sample

This was a quasi-experimental pilot study with a non-equivalent control group design, conducted within a mixed medical-surgical-cardio-neuro-adult ICU of the University Medical Center Utrecht, the Netherlands. During this pilot, up to 16 of the 32 admission beds were occupied by isolated COVID-19 patients, and the opportunities for family members to visit were limited to a maximum of two different people per 24 hours. Participants of this study were first-degree relatives or spouses of critically ill patients who were admitted in the ICU for more than three days and received physiotherapy as daily care. In order to be eligible to participate in this study, both the family member and the patient had to meet all inclusion criteria, and none of the criteria for exclusion (table 1). Per patient, a maximum of two family members were allowed to participate in this study. A sample size of at least 30 family members (15 in both the intervention and control group) was determined in accordance with published guidance for pilot studies [22]. Participants were given information about the intervention and its aim, followed with a choice whether they wanted the intervention or not. If not, they entered the control group. Once the sample of one of the two groups was reached, the inclusion proceeded to reach the sample of the other group only. The study protocol (METC number 21-071) was approved by the Medical Ethics Committee of the University Medical Center Utrecht. All family members provided written consent for their involvement in this study. Consent was not required from patients because family members were asked to sign a broad consent to use patient data collected in usual care for medical research.

Table 1. Inclusion and exclusion criteria for participation in this pilot study

	Inclusion criteria	Exclusion criteria
Patients	 ICU admission for at least three days receiving physiotherapy: ICU patients receive physiotherapy from day three. Sedated patients two times a week and awake patients 3-5 times a week expected to remain in the ICU for more than two days 	 aged < 18 COVID-19 (isolation) patients patients with increased intracranial pressure receiving end of life care no family/contact person
Family	first-degree relative, spouse or other first contact personable to speak and read Dutch	

Intervention development

An intervention was developed by a multidisciplinary team of experts, using an evidence and expert based, iterative process following the MRC framework [21]. The first step of the development was to identify existing evidence by executing a mixed-methods systematic review [20, 21]. The following step was identifying and developing theory, by performing a qualitative study, to gain knowledge on the area of concern, to get an understanding of the future users and their context, and determine which values and requirements the different stakeholders deem important to include in the intervention. Therefore, a qualitative study, using semi-structured interviews with critically ill patients, their family and staff members, was conducted. The interviews demonstrated that patients, their family and staff members have a positive attitude towards the participation of family members in physiotherapy-related care of critically ill patients [19]. Additionally, important components and requirements for the future intervention were collected [19]. As last step in the development phase, all ideas and requirements were merged and prototypes were developed by the project team. Several questionnaires were administered to test these prototypes and procedures with nurses and physiotherapists, as well as critically ill patients and their loved ones. After the prototyping phase, the intervention for this pilot study was developed and validated by the project team, the physiotherapists working in the ICU and some family members.

The intervention

The final intervention consists of three components. The first component is a brochure, including information about the possible physical and psychological

impact of an ICU admission on both critically ill patients and their loved ones, and the concept of family participation in physiotherapy-related tasks. In addition, this brochure contains a menu with activities for family members to participate in (table 2). The activities are divided in category A and B. Category A are simple activities that family members can do to calm the patient (e.g. reading a book, or massaging the hands/feet). Category B are physiotherapyrelated tasks including: passive movement exercises (range of motion), active limb exercises, functional exercises and breathing exercises. All activities in the menu are optional, therefore the menu also contains the option "I do not want to participate (yet)". In the brochure, the physiotherapy-related tasks are written out in more detail and supplemented with QR codes, linked to videos in which the physical exercises are demonstrated. As second component of the intervention, a poster for the patients' room was developed. On this poster all possible activities for family members to participate in, were listed. In the first column the preferred activities are noted by the family members. Thereafter, the physiotherapist marks, after each physiotherapy treatment, exercises appropriate for the patients' functioning in the second column. Subsequently, during the admission, family records when and how often they performed which activities in the third column. This poster makes it visible to everyone in which activities family wants to participate, which of these activities are deemed suitable for family participation by the physiotherapist, and what the frequency of performed activities is. An example of the poster can be found as Appendix 1 (online supplemented material). The last component of the intervention is a real life personalized instruction moment with a physiotherapist. During this meeting the activities are explained and if necessary practiced together.

Table 2. Menu with activities divided in category A (activities to calm the patient) and B (physiotherapy-related tasks)

Menu with activities for family members

- ☐ Read a book or magazine (A)
- \Box Set up music (A)
- □ Apply hand cream or foot cream (A)
- ☐ Massaging the hands and/or feet (A)
- □ Passive movement exercises (range of motion) hand and feet/lower leg (B)
- ☐ Active (limb) exercises in lying and sitting position (B)
- □ Functional exercises (B)
- □ Breathing exercises (e.g. deep breathing) (B)
- □ Other
- □ I would rather not do anything (yet)

Study procedure and data collection

After the first physiotherapy consult, standard at day three or four of ICU admission, the physiotherapist checked whether the patient met the inclusion criteria, and asked the nurse in charge whether there were family members who met the inclusion criteria. If yes, the main investigator (LvD) approached them (real life or by phone) to provide information about the study, and asked for informed consent. If family wanted to participate, family members received the brochure and an appointment with the physiotherapist for instructions in the upcoming two days after inclusion. During that meeting, the brochure and poster were explained, activities were chosen and if necessary exercises were practiced together. After each physiotherapy treatment, the physiotherapist marked the suitable exercises for family members to perform on the poster. Family members were asked to report the executed activities on this poster by recording when and how often they performed which activities, and write down if something unintended happened with medical devices (e.g. dislocation of endotracheal tube or lines) or with the patient (e.g. injuries). Three days after starting, and thereafter once a week, the main investigator evaluated with the family member (phone or real life) if there were any questions or issues to discuss.

Data collection in both groups

As shown in figure 1, demographics of patients and family members were collected as part of usual care. Collected characteristics of family members were: age, sex, relation to the patient and whether or not there was a previous experience in the ICU (i.e. admission or work-related). Collected characteristics of patients were: age, sex, date of ICU admission, type of ICU admission (i.e. planned surgery, medical, emergency surgery), Acute Physiology And Chronic Health Evaluation (APACHE) II score, highest Sequential Organ Failure Assessment (SOFA) score, length of stay and discharge location. At discharge, patients' physical functioning was reported by the physiotherapists, as part of usual care, using the MRC-sum score and ICU Mobility Scale (IMS) [1, 23]. In addition to these data from usual care, at ICU discharge, symptoms of anxiety and depression in family members were measured with the Dutch version of the Hospital Anxiety and Depression Scale (HADS) [24, 25] and PTSD-related symptoms were measured with the Dutch version of the Impact of Event Scale - Revised (IES-R) [26, 27]. These two surveys were sent to family members by email, to be completed privately.

Additional measurements in intervention group

A number of additional data was collected in the intervention group, shown in figure 1. At baseline, the activities chosen by the family members were recorded. During the interim evaluations and at discharge, data regarding the activities, i.e. activities approved by the physiotherapist and activities performed by family members, were collected from the poster. Additionally, adverse events (e.g. dislocation of endotracheal tubes, lines or other medical equipment, or patient injuries) were assessed by interviewing family members during the interim evaluations, and by copying the events noted on the posters. Last, the System Usability Scale (SUS) was completed by family members at discharge, to assess usability of the brochure and folder. The final SUS score ranges from 0 to 100. Higher scores imply higher usability, and SUS score higher than 68 can be considered above average [28].

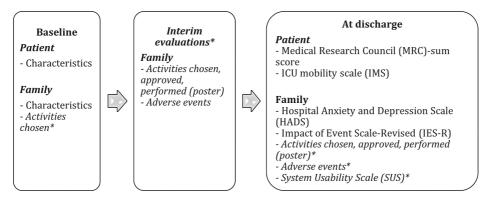


Figure 1. Flowchart of data collection

Study outcomes

Primary outcome

The primary outcome was feasibility of family participation in physiotherapy-related tasks. The following items were assessed to determine feasibility: 1) recruitment rate; 2) percentage of family members who chose physiotherapy-related tasks at baseline; 3) usage of physiotherapy-related tasks; 4) usability of the poster and brochure; and 5) adverse events. For recruitment rate (1), the percentage of eligible family members who consented to participate in this pilot was calculated, and a percentage of 50% was set a priori as the lower limit. Regarding the percentage family members who chose physiotherapy-

^{*} and in italics: measurements within the intervention group

related tasks at baseline (2), a percentage of 70% was set as lower limit. Usage of physiotherapy-related tasks (3) was considered as adequate if physiotherapy-related tasks were performed on an average of 70% of all days that it was possible to participate (i.e. the days from start participating to ICU discharge). Additionally, an overview of the executed physiotherapy-related tasks, i.e. the percentages passive, active, functional and breathing exercises, was made. For the usability of the poster and brochure (4) the mean SUS score was analyzed, where a SUS score higher than 68 can be considered above average [28]. Last, no adverse events (5) should be reported by family members. To state that family participation in physiotherapy-related tasks is feasible, we defined a priori that at least four of the five pre-defined criteria had to be met.

Secondary outcomes

Two secondary outcomes were compared between the intervention group and control group at discharge from the ICU. The first was patients' physical functioning assessed with the MRC-sum score and IMS. The second was symptoms of anxiety, depression and PTSD in family members, using the HADS and IES-R [29-32]. Regarding these two questionnaires, higher scores indicate more symptoms of anxiety, depression and PTSD. In addition to the overall HADS and IES-R scores, the prevalence of family members with symptoms of anxiety or depression, and the prevalence of family members with a post-traumatic stress reaction were examined, where a cutoff HADS score of 8 and greater on the anxiety or depression subscale indicate at least mild anxiety or depression symptoms, and mean IES-R scores of 1.6 and greater indicate a post-traumatic stress reaction with a substantial risk of PTSD [29-32].

Data analysis

All continuous variables were tested for normality with the Kolmogorov-Smirnov test. Participant characteristics were described using descriptive statistics, and tested (intervention group vs. control group) with the chi-square test, Mann Whitney test, or the independent samples *t*-test, where appropriate. Regarding the primary outcome, descriptive statistics were used to summarize the recruitment rate, usage, usability and adverse events [22]. Regarding the secondary outcomes, possible differences between the intervention group and control group in MRC-sum, IMS, HADS and IES-R scores were tested using the Mann Whitney test or the independent samples t-test, where appropriate. No correction for multiple testing was performed because this was a pilot study. Additionally, differences in the proportion of family members who had a HADS score of 8 or greater in each category, and differences in the percentage of family

members with mean IES-R scores of 1.6 and greater between the intervention group and control group were tested, using the chi-square test. As this was a pilot study, the level of missing data was documented but no imputation was undertaken. All data analyses were performed in SPSS.

RESULTS

Participant characteristics

Between March 20th 2021 and June 21th 2021, 34 family members (19 intervention group, 15 control group) of 27 critically ill patients (16 intervention group, 11 control group) were included. Characteristics of the study population are presented in table 3. The majority of the included family members were partners and female, with a mean age of 49.5 (SD 16.0). Regarding the patients, the majority of the patients were male, with a mean age of 55.3 (SD 14.7). There were no significant differences observed in the characteristics of the family members and patients in the intervention and control group.

Table 3. Family and patient demographics

Family demographics	Intervention group (n=19)	Control group (n=15)	P-value
Male, n (%)	6 (31.6)	4 (26.7)	0.755
Age (year), mean (SD)	48.7 (15.6)	50.7 (17.1)	0.734
Relationship to patient, n (%) - Partner	11 (57.9)	9 (60.0)	0.625
- Parent	2 (10.5)	0 (0.0)	
- Child	5 (26.4)	5 (33.4)	
- Sibling	1 (5.3)	1 (6.7)	
Previous ICU experience, n (%)			0.409
- Yes	9 (47.4)	5 (33.3)	
- No	10 (52.6)	10 (66.7)	
	Intervention	Control group	
Patient demographics	group (n=16)	(n=11)	P-value
Male, n (%)	8 (50.0)	6 (54.5)	0.816
Age (year), mean (SD)	51.8 (14.9)	60.4 (13.4)	0.137
Reason for ICU admission, n (%)			0.288
- Medical	9 (56.3)	3 (27.3)	
 Emergency surgery 	6 (37.5)	6 (54.5)	
 Planned surgery 	1 (6.3)	2 (18.2)	
Highest SOFA score, mean (SD) ^a	11.2 (3.0)	9.4 (1.9)	0.087
APACHE II score, mean (SD) ^b	23.9 (6.4)	18.9 (4.3)	0.063

Table 3. [Continued]

Patient demographics	Intervention group (n=16)	Control group (n=11)	P-value
Discharge location, n (%)			0.242
- General ward	14 (87.5)	10 (90.9)	
- Died	2 (12.5)	0 (0.0)	
- Rehabilitation center	0 (0.0)	1 (9.1)	
Length of stay ICU (days), mean (SD)	23.3 (14.9)	19.8 (11.8)	0.529

^a SOFA score: Sequential Organ Failure Assessment score, score ranges from 0 to 24, and higher scores reflect higher levels of organ dysfunction and a higher risk of death

Feasibility

Regarding recruitment, 75.6% (34 out of 45) of the eligible family members who were asked to participate in this study agreed and were included. The percentage family members in the intervention group who chose physiotherapy-related tasks at baseline, was 94.7% (18 out of 19). Within this group, the total number of days that is was possible to participate in physiotherapy-related tasks ranged from 3 days to 40 days and the number of days that family members actually performed physiotherapy-related tasks ranged from 0 to 18 days. Overall, physiotherapy tasks were executed on an average of 56.7% (SD 30.8) of all days that it was possible to participate. Focusing on the amount and type of activities these family members performed, family members executed physiotherapyrelated tasks for 151 times within 15 patients. Of these, 102 times (67.6%) passive movement exercises were done, 42 times (27.8%) it were active limb exercises, 4 times (2.6%) it were functional exercises, and 3 times (2.0%) they executed breathing exercises (figure 2). Regarding usability of the intervention, the mean SUS score was 77.1 (SD 10). No serious adverse events were reported by family members.

^b APACHE II score: Acute Physiology and Chronic Health Evaluation score, score ranges from 0 to 71 and higher scores correspond to more severe disease and a higher risk of death



Figure 2. Distribution of physiotherapy-related tasks performed by family members of critically ill patients

Secondary outcomes

Family members included in the intervention group had a lower mean HADS-depression score (P=0.030) and mean IES-R score (P=0.047) than family members in the control group at ICU discharge (table 4). No significant differences were found regarding the other secondary outcomes.

Table 4. Differences in patients' physical functioning and symptoms of anxiety, depression and PTSD, between the intervention group and control group at ICU discharge

Outcome measure	Intervention group	Control group	P-value
MRC-sum score, mean (SD)	40.0 (10.1)	37.3 (10.4)	0.526
IMS, mean (SD)	3.9 (1.6)	3.3 (1.6)	0.345
HADS- anxiety, median (IQR)	7.0 (5.0-10.0)	10.0 (5.5-14.0)	0.215
HADS- depression, mean (SD)	6.1 (3.3)	9.2 (4.1)	0.030*
IES-R, mean (SD)	19.3 (9.7)	28.0 (13.7)	0.047*
Symptoms of anxiety ^a - Yes, n (%) - No, n (%)	7 (41.2) 10 (58.8)	8 (61.5) 5 (38.5)	0.269
Symptoms of depression ^b - Yes, n (%) - No, n (0%)	6 (35.3) 11 (64.7)	8 (61.5) 5 (38.5)	0.153
Post-traumatic stress reaction ^c - Yes, n (%) - No, n (%)	2 (11.8) 15 (88.2)	4 (30.8) 9 (69.2)	0.197

^a total HADS-anxiety score ≥8, ^b total HADS-depression score ≥8, ^c mean IES-R score ≥1.6

DISCUSSION

This pilot study investigated the feasibility of family participation in physiotherapy-related tasks of critically ill patients. Findings of this study suggest that family participation in physiotherapy-related tasks of critically ill patients is feasible. Additionally, symptoms of depression and PTSD at ICU discharge were lower in family members included the intervention group compared to the control group.

To determine feasibility, pre-set criteria on recruitment rate, percentage of relatives who chose physiotherapy-related tasks, usage of physiotherapy-related tasks, usability, and adverse events were examined. The results of our pilot demonstrated that four of these five criteria met the predefined requirements, concluding that family participation in physiotherapy-related tasks of critically ill patients seems feasible. Usage of physiotherapy-related tasks did not meet the predefined lower limit. Currently, there are very few comparative studies on the usage and feasibility of participation of family members in physiotherapy-related tasks. One recent study, where nurses completed daily observations, examined how often family participated after implementing an intervention including a menu with activities for family involvement in hands-on ICU care. Their observations showed that family executed touching activities (e.g. massage, applying lotion) on average 64% of all days, and personal care activities (e.g. assist with turning and positioning) on average 45% of all days, which is in line with our usage percentage [33]. Possibly it is not feasible for family to participate on a daily basis, however, reasons for this must be further investigated. Additionally, our results showed that family members mainly executed passive movement exercises. To increase the impact of patients' physical functioning by family participation, it is important family members participate frequently and in active exercises. Involving family members in active limb exercises, and thereby increase the frequency of physical activity during the day, may promote patients' physical recovery [19]. A reason why active exercises were executed less than passive exercises could be that many critically ill patients are sedated in the first days of the ICU admission [34], resulting in more possibilities for passive movements than active exercises. Afterwards, critically ill patients are often delirious. Delirium occurs in up to 50% of ICU patients during their admission [35, 36], which can make it hard for family members to execute active limb exercises. Since physical rehabilitation starts early in the ICU it is best to start with this intervention there, but to have more impact on patients' physical functioning we suggest to continue the intervention after discharge from the ICU, at general wards, where physical rehabilitation continues and

family participation in active exercises is possibly more feasible since factors as sedation and delirium play less of a role. Additionally, it might be that family members need more personal guidance and training during the time, since it has been demonstrated that their needs and behavior regarding participating in promoting patients' physical activity change during the ICU admission from passive to more proactive [19, 37]. Unfortunately, we did not examine these factors of influence on the usage and thereby feasibility of active limb exercises in this study.

Focusing on the secondary outcomes, our study did not find significant between group differences in patients' physical functioning at discharge. This may be due to the small sample size and fact that physiotherapy-related tasks, which were mostly passive movements, were performed about half of all possible days. Regarding the other secondary outcome, symptoms of depression and PTSD at ICU discharge were lower in family members included the intervention group compared to the control group. Symptoms of anxiety, the prevalence of family members with at least mild symptoms of anxiety or depression, and the prevalence of family members with a post-traumatic stress reaction did not show significant differences. However, these secondary outcomes may be influenced by the design (e.g. non-equivalent control group with small sample size and assessment of stress-related symptoms solely at ICU discharge) and/or baseline characteristics. For example, the intervention group included more family members with previous experience in the ICU, these family members might have less stress-related symptoms at baseline, resulting in even fewer symptoms at discharge. Currently, only a few studies have evaluated interventions for family members to be involved in the care of adult ICU patients with the goal of reducing stress-related symptoms in family members [33, 38, 39]. These studies investigated outcomes related to long-term psychological distress, where we examined short-term stress-related symptoms, and mostly reported prevalence percentages with variating effects on symptoms of anxiety, depression, and PTSD [33, 38, 39]. Since it is proven that symptoms of anxiety and depression in family members of critically ill patients decrease over time, and disorders as an anxiety/depression disorder and PTSD often arises at a later stage, is recommended to assess anxiety, depression and PTSD-related symptoms in family members from two months after ICU discharge [9, 40, 41]. Therefore, we suggest future large scale studies evaluating the effectiveness of interventions for family participation in physiotherapy-related care to assess long-term effects on the prevalence and symptoms of PTSD, anxiety and depression [41].

