

# BMJ Open The effect on physical performance of a functional assessment and immediate rehabilitation of acutely admitted elderly patients with reduced functional performance: the design of a randomised clinical trial

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## ABSTRACT

**Introduction:** Illness and hospitalisation, even of short duration, pose separate risks for permanently reduced functional performance in elderly medical patients. Functional assessment in the acute pathway will ensure early detection of declining performance and form the basis for mobilisation during hospitalisation and subsequent rehabilitation. For optimal results rehabilitation should begin immediately after discharge. The aim of this study is to investigate the effect of a systematic functional assessment in the emergency department (ED) of elderly medical patients with reduced functional performance when combined with immediate postdischarge rehabilitation.

**Method and analysis:** The study is a two-way factorial randomised clinical trial. Participants will be recruited among patients admitted to the ED who are above 65 years of age with reduced functional performance. Patients will be randomly assigned to one of four groups: (1) functional assessment and immediate rehabilitation; (2) functional assessment and rehabilitation as usual; (3) assessment as usual and immediate rehabilitation; (4) assessment and rehabilitation as usual.

**Primary outcome:** 30 s chair-stand test administered at admission and 3 weeks after discharge.

**Ethics and dissemination:** The study has been approved by the Regional Scientific Ethical Committees of Southern Denmark in February 2014. The study findings will be published in peer-reviewed journals and presented at national and international conferences.

**Trial registration number:** ClinicalTrials.gov Identifier: NCT02062541.

## INTRODUCTION

In Denmark, as in other countries, recent decades have seen changes in the organisation of emergency departments (ED) aiming

at increasing the quality of the acute patient pathway.<sup>1</sup> Admissions to the ED are intended to be of short duration, often less than 18 h; 70–80% of the patients are discharged to community-based care and rehabilitation.<sup>2–3</sup>

A majority of ED patients are older than 65 years of age and have a medical concern.<sup>4</sup> Illness and hospitalisation involves a risk of permanently reduced functional performance,<sup>5–7</sup> after even a few days' physical inactivity or bed rest.<sup>8–13</sup>

The organisational changes in the EDs have led to the introduction of physiotherapist services. By assessing the patients' functional performance, it is possible to support early detection of decline in performance and provide a baseline description for mobilisation efforts during hospitalisation and subsequent rehabilitation after discharge. This application to the acute patient pathway is supported by findings from other studies that have found physiotherapy services to improve and support mobility, providing gait aids, assisting with patient mobility and transfers, chest physiotherapy and discharge planning.<sup>14–20</sup> Physiotherapy services have furthermore been shown to contribute to increased well-being and self-reliance among patients.<sup>14–18 21</sup> However, existing studies of physiotherapy in the acute patient pathway have mainly surveyed or audited the work of physiotherapists, whereas the effect on the functional performance of the patient is less documented.<sup>14 16–18 21 22</sup>

Furthermore, continuous rehabilitation after the hospital discharge is important in order to minimise the risk of inactivity, as elderly patients cannot be expected to

initiate physical exercise activities.<sup>23</sup> In this perspective the challenge is that transfer between healthcare sectors involves a risk of the rehabilitation process being interrupted, because patients discharged from hospital may have to wait for weeks before the municipal rehabilitation is initiated.<sup>24</sup>

In general, the importance of functional assessment is well established<sup>25</sup> but its effect in the acute patient pathway on the functional performance, when combined with immediate rehabilitation after discharge, has not previously been studied.

### Aims and hypotheses

The aim of this study is to investigate the effect of a systematic functional assessment in the ED of elderly medical patients with reduced functional performance when combined with immediate postdischarge rehabilitation. We hypothesise that a functional assessment in the ED or/and immediate rehabilitation will result in sustained or improved performance in comparison to a regimen in which neither of these interventions are offered.