A major strength of this study is the design with only few exclusion criteria, which suggests the results may apply to family members of a wide variety of

patients admitted to an adult mixed ICU. There are, however, also several limitations in the design of our study that may have impacted the results. First, we conducted a pilot study with a non-equivalent control group design. There likely were unmeasured factors between the two groups that limit the interpretation of the results, and external factors that may have influenced the outcomes could not be ruled out. In addition, the non-equivalent control group design, whereby family members were allowed to choose to participate or not, may have resulted in selection bias. To avoid these limitations, larger sample sizes are recommended in future effectiveness evaluations. Additionally, these studies must contain a proper control group and should also assess stressrelated symptoms at baseline to state something about the effectiveness of the intervention on long-term stress-related symptoms. Second, the researcher (LvD) who approached the participants also worked as physiotherapists in the ICU, resulting in the possibility that there was a prior relationship to the patient and/or family as part of clinical care. Future large scale clinical trials on this topic should be conducted by an independent researcher. Besides, we did not identify the possible reasons why family members did not participate in physiotherapy-related tasks on a daily basis. One of these reasons may be that family members did not visit their loved one every day, or that family members needed more personal guidance during the time, or that the patient did not appreciate to exercise during family visits. Additional research, using interviews or surveys, is needed to identify these factors influencing the usage and thereby feasibility of family participation in physiotherapy-related tasks before adjusting the intervention and performing a large scale clinical trial. Third limitation to mention is that this study is conducted during the COVID-19 pandemic. Due to the pandemic, elements of the ICU care were momentary changed. For example, family members of isolated COVID-19 patients were not allowed to visit the ICU daily, and therefore excluded for the intervention and pilot study. Since many ICU beds were used by COVID-19 patients during the pilot and many surgeries had to be postponed [42], the enrollment was likely lower than if there were no COVID-19 patients in the ICU. In addition, the visitation of loved ones in the regular ICU was temporary minimized to a maximum of two different persons per 24 hours, which might have resulted in less possibilities for family involvement. These factors together may negatively have influenced the pilot study and affected the feasibility of family participation during this time period. Probably, family participation in the ICU will be more applicable in the post-pandemic world than during this study period.

In conclusion, the results of this pilot study suggest that family participation in physiotherapy-related tasks of critically ill patients is feasible. Since this is the first study focusing on this specific topic, more research is needed to thoroughly evaluate the effectiveness of an intervention for family participation in physiotherapy-related tasks on patients' physical functioning and long-term symptoms of anxiety, depression and PTSD in family members.

Clinical Messages

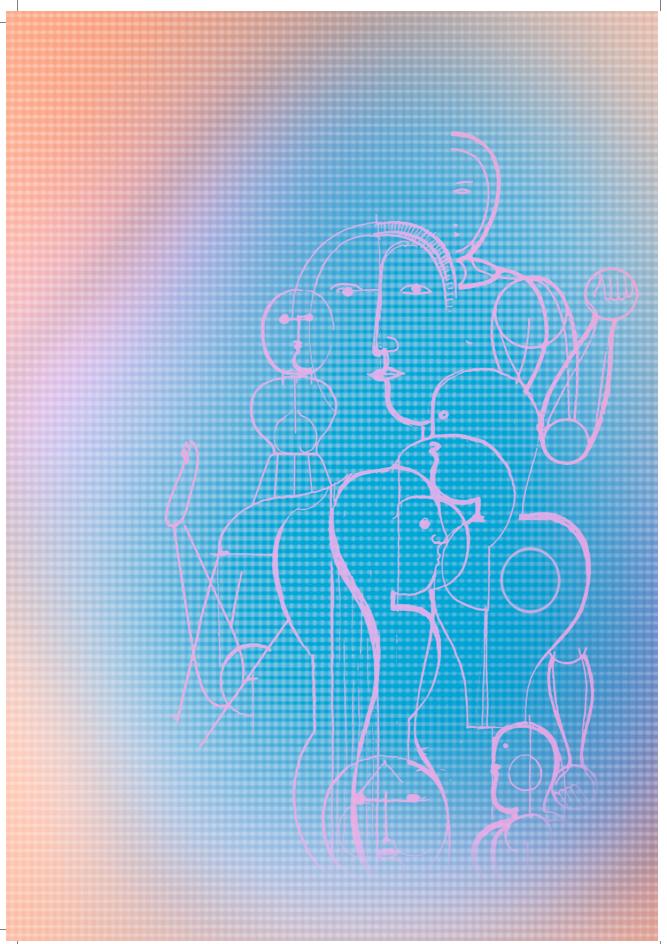
- It seems feasible to involve family members of critically ill patients in performing physiotherapy-related tasks
- An user-centered intervention is needed to increase family participation in physiotherapy-related tasks

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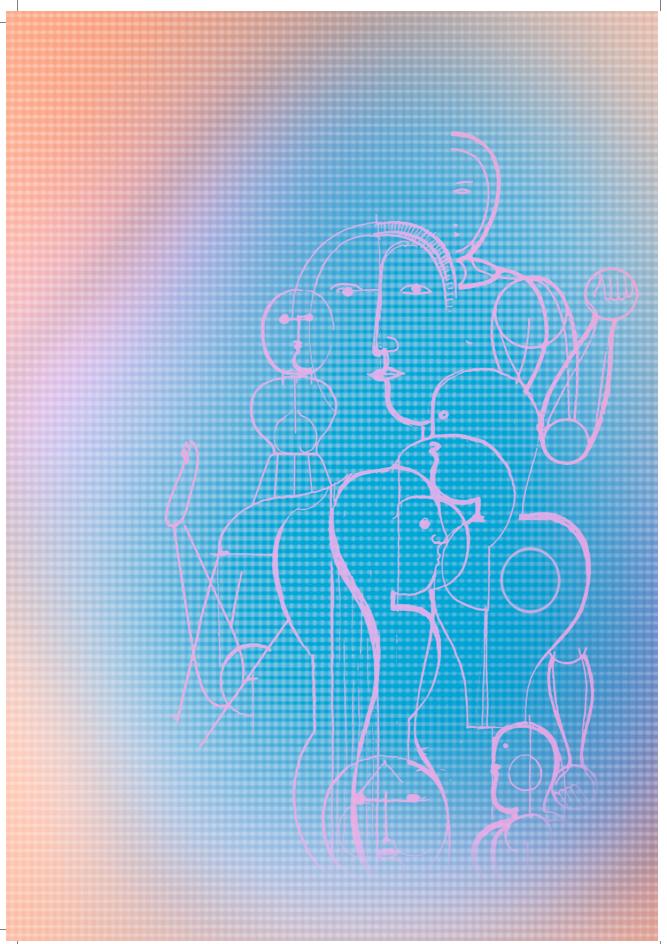
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PART 2

Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve patients' physical behavior during hospitalization



Chapter 5

The evaluation of Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve patients' physical behavior during hospitalization, a mixed methods study protocol

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Published in JMIR research protocols 2019, issue 8, e11341

ABSTRACT

Background: Despite the evidence of the adverse consequences of immobility during hospitalization, patients spend most of the time in bed. Although physical activity is a modifiable factor that can prevent in-hospital functional decline, bed rest is deeply rooted in the hospital culture. To attack this, a multidimensional approach is needed. Therefore, Hospital in Motion, a multidimensional implementation project, was designed to improve physical behavior during hospitalization.

Objective: The primary objective of this study is to investigate the effectiveness of Hospital in Motion on inpatient physical behavior. Secondary objectives are to investigate the effectiveness on length of hospital stay and immobility-related complications of patients during hospitalization and to monitor the implementation process.

Methods: For this study, Hospital in Motion will be implemented within 4 wards (cardiology, cardiothoracic surgery, medical oncology, and hematology) in a Dutch University Medical Center. Per ward, multidisciplinary teams will be composed who follow a step-by-step multidimensional implementation approach including the development and implementation of tailored action plans with multiple interventions to stimulate physical activity in daily care. A prepost observational study design will be used to evaluate the difference in physical behavior before and 1 year after the start of the project, including 40 patients per time point per ward (160 patients in total). The primary outcome measure is the percentage of time spent lying, measured with the behavioral mapping method. In addition, a process evaluation will be performed per ward using caregivers' and patient surveys and semistructured interviews with patients and caregivers.

Results: This study is ongoing. The first participant was enrolled in October 2017 for the premeasurement. The postmeasurements are planned for the end of 2018. The first results are expected to be submitted for publication in autumn 2019.

Conclusions: This study will provide information about the effectiveness of the Hospital in Motion project on physical behavior and about the procedures of the followed implementation process aimed to incorporate physical activity in usual care. These insights will be useful for others interested in changing physical behavior during hospitalization.

BACKGROUND

More than 2 million patients are admitted to Dutch hospitals yearly, with a mean admission time of 7 days [1]. Although hospital admissions are necessary to diagnose or treat patients for health issues, hospital admissions also have downsides. Diverse studies show that hospitalized patients spend most of the time lying in bed, whereas in the last 20 years, a growing body of evidence is established showing the adverse consequences of bed rest [2,3]. Restricted physical activity and immobilization can increase hospital-related complications [3,4], and many studies have proven that inactivity is associated with reduced muscle mass and strength [5]. In addition, bed rest results in an increased risk of diverse medical complications [6-8]. Moreover, lower levels of physical activity are associated with a functional decline and new disability in activities of daily living (ADL) after discharge [3,4,10-13]. This functional decline is labeled as a hospitalization-associated disability (HAD), and HADs have profound implications for patients as it leads to long-term care in nursing homes, readmissions, and even death [12]. In research reports, HADs are described as both preventable and iatrogenic and as a direct result from the actions of a health care provider or institution. HADs can, therefore, be considered as collateral damage of the treatment in a hospital in which health care professionals and policy makers have a responsibility in resolving this problem [14]. Especially, as early mobilization and higher levels of physical activity during hospitalization have proven to decrease the risk of complications and length of stay (LOS) [9].

Nevertheless, patients are reflexively put into pajamas, transferred into bed [15], and spend less than 6% of the day being active [2-4,10]. Lack of knowledge and time is often mentioned by caregivers as a barrier to promote physical activity [16,17]. This lack of time results in nurses prioritizing their medical tasks above assisting with patient mobilization and stimulating physical activity in patients with the ability to perform their own ADL tasks [16,17]. Studies targeting sedentary behavior during hospitalization have shown that physical activity is a modifiable factor that can prevent in-hospital functional decline [9,18-20]. These studies mostly focused on single interventions, whereas sedentary behavior is deeply rooted in the hospital culture. A multidimensional project focusing on environment, caregivers, and patients using multiple interventions may possibly be even more effective [21]. Even so, literature suggests that a comprehensive and flexible framework may help create sustainable interventions, leading to significant changes in clinical practice [22]. However, projects or studies to improve physical behavior focusing on the whole system, integrating physical

activity in all levels of daily hospital care, are not common. Moreover, these studies focused mainly on elderly, whereas low mobility is of all ages [19,22]. Therefore, Hospital in Motion, a multidimensional project to improve patients' physical behavior during hospitalization, has been developed.

OBJECTIVES

The primary objective of this study is to investigate the effectiveness of Hospital in Motion on physical behavior within 4 wards (cardiology, cardiothoracic surgery, medical oncology, and hematology). Secondary objectives are to investigate the effectiveness on length of hospital stay and immobility-related complications of patients during hospitalization and to monitor the implementation process.

METHODS

Context

In November 2015, the project Hospital in Motion was started at the University Medical Center Utrecht (UMC Utrecht). Hospital in Motion is a complex multidimensional project primarily designed to improve physical behavior during hospital stay, defined as a decrease in patients' sedentary behavior (lying) and increase in physical activity (ie, standing, walking, and exercising). This project follows 2 approaches. The first approach focusses on creating a hospital-wide awareness of the high amount of sedentary behavior during the hospital stay and the known associated adverse effects, and the necessity to incorporate physical activity in usual care. The second approach includes the development and implementation of tailored action plans for each clinical ward. In 2016 and 2017, a pilot study was performed on the geriatric department. Preliminary results and gained experiences during this pilot form the basis of this study protocol.

Setting

This study will be conducted within 4 wards (cardiology, cardiothoracic surgery, medical oncology, and hematology) of the UMC Utrecht, the Netherlands. Per ward, a tailored action plan will be implemented. The study protocol was assessed and approved by the medical ethics committee of the UMC Utrecht (study protocol number 16-250). Verbally informed consent was obtained from all patients.

Study Design

An observational study with a prepost design will be used to evaluate the effectiveness of Hospital in Motion on physical behavior. In addition, the implementation process will be evaluated by using a qualitative approach. Data will be collected before and after implementation. The duration of the implementation project is planned for 10 months, starting in January 2018 (Figure 1).



Figure 1. Time line of the implementation project Hospital in Motion.

Implementation Approach and Interventions

Hospital in Motion will be implemented following the step-by-step model of Wensing and Grol (Figure 2) [23]. Steps 1 to 3 include the development of proposal for change, analysis of actual performance, and problem analysis. Step 4 includes the selection of strategies and measures to change practice, which will be identified by a multidisciplinary project team per ward. During step 5, an action plan_consisting of multiple interventions will be developed, tested, and executed at each ward. This plan will consist of 6 general topics:

- 1. Education: Education is an important cornerstone for increasing awareness on the importance of physical activity [17,24], for example, education for the staff members about the dangers of bed rest and posters and leaflets for patients about the importance of staying active during hospital stay.
- 2. Physical activity as part of usual care: For successful implementation, physical activity needs to be incorporated in usual care and all caregivers with direct patient contact need to be involved [17,25], for example, integrating questions on the physical activity level in the anamneses of nurses and physicians, standardized reporting of daily mobility levels in the patient records, and discussing the patients mobility during multidisciplinary meetings.

- 3. Involving third parties: Involving the social environment (ie, family, friends, or volunteers) to improve inpatient physical behavior, for example, family and visit leaflets with information about the importance of physical activity during hospitalization and tips to improve patients' physical activity [26,27].
- 4. Stimulating environment: Currently, hospital wards are not stimulating environments for performing physical activity [28]. Changes in the environment are conditional for stimulating physical activity, for example, by adjustments of the accommodation inpatient areas, introducing shared lunching, and visualizing walking routes.
- 5. Mobilization milestones: Daily mobilization goals are successful in increasing walking distance, ADL activities, and number of mobilization moments out of bed [9]. The use of a mobility scale or activity trackers are examples of interventions, which could be used to set personal mobility goals.
- 6. Technology support: Implementing technological applications such as cycle ergometers with interactive screens, activity trackers, or mobile apps to support, stimulate, and measure physical activity [29].

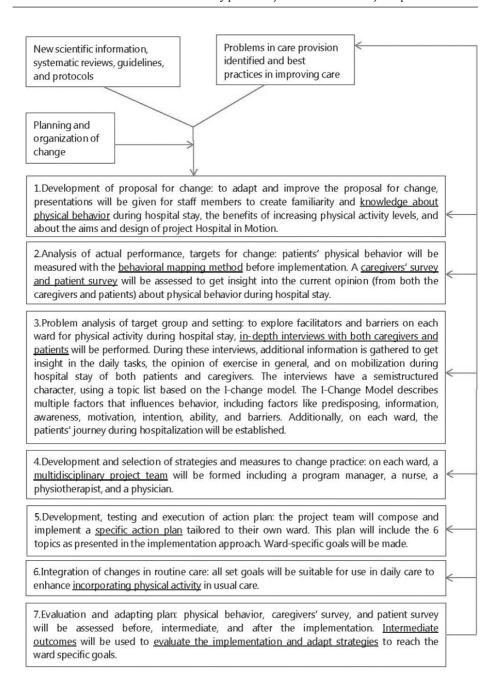


Figure 2. Implementation model based on the study by Wensing and Grol

Outcome Evaluation

In total, 160 patients will be included during a period of 2 months (40 patients per ward). Each patient admitted in the specific ward is eligible to participate in this study. Exclusion criteria for participating in this study were delirium and other cognitive impairments, whereby patients who were not able to provide informed consent were excluded. Patients receiving terminal care were also excluded.

Primary Outcome

Physical behavior will be measured with the behavioral mapping method [30] and will be assessed before and after the implementation period (Figure 1). Patients will be observed on a random weekday of their stay in a fixed order every 10 min for 1 min. During this minute, the patients' location, body position, daily activity, and direct contact will be registered [30]. A maximum of 8 patients per ward per day can be observed, and observations take place from 9 am until 4 pm.

Physical behavior is defined as the percentage of the total observed time that a patient spent in a specific body position. A distinction will be made between lying, sitting (bedside or chair), and moving (standing, transferring, walking, and cycling). The primary outcome in this study is the percentage of time spent lying.

Secondary Outcomes

Secondary outcomes are the percentages of time spent sitting and moving, LOS, and the incidence of immobility-related complications (ie, pneumonia, aspiration, chest infection, pulmonary embolism, deep-vein thrombosis, urinary tract infection, and pressure sores) [31]. LOS and immobility-related complications will be retrospectively retrieved out of the electronic patient file.

Patient Characteristics

Demographic characteristics that will be documented are gender, age, admission reason, specialism, the use of mobilization tools (ie, rollator, walker, crutches, or stick), urine catheter (yes/no), infusion (yes/no), and main perceived limitations during physical activity (eg, pain and exhaustion). In addition, the health perception and physical functioning of patients will be assessed.

The subjective believed health questionnaire is used to obtain the health perception, defined as "individual's experience of physical and mental functioning while living his life the way he wants to, within the actual constraints and limitations of individual existence" [32]. The questionnaire consists of 8 questions; question 1 and 2 focus on subjective health, scored on

a ladder-type scale from 0 to 10. Question 3 to 8 focus on perceived control and acceptance, scored between 1 (completely disagree) and 7 (totally agree) [33].

The Activity Measure for Post-Acute Care (AM-PAC) is a validated measurement instrument based on the activity limitation domain of the International Classification of Functioning, Disability and Health. In this study, the AM-PAC "6-Clicks" measures of basic mobility and daily activity in acute care will be used. These short forms have shown to be valid for assessing patients' activity limitations in acute care settings [34,35]. Handgrip strength can indicate the overall strength of an individual and can provide insight into the level of physical function [36,37]. Handgrip strength will be measured with the Jamar hydraulic hand dynamometer, which is an isometric, hydraulic, and easily accessible tool with excellent test-retest reliability (r>0.80) and interrater reliability (r=0.98) [36,37]. The 30 seconds chair stand test (30-s CST) is a reliable and valid measurement method for lower extremity strength assessment and a good indicator for a person's level of physical function [38].

Sample Size Calculation

In this study, per ward 40 patients will be included per time point. This number is based on earlier studies evaluating physical behavior with the behavioral mapping method [39]. Patients will be included on 4 wards, leading to a total study population of 160 patients. To check if this number is adequate for powered effectiveness analyses, a sample size calculation was performed. For the sample size calculation, unpublished observation data from the UMC Utrecht in 2016 were used, in which 80 patients across the hospital were observed according to the behavioral mapping method. These data demonstrated that patients spent 56.01% of the time lying, with an SD of 32.53. On the basis of an earlier study evaluating the implementation of a multidimensional intervention to improve patients' physical behavior, a decrease of 15% in the time spent in bed is expected to be feasible [18]. According to the sample size calculation, including a power of 80% and a P value of .05, a sample size of 74 patients would be needed. This confirms that the proposed sample size of 160 patients is more than adequate to evaluate the effectiveness of Hospital in Motion.

Process Evaluation

Process evaluations are advised to monitor implementation processes of complex interventions and to evaluate factors of influence on the implementation. In this study, the framework of the medical research council guideline 2008 is followed to guide the process evaluation [40]. The 3 key functions of this framework include implementation, mechanisms of impact, and context.

Implementation contains the goals and interventions that have been delivered by the project, including the adaptations, dose and reach, and how this delivery is achieved. The mechanisms of impact include the response (of caregivers and patients) to the interventions, the mediators, and all unexpected pathways and consequences. Context includes all other factors that may affect the implementation, interventions, and outcomes, such as barriers (eg, openness to changes, motivation, workload, and money) and facilitators [40]. For the process evaluation of the Hospital in Motion study on the different wards, a caregivers' survey, a patient survey, and semistructured interviews with patients and caregivers are developed, which contain items of the 3 key functions of a process evaluation. The caregivers' survey and the patient survey will be conducted before and after the implementation period. The semistructured interviews will be conducted at the end of the implementation period (Figure 3).



Figure 3. Time line of process evaluation

For the caregivers' survey, questions are formulated focusing on the willingness to change and motivation of the caregivers to help improve patients' physical behavior. In addition, questions are included to investigate the current state of the 6 topics of the action plan. The scoring of the questions is based on the visual analog scale; a score between 0% and 100% agreement can be given per question. The survey will be sent to all caregivers of the included wards before and after the implementation period.

For the patient survey, the level of encouragement patients perceived from care providers and the environment to be physically active in the past 2 days will be investigated using 6 statements with a 5-point scale. This patient survey will be performed before and after the implementation period. After the implementation, the survey will be supplemented with questions to investigate the success of the implementation of the action plans per ward.

Semistructured interviews with patients and caregivers: After the implementation, semistructured interviews with both patients and caregivers will be undertaken. The interviews will be guided with a topic list based on the 3 key functions of process evaluation as described before [40].