## METHODS AND ANALYSIS

### Study design

The study is designed as a two-way factorial randomised single-blinded clinical trial, in accordance with the SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials).<sup>26</sup> We will investigate the effect of functional assessment and/or

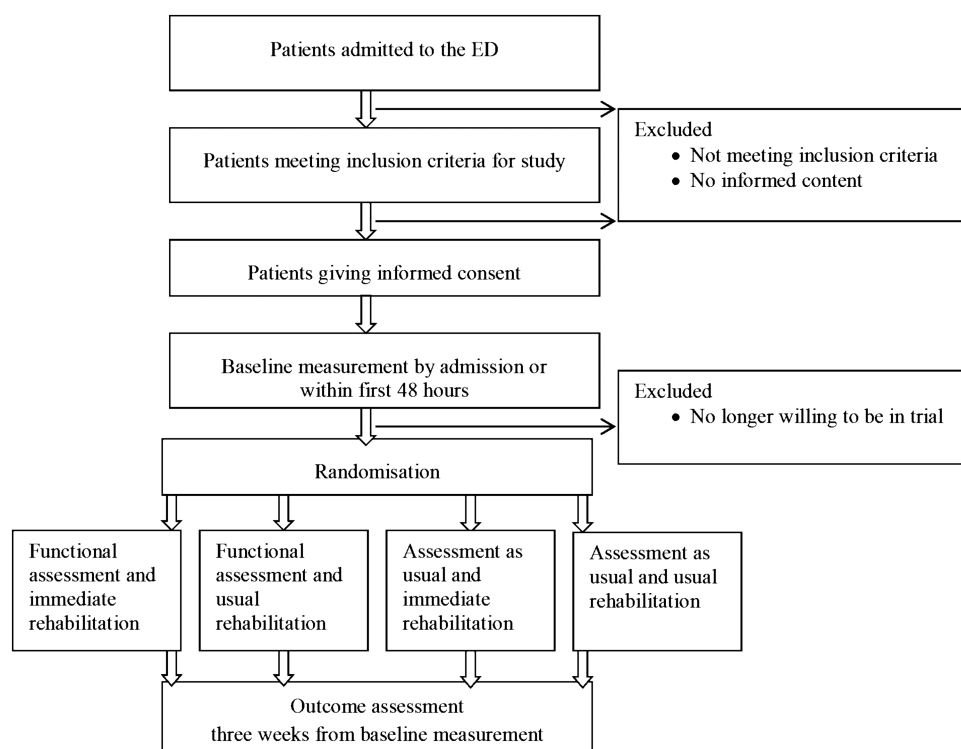
immediate rehabilitation as outlined in figure 1. The study involves a regional hospital and two municipal rehabilitation centres. The trial takes place from 1 February 2015 to 30 June 2016.

A steering group has been appointed to monitor the conduct of the study. The group consists of the participating researchers who are all affiliated to or employed at the University of Southern Denmark or Aarhus University, Denmark. The municipal rehabilitation centres are represented by two heads of department and two heads of section.

### Setting

EDs in Denmark consist of an out patient area including the emergency room and an admission area. Patients will be recruited from the admission area. Patients discharged from the ED and patients transferred to other clinical departments are included in the study. Functional performance will be assessed at admission and 3 weeks later during a scheduled visit at home or in the hospital if the patient has not been discharged.

Responsibility for rehabilitation programmes is shared by the hospital and the municipality. The hospital is in charge of rehabilitation during hospitalisation but if further rehabilitation is needed at discharge a referral correspondence is sent to the municipal rehabilitation centre. Services in hospitals and at municipal rehabilitation centres are free of charge in Denmark. The two participating municipalities have a mixed urban and rural population.



**Figure 1** The study process (ED, emergency department).

## Study sample

### Study population

The study will include patients of 65 years of age or older acutely admitted to the ED with a medical concern who meets the following criteria.

#### Inclusion criteria

- ▶ Can speak and understand Danish.
- ▶ Resident in either of the two included municipalities.
- ▶ Can report personal data and decide on consent.
- ▶ Within the first 48 h of admission are able to sit on an ordinary chair but perform  $\leq 9$  repetitions at the 30 s chair-stand test.<sup>27</sup>

#### Exclusion criteria

- ▶ Patients suffering from a progressive neurological or cognitive deficit or disease.
- ▶ Patients ordinarily unable to walk.

Patients who are excluded, or eligible patients declining participation, will be registered in either of three categories: *Not meeting the inclusion criteria*, *No informed consent* or *No longer willing to be in trial*, in accordance with the SPIRIT 2013 Statement.<sup>26</sup>

### Procedure for recruitment and randomisation

All patients hospitalised on weekdays in the inclusion period will be assessed consecutively by one of two project assistants, who are also responsible for informing the patient about the project in writing and orally and for registering consent and collection of data. After informed consent is obtained and completion of the baseline test the patient is randomised to one of the four groups.

A stratified randomisation by municipality is used due to heterogeneity, furthermore due to sizes a two-to-one ratio. A balanced randomisation is achieved by using random permuted blocks of 8 and 12 for each of the stratified subsets.

A random number table is used for allocation to groups and sequentially numbered envelopes are prepared for concealment. A person who is not in contact with the patients in any other way is responsible for the preparation of an abundant number of opaque envelopes containing the randomisation result, and this person randomises the patient by opening the envelope. The result of the randomisation is communicated to the patient, the hospital physiotherapist and the rehabilitation centre officer in charge of distribution to rehabilitation.

### Sample size

We aim at recruiting 528 patients (132 per group). The sample size calculation is based on Gill and McBurney's investigation of the reliability of the chair-stand test with knee and hip osteoarthritis patients (Mean 6.35, SD 3.35).<sup>28</sup>

It is assumed that functional assessment followed by immediate rehabilitation will improve the patient's ability to sustain functional performance after hospitalisation. The chosen sample size enables us to identify changes in the primary outcome of 20% between the

groups. Power calculations indicated that 110 patients were required in each of the four groups (STATA V.12) to achieve  $\beta$  and  $\alpha$  significance levels of 0.8 and 0.05, respectively. Owing to the vulnerability of this group of patients, a 20% drop-out rate is expected, thus requiring 528 patients with 132 in each group, as illustrated in figure 2.

**Inclusion time:** In the 12 months from 1 January to 31 December 2012, 625 patients admitted to the hospital's ED met the general study criteria (medical concern, age  $\geq 65$  years, resident in one of the two municipalities).<sup>1</sup> It is estimated that 60% of these would have fulfilled all inclusion criteria. With inclusion restricted to Mondays to Fridays, a recruitment period of 16 months is required, with 8–9 entries/week.

### Blinding

The randomisation takes place after the baseline assessment and is concealed from the project assistants. Blinding of hospital physiotherapists, the rehabilitation centre officer in charge of distribution to rehabilitation and patients to the trial condition is not possible.

### Study conditions

Patients will be randomised to one of four groups: (1) functional assessment and immediate rehabilitation; (2) functional assessment and usual rehabilitation; (3) usual assessment and immediate rehabilitation and (4) usual assessment and usual rehabilitation.

### At the hospital

**Functional assessment:** a functional assessment is performed following an algorithm developed especially for this study. Based on the findings from this assessment the physiotherapist suggests a plan for mobilisation, rehabilitation or physical activity during hospitalisation, a plan which follows the patient in case of transferral to another department and will be communicated to the municipal rehabilitation centre when the patient is discharged.

**Usual assessment** will be carried out by nurses and physicians in the ED. Mobilisation and physical activity during hospitalisation is initiated by the nurses. If rehabilitation or physiotherapy is needed during hospitalisation the physiotherapy department is notified with information about the need for physical activity and the department will assist accordingly.

If rehabilitation is needed after discharge the hospital is required by legislation to send a referral letter to the municipality.

### At the municipal rehabilitation centres

The municipal rehabilitation centres offers training and activity. Each patient gets his or her individual plan

<sup>1</sup>According to the patient administration system, 2013.