Statistical Analysis

All statistical analyses will be conducted using IBM SPSS statistics software 25. All outcome variables will be tested on normality with the Kolmogorov-Smirnov test. Patients' characteristics will be described using descriptive statistics and tested with the Chi-square test, Mann Whitney test, or independent samples t test. Physical behavior is defined as the percentages of the total observed time that a patient spent lying, sitting, and moving. For both the primary outcome (the percentage of time spent lying) and the secondary outcomes (percentage of time sitting and moving), the changes in percentages after implementation will be analyzed. In addition, between-group analyses will be performed per ward. The differences between pre- and postmeasurements will be analyzed with an analysis of covariance, whereby the covariate(s) include baseline variables that may differ between pre- and postmeasurements. If data are not normally distributed, log transformation will be executed before testing.

The process evaluation will be based on the caregivers' survey, patient survey, and semistructured interviews. Categorical data will be analyzed using Chi-square test and continuous data by using the Mann Whitney test or independent sample t test. To correct for multiple testing, a post hoc multiple comparison test will be performed. The semistructured interviews will be audio recorded and transcribed. Data analysis will follow 3 steps: coding, categorizing, and selecting themes, which will be performed in NVivo 11.

RESULTS

This study is ongoing. The first participant was enrolled in October 2017 for the premeasurement. The postmeasurements are planned for the end of 2018. The first results are expected to be submitted for publication in autumn 2019.

DISCUSSION

Despite the evidence about the negative consequences of low levels of physical activity, patients still spend most of the day in bed, leading to unnecessary functional decline and new disabilities in ADL [2,3]. Previous studies demonstrated that increased amounts of physical activity during hospitalization may prevent this functional decline [41]. Furthermore, 3 recent studies reported the results of the implementation of a single intervention to improve physical mobility during hospital stays [9,20,42]. The first study implemented a mobility scale and demonstrated an improved level of physical functioning on a general medicine unit [9]. The second study implemented an enforced

mobilization protocol in patients following gastrointestinal cancer surgery and found a reduced number of postoperative pulmonary complications [20]. The third study is a large-scale study in which the implementation of specific mobilization goals (mobilization within 24 hours, mobilization 3 times a day, and progressive and scaled mobility) showed a 10% increase in the frequency of mobilization out of bed [42]. However, to integrate physical activity in usual care, multidimensional approaches with multiple interventions focusing on the whole system are suggested to be more successful [16]. The Eat Walk Engage program of Mudge et al is a good example of a multidimensional approach using multiple interventions, which demonstrated a reduced LOS after the implementation [19]. However, it still remains unclear if physical activity is a modifiable factor during hospital stay.

The Hospital in Motion study has the strength that it contains multiple interventions tailored per ward, developed by a multidisciplinary project team. In addition, it is one of the first known large projects using a multidimensional approach, focusing on the physical environment, caregivers, and patients, instead of only 1 element, to improve physical behavior during hospitalization. Another strength of the Hospital in Motion study is the primary outcome of physical activity. As previous studies mostly included medical outcomes (eg, LOS, remissions, and mortality), levels of physical functioning or frequency of mobilization and the actual amount and change of physical activity have not been evaluated [9,19,20,42]. To get more information about patients' physical behavior, it is important to assess and evaluate the physical activity levels of patients during hospitalization. For this purpose, the behavioral mapping method is used. This method provides insight into the actual activity level of patients during an average hospital day and also assesses environmental factors such as the people in direct contact with the patient and the patients' daily activity. This enables detailed evaluation of inpatient physical behavior and differences per ward.

Diverse factors could influence the success of the implementation of Hospital in Motion. The action plan is a multidimensional package of interventions aimed to improve physical behavior. It contains multiple interventions aimed to incorporate physical activity in usual care procedures, targeting the whole care system. This strength is a challenge at the same time. Many factors may affect the implementation process, such as the functioning of the project team, caregivers' motivation and willingness to change, available time, and perceived workload. The appropriate study design has been discussed extensively within the research team because of the possible influence of confounding factors. As this study primarily aims to integrate physical activity in daily hospital

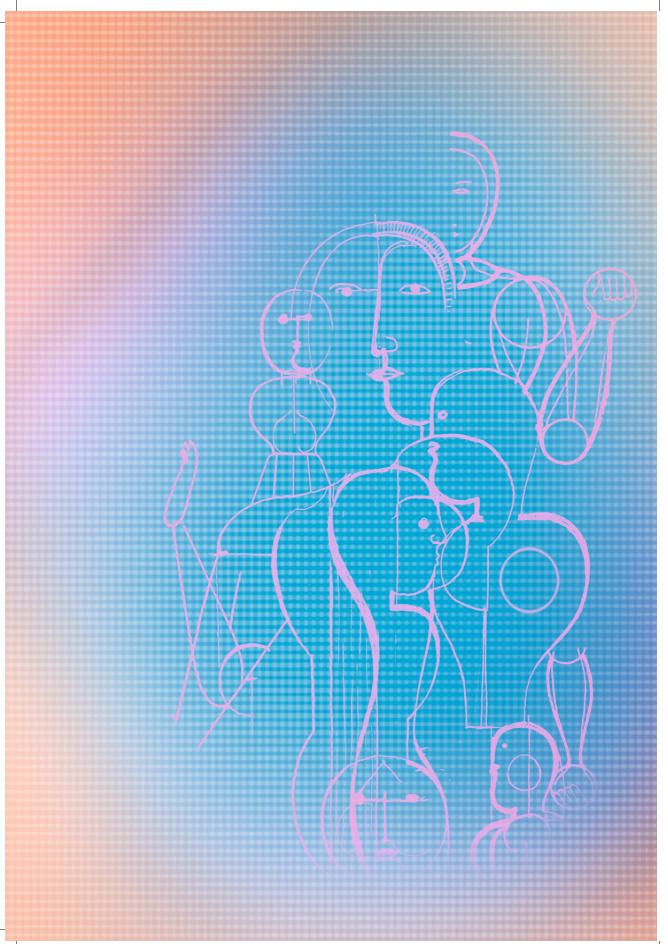
care, more classic research designs (ie, RCT) are less suitable. By following a step-by-step implementation process and by performing a process evaluation, the authors will provide useful insights into the changes in usual care and the successful and unsuccessful elements of the implementation process.

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Chapter 6

The effectiveness of Hospital in Motion, a multidimensional implementation project to improve patients' movement behavior during hospitalization: a prospective, pre-post study

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Published in Physical Therapy Journal 2020, issue 12, pages 2090-2098

ABSTRACT

Background: Hospital in Motion is a multidimensional implementation project aiming to improve movement behavior during hospitalization.

Objective: To investigate the effectiveness of Hospital in Motion on movement behavior.

Design: Prospective, pre-post design.

Methods: Hospital in Motion was conducted at four wards of an Academic Hospital in the Netherlands. Per ward, multidisciplinary teams followed a ten month step-by-step approach including the development and implementation of an ward-specific action plan with multiple interventions to improve movement behavior. Inpatients movement behavior was assessed before the start of the project and one year later, using the behavioral mapping method, where patients were observed between 9AM and 4PM. The primary outcome was the percentage of time spent lying. In addition, sitting and moving, immobility-related complications, length of stay, discharge destination home, discharge destination rehabilitation setting, mortality and 30-days readmissions were investigated. Differences between before and after implementation were analyzed using the chi-square test for dichotomized variables, the Mann Whitney test for non-normal distributed data, or independent samples t-test for normally distributed data.

Results: Patient-observations demonstrated that the primary outcome, the time spent lying, changed from 60.1% to 52.2% (p=0.01). Concerning the secondary outcomes, the time sitting increased from 31.6% to 38.3% (p=0.01) and discharges to a rehabilitation setting reduced from 6 (4.4%) to 1 (0.7%) (p=0.04). No statistical differences were found in the other secondary outcome measures.

Conclusion: The implementation of the multidimensional project Hospital in Motion was associated with improved movement behavior.

INTRODUCTION

Although there is extensive literature describing the detrimental effects of immobility, bedrest and inactivity is still deeply rooted in the hospital culture [1]; hospitalized patients spend 49% to 98% of their time in bed [2-6]. Immobility during hospital-stay is associated with complications like pneumonia, urinary-tract infection, deep venous thrombosis and pressure ulcers, which can result in prolonged hospital stays, more readmissions, higher mortality and increased hospital costs [7-9]. In addition, lower levels of physical activity leads to functional decline and new disabilities in activities of daily living after discharge [10-13]. This functional decline is labelled as hospitalization-associated disability, and lead to long-term care in nursing homes, readmissions or even death [12, 14].

Promoting inpatient mobilization can be challenging since the traditional hospital culture seems to discourage patients to be physically active [15-17]. Care is usually organized around the inactivating hospital bed, with food and drinks supplied within reach. In addition, patients often feel dependent on health care providers (HCPs) for instructions and manual support in mobilizing, even when they are able to move independently. This feeling of dependency on HCPs might be a result of nurses automatically supporting patients in washing, clothing, and eating [17]. All together this has resulted in a culture where many patients are spending most of the time in bed. Recent studies targeting inactivity during hospitalization demonstrated that mobilization and physical activity is a modifiable factor that can prevent in-hospital functional decline [2, 18, 19]. Most of these studies investigated the effect of single interventions on patients' physical function or medical outcomes, instead of on movement behavior itself, which is a crucial first step in the pathway towards improving patient outcomes. The evaluation of movement behavior is important to provide useful information about the successful and unsuccessful elements of interventions.

However, sedentary behavior is deeply rooted in the hospital culture. To overcome this culture and create more sustainable changes, there is a need for effective interventions that integrate physical activity in usual tailored care [17, 20-23]. Multi-component interventions are preferred above single interventions as they have proven to be more effective [24]. Additionally, in line with the social ecological model, multidimensional interventions focusing on the patients, on HCPs and on the built environment, may be more effective [20, 21, 24, 25]. Programs or studies aiming to improve movement behavior focusing on the whole system, by implementing multidisciplinary and multi-

component interventions tailored to local context, are still rare. Existing multicomponent studies mainly focused on elderly [21-23], or focused only on HCPs [23]. Since our aim is to implement physical activity throughout the hospital within current daily care procedures, Hospital in Motion, a multidimensional and multidisciplinary implementation project was developed. The purpose of this study was to investigate the effectiveness of the Hospital in Motion project on inpatients movement behavior. Furthermore, we assessed the effectiveness on length of hospital stay, discharge destination home, discharge destination rehabilitation setting, 30-days readmission, mortality and immobility-related complications of patients during hospitalization.

METHODS

Study design

A pre-post design was used to evaluate the effectiveness of Hospital in Motion. The project started in January 2018 and ended 10 months later (November 2018). Baseline measurements were performed two months before the start of the project, and the post-implementation measurement one year later, in November and December 2018. For more detailed information about the design and timeline we refer to our published study protocol [26].

Setting

This study was conducted within four participating wards of the University Medical Center Utrecht, the Netherlands; Cardiology, Cardiothoracic Surgery, Medical Oncology, and Hematology. The study protocol was assessed and approved by the local Medical Ethics Committee (study protocol number 16-250). Verbal informed consent was obtained from all included patients.

Study population

Patients admitted to one of the four participating wards were eligible to be included for the evaluation of Hospital in Motion. Exclusion criteria were cognitive impairments like delirium (defined as an acute disorder of attention and cognition, estimated by the medical and nursing staff) and language restrictions making a patient unable to provide informed consent. In addition, patients receiving terminal care were excluded. The day before the observations PB, LvD or KV discussed with the coordinating nurse of the ward which of the admitted patients were eligible to participate. Eligible patients were asked in random order and inclusion stopped when 8 patients wanted to participate, or when no more eligible patients were available [26].

Hospital in Motion

Hospital in Motion is a multidisciplinary and multidimensional implementation project designed to improve patients movement behavior during hospitalization. Per ward a multidisciplinary project team was formed, including a project manager (LvD or PB, both PhD student and physical therapist), a unit-manager, physical therapist(s), nurse(s) and physician(s). The Implementation of Change Model, developed by Grol and Wensing, was followed [27]. This model is developed especially for the implementation of change in clinical practices and contains seven steps. Steps one to three include the development of proposal for change, analysis of actual performance and problem analysis. During these steps, on each ward the opinion of patients about perceived promotion to be physically active was assessed using short statements, surveys were performed among HCPs and in depth interviews per performed with HCPs and patients. Furthermore, the baseline measurement of the movement behavior of patients was performed. Step four of the model includes the selection of strategies and measures to change practice, and step five focusses on the development, testing and execution of the implementation plan. During step four and five, each project team identified multiple interventions to be implemented to stimulate inpatient physical activity in usual care and developed an action plan with this interventions for their ward. Interventions were focusing on three levels of the social ecological model, a conceptual framework depicting spheres of influence over human behavior, namely individual, interpersonal and organizational [25]. In 2016 and 2017, a pilot study was performed on the geriatric department. Preliminary results and gained experiences during this pilot formed the six topics for the action plan, focusing on patients, HCPs and environment: education of staff and patients, physical activity as part of daily usual care, involvement of third parties such as family members or volunteers, creation of a stimulating environment and mobilization milestones and technology support. Step six and seven contain the integration of changes in routine care, and the evaluation of the implementation plan. In these steps the patient statements and the survey among HCPs were repeated. Furthermore, the followup measurement of the movement behavior of patients was performed and in depth interviews were performed with HCPs from within and outside the project team. For more detailed information about the interventions and the followed approach see Appendices 1 and 2, and our published study protocol [26].

Patient involvement

In this study patients were involved in the development and implementation of the interventions (action plan). Before the start of the project patients' opinions were investigated using semi-structured interviews. At the end of the implementation period, patients were interviewed for the process evaluation [26].

Outcome evaluation

Patient characteristics

Demographic and clinical characteristics including the use of a walking aid (i.e. rollator, walker, crutches, or stick) and urine catheter were recorded. In addition, physical functioning was assessed using the Activity Measure for Post-Acute Care Basic Mobility "6-Clicks" (AM-PAC) and by measuring handgrip strength. The AM-PAC includes six items: turning over in bed, sitting down on and standing up from a chair with arms, moving from lying on the back to sitting on the side of the bed, moving to and from a bed to a chair, walking in a hospital room and climbing 3-5 steps with a railing. All activities were scored on a scale of 1 (unable to do/total assistance required) to 4 (no assistance required). The sum of the scores ranges from 6 (indicating total assistance or 'cannot do at all') to 24 (indicating completely independent functioning). The AM-PAC demonstrated to be reliable and valid for assessing patients' basic mobility in acute care settings [28, 29]. Handgrip strength was measured to get insight into the overall muscle strength and level of physical function. Handgrip strength was measured with the Jamar hydraulic hand dynamometer, which is an easily accessible tool with excellent psychometric characteristics [30, 31].

Movement behavior

Movement behavior was assessed two months before and after implementation, using the behavioral mapping method [26, 32, 33]. Behavioral mapping is a structured method where participants are intermittently observed at set intervals. It has a good to excellent inter-rater reliability and analyses showed that the level of agreement with accelerometers was strong for identifying physical activity [2, 31, 32]. For this study, a maximum of 8 patients per ward per day were observed on a random weekday. The observations took place from 9 am until 4 pm, in a fixed order every 10 minutes, during 1 minute. During this minute, the patients' location, body position, daily activity, and direct contact was noted. Patients could be included in the observations more than once during the same hospital admission because the observations are a reflection of the patient population at that moment. For this study movement behavior was defined as the percentage of the total observed time that a patient spent in a specific body position. A distinction was made between lying (in bed),

sitting (bedside or chair), and moving (standing, transferring, walking, and cycling) [26, 33]. The percentage of time spent lying in bed was studied as primary outcome. Sitting and moving were included as secondary outcomes [26]. The physical function measurements (AM-PAC and handgrip strength) and the observations (behavioral mapping) were performed following a strict protocol *by* trained physiotherapy students who were not involved during the implementation phase.

Medical outcomes

Furthermore, length of stay (LOS), discharge destination home, discharge destination rehabilitation setting, mortality, 30-day readmission rate and the incidence of immobility-related complications (i.e. pneumonia, pulmonary embolism, deep-venous thrombosis, urinary tract infection, and pressure sores [34]) were included as secondary outcomes. Data on these outcomes were retrospectively retrieved from the electronic patient files by data managers and a trained independent research assistant of the patients who were included for the observations.

Sample size and data analyses

The calculation of the required sample size was based on a statistical power of 80%, a P value of .05, and an decrease of 15% of the time lying in bed [2, 26]. This calculation gave a sample size of at least 74 patient-observations for both the baseline period and the post-implementation period [26]. All continuous variables were tested for normality with the Kolmogorov-Smirnov test. Patient characteristics were described using descriptive statistics and tested with the Chi-square test, Mann Whitney test or independent samples t test, where appropriate. For the movement behavior data, first, the time spent per category of movement behavior (i.e. lying, sitting and moving) was calculated per participant. Second, the percentage of observed time in a specific category was calculated per participant. Subsequently, for both periods (baseline and post-implementation), the mean percentages of observed time per category of movement behavior were calculated. Differences in movement behavior and medical outcomes between the two periods were tested using the Chi-square test, Mann Whitney test or the independent samples t test, where appropriate. In addition to overall analyses, we stratified per ward [26]. Statistical analyses were conducted using IBM SPSS statistics software 25.

RESULTS

A total of 171 patient-observations on 138 patients were performed during the baseline period. After the implementation period, 163 patient-observations on 150 patients were performed. Characteristics of the total study population are presented in table 1. The majority of the participants were male, with a mean age of 59.5 years (16.1SD). Around 80% of the patients were able to transfer to chair and walk without assistance. There were no significant differences observed in the characteristics of the population before and after implementation (p>0.05). Baseline characteristics and context per ward are demonstrated in table 2.

Table 1. Characteristics of observed patients

	Baseline	Post-implementation	P-value
Age (years); mean (SD)	60.6 (15.8)	58.3 (16.3)	0.356
Male; N (%)	109 (63.7%)	114 (69.9%)	0.230
Surgery; N (%)	59 (35.5%)	51 (31.5%)	0.436
Physical Functioning (AM-PAC 6-click BM); mean (SD)	22.2 (4.1)	22.4 (3.1)	0.245 0.185
 Mobilizing independently in room; N (%)** 	143 (83.6%)	127 (77.9%)	
Handgrip strength (kg); mean (SD)	28.5 (12.1)	30.1 (12.5)	0.280
Mobilizing without walking aid; N (%)	130 (76.9%)	134 (82.7%)	0.394
Urinary Catheter; N (%)	8 (4.7%)	7 (4.5%)	0.915

^{*} significant p<0.05 ** AMPAC-BM 1 to 5 without assistance required

Table 2. Characteristics and baseline context per ward

		Cardiothoracic	Medical	
	Cardiology	surgery	Oncology	Hematology
Population	Medical	Surgical	Medical	Medical
Number of admission places	32	22	14	20
Baseline characteristics of included patients	N=41	N=45	N=42	N=43
• Length of Stay; mean (SD)	14 (14)	15 (15)	8 (6)	32 (24)
• Age; mean (SD)	64 (16)	(16)	60 (16)	58 (15)
• AMPAC score; mean (SD)	23 (2)	22 (4)	21 (6)	23(3)
 Mobilizing independently in room; ** 	88%	82%	%62	93%
Baseline statements patients **	N=40	N=41	N=36	N=42
 I find the environment stimulating 				
(% agrees or strongly agrees)	30%	44%	33%	21%
 I received information about the importance of mobilization and 				
physical activity during hospitalization (% agrees or strongly agrees)	%09	%99	20%	74%
 The nurse stimulated me to be physically activity 				
(% agrees or strongly agrees)	20%	%92	61%	%19
Baseline surveys HCPs (nurses & physicians)				
• In what percentage of the new admissions do you provide information	N = 28	N = 24	N=13	N = 20
about the importance of physical activity during hospitalization to				
your patients?	39%	75%	25%	26%
 Mobilization of my patients is high on my priority list, also during 				
busy days. (rank from 0 to 10)	4	7	9	9
• I am willing to actively involve myself in promoting mobilization and				
physical activity of patients. (rank from 0 to 10)	7	8	8	7

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		Cardiothoracic Medical	Medical	
	Cardiology	surgery	Oncology	Hematology
Project team	Project	Project	Project	Project
	manager	manager (LvD)	manager	
	(LvD)	Nurses (n=2)	(PB)	
	Nurses (n=2)	Physical	Nurses	Nuı
	Physical	therapist	(n=2)	
	therapist	Unit manager	Physical	
	Cardiologist		therapist	
	Unit manager		Unit	manager
			manager	

** AMPAC-BM 1 to 5 without assistance required ** Based on a 5-poin Likert scale from totally not agree to totally agree

Throughout the implementation period diverse interventions were developed. In total 15 interventions were implemented within the actions plans. See table 3 for an overview of the final delivered interventions per ward. A detailed description of these interventions can be found in Appendix 2 (online supplemented materials).

Table 3. Overview of implemented interventions per ward, displayed per topic of the action plan

Intervention	Cardiology	Cardiothoracic surgery	Medical Oncology	Hematology
Education:				
 Patient information brochure 	X	X	X	X
- Patient information poster	X	X	X	
- Education to staff	X	X	X	X
- Pre-admission information		X		X
Physical activity as part of usual care:				
 Joint lunch for patients (in living room) 	X	X	X	X
- Eating out of bed	X	X	X	X
 Exercise guides & 7 minutes workout videos with exercises (lying, sitting and standing) 	X		X	X
Stimulating environment:				
 Improving the patient living room 	X	X		
 Exercise material and walking aids available 	X	X		
 QR-code walking route 	X	X	X	X
 Department map with all facilities 	X	X	X	X
Involving third parties: - Stimulating visitors to go walking or do the exercises from the guides with the patient - Mobility icons	X		X	X
Mobilization milestones & technology: - Daily activity schedule per patient - Highest level of mobility card per patient		X	X	
- mgnest level of mounity card per patient			Λ	

During the baseline period, patients were lying in bed 60.1% (28.9SD) of the time between 9 AM and 4 PM. This percentage decreased after implementation to 52.2% (28.6SD) (p=0.010). The percentage sitting increased from 31.6% (25.5SD) to 38.3% (25.3SD) (p=0.012). The percentage moving did not significantly improve after implementation, it changed from 8.3% (7.8SD) to 9.6% (7.9SD) (p=0.308). See table 4.

Table 4. Differences in movement behavior pre and post-implementation

	Baseline (N=171)	Post-implementation (N=163)	P-value
Percentage lying; mean (SD)	60.1 (28.9)	52.2 (28.6)	0.010*
Percentage sitting; mean (SD)	31.6 (25.5)	38.3 (25.3)	0.012*
Percentage moving; mean (SD)	8.3 (7.8)	9.6 (7.9)	0.308

^{*} significant p<0.05

Analyses per ward show comparable changes in percentages lying, sitting and moving after implementation (see table 5). The time moving increased most on the cardiothoracic surgery ward from 8.2% to 12.7% of the day (p=0.019), which is in contrast to the medical oncology ward, where the percentage moving decreased from 8.4% to 5.4% (p=0.022).

Table 5. Differences in movement behavior per ward

	Baseline	Post-implementation	Δ	P-value
Cardiology; mean (SD)	N=41	N=39		
Percentage lying	51.0 (29.6)	41.6 (24.1)	9	0.136
 Percentage sitting 	38.9 (24.8)	45.9 (20.8)	7	0.146
 Percentage moving 	10.2 (9.8)	12.4 (10.1)	2	0.335
Cardiothoracic surgery; mean (SD)	N=45	N=40		
 Percentage lying 	54.5 (29.7)	46.7 (21.2)	8	0.208
 Percentage sitting 	37.3 (26.4)	40.7 (18.9)	3	0.484
 Percentage moving 	8.2 (7.8)	12.7 (9.2)	5	0.019*
Medical oncology; mean (SD)	N=42	N=43		
 Percentage lying 	69.3 (24.8)	62.0 (30.2)	7	0.349
 Percentage sitting 	22.3 (21.0)	32.6 (28.1)	10	0.096
 Percentage moving 	8.4 (7.0)	5.4 (6.8)	-3	0.022*
Hematology; mean (SD)	N=43	N=41		
 Percentage lying 	65.5 (28.1)	57.2 (33.1)	9	0.336
 Percentage sitting 	27.9 (26.6)	34.7 (29.7)	7	0.418
Percentage moving	6.6 (6.3)	8.1 (6.7)	2	0.268

^{*} significant p<0.05

Concerning the medical outcomes, the number patients who were discharged to a rehabilitation center significantly decreased from 6~(4.4%) to 1~(0.7%) (p=0.044). No statistical differences were found in the other secondary outcome measures (see table 6).

	Baseline (N=136)	Post-implementation (N=146)	P-value
Patients with one or more immobility related complication(s) total; N (%)	24 (17.6)	16 (11.0)	0.108
Length of stay, in days; mean (SD)	16.9 (17.6)	15.8 (13.6)	0.727
Mortality during hospital stay; N(%)	4 (3.0)	1 (0.7)	0.149
Discharged to rehabilitation setting; N(%)	6 (4.4)	1 (0.7)	0.043*
Discharged home; N (%)	108 (80.0)	126 (86.3)	0.157

21 (15.6)

20 (13.7)

0.660

Table 6. Differences in medical outcome before and after Hospital in Motion

Readmission within 30 days; N (%)

DISCUSSION

In summary, the multidimensional and multidisciplinary Hospital in Motion project was associated with an overall decline in the time spent lying in bed (-7.9%). Additionally, the time spent sitting up (+6.7%) increased and the amount of patients' discharged to a rehabilitation center decreased.

An important strength of the Hospital in Motion study is the use of a wardspecific, multidisciplinary and multidimensional approach [26]. Since patient populations and daily care processes can differ greatly per ward, implementation projects need to be the tailored per ward to fulfil specific requirements. Changing the culture regarding physical activity requires fundamental changes to current thinking and practice to patient mobility within the whole organization, including all disciplines [20]. Therefore, the project teams were multidisciplinary including physical therapists, nurses, physicians and unitmanagers. Single initiatives might not be enough to ensure success for change in behavior or for creating sustainable and continual improvement of processes [20, 21]. Integrating physical activity in usual care by multidimensional approaches including interventions aiming at several social ecological levels are more likely to be successful [17, 21, 25]. Another strength of this study is the primary outcome of movement behavior, measured with the behavioral mapping method, as improving movement behavior is the crucial step in the pathway towards improving patient outcomes. This provided insight into the actual physical activity level of patients as well as insight into the context in which the physical activity or bedrest takes place. This enables detailed evaluation of movement behavior and provides insight in ward-specific opportunities to develop targeted

^{*} significant p<0.05

interventions [26]. A limitation of this study is the pre-post design to evaluate the action plan, whereby external factors that may have influenced the outcomes of Hospital in Motion could not be ruled out. In addition, this study investigated the effect of implementing an action plan with multiple interventions, resulting that only statements can be made about the impact of the entire action plan and not the individual interventions. A limitation concerning the behavior mapping method is the fact that the behavior of patients or HCPs may have been influenced by the observers' presence during the day. However, a recent study show a high level of agreement between the behavioral mapping method and an accelerometer [33].

Studies improving movement behavior in usual care, by implementing multidisciplinary and multi-component interventions tailored to local context, are still rare. To our knowledge one previous study investigated the effect of multi- component interventions on movement behavior itself [2]. Van de Port et. al, investigated the implementation of multi-component interventions at a neurology department to increase physical activity of stroke patients and also used the behavioral mapping method. After implementing a daily therapy group, a brochure with exercises and HCPs education, patients spent less time lying (-20%)[2]. Additionally, three previous studies implemented multi-component interventions to promote physical activity and found positive results on physical and medical outcomes [21-23]. Their implementation models are comparable with the Implementation of Change Model used in this study [27]. However, these programs focused mainly on elderly, whereas low mobility during hospitalization is of all ages. In addition, Liu et al. implemented interventions only focusing on HCPs [23]. The study of Mudge et al. contained interventions using newly contracted and paid staff, instead of changing current usual care, which was one of our main aims for creating sustainable and continual improvement [22]. In addition to the diverse approaches used, it is not possible to compare their effect sizes with our study due to the differences in outcome measures.

Before the start of the project the mean percentage of lying in bed was 60%, which is consistent with previous observational studies reporting percentages of lying in bed between 49% to 70% of the daytime [2, 3, 6]. After the implementation the percentage of lying was reduced to 52%, and the time sitting increased from 32% to 38%, which means patients on average spent 33 minutes more out of bed between 9 AM and 4 PM. The percentage moving did not increase significantly. Based on these results, it cannot be stated that patients moved from sedentary (<1.5 METs) to physical active (>1.5 METs) [35]. However, it is also clinically relevant to decrease the time spent lying in bed

as research shows that this can decrease complications [36-38]. Currently, no data is known about how much change of time spent in bed is clinically relevant. However, we did not achieve the 15% reduction of time lying in bed which we aimed for a priori as we found a decrease of 8% in time lying in bed. Although, the clinical relevance of this decrease is unclear, these results may be a promising first step in changing the hospital culture regarding movement behavior.

The decreases in time spent lying are comparable at the four included wards (range 7.3% - 9.4%). Remarkably, the time spent moving only increased at the cardiothoracic surgery ward, from 8.2% to 12.7%. This was the only surgical ward included in this study and majority of admissions was elective. One of the interventions characteristic for this ward was that information was sent home to all patients about the importance of and schedule for mobilization after the operation before their admission. Therefore, patients might have been prepared better at getting physically active during their hospital stay. The highest percentage of lying in bed is found at the medical oncology ward (before and after the project), and the time spent moving decreased at this ward after implementation. Reasons for this are unclear.

We have chosen to identify six topics a priori in which interventions could be created by the project teams. Although the aim of Hospital in Motion was to form tailored action plans per ward, the final four action plans included very similar interventions, which might have been the result of the predefined topics. However, the final interventions might not be equally implemented and effective at all four wards. Most interventions within the action plans primarily focused on emphasizing the importance of getting out of bed instead of getting physically active more. This might explain our finding that patients did not move more after the implementation, but mostly exchanges time lying for time sitting up. To provide more insight into the reach, adaptations and impact of the implemented interventions within the action plans, the successful and unsuccessful elements of the implementation approach of Hospital in Motion and the maintenance in daily care, a process evaluation is crucial. Therefore, a detailed process evaluation was performed per ward alongside the effectiveness measurements, following the Medical Research Council (MRC) guidance of Moore et al. 2015 [26, 39]. Aspects like the reach and adoption per intervention, and barriers and facilitators during the implementation were evaluated. The results of the process evaluation will be reported in two separate studies. These results will hopefully help others to develop and implement effective interventions to improve inpatient physical activity. Since this is one of the first studies showing the results of multi-component interventions on movement

behavior on different wards of a hospital, more studies are needed investigating interventions designed to change movement behavior during hospitalization. We recommend that future studies investigate interventions that specifically focus on improving time spent moving by patients, in addition to decreasing time spend lying and sitting.

Clinical messages

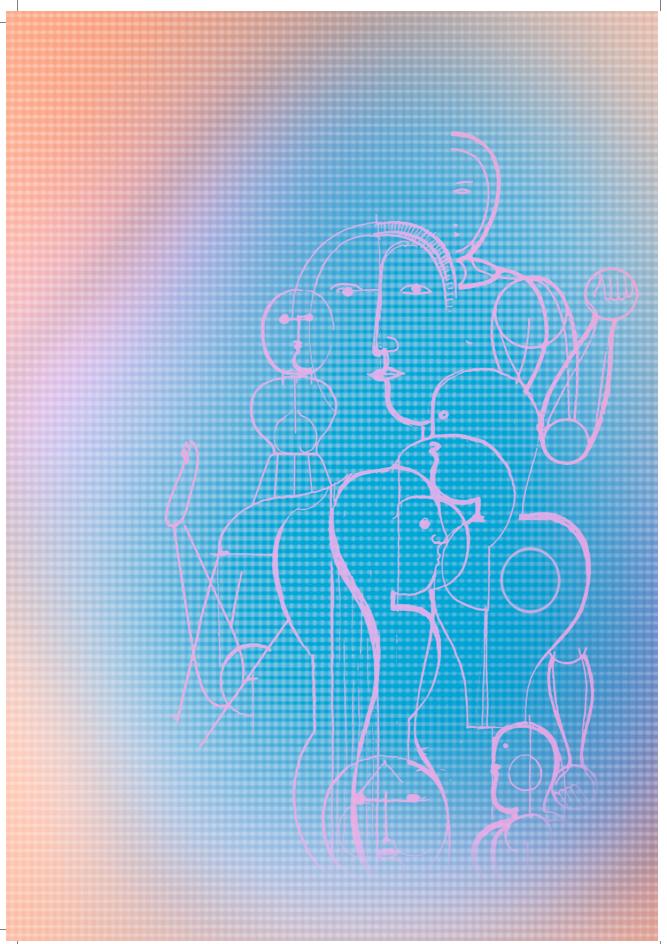
- The time spent lying by patients can be decreased by implementing a multidimensional action plan.
- An in depth process evaluation is needed to give more insight in the successful and unsuccessful elements of Hospital in Motion.

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Chapter 7

Perceived factors of influence on the implementation of a multidimensional project to improve patients' movement behavior during hospitalization – a qualitative study

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Published in Physical Therapy Journal 2021, online ahead of print

ABSTRACT

Objective: To explore perceived factors of influence on the implementation of Hospital in Motion (HiM), a multidimensional and multidisciplinary implementation project to improve inpatients' movement behavior.

Methods: This qualitative study was conducted on four wards. Per ward, a tailored action plan was implemented consisting of multiple tools and interventions to stimulate the integration of inpatient physical activity in usual care processes. After implementation, semi-structured interviews were performed with healthcare professionals and patients to explore perceived factors of influence on the implementation of the HiM project. A content analysis was performed using the framework of the Medical Research Council for complex interventions as guidance for the identification of categories and themes.

Results: In total 16 interviews were conducted with healthcare professionals and 12 with patients. The results were categorized into the three key components of the Medical Research Council framework: implementation, mechanisms of impact and context. An important factor of influence within the theme 'implementation' was the iterative and multidisciplinary approach. Within the theme 'mechanisms of impact' continuous attention and the interaction of multiple interventions, tailored to the target group and targeting multiple dimensions (individual, inter-professional, community and society), were perceived as important. Within the theme 'context' the intrinsic motivation and inter-professional, community and societal culture towards physical activity was perceived to be of influence.

Conclusion: Impact can be achieved and maintained by creating continuous attention to inpatient physical activity and by the interaction between different interventions and dimensions during implementation. To maintain enough focus, the amount of activities at one time should be limited.

Impact Statement: To improve inpatients' movement behavior, implementation project teams should be multidisciplinary and they should implement a small set of tailored interventions which target multiple dimensions. Intermediate evaluation of the implementation process, strategies and interventions is recommended.

INTRODUCTION

Higher physical activity levels during hospitalization lead to a reduction in diverse complications, functional decline and outplacement to a rehabilitation setting.¹⁻⁵ However, promoting physical activity can be challenging since physical inactivity is deeply rooted in the hospital culture.⁶⁻⁸ It is suggested that, to integrate physical activity in usual care, interventions should be multidimensional (e.g. individual, inter-professional, community and society) and implementation should follow a dynamic approach.⁹⁻¹³ Although previous studies showed that inpatient physical activity can be improved, the content of the interventions and used implementation approaches vary widely which make studies difficult to compare and translate to other settings.^{2, 11, 14}

To understand the whole range of effects, the variety and the interaction during the implementation of complex interventions, it is important to understand the underlying implementation processes. ^{11, 15, 16} Insight into the perceived barriers and facilitators during the implementation of interventions aiming to promote inpatient physical activity is required to successfully and sustainably change the immobility culture in hospitals around the world. ¹⁵

The Medical Research Counsel developed a framework for the process evaluation of complex interventions. ^{15, 16} This framework consists of three key components including implementation, mechanisms of impact and context. This framework can be used as guidance during the evaluation of an implementation process.

Therefore, this qualitative study was performed using the Medical Research Counsel as guidance during data analysis. This study was performed after the implementation of the multidisciplinary and multidimensional implementation project Hospital in Motion which aimed to improve inpatient movement behavior^{5, 17}. The aim of the current study was to explore the perceived factors of influence on the implementation of interventions to improve patients' movement behavior during hospitalization by health care professionals and patients.

METHOD

Hospital in Motion

The project Hospital in Motion (HiM) aims to improve inpatient movement behavior and was initiated in 2016 at the University Medical Centre Utrecht, The Netherlands with a pilot study on the geriatrics ward. During this pilot the multidisciplinary project team identified the lack of proper tools and information

resources to address the importance of physical activity with patients. Therefore, several tools were developed like an information brochure and video animation on physical activity during hospital stay, 7-minute workout videos and exercise guides with exercises in lying, sitting and standing position, and posters to increase awareness on physical activity during hospitalization. Following, this set of tools was implemented. Furthermore, a 2-weekly movement group session, a daily group lunch and the use of a home trainer with interactive screen were implemented as interventions to promote physical activity. The results on inpatient movement behavior were published in a Dutch journal for gerontology physiotherapists.¹⁸

After the pilot, between January and November 2018 the project HiM was implemented on four other clinical wards: cardiology, cardiothoracic surgery, medical oncology, and hematology. Per ward, a multidisciplinary project team was formed that composed a tailored action plan. This action plan contained multiple implementation strategies, interventions and tools to promote physical activity which were allocated into one of the five topics of the action plan: 1) education of staff and patients; 2) integration of physical activity in usual care; 3) involvement of third parties such as family members or volunteers; 4) creation of a stimulating environment; 5) mobilization milestones & technological support. 5, 17 An overview of the strategies, interventions and tools per ward can be found in Appendix 1 (online supplemented materials).

Following, the project teams used the Implementation of Change Model as guideline during implementation. This model is developed especially for clinical practices. The results of the implementation on movement behavior of patients during hospital stay was investigated using a prospective pre-post design. Patient observations (n=334) demonstrated that the time spent lying decreased from 60.1% to 52.2% (p=0.01) and the time spent sitting increased from 31.6% to 38.3% (p=0.01). The time spent moving did not change (8.3% - 9.6% (p=0.31)).

Setting and design

This single-center study was conducted after the implementation of project HiM on the cardiology, cardiothoracic surgery, medical oncology, and hematology wards in 2018. The study was performed at the University Medical Centre Utrecht, a 800-bed academic teaching hospital in Utrecht, the Netherlands. A qualitative content analysis was performed, using individual semi-structured interviews with open ended questions. For reporting this study, the Standards for Reporting Qualitative Research was used.

Study procedure and participants

Research team members PB (physical therapist and PhD student) and LvD (physical therapist and PhD student) approached potential participants for inclusion. Both HCPs and patients of the four wards of interest were included in the semi-structured interviews to explore factors of influence on the implementation of HiM. HCPs who participated in the HiM project teams as well as HCPs outside the project teams were purposefully sampled based on discipline (nurse, physical therapist, unit manager) and years of work experience. Additionally, patients who were admitted for at least 3 days, did not have strict bed rest orders and were not receiving end-of-life care were eligible to be included. For the inclusion of patients, the head nurse was consulted to create a list of eligible patients. To ensure heterogeneity, patients were also purposefully sampled based on age, gender, ward, level of physical functioning and length of hospital stay. Inclusion of participants ended when theoretical saturation was reached.¹⁷

PB and LvD were participating in the HiM project teams (PB on the medical oncology and hematology wards, LvD on the cardiology and cardiothoracic surgery wards). To prevent bias as much as possible, the participant inclusion and interviews were carried out on the wards where the researcher was not involved in the project teams. Participants were informed about the reasons for research and the role of the interviewers in the implementation project. Written informed consent was obtained from all participants included in the study. Ethical approval was granted by the Medical Ethics Committee Utrecht (16-316).

Data collection

The semi-structured interviews were guided by a topic list: one for the patients, and one for the HCPs (table 1) The topics HCPs included 'interventions', 'factors of influence on implementation', 'evaluation of the design of HiM' and 'sustainability'. The topics for patients included the topics of the action plans and the implemented interventions. For the HCPs who also participated in one of the HiM project teams, supplementary questions were added. All interviews took place face-to-face at one of the four participating hospital wards and were audio-recorded. At the end of each interview, a member check was performed by providing a verbal summary of the findings to the participant.

To warrant the quality and consistency of the interviews, a third researcher (KV – senior researcher) observed one of the first three interviews of both PB and LvD. KV did not actively participate in the interviews. After the observations by KV, the interview techniques (eg. neutral phrasing of interview questions

and consistent use of the topic list) and differences between PB and LvD were discussed to increase homogeneity of the interview styles of PB and LvD.

In addition to the interview data, characteristics of the participants were collected. Collected characteristics of the HCPs were: ward, gender, age, discipline and years of work experience. Characteristics of the patients included: ward, gender, age and the level of physical functioning. Physical functioning was assessed using the Activity Measure of Post-Acute Care Basic Mobility "6-clicks" (AM-PAC BM), which measures the ability of performing basic activities such as turning in bed and climbing 3-5 steps. ^{21, 22} The sum score ranges from 6 (total assistance or 'cannot do at all') to 24 (completely independent functioning).