**Figure 2** Patients by trial group (N).

Hospital	Municipality	
	Immediate rehabilitation	Usual rehabilitation
	Functional assessment by physiotherapist	Usual assessment
	132 patients	132 patients
	132 patients	132 patients

aiming at the patient's previous level of functionality or the best possible performance.

*Immediate rehabilitation* is initiated within 5 days after discharge.

*Usual rehabilitation* is initiated as early as possible respecting the existing waiting time.

### Study outcomes

Data as described in table 1 will be collected by project assistants, specifically trained for the assignment. Inter-rater reliability will be tested. A procedure will ensure that the collection of data at admission and 3 weeks later are not performed by the same projects assistant. If a patient is no longer available, the reason will be identified.

### Primary outcome

*The 30 s chair-stand test* is a valid and reliable indicator of lower body muscle strength and functional capacity in older adults.<sup>29 30</sup> A Danish translation of the original English-language version will be used.<sup>31</sup>

### Secondary outcomes

*The Barthel Index* provides a reasonably reliable and valid test of treatment efficacy for geriatric patients.<sup>32–34</sup> The

calculation is based on the patients' responses. The instructor will have access to a Danish translation of the original English-language version.<sup>35</sup>

*The Self-efficacy for Functional Activities* (SEFA) questionnaire assesses an elderly person's confidence by assessing their responses to nine items. Tests have shown that SEFA is a reliable and valid tool when used with elderly citizens.<sup>36</sup>

*Patient satisfaction*: a questionnaire will be developed to assess the patient satisfaction. The questionnaire will be tested for face and content validity before use.

*Length of stay*: data are obtained from the hospital patient administration system.

### Patient characteristics

Information will be collected on patient's age, gender, living arrangement, educational level, body mass index, multiple medication use (if any) and physical activity level.

### Intervention implementation

The number of days from discharge to the start of rehabilitation is recorded for the trial. Data are obtained from the patient administration systems of the municipalities.

### Data management

An automated forms processing system will be used for the transfer of data from paper to the electronic format. This method is a validated alternative to double entry of data.<sup>37</sup> Until scanning, paper records are stored in a locked unit. The resulting database will not be opened before analysis.

### Data analysis

#### Descriptive analysis

Categorical data will be represented by numbers and proportions; continuous variables are shown by medians and quartiles. Baseline data will be compared with control for the comparability of randomised groups. The  $\chi^2$  test or Fisher's exact test are used for the analysis of categorical variables. For analysis of continuous variables, one-way analysis of variance (ANOVA) and Kruskal-Wallis tests are used for non-parametric and normally distributed variables, respectively.

#### Primary and secondary analysis

All analyses will be conducted based on the intention-to-treat principle. Missing outcomes will be imputed and for non-adherence to protocol, a per-protocol analysis will be conducted as sensitivity analysis.

**Table 1** Patient characteristics, outcome measures and intervention implementation

Variable	Baseline	At discharge	3 Weeks after admission
Age	x		
Gender	x		
Living arrangement	x		
Educational level	x		
Body mass index	x		
Multiple medication use	x		
Physical activity level	x		
30 s chair-stand test	x		x
Barthel Index	x		x
SEFA	x		x
Patient satisfaction	x		x
Length of stay		x	
Days from discharge			x



A non-response analysis will be carried out for excluded patients and non-completers.

Data will be analysed according to the 2x2 randomised factorial study designs. The two-way ANOVA will be used for the chair-stand test, Barthel Index, SEFA and length of hospitalisation. A pair-wise comparison between groups will be conducted. STATA V.13 will be used for all statistical analyses.

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**Competing interests** None.

**Patient consent** Obtained.

**Ethics approval** The study has been approved by the Regional Scientific Ethical Committees of Southern Denmark (project-ID S-20130168) and the Danish Data Protection Agency. The trial is registered in the ClinicalTrials.gov number NCT02062541.

**Provenance and peer review** Not commissioned; peer reviewed for ethical and funding approval prior to submission.

**Data sharing statement** It is a study protocol, which has been approved by the Danish Data Protection Agency.

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