Table 1. Topic list of the semi structured interviews of both HCPs and patients

Topic	Subtopic
HCPs	
Interventions	OpinionFamiliarityUsageAdoptionReactionConsequences
Factors of influence	 Hospital wide, ward-specific or personal Why and how was this of influence Was it preventable or utilized
Evaluation of the design of HiM	Design and execution of the projectOutput of the project
Sustainability	 Changed behavior
Patients	
Education	 Getting information about the importance of physical activity who, when and how Involvement of family Opinion about the achieved information
Physical activity as part of usual care	 Opinion about environment and implemented interventions Joint lunch for patients (in living room) Eating out of bed

Table 1. [Continued]

Topic	Subtopic
Involvement of third parties	 Encouragement of visitors to do exercises, walk or go to the living room Stimulation from food services to eat while sitting in the chair
Stimulation environment and technology	 Stimulation environment QR-code walking theme route at the hallway of the wards Good and sufficient patient seats available Availability of training material and walking aids at the department Attractive space to go
Mobilization mile stones	Mobilization card (familiarity, usage, opinion)Day schedules
Barriers and enablers of implemented interventions	 Opinion about the implemented interventions Influence on movement behavior, how and why Barriers and facilitators of the usage of the interventions

Data analysis

All interviews were audio-recorded and transcribed verbatim. Following, the text of the interviews was read and re-read word by word to gain a general understanding of the perceptions of the participants.

A conventional content analysis was performed as coding categories were derived directly from the text data. ²⁰ Firstly, the text data was labelled with codes (PB and LvD) to describe the meaning of condensed parts of the text. The first three interviews were independently coded by two researchers (PB and LvD). The subsequent interviews were independently coded by one researcher (HCPs by PB, patients by LvD) and checked and supplemented by the second researcher to create rigor and trustworthiness. Secondly, categories were formed (PB and LvD) by grouping the codes together that were related to each other. The categories were discussed with a third researcher (KV) until consensus was reached. Finally, these codes were allocated into one of the three key components of the MRC framework in a consensus meeting (PB, LvD, KV and CV): implementation, mechanisms of impact and context (Figure 1). ^{15, 16, 20} NVivo 12 was used for the qualitative analysis.

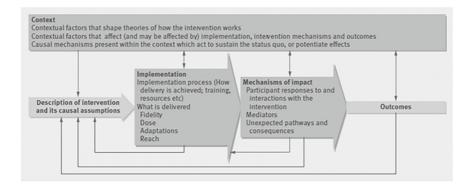


Figure 1. Key components of a process evaluation according to the MRC 15, 16

RESULTS

Participant characteristics

Participant characteristics are shown in Table 2. Between December 2018 and February 2019 a total of 28 participants were included in the study: 16 HCPs and 12 patients. HCPs were working as nurse (n=9), physical therapist (n=3) or unit manager (n=4) and were mostly female (n=13). Patients were mostly male (n=11) and admitted on the cardiology (n=3), cardiothoracic surgery (n=2), medical oncology (n=4) or the hematology ward (n=3).

Table 2. Demographic data of the participants

	HCPs	Patients
	n=16	n=12
Ward, n(%)		
- Cardiology	4(25)	3(25)
- Cardiothoracic Surgery	4(25)	2(17)
- Medical oncology	4(25)	4(33)
- Haematology	4(25)	3(25)
Male, n(%)	3(5)	11(92)
Age (years), mean±SD	39±13	61±18
Discipline, n(%)		
- Nurse	9(56)	N.A.
- Physical therapist	3(5)	N.A.
- Unit management	4(25)	N.A.
Years of work experience, mean±SD	14±12	N.A.
Physical Functioning (AM-PAC 6-clicks BM), mean±SD	N.A.	23±4
Duration of the interview in minutes, mean±SD	26±5	21±4

HCPs; healthcare professionals, AM-PAC 6-click BM; Activity Measure of Post-Acute Care Basic Mobility "6-clicks", N.A. = not applicable

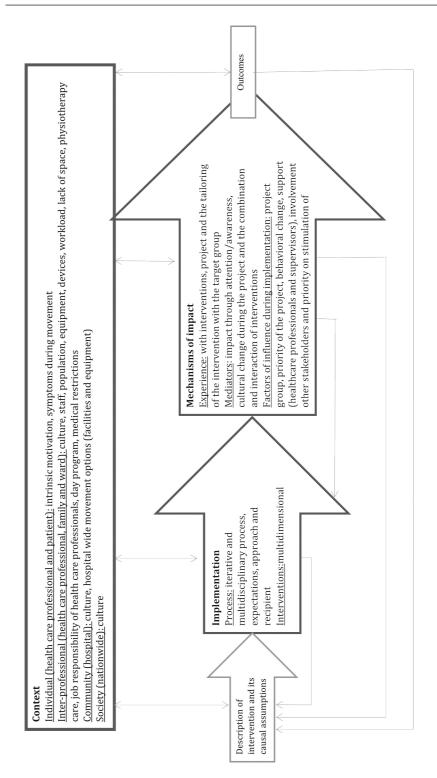


Figure 2. Perceived factors of influence on the success of an implementation project to improve patients' movement behavior during hospitalization categorized in the MRC framework. 15

Perceived factors of influence on the implementation of HiM

The results from the interviews are displayed using the framework of the MRC as guidance (Figure 2). Additionally, a narrative synthesis is provided.

Implementation

The theme implementation was divided in two subthemes: the process of the implementation and the implementation of the interventions.

Process

Changing physical behavior during hospitalization in usual care was mentioned as an organic, iterative and multidisciplinary process, since physical inactivity is deeply rooted in the hospital culture. To change this culture of inactivity, the implementation should follow an iterative approach. Progress can be made step-by-step and takes time (HCP3). Additionally, the involvement of different disciplines in the project group was experienced as a positive modifier. Different disciplines have different approaches and perspectives. By working together, this may help to overcome barriers and promote change in daily care (HCP12).

"This is an organic process, step by step you will make more progress" [HCP3, female, nurse, cardiology]

The expectations and attitudes of HCPs and the way the ward adopted the project were perceived as factors of influence on the success of the implementation. It could have a stimulating effect if the recipient has a positive attitude towards the aim of the project. However, when expectations and intentions were not clearly specified at the beginning of the project, this was perceived as barrier (HCP8).

"There has been some resistance to the project. There has been a feeling of an increased workload for the nursing staff because the physiotherapist told us to do something with my patient [like education or mobilization]. This was not the purpose of course, but some colleagues might have experienced it like that"

[HCP8, female, nurse, medical oncology]

Interventions

The fact that during the HiM project multiple interventions across multiple dimensions were implemented, had both advantages and disadvantages. Mentioned advantages were that the interventions were implemented on different social ecological levels and thereby interacted with each other. On

the other hand, as different interventions were implemented at the same time this diminished the involvement and focus of HCPs (HCP7).

"Now (after implementation) I think, many things are created, but we haven't found the time yet to fully implement the changes which makes it not running smoothly yet. There have been moments where suddenly three or more things had to be done at the same time, which made some of us give up"

[HCP7, female, nurse, hematology]

Mechanisms of impact

The theme mechanisms of impact during and after the implementation of the intervention was categorized in three subthemes: the experience with the interventions and the overall project, mediators (including factors that arose as a consequence of the intervention or project) and factors of influence during the implementation.

Experience

The experience with the different interventions and the overall aim of the implementation project can promote or obstruct the effect on the wanted outcome (HCP3). Additionally, tailoring the intervention to the target group was one of the factors, which was mentioned by the HCPs, that interacted with the outcome and thereby the success of the implementation (HCP8).

"I think this project is fantastic, also because we have a very enthusiastic team and we got some budget, which creates more opportunities"

[HCP3, female, nurse, cardiology]

Mediators

HCPs stated that the impact of the implementation was derived through the attention and awareness of the importance of movement behavior (HCP3 and HCP10). Achieved cultural changes on the participating ward during the implementation period improved the implementation outcomes. For example, if mobilization became more common in daily care and was stimulated more by several disciplines, this positively affected the implementation processes. Or if the implementation of the group lunch was successful, this might have motivated both nurses and catering assistants in a positive way to embrace other interventions as well. Simultaneously, if an intervention was not received well, this might negatively impact further implementation.

"Everything that gets your attention repeatedly, will grow" [HCP3, female, nurse, cardiology]

Factors of influence during the implementation

During the implementation several factors arose as consequences of the implementation process. First, the way the project group functioned was mentioned as an important factor for successful implementation. If the participants of the project group were the driving force on the ward, they were able to involve the rest of the department more easily (HCP12). On the other hand, it was hard to involve everyone since the participants of the project group were not working every day of the week, or not working on the ward for a longer period of time (HCP7).

"I think that we were in the luxury position of having a few nurses on the ward who were really fanatically involved and really keen to promote the importance of regular movement for patients and as part of a healthy lifestyle. As a ward we have used these colleagues as ambassadors of exercise and an active lifestyle, both for patients and health care professionals"

[HCP12, female, unit manager, cardiology]

"It proves challenging to reach everyone with this message. I was with my colleague, who is not working that many hours and I am only working here for just a year, making it hard to involve everyone, especially the older generation" [HCP7, female, nurse, hematology]

Furthermore, the openness of the HCP's on the ward to behavioral change, the priority given to the project (HCP9) and the support from other HCPs and supervisors were important for the involvement on the ward (HCP7 and HCP12). Additionally, the involvement of other stakeholders, all propagating the same message, was considered to be helpful (HCP2).

Context

The theme context includes four subthemes; individual (HCP or patients), interprofessional (HCP, family or ward), community (hospital) and society.

Individual

Individual factors that were mentioned were the intrinsic motivation of HCPs and patients, and the experienced symptoms by patients during movement

(PT7). Examples of symptoms to reduce a patient's likeliness to exercise were fear, nausea, pain and fatigue.

"But exercise, I think everybody knows the importance of exercise. But you have to do it, you need to have the energy. And I guess, that is the hard part. You wake up in the morning, still feeling tired. You really want to sleep all day. So the energy to do it... I can imagine some people were thinking.. oh no.. But I think, I just have to do it, otherwise....I never make any progress. So, let's do it and it's done"

[PT7 male, 58 year, hematology]

Inter-professional

Each ward in the hospital has its own culture and patient population, which may both impact the implementation positively or negatively. On some wards, movement is already part of daily care, on other wards movement is seen as one of many extra tasks. On these latter wards, HCPs may struggle with the question who's responsibility it is to mobilize the patients (HCP4).

"A while ago we got some criticism 'it is your job to exercise with the patient'.

That was unfair as we weren't talking about exercising, but about delivering care.

Supporting someone to wash him/herself independently by just putting him/her in front of a wash basin is a form of exercise as well"

[HCP4 female, physical therapist, medical oncology]

Additionally, workload is a theme which came forward frequently both in the HCPs' and patients' interviews. HCPs stated that they have an extensive range of tasks which should be arranged for the patients, of which mobilization is just one of the many tasks (HCP12). When the workload is high, tasks were prioritized. The high workload of HCPs also has impact on the patients. If they feel HCP's experience high pressure, it is a barrier to disturb them and ask for help (PT8).

"The barrier to change has been the high workload, due to the many tasks we have to do in collaboration with the patient, the shorter lengths of stay, more work in less time, which makes us forget the importance of daily exercise for the patients, although it should be part of our daily care routine"

[HCP12 female, unit manager, cardiology]

Other subthemes which came forward were focused on the built environment of the ward, the lack of space in the patient room, the possibility and attractiveness to walk in the corridors or to go to another room (e.g. a family or exercise room) or outside the ward (HCP10)(HCP7). Additionally, there was a wide variety of equipment and devices on the ward that could promote healthy behavior.

"You see patients walk '100.000' times around the ward and that gets boring. You see people want to be active, but it proves hard to find them a good way of doing so. This will almost encourage them to go back to their rooms"

[HCP7, female, nurse, hematology]

Community and society

HCPs stated that the culture and attention about the importance of movement behavior during hospitalization in both the community (hospital) and in the society (nationwide) may influence implementation.

"It is a topic other hospitals as well. In a journal for nurses, there also was a topic about the importance of inpatient physical activity."

[HCP3, female, 55 year, nurse, cardiology]

DISCUSSION

This study explored the perceived factors of influence on the implementation of interventions to improve inpatient movement behavior. This study found that using an iterative and step-by-step process was an important positive factor of influence within the theme implementation. Within the theme mechanisms of impact, continuous attention and the interaction of multiple interventions targeting multiple dimensions (individual, inter-professional, community and society) were perceived important. Within the theme context, the intrinsic motivation and inter-professional, community and societal culture towards physical activity was perceived to be of influence. To maintain enough focus on individual tools or interventions to be implemented, the amount of activities at one time should be limited. In addition, it is important to tailor the tools and interventions to the target group.

Changing the culture of physical inactivity requires fundamental changes in the current beliefs, practice and perception of inpatient movement behavior. This study showed that an iterative and step-by-step process, although time consuming, were perceived as successful ingredients of the implementation approach. One of the mechanisms of impact found in this study was the continuous attention, which is a never-ending process to maintain achieved awareness and changes of inpatients movement behavior. Additionally, this

study highlighted the importance of a multidisciplinary approach. This is in line with a previous published study which stated that an inter-professional communication, collaboration and teamwork is needed to change the culture of inactivity in the hospital.²³ The involvement of different disciplines all propagating the importance of physical activity, will strengthen the message. Thereby, it might enhance the incorporation of movement behavior in daily practice, which is important to achieve sustainable changes.⁹ Additionally, engagement of the project team and involvement of important stakeholders on the ward had a crucial role in the success of the implementation project.

Comparable to our results, previous studies also reported the advantages of implementing a set of single interventions to change inpatients movement behavior. ^{12, 24} However, analyses on the adoption and reach of HiM showed a wide range in the familiarity of the single interventions (54-86%)(unpublished results). This indicates that a downside of implementing multiple interventions at the same time is that you might lose the focus of HCPs. This is acknowledged by HCPs in the interviews. For HCPs, the promotion of physical activity is just one of their many tasks. HCPs mentioned that the promotion of physical activity is important, but nevertheless it often ends at the bottom of the priority list. ^{25, 26} Therefore, to increase the reach and adoption of the single interventions, the number of interventions should be limited to maintain the focus.

Furthermore, our results show that each intervention should target multiple dimensions like those suggested by the Social Ecological Model (individual, inter-professional, community and society). ¹³ For example, for the group lunches on the ward patients received information and were stimulated to eat lunch outside the patient room (individual dimension). At the same time, the HCPs cooperated with the catering assistants and the ward assistant to facilitate the lunch (inter-professional dimension) and a designated area on the ward was created were the lunches could take place (community dimension).

Finally, each intervention should be tailored to the target group. This is in line with a previous study which stated that an existing intervention cannot easily be incorporated in another setting, but requires a site-specific analysis. ¹¹ Even though the aim of HiM was to implement a tailored action plan per ward, several tools and interventions were implemented on all four wards. HCPs mentioned that there was some doubt if the interventions were suitable for their population. Although the project teams made conscious choices on which tools and interventions were implemented on their ward, the interventions might not have been tailored enough to the target population. More effort to tailor the interventions during the implementation is necessary to fulfill the specific needs per population. ²⁷ Therefore, to enhance the success of future studies

aiming to improve inpatients movement behavior, we recommend to explore the context in detail before developing or implementing interventions. In addition, we suggest to evaluate the adoption and appreciation of the individual interventions during the development and implementation frequently in order to optimize the integration of the interventions in practice.^{28, 29}

Previous research that aimed to improve inpatient movement behavior showed a wide variety in the content of the interventions. ^{2, 3, 11, 14, 30} Since it is important that interventions are tailored, the variety of the interventions might increase, which makes it hard to compare effectiveness. Therefore it is important to gain insight in the 'active ingredients' of the interventions. This study provides insight in the perceived factors of influence of the implementation process. However, the active ingredients of the single interventions remain unclear. The classification of behavioral change techniques might be a suitable way to identify these active ingredients of interventions, which might contribute to the comparability of interventions between studies and aids in the development of effective interventions.³¹

Strengths and limitations

The strength of this study is the in-depth analysis of the perceived factors of influence of the HiM implementation process. Although some of our findings are not unique^{2, 19, 32, 33}, they help contextualize what might need to be considered for implementation efforts to promote movement behavior in an acute care setting. As the promotion of inpatient physical activity is a fairly new topic in scientific literature, it is important to have an overview highlighting the main factors of influence for implementation projects similar to HiM. Therefore, the gained insights might provide useful information for others who are about to start with the implementation of a similar project in a similar setting.

A limitation of this study is the single center study design as participants were only familiar with the HiM project. Therefore, the single center design might have influenced the generalizability of our results. Another limitation is the execution of this study after the implementation period, making it difficult to adjust strategies during implementation. Finally, the involvement of the researchers in both the implementation process and the implementation evaluation might have led to reporting bias.

CONCLUSION

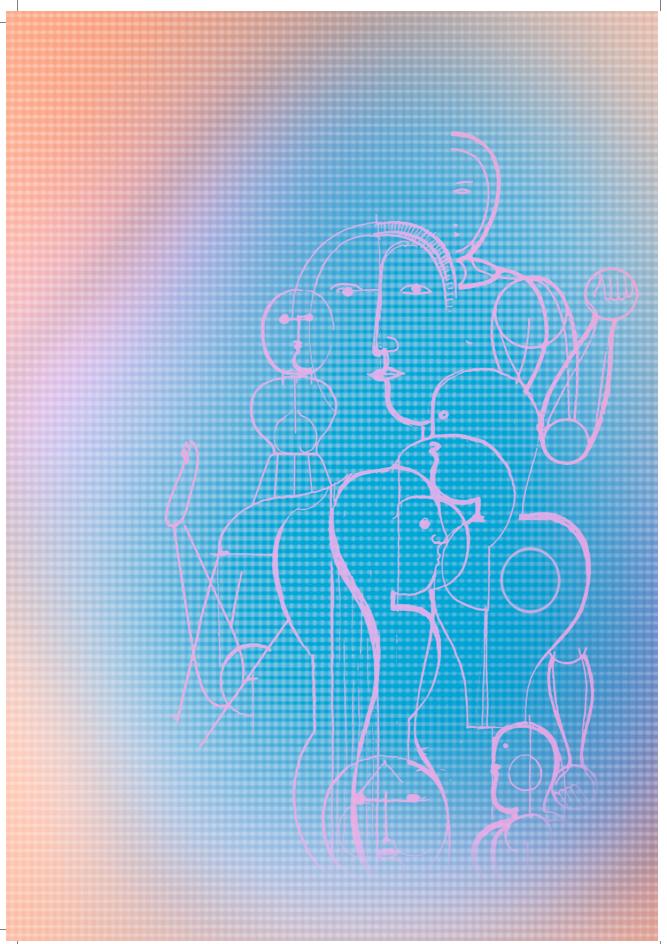
Many factors, within both the context, implementation and mechanisms of impact influenced the implementation of HiM. This finding emphasizes the complexity of implementation projects to improve inpatients' movement behavior. Impact can be achieved by creating continuous attention and by the interaction between different interventions. This applies for both during and after the implementation to attain sustainable results. Our results highlight the importance of a multidisciplinary approach and implementing a set of tailored interventions targeting multiple dimensions. We recommend future projects to include a process evaluation, with frequent evaluations during the implementation process of the implemented strategies, tools and interventions to enable adjustments during implementation when needed.

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Chapter 8

General discussion

It is well known that hospital admissions harmfully affect patients physical functioning, often resulting in long term dependence in performing activities of daily living [1-7]. The last twenty year, a lot of evidence has emerged about the importance of early mobilization and physical activity during hospitalization [8-12]. In order to prevent functional decline or restore physical functioning during hospitalization, it is necessary that patients remain physically active as much as possible during their hospital stay [7, 13]. Nevertheless, sedentary behavior is still deeply rooted in the hospital culture and successful projects implementing sustainable interventions aiming to stimulate physical activity during hospitalization are still rare. To overcome this culture and create sustainable changes, there is a need for an interdisciplinary and systems approach developing and implementing complex interventions integrating physical activity in usual care [12, 14-16]. Complex interventions have a number of interacting components, often require new behaviors by those delivering or receiving the intervention or have a variety of outcomes [17]. Currently there is little knowledge about the optimal content and effectiveness of such interventions. Additionally, to maximize their benefits, insight in the factors of influence on the implementation of interventions is the key to ensure that interventions are adopted in clinical practice [18, 19]. However, information about these factors and implementation processes is often missing. To contribute to these gaps in knowledge and need for effective interventions, we investigated two complex interventions aiming to increase physical activity during hospitalization:

- Family participation in physiotherapy-related tasks of critically ill patients
- Hospital in Motion, a multidimensional and multidisciplinary implementation project to improve patients' movement behavior during hospitalization

In this general discussion the main findings of the studies are reviewed and discussed. In addition, upcoming perspectives and future challenges are included.

Part 1: Development of an intervention for family participation in physiotherapy-related tasks of critically ill patients

The first part (chapter 2, 3 and 4) of this thesis focused on the development and feasibility of an intervention aiming to increase family participation in physiotherapy-related tasks of critically ill patients, with the goal of improving patients' physical functioning and reducing stress-related symptoms in family members. Since this is, to our knowledge, the first intervention focusing on this specific theme, an evidence based, step-by-step development approach and pilot are of high importance. Therefore we used the MRC framework for developing and implementing complex interventions. Key principles of intervention development are that the approach is dynamic, iterative, open to change and forward looking to future evaluation and implementation [17, 19, 20]. Additionally, it is very important to actively involve the prospective users in every phase of the intervention development. Since adults are heterogeneous in their experience and ability to use a product, a one-size fits all intervention is unlikely to work [21, 22]. In light of this, there is a need for user-centered design in interventions, in order to create effective products that reach a broad variety of users [22].

The first phase of the MRC framework involves the development of an intervention's theoretical rationale, describing the future users and their context, identifying the key intervention elements (i.e. the elements that should bring about behavioral change in the end-users, called the active ingredients of an intervention) and the mechanisms via which these active ingredients are intended to realize positive outcomes (i.e. how these elements are expected to interact with each other, and with the context of delivery to generate outcomes) [19, 20]. To explore these topics we conducted a mixed methods systematic review (chapter 2) [23] and qualitative study (chapter 3) [24]. The results of our review exhibit a general appreciation for involvement of relatives in physiotherapy-related tasks, but studies focusing on interventions for family participation in physiotherapy-related tasks are lacking. Our qualitative study, using semi-structured interview, identified diverse elements and requirements for the future intervention, as described in chapter 3 [24]. Recently, a comparable study has been published, focusing on ICU family participation during physical activity [21]. This longitudinal qualitative study explored the needs, beliefs, feeling and behaviors of relatives regarding family participation during physical activity of critically ill patients. Their results showed that family was motivated to participate in promoting physical activity if they were invited, informed and actively guided by HCPs. In addition, they mentioned that family participation during physical activity changes in time, from a passive role to a more proactive participatory role [21]. In the last step of the development phase our results were merged, key intervention components were elaborated by the project team, prototypes were tested with prospective users (i.e. family, physiotherapists, patients) and afterwards the final intervention was designed (**chapter 4**) [25].

Behavioral change techniques

Our final intervention included diverse behavior change techniques (BCTs). BCTs are a way of coding the content of interventions, enabling the identification of the active ingredients (i.e. the elements that should bring about the behavioral change) within interventions [26]. The focus upon BCTs represents an attempt to develop a common language relating to key aspects of intervention content. Reporting these active ingredients of interventions makes it possible for others to understand, evaluate, and replicate the active content of behavior change interventions [27, 28]. Diverse BCTs were incorporated in our intervention components, as shown in table 1. The final developed intervention contained three main components: 1) a brochure including background information and a menu with activities divided in activities to calm the patient and physiotherapy-related tasks; 2) a poster in the patient room demonstrating the activities that family chose and that the physiotherapist approved to perform; and 3) real-life instruction and practicing moment (table 1).

Table 1. The included behavior change techniques (BCTs) from the BCT taxonomy, supplemented by the components that incorporate this BCTs [26].

Behavior change techniques (BCTs)	Intervention component
Information about health consequences	Brochure ^a
Information about emotional consequences	Brochure ^a
Instruction on how to perform a behavior	Brochure ^a Real life appointment ^b
Prompts/cues	Poster in patient room ^c
Self-monitoring of behavior	Poster in patient room ^c
Demonstration of the behavior	Real life appointment ^b
Behavioral practice/rehearsal	Real life appointment ^b

^a Brochure: including information and a menu with activities for family to participate in, supplemented with QR codes linked to instruction videos of the physiotherapy-related tasks ^b Real life appointment: personalized instruction and training moment with the physiotherapist, in the patient room. During this appointment the poster and activities are explained and practiced together if necessary. ^c Poster in patient room: the physiotherapist marks the suitable exercises after each treatment, and family members report their executed activities (which activities they have performed, and when).

The importance of a pilot study

After designing an intervention, the next step was a pilot study evaluating the feasibility of family participation in physiotherapy-related tasks of critically ill patients (chapter 4) [25], which is recommended before conducting large scale clinical trials. Pilots are required to examine topics as feasibility and acceptability, to discover and delete weaknesses and false assumptions, and to improve the intervention and processes where necessary. It is useful to include these findings before designing an effectiveness study. By incorporating the lessons learned from the pilot in the next steps of adjusting the intervention and study design, the intervention ultimately matches better with its aim and future users, which eventually increases the impact of the intervention [17, 19, 20, 29]. The findings of our pilot, reported in chapter 4, demonstrate that family participation in physiotherapy-related tasks is feasible [25]. However, we did not find between group differences in patients' physical functioning at discharge from the ICU. This might be partly due to the fact that family members mainly executed passive movements. Unfortunately, we did not investigate why family mainly performed passive exercises instead of active exercises. Before conducting an effectiveness study on this topic it is necessary to examine the possible reasons why family members did not execute more active limb exercises, and why they did not participate in physiotherapy-related tasks on a daily basis. We advise investigators of future pilot studies on this topic to add interviews, identifying these factors of influence on the usage and thereby feasibility of family participation in active physiotherapy-related tasks.

Influence of COVID-19 on family participation in the ICU

An important factor of influence to mention regarding the feasibility of family participation in the ICU is the COVID-19 pandemic, because due to the pandemic elements of the ICU care were temporary changed. For example, relatives of isolated COVID-19 patients were not allowed to visit the ICU daily and therefore excluded in our pilot study. Even more important, the visitation of loved ones in our regular ICU was temporary minimized to a maximum of two different people per 24 hours. These factors together might negatively have affected our results about the feasibility of family participation in physiotherapy-related tasks of critically ill patients. Future studies must take this into account and will experience the possible consequences. We expect that now that the majority of the population is vaccinated, the proportion of ICU patients with COVID-19 will further decrease and family participation will be more applicable in the post pandemic world.

Part 2: Implementation and evaluation of Hospital in Motion

Part 2 of this thesis (chapter 5, 6 and 7) evaluated the implementation of Hospital in Motion, a multidimensional and multidisciplinary intervention project aiming to improve inpatients' movement behavior at general wards. This part focused on phase three and four of the MRC framework (i.e. evaluation and implementation). **Chapter 5** was the research protocol, describing the content, implementation process and outcome evaluation of Hospital in Motion [30]. To create sustainable changes, not only the content of the intervention but also a structured implementation approach is of high importance [18, 31]. Therefore, the implementation of Hospital in Motion followed a ten month dynamic stepby-step approach using an evidence based framework: the Implementation of Change Model developed by Grol and Wensing [32]. After the implementation of a ward specific action plan including interventions primary aiming to decrease the time spent lying in bed and secondary to increase the time spent moving, the time spent lying during the day decreased from 60.1% to 52.2% (p=0.01) (**chapter 6**) [33]. Currently no data is known about how much change of time spent lying in bed is clinically relevant, but we did not achieve the 15% reduction of time spent lying in bed which we aimed for a priori. Additionally, the percentage time spent moving did not increase. Nevertheless, our outcomes are in line with comparable implementation projects conducted at other University Medical Centers in the Netherlands [34, 35]. Their findings showed similar percentages and also demonstrated that patients mostly change lying in bed for sitting, and do not walk much more. These results, in combination with our results and previous studies demonstrate that it is possible to change inpatients' movement behavior by implementing multidimensional intervention projects tailored to the context of a hospital ward, but also show the complexity of improving inpatients' movement behavior and the time spent moving in particular [12, 36, 37].

Patient-tailored and goal-directed interventions to increase levels of physical activity

Although we did not reach the a priori defined goals, we think that our results are a promising first step in changing the hospital culture regarding movement behavior. This first step created awareness and resulted in getting patients out of bed more time during the day, but also demonstrated that more effort is needed to increase levels of physical activity [33]. We believe that, to improve inpatients' physical activity, patient-tailored and goal-directed interventions are needed in addition to projects such as Hospital in Motion which are tailored to the context of the ward. Previous research demonstrated that goal-

directed interventions using activity trackers as an important component of the intervention have the potential to increase physical activity during hospitalization [38-40]. Additionally, goal-directed interventions incorporating a theoretical model and using multiple BCTs (e.g. Feedback on Behavior, Goal Setting, Self-monitoring of Behavior, Graded Tasks, Action Planning, Adding objects to the environment), in combination with coaching by a HCP seem to increase the effects on patients' physical activity [40]. Our suggestion for future projects is to implement an intervention tailored to the context of the ward, such as Hospital in Motion, together with a patient-tailored and goal-directed intervention such as accelerometers in combination with a mobile application in daily care to monitor physical activity adjusted with personal walking and/ or exercising goals which are supervised by a HCP.

Evaluating the use, adoption and appreciation of interventions

Our study in **chapter 6** focused on the evaluation of pre-post differences in movement behavior after implementing an action plan with multidimensional interventions. However, in the pre-post design we used to evaluate the effectiveness, external factors that may have influenced the outcomes could not be ruled out. Besides, we did not perform a detailed evaluation of the individual interventions during and after the implementation procedure, resulting in the fact that only statements can be made about the impact of the entire action plan and not the individual interventions. We did not pay attention to monitoring the use and thereby impact of the individual interventions, it remains unclear to which extent the individual interventions of Hospital in Motion were perceived and used. Additionally, a major challenge of implementing complex interventions is long-term maintenance of behavioral change. It is therefore important to evaluate the extent to which the individual interventions are sustained over time, but we did not investigate the long-term use of the implemented interventions. To create more impact, future projects implementing complex interventions aiming to increase inpatients' physical activity, should evaluate the use, adoption and appreciation of the individual interventions during and after the implementation frequently in order to create sustainable changes in daily care. We suggest using the RE-AIM framework for this evaluation (table 2) [41]. This framework is a valuable tool for implementation scientists, health promotion professionals and practitioners, and has been applied to evaluate intervention impact in a variety of settings and across a broad range of behavioral outcomes. It can be used to assist with the translation of research to practice and to increase impact of multidimensional interventions. RE-AIM is an acronym for the framework's five evaluation components: Reach, Efficacy,

Adoption, Implementation, and Maintenance. Through these components, the use and impact of interventions can be evaluated at both individual and organizational levels [41].

Table 2. RE-AIM framework for evaluating complex interventions [41].

Dimension	Level
Reach: proportion of the target population that participated in the intervention	Individual
Efficacy: success rate if implemented as in guidelines; defined as positive outcomes minus negative outcomes	Individual
Adoption: proportion of settings, practices, and plans that will adopt this intervention	Organization
Implementation: extent to which the intervention is implemented as intended in the real world	Organization
Maintenance: extent to which a program is sustained over time	Individual and organization

Factors of influence on the implementation of Hospital in Motion

In chapter 7 we investigated the perceived factors of influence on the implementation of a ward-specific action plan, including multiple interventions, aiming to improve inpatients' movement behavior, using in-depth interviews with HCPs and patients at the end of our implementation period [42]. Understanding factors of influence on the implementation of complex interventions aiming to promote inpatients' physical activity is required to successfully and sustainably change the immobility culture in hospitals [12, 18, 19]. Additionally, it provides valuable information on how to successfully integrate interventions aiming to improve patients' movement behavior in usual care. Overall, we found multiple factors, as described in **chapter 7**, having influence on the implementation of Hospital in Motion, which emphasizes the complexity of improving inpatients' movement behavior [42]. To improve inpatients' movement behavior, it is important that a multidisciplinary project team makes a structured project plan with a multidimensional approach. We advise project teams to choose a limited set of interventions, which should target multiple dimensions and must be tailored to the context of the target group. We suggest to use an iterative and step-by-step implementation process per individual intervention. Besides, we highly recommend regular intermediate evaluations of the implementation processes and individual delivered interventions to create more impact and sustainable changes in daily care, a factor which was missing in our implementation approach [42]. Additionally, we believe that changing inpatients' movement behavior is team work. Team work may help to overcome barriers and it may enhance the incorporation of movement behavior in daily practice, which is important to achieve sustainable changes [42].

Upcoming perspectives and future challenges

The last decade there is a growing body of research projects that focus on interventions promoting physical activity during hospitalization with the goal of improving or maintaining patients' physical functioning. The two projects described in this thesis showed that it is possible to change inpatients movement behavior, but also demonstrated the complexity of increasing inpatients level of physical activity. More research needs to be performed into the effectiveness and implementation of patient-tailored and goal-directed interventions aiming to increase physical activity, using for example, accelerometers and/or mobile applications in daily care. In addition to these patient-tailored interventions, future projects should also continue focusing on their context, HCPs and the built environment. Regarding family participation in physiotherapy-related tasks of critically ill patients, patient- and family-centered care is becoming increasingly important in the ICU, but family participation in physiotherapyrelated tasks is a new and limited researched topic. Our pilot demonstrated positive results on feasibility, but did not show differences in patients' physical functioning. Future studies first need to investigate the factors of influence on the usage and feasibility of family participation in active exercises before redesigning the intervention and evaluating its effectiveness. If it is not feasible for family members to frequently perform active exercises with their loved one in the ICU, this part of the intervention might be more applicable in the period after an ICU admission, for example at general wards, where physical rehabilitation continues. Additionally, it is interesting to investigate effects of family participation in promoting physical activity during an ICU admission and/or general hospital stay on patients' psychosocial outcomes, since these factors also influence long-term outcomes as independence in the activities of daily living, participation and quality of life.

Another major challenge for future projects is to answer the questions; "How active do patients need to be during hospitalization to prevent physical decline? How much movement is enough in this particular patient to maintain or improve inpatients physical functioning?", because currently it is not known how physically active patients need to be during their hospital stay to prevent physical deterioration. An important topic to take into account when answering these questions is the changing healthcare. For example the fact

that hospital stays become shorter [43, 44]. This decrease in length of stay is caused by the introduction of new treatments, such as minimally invasive surgery, streamlining care processes via clinical care pathways and the substitution of care from secondary to primary care and one- and a half line care. Additionally financial pressures including salary demands and changes in hospital reimbursement have influence on the length of stay [43, 44]. Patients are being discharged earlier than ever before, even though today's patients tend to be older and sicker. How bad is it when patients are physically inactive during their hospital stay of only few days, if they are active enough before and directly after their admission? If hospital stays become shorter, they will physically lose less during hospitalization, resulting in less importance of promoting physical activity during hospitalization. During hospital stay patients still need to be physically active enough to make sure they can return home as fast as possible, but interventions stimulating physical activity after hospitalization will become more important.

In line with this, themes as prevention and e-health are becoming increasingly important in healthcare policies. An example of this is the national program the Right Care in the Right Place (Juiste Zorg op de Juiste Plek), which focusses on three themes in healthcare: 1) prevent (more expensive) care; 2) move care (organizing around the people); 3) replace care by using smart care as e-health [45]. We suggest future projects aiming to increase patients' physical activity to incorporate more e-health interventions (e.g. accelerometers and/ or mobile applications) and focus more on the whole patient journey, including topics as prevention and lifestyle, with patients' physical functioning as the primary outcome. During hospital stay the attention still needs to be on implementing effective interventions aiming to prevent physical decline during hospitalization, e.g. the two interventions described in this thesis, but in my opinion effective interventions improving or maintaining physical functioning before and after hospitalization need to become more important. Besides, we think that it is important to identify the vulnerable patients, i.e. patient groups with an increased risk of losing physical function such as frail elderly, and focus more on these groups. A major challenge for future projects focusing on e-heath interventions such as mobile applications is how to reach the patients with low health literacy skills, such as elderly and low educated people [46-48]. HCPs are increasingly asking from patients in the field of digital skills, but for one third of the Dutch population the use of e-health is a barrier to accessing healthcare because they have limited skills, a factor researchers and project managers need to take seriously when developing such interventions [46-48]. When developing e-health interventions, it is very important to actively involve the prospective users in every phase, i.e. user-centered design, in order to create effective products.

Clinical messages

- It seems feasible to involve family members of critically ill patients in performing physiotherapy-related tasks.
- The development of an intervention for family participation in the ICU should follow an evidence based, user-centered and iterative approach, involving the prospective users in every phase. An intervention must be tailored to the target group and should contain multiple BCTs.
- Multidimensional interventions focusing on the patient, HCP and hospital environment seem effective to improve patients' movement behavior during hospitalization.
- Interventions should be implemented in daily care following an theoretical, iterative, and multidimensional implementation approach per intervention. To create more impact and make sustainable changes, intermediate evaluations of both the individual delivered interventions as the implementation processes are highly recommended.

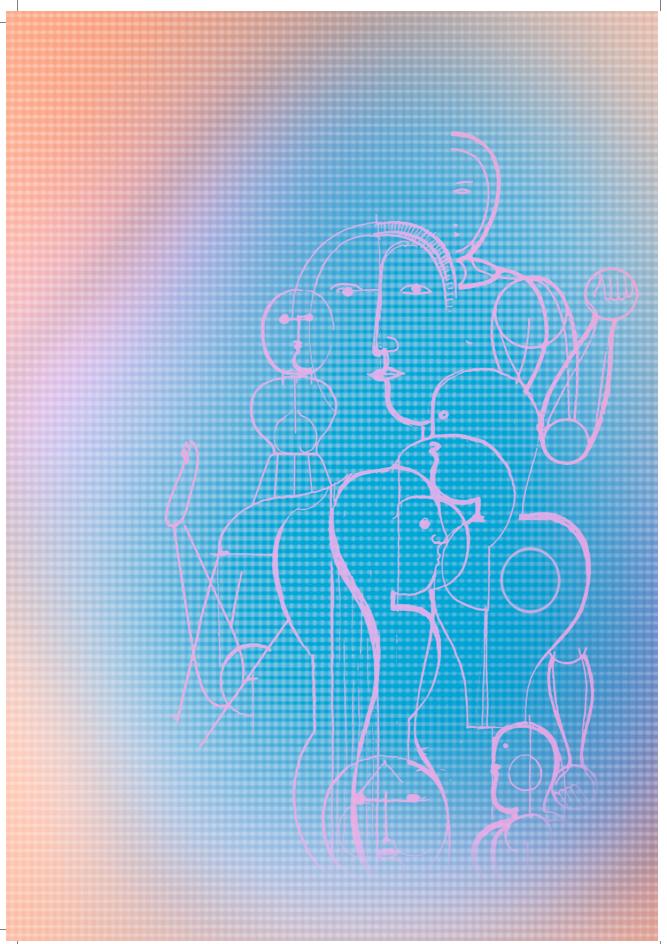
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Chapter 9

Summary & Samenvatting

The last twenty year, a lot of evidence has emerged about the importance of early mobilization and physical activity during hospitalization. In order to prevent functional decline or to restore physical functioning, it is necessary that patients remain physically active as much as possible during their hospital stay. However, sedentary behavior is still deeply rooted in the hospital culture. Promoting inpatients' movement behavior is challenging since the traditional hospital culture seems to discourage patients to be physically active. To overcome this culture and create more sustainable changes in movement behavior, there is a need for effective interventions integrating physical activity in usual care.

In this thesis, we investigated two intervention projects aiming to increase physical activity during hospitalization. Part 1 (chapter 2,3 and 4) focusses on the development and feasibility of an intervention for family participation in physiotherapy-related tasks of critically ill patients. Part 2 (chapter 5,6, and 7) focusses on the implementation and evaluation of Hospital in Motion, a multidimensional and multidisciplinary implementation project aiming to improve inpatients' movement behavior at general wards.

The mixed-methods systematic review in **chapter 2** provided an overview of studies on family participation in physiotherapy-related tasks of critically ill patients, addressing two research questions (RQ): 1) What are the perceptions of patients, relatives, and healthcare professionals (HCPs) regarding family participation in physiotherapy-related tasks? and 2) What are the effects of interventions including family participation in physiotherapy-related tasks? A convergent segregated approach was used to analyze all findings. Eighteen articles, reporting on family participation in physiotherapy-related tasks of adult critically ill patients were included; 13 for RQ1, and 5 for RQ2. The studies exhibited a general appreciation for involvement of relatives in physiotherapyrelated tasks, although most of the studies reported on family involvement in general care and incorporated diverse physiotherapy-related tasks. The conclusion of this review was that positive attitudes are observed among patients, their relatives and HCPs towards family participation in physiotherapyrelated tasks of critically ill patients, but limited research has been done into the feasibility and effectiveness of interventions containing family participation in physiotherapy-related tasks.

In **Chapter 3**, a multicenter study, including one academic hospital and one general hospital, with a qualitative design investigated the perceptions of critically ill patients, their family and HCPs regarding family participation in physiotherapy-related tasks of critically ill patients and the future intervention. Altogether 22 participants were interviewed between May 2019 and February 2020; four patients, five family members, and 13 ICU HCPs. Both patients,

family members and HCPs supported the idea of increased family participation in physiotherapy-related tasks, and suggested important components of an intervention. Six themes emerged: 1) prerequisites for family participation (e.g. permission and capability); 2) timing and interactive aspects of engaging family (e.g. communication); 3) eligibility of patients and family (e.g. first-degree relatives and spouses, long stay patients); 4) suitability of physiotherapy-related tasks for family (e.g. passive, active and breathing exercises); 5) expected effects (e.g. physical recovery, psychological wellbeing), and 6) barriers and facilitators which may affect the feasibility (e.g. safety, privacy, and responsibility). These findings were included in the further development of an intervention focusing on family participation in physiotherapy-related tasks of critically ill patients.

Feasibility of an intervention aiming to increase family participation in physiotherapy-related tasks was examined in **chapter 4**, using a quasiexperimental pilot study with a non-equivalent control group, conducted within a mixed adult ICU. The intervention contained three components: 1) an information brochure including a menu with activities divided by category A and B; category A were simple activities to calm the patient (e.g. reading a book, or massage) and category B were physiotherapy-related tasks (i.e. passive movement exercises, active limb exercises, functional exercises and breathing exercises); 2) poster in patient room; and 3) real-life instructions. The main sample of this study were first-degree relatives and/or spouses of critically ill patients who were admitted to the ICU for more than three days and received physiotherapy. After the first physiotherapy consult, family was asked to participate and received the intervention. The primary outcome was feasibility, based on a priori defined minimal 1) recruitment rate; 2) percentage of relatives who chose physiotherapy-related tasks; 3) usage of physiotherapyrelated tasks; 4) usability of the poster and brochure; and 5) maximum number of adverse events. As secondary outcomes two outcomes were compared between the intervention and control group, at discharge from the ICU. First, patients' physical functioning, which was evaluated with the Medical Research Council (MRC) sum score and ICU Mobility Scale (IMS), and second, symptoms of anxiety, depression and post-traumatic stress disorder (PTSD) in family members, measured with the Hospital Anxiety and Depression Scale (HADS) and Impact of Event Scale-Revised (IES-R). Between March and June 2021, 34 family members (19 intervention group, 15 control group) of 27 critically ill patients were included. The recruitment rate was 75.6%. Concerning usage, the percentage relatives who chose physiotherapy-related tasks at baseline was 94.5%. The average percentage of days that these relatives performed physiotherapy-related tasks, of the total number of days that family could participate, was 56.7%. Focusing on the type of activities these family members performed, 68% of the executed physiotherapy-related-tasks were passive movement exercises and 28% were active limb exercises. The intervention had a good usability and no adverse events were reported. Regarding the secondary outcomes, there was a significant difference at ICU discharge in the mean HADS-depression score (P=0.030) and mean IES-R (P=0.047) score between the intervention and control group, in favor of the intervention group. No differences were found in the other secondary outcomes. In conclusion, results showed that family participation in physiotherapy-related tasks of critically ill patients is feasible.

The following three chapters focused on the implementation project Hospital in Motion. Chapter 5 described the study protocol for a mixed-methods study evaluating the effectiveness and implementation process of Hospital in Motion, a ward specific multidimensional implementation project aiming to improve patients' physical behavior during hospitalization. Per ward, multidisciplinary teams followed a ten month step-by-step approach including the development and implementation of a ward-specific action plan with multidimensional interventions to improve movement behavior. The implementation of change model, developed by Grol and Wensing, was used for the development and implementation of the action plan. This model contains seven steps: 1) development of a proposal for change; 2) analysis of actual care; 3) target group and setting analysis; 4) development and selection of interventions; 5) executing implementation plan; 6) integration in healthcare; 7) evaluation of the implementation. The primary outcome measure was the percentage of time spent lying, measured with the behavioral mapping method. In addition, a process evaluation was performed per ward using a HCPs and patient surveys and semi-structured interviews with HCPs and patients.

The effectiveness of Hospital in Motion on movement behavior and medical outcomes was investigated in **chapter 6**, using a prospective, pre-post design. In 2018 Hospital in Motion was conducted at four wards of the University Medical Center Utrecht; cardiology, cardiothoracic surgery, medical oncology and hematology. Movement behavior of 160 inpatients (40 per ward) was assessed before the start of the project and one year later, using the behavioral mapping method, where patients were observed between 9AM and 4PM. The primary outcome was the percentage of time spent lying. In addition, sitting and moving, immobility-related complications, length of stay, discharge destination home, discharge destination rehabilitation setting, mortality and 30-days readmissions were investigated. Patient-observations demonstrated that the primary outcome, the time spent lying, decreased from 60.1% to 52.2%

(p=0.01). Concerning the secondary outcomes, the time spent sitting increased from 31.6% to 38.3% (p=0.01) and discharges to a rehabilitation setting reduced from 6 (4.4%) to 1 (0.7%) (p=0.04). No statistical differences were found within the other secondary outcome measures. The results of this study indicate that it is possible to change inpatients' movement behavior by implementing multidimensional intervention projects tailored to the context of a hospital ward (Hospital in Motion), but also show the complexity of improving inpatients' movement behavior.

Chapter 7 focused on the perceived factors of influence on the implementation of Hospital in Motion, using a qualitative study design. Between December 2018 and February 2019, at the end of the implementation of Hospital in Motion, 28 semi-structured interviews were conducted with 16 HCPs and 12 patients. The framework of the Medical Research Council 2008 was used as guidance when selecting categories and themes during the analyses. The results were displayed in three major themes; implementation, mechanisms of impact and context. Factors of influence within the process of the implementation were the iterative and multidisciplinary approach. Impact can be achieved by continuous attention and awareness during the implementation. Multiple interventions, tailored to the target group, should be implemented within multiple dimensions (individual, inter-professional, community and society), since the interaction between the different interventions was found to be one of the mechanisms of impact. However, to maintain the focus, the amount of the interventions should be limited. This study confirmed the importance of a multidimensional, multidisciplinary and tailored implementation approach to improve inpatients movement behavior. To further optimize the outcomes, it is important to take into account factors of influence within the context, implementation and mechanisms of impact. Awareness of these factors might help future projects to successfully integrate interventions in usual care and thereby sustainably change inpatient movement behavior.

In **chapter 8** the main findings of this thesis are discussed. Through the research in this thesis, it became clear that developing sustainable interventions aiming to increase inpatients' physical activity during hospitalization, and implementing them successfully in daily care, is a complicated and long lasting process. The development of complex interventions should follow an evidence based, user-centered and iterative approach, involving the prospective users in every step. Interventions must be tailored to the target group and contain multiple BCTs in order to create effective and sustainable changes. Afterwards, interventions should be implemented in daily care following an iterative, multidimensional and step-by-step implementation approach per individual

intervention. Additionally, regular intermediate evaluations of both the individual delivered interventions as the implementation processes are highly recommended. The two intervention projects described in this thesis showed that it is feasible to involve family in promoting physical activity in the ICU, and that it is possible to change inpatients' movement behavior (i.e. time spent lying) by projects such as Hospital in Motion, but also demonstrated that more effort is needed to increase the time spent moving.

NEDERLANDSE SAMENVATTING

De laatste twintig jaar is er veel onderzoek gedaan naar het belang van vroeg-mobilisatie en fysieke activiteit tijdens een ziekenhuisopname. Om fysieke achteruitgang te voorkomen of het fysiek functioneren te herstellen, is het noodzakelijk dat patiënten tijdens hun verblijf in het ziekenhuis zoveel mogelijk in beweging blijven. Sedentair gedrag is echter nog diep geworteld in de ziekenhuiscultuur. Doordat de hele ziekenhuiscultuur patiënten lijkt te ontmoedigen om fysiek actief te zijn, is het een grote uitdaging om het beweeggedrag van ziekenhuispatiënten te verbeteren. Om deze cultuur te overwinnen en duurzamere veranderingen in het beweeggedrag tot stand te brengen, is er behoefte aan effectieve interventies die fysieke activiteit in de dagelijkse zorg integreren.

In dit proefschrift zijn twee interventies met als doel het vergroten van fysieke activiteit van patiënten opgenomen in het ziekenhuis onderzocht. Deel 1 (hoofdstuk 2,3 en 4) richt zich op de ontwikkeling en haalbaarheid van een interventie voor familieparticipatie in fysiotherapie-gerelateerde activiteiten bij IC patiënten. Deel 2 (hoofdstuk 5,6 en 7) richt zich op de implementatie en evaluatie van Hospital in Motion, een multidimensionaal en multidisciplinair implementatieproject gericht op het verbeteren van het beweeggedrag van patiënten opgenomen op algemene verpleegafdelingen.

De systematische review in **hoofdstuk 2** geeft een overzicht van studies die hebben gekeken naar familieparticipatie in o.a. fysiotherapeutische activiteiten bij IC patiënten. In deze review werden twee onderzoeksvragen beantwoord: 1) Wat zijn de percepties van patiënten, familieleden en zorgverleners met betrekking tot familieparticipatie in fysiotherapeutische activiteiten? en 2) Wat zijn de effecten van interventies gericht op familieparticipatie in fysiotherapeutische activiteiten? Er werd gebruik gemaakt van een convergente segregatiebenadering voor mixed-methods reviews. Achttien artikelen die iets rapporteerden over familieparticipatie in fysiotherapie-gerelateerde taken bij volwassen IC patiënten werden geïncludeerd; 13 voor vraagstelling 1, en vijf voor vraagstelling 2. De studies toonden positieve waardering voor betrokkenheid van familieleden bij fysiotherapie-gerelateerde taken, hoewel de meeste studies gingen over familieparticipatie in algemene zorg en daarbij enkele fysiotherapiegerelateerde taken noemde. De conclusie van deze review was dat er positieve attitudes werden waargenomen bij patiënten, hun naasten en zorgverleners ten aanzien van familieparticipatie in fysiotherapie-gerelateerde taken bij IC patiënten, maar dat er beperkt onderzoek is gedaan naar de haalbaarheid

en effectiviteit van interventies die zich richten op familieparticipatie in fysiotherapie-gerelateerde taken.

In hoofdstuk 3, een multicenter studie (één academisch ziekenhuis en één algemeen ziekenhuis) met een kwalitatief design, werden de percepties van IC patiënten, familieleden en zorgverleners onderzocht met betrekking tot familieparticipatie in fysiotherapie-gerelateerde taken bij IC patiënten en de toekomstige interventie. In totaal werden 22 deelnemers geïnterviewd tussen mei 2019 en februari 2020; vier patiënten, vijf familieleden, en 13 zorgverleners. Zowel patiënten, familieleden als zorgverleners steunden het idee van familieparticipatie in fysiotherapie-gerelateerde taken, en benoemde belangrijke componenten voor een toekomstige interventie. Zes hoofdthema's kwamen naar voren: 1) voorwaarden voor familieparticipatie (bijv. toestemming en keuze mogelijkheden); 2) timing en interactieve aspecten van het betrekken van familie (bijv. communicatie); 3) geschiktheid van patiënten en familie (bijv. eerstegraads familieleden en echtgenoten, patiënten die lang op de IC verblijven); 4) geschiktheid van fysiotherapie-gerelateerde taken voor familie (bijv. passieve, actieve en ademhalingsoefeningen; 5) verwachte effecten (by. fysiek herstel, psychologisch welbevinden); en 6) belemmeringen en bevorderaars die de haalbaarheid kunnen beïnvloeden (bv. veiligheid, privacy en verantwoordelijkheid). Deze bevindingen werden geïncludeerd in de verdere ontwikkeling van een interventie die gericht is op familieparticipatie in fysiotherapie-gerelateerde taken bij IC patiënten.

De haalbaarheid van de ontwikkelde interventie voor familieparticipatie in fysiotherapie-gerelateerde taken bij IC patiënten werd onderzocht in hoofdstuk 4, door middel van een quasi-experimentele pilotstudie met een niet-equivalent controlegroep design. Deze pilot is uitgevoerd binnen een gemengde IC voor volwassenen. De ontwikkelde interventie bevatte drie componenten: 1) een informatiebrochure inclusief een keuzemenu met activiteiten verdeeld in categorie A en B; categorie A waren eenvoudige activiteiten om de patiënt te kalmeren (bijv. een boek lezen, of massage) en categorie B waren fysiotherapie-gerelateerde taken (d.w.z. passief door bewegen, actieve ledemaatoefeningen, functionele oefeningen en ademhalingsoefeningen); 2) poster in patiëntenkamer; en 3) instructies/oefenmoment. De deelnemers van deze studie bestond uit eerstegraads familieleden en/of echtgenoten van IC patiënten die langer dan drie dagen op de IC waren opgenomen en fysiotherapie kregen. Na het eerste fysiotherapie consult werd familie gevraagd deel te nemen aan de studie en kregen zij de interventie aangeboden. De primaire uitkomstmaat was haalbaarheid, gedefinieerd door een minimaal: 1) rekruteringspercentage; 2) percentage familieleden dat fysiotherapiegerelateerde taken kiest; 3) gebruik van fysiotherapie-gerelateerde taken; 4) bruikbaarheid van de folder en poster; en maximum 5) ongewenste voorvallen. Als secundaire uitkomsten werden twee uitkomstenmaten vergeleken tussen de interventiegroep en de controlegroep bij ontslag van de IC. Ten eerste, fysiek functioneren van de patiënt, geëvalueerd met de Medical Research Council (MRC) som score en ICU Mobility Scale (IMS), en ten tweede, symptomen van angst, depressie en post-traumatisch stress syndroom (PTSS) bij familieleden, gemeten met de Hospital Anxiety and Depression Scale (HADS) en Impact of Event Scale-Revised (IES-R). Tussen maart en juni 2021 werden 34 familieleden (19 interventiegroep, 15 controlegroep) van 27 IC patiënten geïncludeerd. Het rekruteringspercentage was 75,6%. Het percentage familieleden dat op baseline waren fysiotherapie-gerelateerde taken koos was 94,5%. Het gemiddelde percentage van dagen dat deze waren fysiotherapie-gerelateerde taken uitvoerden, van het totale aantal dagen dat de familie kon participeren, was 56.7%. Kijkend naar het soort activiteiten dat familie uitvoerden, dan waren 68% van de uitgevoerde fysiotherapie-gerelateerde taken passieve bewegingen en 28% waren actieve ledemaatoefeningen. De bruikbaarheid van de interventie was goed en er werden geen ongewenste voorvallen gerapporteerd. Wat de secundaire uitkomsten betreft, de interventiegroep scoorde lager op de gemiddelde HADS-depressiescore (P=0.030) en de gemiddelde IES-R-score (P=0.047) dan controlegroep. Er werden geen verschillen gevonden in de andere secundaire uitkomsten. De bevindingen van deze pilotstudie laten zien dat familieparticipatie in fysiotherapie-gerelateerde taken bij IC patiënten haalbaar is.

De volgende drie hoofdstukken richten zich op het project Hospital in Motion. **Hoofdstuk 5** beschrijft het onderzoeksprotocol voor een mixedmethods studie waarin de effectiviteit en het implementatieproces van Hospital in Motion worden geëvalueerd. Hospital in Motion is een afdelingsspecifiek, multidimensionaal implementatieproject met als doel het beweeggedrag van patiënten tijdens ziekenhuisopname te verbeteren. Per afdeling volgen multidisciplinaire teams een tien maanden durende, stapsgewijze aanpak. Dit project bevat de ontwikkeling en implementatie van een afdelingsspecifiek actieplan met multidimensionale interventies ter verbetering van het beweeggedrag, afgestemd op de dagelijkse zorg van de desbetreffende afdeling. Voor de ontwikkeling en implementatie van het actieplan wordt gebruik gemaakt van het Implementation of Change Model, ontwikkeld door Grol en Wensing. Dit model bevat zeven stappen: 1) ontwikkeling van een veranderingsvoorstel; 2) analyse van de feitelijke zorg; 3) doelgroep- en setting analyse; 4) ontwikkeling en selectie van interventies; 5) uitvoering van het

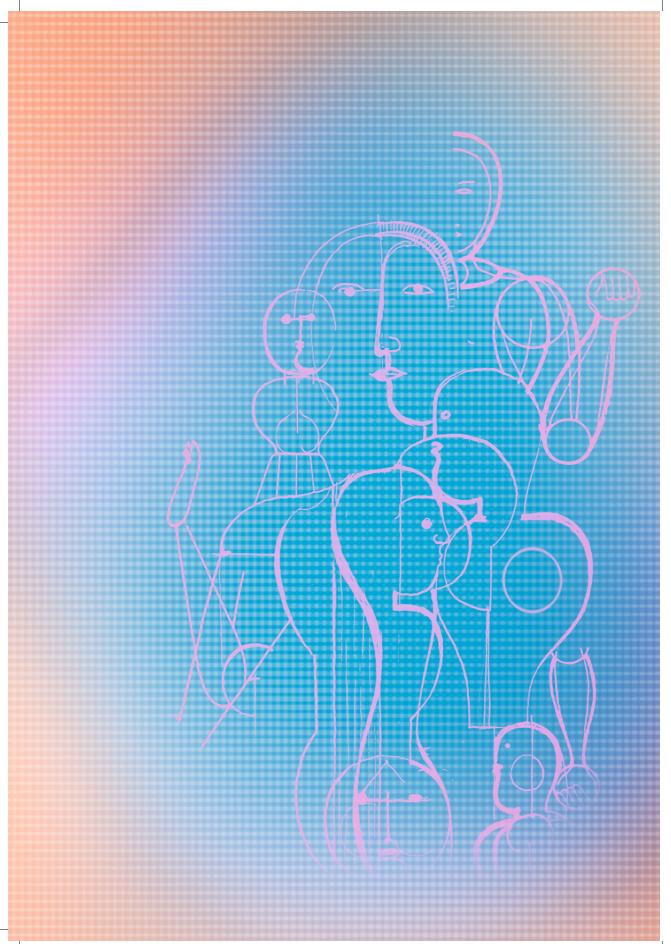
implementatieplan; 6) integratie in de zorg; 7) evaluatie van de implementatie. De primaire uitkomstmaat is het percentage tijd gedurende de dag dat patiënten in bed liggen, gemeten met de behavioral-mapping methode. Daarnaast wordt per afdeling een procesevaluatie uitgevoerd met behulp van een zorgverlenersen patiënten enquête en semigestructureerde interviews met patiënten en zorgverleners.

De effectiviteit van Hospital in Motion op het beweeggedrag en medische uitkomsten is onderzocht in **hoofdstuk 6**, met behulp van een prospectief, pre-post design. In 2018 werd Hospital in Motion uitgevoerd op vier afdelingen van het Universitair Medisch Centrum Utrecht; cardiologie, cardio-thoracale chirurgie, medische oncologie en hematologie. Het beweeggedrag van 160 opgenomen patiënten (40 per afdeling) werd gemeten voor de start van het project en een jaar later, met behulp van de behavioral-mapping methode, waarbij patiënten werden geobserveerd tussen 9 uur 's ochtends en 4 uur 's middags. De primaire uitkomstmaat was het percentage tijd gedurende de dag dat patiënten in bed lagen. Daarnaast werden de percentages tijd gedurende de dag dat patiënten zaten en bewogen, immobiliteit gerelateerde complicaties, verblijfsduur, ontslagbestemming thuis, ontslagbestemming revalidatie, mortaliteit en 30-dagen heropnames onderzocht. De resultaten toonden aan dat de primaire uitkomstmaat, percentage tijd liggend in bed, daalde van 60,1% naar 52,2% (p=0,01). Wat de secundaire uitkomsten betreft, het percentage tijd zittend nam toe van 31,6% tot 38,3% (p=0,01) en het aantal ontslagen naar een revalidatie instelling nam af van 6 (4,4%) tot 1 (0,7%) (p=0,04). Er werden geen statistische verschillen gevonden bij de andere secundaire uitkomstmaten. De resultaten van deze studie tonen aan dat het mogelijk is om het beweeggedrag van patiënten te veranderen door multidimensionale interventies te implementeren die aangepast zijn naar de context van een ziekenhuisafdeling, maar tonen ook de complexiteit aan van het verbeteren van het beweeggedrag van patiënten.

Hoofdstuk 7 onderzocht de ervaren factoren van invloed op de implementatie van Hospital in Motion, met behulp van een kwalitatief onderzoeksdesign. Tussen december 2018 en februari 2019, aan het einde van de implementatie van Hospital in Motion, werden 28 semigestructureerde interviews afgenomen met 16 zorgverleners en 12 patiënten. Het model van de Medical Research Council 2008 werd gebruikt als leidraad bij het selecteren van categorieën en thema's. De resultaten werden weergegeven in drie grote thema's; implementatie, mechanismen van invloed en context. Factoren van invloed binnen het proces van de implementatie waren de iteratieve en multidisciplinaire aanpak. Impact kan worden bereikt door continue aandacht en bewustwording tijdens

de implementatieperiode. Meerdere interventies, afgestemd op de doelgroep, moeten worden geïmplementeerd binnen meerdere dimensies (individueel, interprofessioneel, gemeenschap en maatschappij), aangezien de interactie tussen de verschillende interventies een van de mechanismen van impact bleek te zijn. Om de focus te behouden, moet het aantal interventies echter beperkt blijven. Deze studie bevestigt het belang van een multidimensionale, multidisciplinaire en op maat gemaakte implementatiebenadering om het beweeggedrag van opgenomen patiënten te verbeteren. Om de uitkomsten verder te optimaliseren, is het belangrijk om rekening te houden met factoren die van invloed zijn binnen de context, de implementatie en de mechanismen van impact. Bewustwording van deze factoren kan toekomstige projecten helpen om interventies succesvol te integreren in de dagelijkse zorg en daarmee het beweeggedrag van ziekenhuispatiënten duurzaam te veranderen.

In **hoofdstuk 8** worden de belangrijkste bevindingen van dit proefschrift bediscussieerd. Door de onderzoeken gedaan in dit proefschrift is het duidelijk geworden dat het ontwikkelen van duurzame interventies met als doel het vergroten van fysieke activiteit tijdens een ziekenhuisopname, en het succesvol implementeren van deze interventies in de dagelijkse zorg, een ingewikkeld en langdurig proces is. Bij de ontwikkeling van complexe interventies moet een theoretisch, gebruikersgerichte en iteratieve aanpak gevolgd worden, waarbij de toekomstige gebruiker bij elke stap van de interventieontwikkeling betrokken moet worden. Interventies moeten op de doelgroep afgestemd zijn en meerdere gedragsveranderingstechnieken bevatten om doeltreffende en duurzame veranderingen tot stand te kunnen brengen. Daarna moeten deze interventies multidimensionaal en stapsgewijs per individuele interventie geïmplementeerd worden. Daarnaast zijn tussentijdse evaluaties van zowel de individueel geleverde interventie als het implementatieproces belangrijk. De twee interventie projecten beschreven in dit proefschrift hebben laten zien dat het haalbaar is om familie te betrekken bij het bevorderen van fysieke activiteit op de IC, en dat het mogelijk is om het bewegingsgedrag van ziekenhuispatiënten te verbeteren door projecten zoals Hospital in Motion, maar hebben ook laten zien dat er meer inspanning nodig is om de tijd die patiënten gedurende de dag fysiek actief zijn te vergroten.



Appendices

List of publications PhD Portfolio Curriculum Vitae Dankwoord

LIST OF PUBLICATIONS

Peer-reviewed publications

van Delft LMM, Bor P, Valkenet K, Veenhof C. Hospital in Motion, a Multidimensional Implementation Project to Improve Patients' Physical Behavior During Hospitalization: Protocol for a Mixed-Methods Study. JMIR Res Protoc. 2019 Apr 9;8(4):e11341.

Valkenet K, Bor P, **van Delft LMM**, Veenhof C. Measuring physical activity levels in hospitalized patients: a comparison between behavioral mapping and data from an accelerometer. Clin Rehabil. 2019 Jul;33(7):1233-1240.

van Delft LMM, Bor P, Valkenet K, Slooter AJC, Veenhof C. The Effectiveness of Hospital in Motion, a Multidimensional Implementation Project to Improve Patients' Movement Behavior During Hospitalization. Phys Ther. (PTJ) 2020 Dec 7;100(12):2090-2098.

van Delft LMM, Valkenet K, Slooter AJC, Veenhof C. Family participation in physiotherapy-related tasks of critically ill patients: A mixed methods systematic review. J Crit Care. (JCC) 2021 Apr;62:49-57.

van Delft LMM, Valkenet K, Slooter AJC, Veenhof C. Perceptions and ideas of critically ill patients, their family and staff members regarding family participation in the physiotherapy-related care of critically ill patients: a qualitative study. Phys. Ther. Theory and Prac. 2021 Published online ahead of print

Bor P, **van Delft LMM**, Valkenet K, Veenhof C. Perceived factors of influence on the implementation of a multidimensional project to improve patients' movement behavior during hospitalization – a qualitative study. Phys Ther. (PTJ) 2021 Published online ahead of print

Submitted manuscripts

Karin Valkenet, Elja Reijneveld, Marielle Jans, Petra Bor, **Lotte van Delft,** Daniel Young, Prue McRae, Cindy Veenhof. Inpatient physical activity across a large university city hospital: a behavioral mapping study. 2021 Submitted

van Delft LMM, Valkenet K, Slooter AJC, Veenhof C. Increasing family participation in physiotherapy-related tasks of critically ill patients: a pilot study on the feasibility of an intervention. 2021 Submitted

Other publications

Lotte van Delft, Karin Valkenet, Petra Bor en Cindy Veenhof. UMC Utrecht in Beweging. FysioPraxis, oktober 2019

Sven Geelen, **Lotte van Delft**. Bewegen tijdens ziekenhuisopname. Nurse Academy, nummer 2, 2021

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PHD PORTFOLIO

PhD training	Year	ECTS*
Courses and certificates		
Academic Writing in English course, Babel	2017	2.0
Introduction PhD, UU	2017	0.5
Basic course on Regulations and Organization of Clinical Trials (BROK), UMCU	2018	1.5
Workshop Implementing an Inter-Professional Culture of Mobility Across the Hospital, John Hopkins Medicine, USA	2018	0.6
Course Qualitative Research in Healthcare, Kwalimetrika, UMCU	2019	0.55
Introductory Biostatistics for Researchers, UU	2020	3.0
Project Management, Schouten en Nelissen	2020-2021	1.0
National and international conferences		
European Conference on Weaning & Rehabilitation in Critically Ill Patients, Leuven	2018	0.55
Dag van de Fysiotherapie (poster)	2018	0.3
Dag van de Fysiotherapie (oral presentation)	2019	0.35
European Conference on Weaning & Rehabilitation in Critically Ill Patients, Amsterdam	2019	0.55
World Confederation for Physical Therapy conference, Geneve (poster)	2019	1.3
Move & Match festival Beweegziekenhuizen, UMCU (organization and poster)	2019	1.0
EndPJparalysis Global Summit, University of Salford, online (oral presentation)	2019	0.5
World Confederation for Physical Therapy conference, Dubai, online (two oral presentations)	2021	1.15
Johns Hopkins Annual Hospital Activity and Mobility Conference, USA, online (oral presentation)	2021	0.5
European Implementation Event, Rotterdam, online (poster presentation)	2021	0.5
Meetings		
Weekly research meeting (research group)	2017-2021	0.1
Expert and research meetings (Beweegziekenhuizen, promovendi)	2017-2021	0.1

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Teaching/supervising		
Supervising bachelor and master students with their (graduation) research, UMCU	2017-2021	1.0
Lecture, course "Beweegziekenhuizen", UMCU	2018-2020	0.85
Lecture, symposium "Ziekenhuis fysiotherapie van de toekomst", UMCG	2018	0.5
Lecture, course Implementation in healthcare, master Healthcare sciences, UU	2019	0.15
Lecture, summer school, UU	2019	0.15
Lecture, course Implementation in healthcare, Rehabilitation medicine, UMCU	2019	0.2
Lecture, master Geriatric Physical Therapy, HU	2021	0.2
Peer-reviewing	2020 2024	4.0
Disability and Rehabilitation, Netherlands Journal of Critical Care	2020-2021	1.0
Other		
Part of the Scientific Committee of EndPJparalysis Global Summit, University of Salford	2019	1.0

CURRICULUM VITAE



Lotte van Delft was born on December 6th, 1991, in Leiden, the Netherlands. In 1999 she moved with her parents and older sister to Cadier en Keer, a small town near Maastricht. After graduating from secondary school in Maastricht, she obtained the Bachelor degree in Physiotherapy at Zuyd University of Applied Sciences, in 2013. After graduation she went to Peru to do volunteer work as a physiotherapist in a medical center in Cusco. When she came back to the Netherlands, she started with a Master in Health Sciences, i.e. Human Movement Sciences, at the University of Maastricht.

Additionally she started working as physiotherapist at Maastricht University Medical Center.

After obtaining her Master of Science degree in 2015, she moved to Amsterdam and worked s few months as physiotherapist at Westfriesgasthuis. In January 2016 she started working as physiotherapist at University Medical Center Utrecht. In September 2017 she started her PhD study at University Medical Center Utrecht. She continued working as a physiotherapist at the Intensive Care Unit, in combination with her PhD research. In the end of 2021 she completed her PhD project and started working as project manager at 'Het Potentieel Pakken', a foundation that is committed to the great shortage of employees in among others health care.

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DANKWOORD

Toen er in 2017 een interne vacature kwam om deeltijd onderzoek te gaan doen twijfelde ik eerst, is onderzoek doen wel echt iets voor mij, en is een promotietraject wel haalbaar naast mijn baan als fysiotherapeute? Nu, ruim 4 jaar verder, is mijn eigen promotie in zicht. Ik heb de afgelopen jaren veel geleerd op zowel onderzoeksgebied als op persoonlijk vlak, maar daarnaast vooral veel plezier gehad in alle werkzaamheden en activiteiten buiten werk. Er hebben dan ook veel mensen bijgedragen aan de totstandkoming van dit proefschrift, waarvoor mijn dank. Als eerste wil ik alle patiënten en familieleden bedanken die hebben deelgenomen aan mijn onderzoek, op de verpleegafdelingen maar vooral ook op de Intensive Care (IC). Een IC opname is een heftige periode, niet alleen voor de patiënt maar vooral ook voor de direct naasten. Mijn dank is groot dat jullie de moeite namen om deel te nemen aan mijn studies. Daarnaast wil ik een aantal mensen graag persoonlijk benoemen.

Als eerst mijn beide promotoren. Beste Cindy, dankjewel voor alle fijne begeleiding die ik heb gehad. Hoe druk jij het ook hebt, je bent altijd erg betrokken en oprecht geïnteresseerd. Jouw enthousiasme, energie en waardering waren erg fijn om de afgelopen jaren om me heen te hebben. Ik wil je dan ook heel erg bedanken voor alle prettige begeleiding bij mijn eigen onderzoek, maar daarnaast ook voor alles wat ik door jou en de onderzoeksgroep heb geleerd op het gebied van innovatie en implementatie. En natuurlijk wil ik je ook bedanken voor alle leuke uitjes, dinertjes en reisjes die we samen hebben meegemaakt. Met onze villa in Genève als een van de hoogtepunten!

Beste Arjen, vanaf 2018 ben jij betrokken geraakt bij mijn promotietraject in verband met het project familie participatie op de IC. Je was altijd laagdrempelig te benaderen en je hebt, door middel van je inzet, netwerk, en fijne begeleiding er mede voor gezorgd dat ik dit project op de IC succesvol heb kunnen uitvoeren, ondanks alle drukte en chaos tijdens de COVID-19 pandemie daar. Dank daarvoor!

Uiteraard wil ik ook Karin, mijn copromotor, erg bedanken voor de fijne samenwerking de afgelopen jaren, met jou als mijn dagelijkse begeleider en als projectleider van UMC Utrecht in Beweging. Ik heb erg veel geleerd van jouw kijk op onderzoek doen, jouw kennis over innovatie en implementatie en jouw feedback op alles wat ik deed en schreef. Mede door jou ben ik de afgelopen jaren erg gegroeid als wetenschappelijk onderzoeker en projectmanager, dank hiervoor!

Daarnaast wil ik Petra, mijn mede promovendus op het project UMC Utrecht in Beweging bedanken. Eind 2017 begonnen we samen aan dit avonduur. Nu, ruim 4 jaar later, gaat de eerste van ons promoveren. Ik vond het erg fijn om samen met jou hieraan te beginnen, en heb veel gehad aan jouw parate kennis op o.a. het gebied van statistiek. Ons gezamenlijke hoogtepunt was toch wel onze eerste werktrip naar het John Hopkins Hospital in Baltimore, Amerika, waar we samen met Hanneke per ongeluk in een hele verkeerde wijk en hotel terecht waren gekomen... Dank voor deze bijzondere maar vooral ook hele leuke ervaring die ik niet snel zal vergeten!

Beste 'beweeg' promovendi-genootjes; Hanneke, Niek, Emily, Sven en Petra. Promoveren zonder burn-out is de naam die we 4 jaar geleden bedacht hadden voor onze app-groep. En het is ons tot nu toe gelukt! Bedankt voor de fijne promovendi-overleggen, de gezellige 'Beweegziekenhuizen' vergaderingen, en de leuke borrels. Op naar de volgende promotie!

Lieve leuke, gekke collega's van de afdeling Revalidatie, Fysiotherapie-wetenschap en Sport. Graag wil ik iedereen bedanken voor de leuke jaren waarin ik als fysiotherapeute en onderzoeker op de afdeling heb gewerkt. Toen ik op 1 januari 2016 begon als een van de 'jonge honden' had ik nooit verwacht dat ik me hier zo thuis zou gaan voelen. Ik weet dan ook zeker dat ik jullie allemaal heel erg ga missen. Maar er zijn een aantal dingen die ik het meest ga missen. Zoals natuurlijk de vrijdagmiddag lunches en de vrijdagmiddagborrels, waarbij de gespreksonderwerpen altijd binnen enkele minuten totaal escaleerden, thanks daarvoor Germijn, Olmo, Guido, David, en de rest! Maar ook de vele gezellige koffie-dates met menig collega, de lunchwandelingen, het samen sporten op werk, de hardloopwedstrijden, personeelsuitjes, en natuurlijk de dinertjes in de tuin van Wytze.

Daarnaast wil ik graag mijn directe collega IC fysiotherapeuten, Marloes, Pien, Juul, en Pim, enorm bedanken. Ten eerste voor jullie bijdrages aan mijn project en onderzoek, maar vooral voor de fijne samenwerking de afgelopen jaren op de IC. Ik ben erg trots op ons, als ik terug kijk hoe wij als fysiotherapie zijn gegroeid op de IC en nu niet meer weg te denken zijn uit de dagelijkse zorg. Maar vooral wil ik jullie bedanken voor de bijzondere en grappige herinneringen aan onze werkzaamheden. Zo zal ik het verhaal van de poeploopband nooit vergeten Marloes! En ons tripje naar Leuven waar Juul in een mini kinderbedje boven ons sliep, en we vervolgens de bus de verkeerde kant op hadden genomen waardoor we veel te laat bij het congres waren. Ook zal ik nog regelmatig terug denken aan de COVID-19 golven, waarbij we opeens meer dan 60 IC patiënten moesten zien. Ik ben, als ik daaraan terug denk, vooral super trots op hoe wij dit als IC-team hebben gedaan.

Germijn, wat ben ik blij dat jij ervoor gezorgd hebt dat ik tóch in het UMC Utrecht mocht komen werken. Zonder jou had ik vandaag niet hier gestaan. Ik wil jou bedanken voor alles wat je mij hebt geleerd op de IC. Maar eigenlijk wil ik je nog het meest bedanken voor alle leuke jaren die we samen gewerkt hebben, voor jouw humor, je lekker directe opmerkingen, en alle andere kattenkwaad die we samen hebben uitgehaald.

Naast mijn collega's wil ik ook mijn lieve vriendinnetjes van de opleiding fysiotherapie (Mirthe, Ineke, Eline, Lieve, Simone, Iris en Auke) bedanken voor alle leuke herinneringen buiten studie- en werktijd. Sinds het eerste jaar van fysiotherapie zijn we goede vriendinnetjes, beginnend met de fysiofeesten, avonden stappen in Maastricht en reisjes naar Luigi in Italië, tot op de dag van vandaag het jaarlijkse zomer en winterdiner. In het bijzonder wil ik Mirthe en Ineke bedanken. Door jullie mis ik Maastricht eigenlijk nog elke dag. En Mirth, bedankt voor al onze fijne logeerpartijtjes, de vele dansjes op onder andere het Lentekabinet, onze fijne (strand)wandelingen, carnaval met iets te veel port, en als hoogtepunt toch wel onze reis naar New York. Een hele week met jou de slappe lach, eten en drinken, dansen, en veel te veel shoppen is de beste afleiding van je promotieonderzoek die er is! Ik ben dan ook super blij en dankbaar dat jij als paranimf naast mij wilt staan.

Ook wil ik al mijn vriendinnen wonend in Amsterdam, Utrecht en Eindhoven bedanken. Maxime, Annie, Aniek, Mathilde, Eline, Flup, Maud, Mariek, en Mies, onder andere de vele avondjes samen sporten, gezellige etentjes en borrels, hebben ervoor gezorgd dat ik naast werken een fijne tijd in Amsterdam heb gehad. Lieve Elien, Flup en Mats, dank jullie wel voor de fijne eerste jaren van mijn promotietraject in ons poppenhuisje op de Vrijheidslaan. Dankjewel Max, voor de vele dates die wij al hebben gehad, van ons pre-corona ritueel: eten en dansen in de School, tot nu bijna buurtjes en brave lunchwandelingetjes tijdens het thuiswerken. En Maudje, altijd in voor een wijntje en avondje lachen. Ohja, en offcourse thanks for being the best cat sitter ever! Flup, dankjewel dat je er bent als goed vriendinnetje, altijd oprecht geïnteresseerd, in om samen naar yoga te gaan, of lekker op de bank te eten en tv te kijken (helaas zijn we over onze GTST verslaving heen gekomen). Lieve Mats, wij hebben al veel samen meegemaakt, van samen a-tijd lopen, een halve marathon rennen, met 'nep geld' de taxi betalen, tot huisgenootjes zijn en de laatste jaren braaf op woensdag na werk in Utrecht een rondje rennen om te praten over onze onderzoeken.

Ik vind het dan ook heel bijzonder dat ik eerst jouw paranimf mocht zijn en jij nu ook die van mij bent!

Corry en Rob, dank jullie wel voor de vele fijne jaren dat ik al bij jullie in huis kom als vriendin van Luc. Altijd heerlijk eten, een lekker wijntje erbij en goede gesprekken. En Rob, nogmaals bedankt voor het maken van de kaft van dit proefschrift.

Lieve zus, Myrthe, ondanks onze grote verschillen in persoonlijkheid en vele ruzies als kind zijnde, lijken we op werkgebied toch veel op elkaar. Eerst "samen" die ellendige BROK-toets, en nu beide (ik bijna) gepromoveerd. Ik vind het fijn om jou als oudere zus in mijn leven te hebben, en ben blij dat, nu ik in Amsterdam woon en jij met Pieter en Bente in Leiden, we elkaar steeds vaker zien en er altijd voor elkaar zijn. Dankjewel voor alles!

Papa, ondanks dat we elkaar een hele tijd niet hebben gesproken en we elkaar niet zo vaak zien, zijn Myrthe en ik beide toch jouw pad achterna gegaan waardoor je nu (bijna) twee doctors als dochters hebt. Ik wil dan ook vooral zeggen dat ik heel blij ben dat je er bij deze speciale dag in mijn leven bij bent. Dankjewel daarvoor!

Lieve mama, jij kent mij het langste van iedereen. Het feit dat ik geen economie ben gaan studeren maar fysiotherapie en bewegingswetenschappen heb ik vooral aan jou te danken. Ik ben heel blij dat je mij hebt geholpen die keuze te maken, anders stond ik nu niet waar ik nu sta. Een weekend in Cadier en Keer, waarbij we een lange wandeling maken door het heuvelland, laadt mij altijd weer helemaal op voor een volle werkweek en het drukke leven Amsterdam. Dankjewel dat de deur in Cadier en Keer altijd voor me open staan en jij er altijd voor mij bent.

En tot slot, liefste Luc. Wat ben ik blij dat ik jou lang geleden heb aangesproken, en dat jij het nu, vele jaren later, nog steeds met deze nerd uithoudt. Samen met je tweede grote liefde 'Sambal' ben jij mijn fijnste thuis. Ik bof nogal met jou en het feit dat er de afgelopen jaren na werk regelmatig binnen twee minuten een overheerlijke maaltijd voor me op tafel stond, of er tijdens het thuiswerken aan dit proefschrift koffie voor me werd gezet en een lunch-eitje werd gebakken. Maar ik ben vooral dankbaar voor al het fijns wat wij samen al hebben meegemaakt. Ik heb dan ook heel veel zin in de vele avonturen die nog gaan komen!